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NO. 57850-2-I

Snohomish County No. 02-2-08819-6

COURT OF APPEALS FOR DIVISION I
STATE OF WASHINGTON

MICHAEL S. JONES, R.Ph.,

Respondent/Plaintiff,

v.

STATE OF WASHINGTON AND ITS DEPARTMENT OF HEALTH, WASHINGTON STATE BOARD OF PHARMACY; PHYLLIS WENE; and STAN JEPPESEN, individually and as investigators for the Washington State Board of Pharmacy, and DONALD WILLIAMS, individually and as executive director of the Board of Pharmacy,

Petitioners/Defendants.

PETITIONERS' OPENING BRIEF

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I. CASE SUMMARY

This tort case arises out of the Washington State Pharmacy Board's suspension of the professional licenses of the plaintiff, Michael Jones, who owned and operated a pharmacy in Marysville, Washington. Mr. Jones' professional licenses were summarily suspended by the Board, as the Legislature has authorized it to do in RCW 18.130.050 (7), after his pharmacy received failing scores at two consecutive inspections in July and August of 1999. In an unsuccessful effort to stay the summary suspension, Mr. Jones and his attorney submitted declarations to the Pharmacy Board admitting to many of the health and safety violations noted at the failing inspections, but representing that Mr. Jones had made changes and brought his pharmacy into compliance. Mr. Jones later entered into a stipulated order agreeing to the suspension of his licenses for five years and waiving any further administrative hearings that were available.

Nevertheless, based on the license suspensions, Mr. Jones filed this case asserting claims under 42 USC § 1983 for denial of procedural due process, as well as claims for negligence, tortious interference with a business expectancy, recklessness, and injunctive relief.[1] Because Mr.

[1] Some of Mr. Jones' claims are asserted against former Executive Director of the Pharmacy Board, Donald Williams, as well as two of the Board's investigators, Stan

Jones conceded that his claims for negligent investigation, recklessness, and injunctive relief should be dismissed, the trial court dismissed those claims. However, the trial court denied the State's motion for summary judgment dismissal of Mr. Jones' claim for denial of procedural due process under § 1983, as well as his state law claims for intentional interference with a business relationship and negligent supervision. It again refused to dismiss these three claims when it denied the State's motion for reconsideration.

The defendants in this case are officials charged with investigating pharmacists and prosecuting those who do not comply with federal and state health and safety laws. By enacting these laws, the Legislature and Congress intended to protect the public from the irreparable injury and harm that can result from the improper maintenance or dispensation of these drugs. Conferring officials responsible for enforcing these laws absolute and qualified immunity allows the public to rely on officials who perform these vital functions to act independently and without fear of harassment, intimidation, and liability. Here, where a pharmacist admitted to numerous health and safety violations, the importance of granting these immunities cannot be overstated. The trial court's decision denying these immunities to the individual defendants was error. Furthermore, the

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Jeppesen and Phyllis Wene. In giving a procedural history of this case, all defendants may collectively be referred to as "the State" in this brief.

State's actions against Mr. Jones were authorized by RCW 18.150.030 (7) and related Pharmacy Board regulations, which afford significant due process with multiple prompt opportunities for a hearing and extensive review procedures. The trial court's decision holding that Mr. Jones' state law tort claims were not barred by his failure to exhaust the remedies available in this process and his agreement to the suspensions of his licenses was also error.

Thus, the trial court's partial denial of the State's motion for summary judgment should be reversed for several reasons. Executive Director Williams, the official charged with deciding to the initiate disciplinary proceedings against Mr. Jones, is entitled to absolute prosecutorial immunity from all claims asserted by Mr. Jones. In addition, all of the individual defendants are entitled to qualified immunity on Mr. Jones' civil rights claim under § 1983. Finally, Mr. Jones' remaining state law claims, which are premised on the suspension of his licenses, are barred by his voluntary agreement to these suspensions and his waiver of the available administrative remedies. If this court reverses these three rulings by the trial court, as it should, then all of Mr. Jones' claims must be dismissed as a matter of law.

II. ASSIGNMENTS OF ERROR

A. Grounds for Reversal of Trial Court's Decision and Entry of an Order of Summary Judgment Dismissal of all Claims

(1) The trial court erred in partially denying the State's motions for summary judgment and reconsideration, because in doing so it erroneously held that all Mr. Jones' claims against Donald Williams, former Executive Director of the Pharmacy Board, are not barred by Williams' absolute immunity. CP at 128-31, 22-24.

(2) The trial court erred in partially denying the State's motions for summary judgment and reconsideration, because in doing so it erroneously held that Mr. Jones' claims under 42 USC § 1983 against Donald Williams, Phyllis Wene, and Stan Jeppesen were not barred by their qualified immunity. CP at 128-31, 22-24.

(3) The trial court erred in partially denying the State's motions for summary judgment and reconsideration, because in doing so it erroneously held that Mr. Jones' state law tort claims were not barred by his voluntary agreement in a stipulated order to the suspension of his licenses and his failure to exhaust the available administrative remedies. CP at 128-31, 22-24.

(4) The trial court erred in partially denying the State's motions for summary judgment and reconsideration to the extent that it concluded that genuine issues of material fact were raised by Mr. Jones' declaration testimony that contradicted prior declarations by Mr. Jones and his attorney, because the doctrine of judicial estoppel precludes Mr. Jones from relying on such contradictory testimony to overcome summary judgment. CP at 128-31, 22-24.

(5) The trial court erred in partially denying the State's motions for summary judgment and reconsideration to the extent that it concluded that genuine issues of material fact were raised by hearsay statements contained in the declaration by Mr. Jones. CP at 128-31, 22-24, 132-33.

(6) The trial court erred when it denied in part the State's motion to strike hearsay portions of the declaration of Mr. Jones that were

relied on for purposes of opposing the State's motion for summary judgment. CP at 132-33.

B. Issues Related to Assignments of Error

(1) Was Executive Director Williams entitled to absolute immunity where the undisputed evidence established that his conduct was prosecutorial in nature?

(2) Was it error to deny Investigators Jeppesen and Wene qualified immunity, where Mr. Jones submitted no evidence on summary judgment to demonstrate that they engaged in any conduct that violated his right to procedural due process?

(3) Was it error to deny all of the individual defendants below qualified immunity, because Mr. Jones failed to establish that any of the individual defendants violated any clearly established right under the circumstances of this case?

(4) Could a reasonable public official have believed that invoking a legislatively authorized procedure to summarily suspend Mr. Jones' pharmacy licenses was lawful where Mr. Jones admitted to numerous health and safety violations that could potentially endanger the public?

(5) Is an individual who makes statements in a declaration under penalty of perjury in a disciplinary proceeding before the Pharmacy Board judicially estopped from later contradicting those statements when opposing a motion for summary judgment in his tort lawsuit against the Board?

(6) Must the trial court strike and refuse to consider self-serving hearsay testimony submitted by a plaintiff in opposition to a defendant's motion for summary judgment?

III. STATEMENT OF THE CASE

A. Statement of Procedural Facts Relating to Mr. Jones' Disciplinary Proceedings before the Pharmacy Board

On July 12, 1999, Pharmacy Board Investigators Phyllis Wene and Stan Jeppesen conducted an inspection of the Medicine Shoppe Pharmacy in Marysville, Washington, which was owned and operated by Michael. Jones. CP at 268. After the inspection, Mr. Jones received a failing or unsatisfactory score of 48 out of 100.[2] CP at 268, 280. On August 10, 1999, Jeppesen returned to the Medicine Shoppe to conduct a re-inspection of the pharmacy. CP at 270-73, 287. The re-inspection resulted in another unsatisfactory score of 56. CP at 273, 287. The inspection reports completed by Investigator Jeppesen alleged numerous violations of laws and regulations pertaining to pharmacists. CP at 269-73, 279-89.

At the time these inspections occurred, Donald Williams was Executive Director of the Pharmacy Board. CP at 267-68. As Executive Director, one of Williams' duties was initiating disciplinary proceedings in circumstances where he received information suggesting that a pharmacist

[2] Board of Pharmacy regulations provide that all pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy. WAC 246-869-190. The inspections are graded based on a score between 0 and 100 and are classified into three categories: (a) "Class A" – for inspection scores of 90 to 100; (b) "Conditional" – for inspection scores of 80 to 89; and (c) "Unsatisfactory" – for inspection scores below 80. *Id.* If a pharmacy receives an "unsatisfactory" score, the pharmacy must raise its score to 90 or better within fourteen (14) days. WAC 246-869-190 (5).

had engaged in unprofessional conduct. CP at 267-68. On August 16, 1999, following the inspections of Mr. Jones' pharmacy, Executive Director Williams made an ex parte motion for an order of summary suspension of Mr. Jones' licenses to the Pharmacy Board based on the information related in the reports of these inspections, and filed a Statement of Charges against Mr. Jones.[3] CP at 273, 290-318. On August 17, 1999, the Pharmacy Board granted the motion for an ex parte order summarily suspending Mr. Jones' licenses[4]. CP at 273, 319-26. Later that same day, Phyllis Wene served the Statement of Charges and Ex Parte Order of Summary Action, along with a Notice for Opportunity of Settlement and Hearing, on Mr. Jones. CP at 334-36.

On August 30, 1999, Mr. Jones filed a motion to modify and stay the summary suspension, thereby waiving his right to a "prompt hearing," which would have been required to occur within 20 days of the summary

[3] The Pharmacy Board follows the adjudicative procedures of the Administrative Procedures Act (APA) and has adopted the model procedural rules for adjudicative proceedings. RCW 18.130.100; WAC 246-856-001. Under the rules, the Board can take emergency action and summarily suspend a pharmacist's license pending further disciplinary proceedings if, after reviewing evidence, it determines that there is an immediate danger to the public health, safety, or welfare that can only be addressed by summary action. RCW 18.130.050 (7); WAC 246-869-190 (8); WAC 246-11-300. Summary action takes effect upon the entry of the order, but no one is required to comply with a summary action order until the person is either served with the order or has knowledge of it. WAC 246-11-310.

[4] A copy of the summary suspension order is attached as Appendix A.

suspension had he requested it.[5] CP at 337-38. Mr. Jones and his attorney filed declarations in support of the motion, in which they acknowledged many of the problems identified as violations in the investigators' inspection reports, but represented to the Board that these problems had been corrected.[6] CP at 339-52. Mr. Jones had the opportunity to give oral argument on the motion to stay the summary suspension, but he elected not to do so. CP at 355. A full three-member panel of the Board decided Mr. Jones' motion on September 7, 1999, just twenty-one (21) days after it entered the summary suspension order.[7] CP at 354-58. After considering the declarations and other supporting materials filed by Mr. Jones, the Board denied his motion, reasoning that "it could not be assured by [Mr. Jones'] assertions that he has corrected the problems and that he will remain in compliance." CP at 357. It was particularly concerned that "[Mr. Jones had] a history of committing violations of the pharmacy law, correcting the violations, but then violating the laws again," ultimately concluding that "the concerns for the protection of the public outweigh

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[5] A "prompt hearing" must occur within twenty days of summary action, if requested. WAC 246-11-330. The Notice Mr. Jones received informed him that he could contest the summary action by written motion, in which case he would waive his right to a "prompt" hearing, but not a "regularly scheduled" hearing. CP at 330.

[6] Copies of the declarations by Mr. Jones and his attorney are attached as Appendix B. The specific admissions by Mr. Jones and his attorney that were made in these declarations are discussed in more detail in Section II.B. and in Section IV.C.2., discussing qualified immunity.

[7] A copy of the Board's order denying Mr. Jones' motion to stay the summary suspension is attached as Appendix C.

[Mr. Jones'] assertions that the violations have been corrected." CP at 357.

Although Mr. Jones initially contested the allegations against him, on January 11, 2000, he and his attorney signed stipulated findings of fact, conclusions of law, and an agreed order, resolving the Board's administrative actions relating to the July and August 1999 inspections.[8] CP at 412-31. In the "procedural stipulations" portion of the order, Mr. Jones stipulated and agreed that he understood that the State was prepared to proceed to a hearing, that he had a right to defend himself at the hearing, and that he was waiving his opportunity to that hearing. CP at 414. In the "stipulated facts" section of the order, Mr. Jones "acknowledge[d] that the evidence [was] sufficient to justify" the facts set forth therein. CP at 415-23. In the "conclusions of law" portion of the order, Mr. Jones agreed that the Board had jurisdiction over him and that the facts alleged constituted unprofessional conduct that were grounds for the imposition of sanctions. CP at 423. By signing the order, Mr. Jones agreed to suspension of his pharmacist's license, as well as to revocation of the pharmacy location license for the Medicine Shoppe, for a period of five years, in addition to other conditions and restrictions. CP at 424-30.

[8] A copy of the stipulated findings of fact, conclusions of law and agreed order is attached as Appendix D.

The Board signed and entered the stipulated order on February 4, 2000. CP at 430.

B. Summary of Facts Relating to the July and August 1999 Inspections, and Mr. Jones' Admissions to Health and Safety Violations in Declarations Submitted to the Pharmacy Board

As stated above, Mr. Jones and the attorney representing him in the disciplinary proceedings each filed declarations in an effort to persuade the Pharmacy Board to lift the summary suspensions. CP at 339-52. In these declarations, Mr. Jones admitted to or acknowledged many of the violations enumerated in the investigators' inspection reports, but represented to the Board that the problems had been rectified. The following discussion summarizes some of the investigators' findings at the July and August 1999 inspections, as documented in the reports of the inspections, explains the legal source of these violations[9], and refers the court to where Mr. Jones admitted to the violations.

1. Patient Medical Records: Adverse Reactions and Drug Interactions

WAC 246-875-001 requires that a pharmacist maintain either a manual or an automated patient medical records system. WAC 246-875-020 provides that an automated patient medical record system must record

[9] Federal statutes and regulations pertaining to pharmacists that are discussed in this section are attached as Appendix E. Provisions of Washington statutes pertaining to the Pharmacy Board that are discussed are attached as Appendix F. Provisions from the Washington Administrative Code relating to the regulation of pharmacists and pharmacies discussed in this section are attached as Appendix G.

"any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization." WAC 246-875-020. In addition WAC 246-875-040 requires that such a system "determine the possibility of a clinically significant drug interaction, reaction, or therapeutic duplication..."

Mr. Jones utilized an automated computer patient medical records system known as QS-1. Inspector Jeppesen indicated in his report of the July 1999 inspection, "During approximately 4 hours of observing Mr. Jones process prescriptions, the QS-1 system in no case demonstrated an alert for allergy, therapeutic duplication, or disease state interactions or other warnings." CP at 284. He indicated in his report of the August 1999 inspection that there were "six patients noted in computer system with no allergy information. 2 of 5 patients without disease state data. Drug-disease state interaction module has been turned off. Pharmacist without knowledge of meaning of drug-drug interaction levels or how to find definitions or meanings. Pt. profile do [sic] not reflect what the patient actually received...." CP at 288.

Mr. Jones later admitted in a declaration he submitted to the Pharmacy Board that the disease state-drug interaction fields of this computer system were indeed not turned on until the investigators brought the issue to his attention during the second inspection in August 1999, at

which point he contacted his computer system's vendor, whom he blamed for this error, to have this feature turned on. CP at 341. Without this system functioning, as it is undisputed that it was not, Mr. Jones would be unable to detect potentially fatal allergic reactions of his patients. CP at 274.

2. Patient Medical Records: Audit Trail

Patient medical records systems, such as the QS-1 system used by Mr. Jones, are required to provide an "audit trail," meaning all materials and documents required for the entire process of filling a prescription, which must be sufficient to document or reconstruct the origin of the prescription order and authorization of subsequent modifications of the order. WAC 246-875-001; WAC 246-875-010. The purpose of this requirement is to provide the pharmacist a means to retrieve all new prescription and refill prescription information relevant to patients, to provide safeguards against improper manipulation or alteration of records, and to ensure that health and welfare of patients. *Id.* With respect to a computerized or automated system, such as Mr. Jones', WAC 246-875-040 requires that the system document any changes to a prescription order, such as drug name, dose, route, dose form or directions for use, in the audit trail.

In his report of the July 1999 inspection, Inspector Jeppesen stated that when Mr. Jones was asked about his computer system, "it took a number of verbal transactions to determine that the system is capable to [sic] changing any Rx data, without any audit trail to track changes." CP at 284. Later, Inspector Jeppesen indicated in his August 1999 inspection report that Mr. Jones' computer system did "not have the ability to track changes made to the prescription record. No tracking for audit purposes possible." CP at 289.

Mr. Jones later testified in a declaration in August 1999 that the investigators had been "concerned that our QS-1 system was inadequate for the minimum procedures for utilization of the patient medication system and for creating an accurate and complete audit trail for changes made to the prescriptions after filling." CP at 344. Only after the August 1999 inspection did Mr. Jones indicate that he had spoken with the QS-1 technical support personnel to confirm that the system was capable of performing these functions and familiarize himself with how to use them. CP at 344.

3. Child Resistant Caps

WAC 246-869-230 requires that all legend drugs be dispensed in a child resistant container (CRC), unless an authorization is received by the pharmacist from the patient, the patient's representative, or the

prescribed.[10] Investigator Jeppesen indicated in his report that Mr. Jones could not locate patient authorizations for many customers to whom he was dispensing drugs in non-CRC's: "the blue three ring binder where [Mr. Jones] had patients sign for authorization to have non safety caps dispensed...is divided into alphabetic sections, with several to many pages of signatures listed down each page, on both sides. Many signatures are difficult to impossible to read, and are not in alphabetic order within the section." CP at 283. Mr. Jeppesen's report indicated that when Mr. Jones was requested to locate authorizations for seven patients, all of whose last name started with the letter "B," Mr. Jones could locate only two of the seven required authorizations in his records. CP at 283. At the August 1999 inspection, Mr. Jeppesen's report indicated that there were 41 prescriptions on Mr. Jones' will-call shelf, only one of which was a child-resistant container.[11] CP at 288. Only one authorization for a non child-resistant container for these prescriptions could be located. CP at 288. Mr. Jones later confirmed in a declaration that his patient authorizations "may not have been organized for ease of reference," and Mr. Jones'

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[10] This requirement is consistent with the federal Poison Prevention Packaging Act and its accompanying regulations, which generally require that controlled substances and prescription drugs be dispensed in child-resistant packaging. 15 USC § 1471-1476; 16 CFR § 1700.5. *See* App. E.

[11] As the Statement of Charges reflects, the one prescription container that did have a child-resistant cap was in a container that had been supplied by the drug manufacturer. CP 302.

attorney verified that Mr. Jones' "record-keeping system did not allow for one to readily verify specific signatures." CP at 342, 349.

4. Outdated/Deteriorated Stock

The federal Food and Drug Administration requires that drugs be assigned expiration dates based on testing that is designed to assess drug stability. 21 USC § 321; 21 CFR § 211.137; 21 CFR § 211.166. Investigator Jeppesen's report regarding his July 1999 inspection of Mr. Jones' pharmacy indicates that 38 items found in Mr. Jones' prescription stock area were outdated. CP at 280. Investigator Jeppesen's report regarding his August 1999 re-inspection of the pharmacy indicated that eleven items were found on Mr. Jones' shelves and in his refrigerator that were outdated. CP at 288. When Mr. Jones moved to stay the Board's summary suspension order, he admitted to having outdated prescriptions on his shelves, representing to the Board that he subsequently removed these items. CP at 343. Mr. Jones' attorney verified that that some of these outdated items had "slipped through the cracks." CP at 350.

5. Record-Keeping Deficiencies Regarding Prescription Inventory Records

Pharmacists are required to keep detailed records of all quantities of controlled substances purchased and sold, and they must perform an inventory of each substance every two years. 21 USC § 827. The

inventory must contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken and must be maintained at the registered location. 21 CFR § 1304.11 (a). There are both civil and criminal penalties for failure to keep these required records. 21 USC § 842. WAC 246-887-020 implements these requirements in Washington and provides the pharmacists in this state are subject to all of the above requirements.

Investigator Jeppesen indicated in his report regarding the July 1999 inspection that Mr. Jones' inventory records were not complete, and that he could not locate all of the requested inventory records even after being allowed an extra day. CP at 284-85. Mr. Jeppesen's August 1999 inspection report indicated that Mr. Jones had "numerous voids (holes) found in prescription files, with 21 noted missing in two consecutive days." CP at 289.

In his declaration submitted to the Pharmacy Board, Mr. Jones himself admitted that he was missing prescription records at the time of the August 1999 inspection, acknowledging that he "had an employee spend a week going through all of our prescription files to make sure they were in proper order and otherwise in compliance," and explaining that certain prescription records could not be located at the time of the inspection, because "[t]hey had simply been misfiled." CP at 343-44. In

his more recent declaration submitted in response to the State's summary judgment motion, Mr. Jones further admitted that there were additional "missing prescriptions" that he could not locate. CP at 214-15. He placed the blame for these missing prescription records on a former employee whom he contends, without any evidence, stole them. CP at 214-15.

6. Record-keeping Deficiencies Regarding Schedule II Drug DEA Forms

Special record-keeping requirements are imposed with respect to Schedule II drugs. The U.S. Attorney General has made a determination that Schedule II drugs have a high potential for abuse which may lead to severe psychological or physical dependence. 21 USC § 812 (b)(2). Examples of Schedule II drugs include morphine, phencyclidine (PCP), cocaine, methadone, and methamphetamine. 21 CFR § 1308.12. Schedule II inventory records must be kept separately from all other records. 21 USC 827 (b). In addition, DEA order forms (DEA Form 222) for Schedule II drugs must be prepared and executed by any pharmacist who dispenses these drugs, and the pharmacist must maintain these forms for a period of at least two years. 21 CFR § 1305.06; 21 CFR 1305.13. These DEA order forms are "required to be used for all orders of Schedule II controlled substances and to record the amount of drugs actually received by the purchaser and the date of their receipt." *United*

States v. Poulin, 926 F. Supp. 246, 249 (D. Mass 1996). WAC 246-887-020 implements the above requirements in Washington.

During the July 1999 inspection, Mr. Jeppesen's report indicated that Mr. Jones was not able to locate Schedule II prescription records. CP at 280, 284-85. He further indicated that even after the investigators allowed Mr. Jones an additional day, he still had not located them. CP at 285. Investigator Jeppesen's report regarding the August 1999 inspection indicates that, once again, Mr. Jones' DEA forms were not complete, that the Schedule II inventory was not signed, that the Schedule II invoices were filed with general invoice records and not filed separately, and that the firm DEA number was not on the Schedule II inventory. CP at 287-89. In a declaration submitted to the Pharmacy Board, Mr. Jones admitted several of these DEA forms were incomplete, or else missing altogether. CP at 344. Again, he offered excuses ranging from one of the forms being lost to one of them not being "checked in yet." CP at 344.

C. Procedural History of This Lawsuit

Mr. Jones filed two identical complaints in the Snohomish County Superior Court, alleging a claim under 42 USC § 1983 for denial of procedural due process, as well as claims for negligence, recklessness, intentional interference with a business expectancy, and injunctive relief. CP at 470-77, 505-12. The trial court consolidated these identical

lawsuits. CP at 135-37. The State moved for summary judgment, arguing that Executive Director Williams was entitled to absolute prosecutorial immunity, that all the individual defendants were entitled to qualified immunity on Mr. Jones' § 1983 claim, and that Mr. Jones' state law claims were precluded by his voluntarily entering into a stipulated order in which he agreed to the suspensions of his licenses and waived the extensive hearing process available. CP at 432-58. The State also moved for summary judgment on several other grounds, which are not the subject of this appeal. CP at 432-58. In addition, the State filed a motion to strike hearsay portions of Mr. Jones' declaration, which was offered in opposition to the motion for summary judgment. CP at 167-78.

On February 9, 2006, the court entered an order partially granting and partially denying the State's motion for summary judgment, dismissing only Mr. Jones' claims for negligent investigation and injunctive relief, because Mr. Jones conceded these claims should be dismissed.[12] CP at 128-31. The court denied the State's motion with respect to all the remaining claims, effectively holding that the individual defendants were not entitled to absolute immunity or qualified immunity and that Mr. Jones was not precluded from asserting tort claims against the

[12] Mr. Jones agreed to the dismissal of his claim for injunctive relief and did not oppose the State's motion to the extent it requested dismissal of a claim for negligent investigation. CP 179-210, 223-27.

State by his entering into a stipulated order agreeing to the suspensions. CP at 128-31. In addition, the trial court entered an order indicating it was admitting the hearsay portions of Mr. Jones' declaration for "background," but that it was not admitting them for the truth of the matter asserted. CP at 132-33.

On February 13, 2006, the State filed a motion for reconsideration of the partial denial of its motion for summary judgment. CP at 89-127. On May 17, 2006, the trial court granted the motion for reconsideration to the extent that it requested dismissal of Mr. Jones' claim for recklessness, because Mr. Jones conceded in his response that this claim should be dismissed. CP at 24. The court denied the State's motion for reconsideration in all other respects. CP at 23-24.

On March 9, 2006, the State filed its notice of discretionary review of the partial denial of its motion for summary judgment and the partial denial of its motion to strike. CP at 26-35. The State filed an amended notice of discretionary review on May 18, 2006, adding the trial court's denial of the motion for reconsideration in its request for this court's review. CP at 8-24. This court has accepted discretionary review of all the issues raised in the State's motion for discretionary review.

IV. THE PARTIAL DENIAL OF THE STATE'S MOTIONS FOR SUMMARY JUDGMENT AND RECONSIDERATION WAS ERROR AND SHOULD BE REVERSED

A. Standard of Review

Review of a trial court's ruling on a motion for summary judgment is *de novo*, and the reviewing court engages in the same in inquiry as the trial court. *Korslund v. Dyncorp Tri-Cities Services*, 156 Wn.2d 168, 177, 125 P.3d 119 (2005). While a denial of a motion for summary judgment is not ordinarily appealable as a matter of right, the court may, as here, accept discretionary review of the denial of a motion for summary judgment involving a federal immunity so long as the petitioning party shows the trial court's decision was obvious or probable error. *Walden v. City of Seattle*, 77 Wn. App. 784, 790, 892 P.2d 745 (1995). A summary judgment motion must be granted where the admissible evidence establishes the absence of a dispute as to any material fact. CR 56 (c). A material fact is one upon which the outcome of litigation depends. *Spurrell v. Block,* 40 Wn. App. 854, 860, 701 P.2d 529 (1985), *rev. denied*, 104 Wn.2d 1014 (1985). "A party opposing summary judgment may not rely on 'mere allegations or denials' set forth in the pleadings, but rather 'must set forth specific facts showing that there is a genuine issue for trial.'" *Tiffany Family Trust Corp. v. City of Kent*, 155 Wn.2d 225, 328-29, 119 P.3d 325 (2005) (quoting CR 56 (e)). At the summary judgment stage, the

court must consider the evidence in the light most favorable to the non-moving party. *Clements v. Travelers Indem. Co.*, 121 Wn.2d 243, 249, 850 P.2d 1298 (1993). Where issues of material fact do not exist, an order of dismissal is necessary to avoid a useless trial. *Olympia Fish Products, Inc. v. Lloyd,* 93 Wn.2d 596, 602, 611 P.2d 737 (1980).

B. The Trial Court's Failure to Confer Absolute Immunity to Executive Director Williams Was Error

The trial court erred by refusing to confer Executive Director Williams absolute immunity, because his liability is premised on conduct that is a prosecutorial function. A prosecutor is protected by absolute immunity from liability for damages when performing the traditional functions of an advocate. *Kalina v. Fletcher*, 522 U.S. 118, 127, 118 S. Ct. 2606, 125 L. Ed. 2d 209 (1993). For example, "[t]he charging function is so intimately related to the judicial process that prosecutorial immunity must apply." *Collins v. King County*, 49 Wn. App. 264, 268, 742 P.2d 185 (1987). "The public policy of allowing the prosecutor the freedom to charge or not to charge must be upheld to ensure the independence of that decision-making process." *Id.* at 272-73.

However, absolute prosecutorial immunity is not limited to prosecuting attorneys, as application of the immunity depends on the nature of the function performed, not the identity of the actor who

performed it. *Kalina*, 522 U.S. at 127. The courts employ a functional approach when analyzing whether absolute immunity attaches and determine whether the actions taken by the official claiming the immunity are functionally comparable to those taken by judges or prosecutors. *Olsen v. Idaho State Board of Medicine*, 363 F.3d 916, 923 (9th Cir. 2004). Thus, courts have determined that the immunity shields administrative agency officials who participate in agency adjudications. *Id.; Butz v. Economou*, 438 US 478, 512, 98 S. Ct. 2894, 57 L. Ed. 2d 895 (1978). It is well settled that administrative decision makers are absolutely immune to lawsuits premised on their initiation of disciplinary proceedings. *See, e.g., Hannum v. Friedt*, 88 Wn. App. 881, 947 P.2d 760 (1997); *Mischler v. Nevada State Bd. Of Medical Examiners*, 191 F.3d 998, 1008 (9th Cir. 1999). If a defendant is absolutely immune, the immunity precludes any liability under either 42 USC § 1983 or under state law tort causes of action. *See, e.g., Musso-Escude v. Edwards*, 101 Wn. App. 560, 567-68, 4 P.3d 151 (2000).

In the case at bar, Executive Director Williams made the decision to pursue a summary suspension of Mr. Jones' professional licenses and to file a Statement of Charges against him based on Investigator Jeppesen's reports. This conduct is indisputably a prosecutorial function for which Williams is entitled to absolute immunity as a matter of law.

Hannum, a case remarkably similar to this one, is instructive. There, the plaintiff was an automobile dealer. *Hannum,* 88 Wn. App. at 882. Based on an investigation indicating that the odometers of automobiles the plaintiff had sold had been illegally manipulated, the Director of the Department of Licensing filed a statement of charges against the plaintiff and summarily suspended his dealer's license. *Id.* at 883. The plaintiff then brought an action under 42 USC § 1983 based on violation of his due process rights. *Id.* at 884. Affirming summary judgment in favor of the defendants, the Court of Appeals held in no uncertain terms that the Director was absolutely immune to liability based on filing a statement of charges and summarily suspending the plaintiff's license:

> Even viewing the evidence in the light most favorable to Hannum, there is no genuine issue of material fact regarding whether Friedt, the director of DOL, and Hamilton, an administrator at DOL, enjoy absolute immunity from suit. Friedt was initiating an administrative adjudication when she signed the original and amended statement of charges and notice and order of summary suspension. Friedt is entitled to absolute immunity with respect to her decision to charge Hannum...and with respect to her decision to summarily suspend his vehicle dealer license because she was an agency official performing functions analogous to those of a prosecutor.

Id. at 888. Executive Director Williams, by deciding to initiate disciplinary proceedings against Mr. Jones, performed the same function

that the Director of DOL, Friedt, performed in *Hannum*. He is consequently entitled to the same absolute immunity.

Hamilton, a DOL administrator, was also sued in the *Hannum* case based on allegations that she investigated the complaints against the plaintiff and recommended that the plaintiff be charged and that his license be summarily suspended. Hamilton was similarly held to be absolutely immune, because she too was acting in a prosecutorial role. *Id.* at 888-89. There is no material distinction that can be drawn between the function that the *Hannum* defendants were serving and the function that Executive Director Williams was serving in this case. Taking the undisputed evidence in the light most favorable to Mr. Jones, this court can only conclude that Williams was functioning in a prosecutorial role, entitling him to absolute immunity.

Mr. Jones argued in response to the State's summary judgment motion that a question of fact remained with respect to Executive Director Williams' absolute immunity, because an Assistant Attorney General (AAG) signed the Statement of Charges and motion for summary action along with Williams. CP at 196-97. In essence, Mr. Jones contends that the AAG acted as the prosecutor, and that consequently Williams' role was therefore not prosecutorial. This argument misconstrues the

prosecutorial function" test and belies Mr. Jones' own allegations in the Amended Complaint.[13]

The co-signature of an AAG in filing charging documents does not destroy the Executive Director's absolute immunity so long as Williams' conduct was prosecutorial in nature. In many cases both a prosecuting attorney and an agency official have been conferred absolute immunity. For example, in *Olsen v. Idaho State Bd. Of Medicine*, 363 F.3d 916 (9th Cir. 2004), a factually analogous case in which a doctor asserted a § 1983 procedural due process claim based on disciplinary proceedings that had been brought against him, the Ninth Circuit afforded prosecutorial immunity to both the Executive Director of the Idaho Medical Board, along with its members, counsel, other staff. *Id.* at 925-26. Furthermore, in *Hannum*, this court conferred absolute immunity to a state official who had no prosecutorial authority, but simply recommended that disciplinary action against the plaintiff be taken. *Hannum*, 88 Wn. App. at 888-89.

Regardless of the number of persons involved in the initiation of the disciplinary proceedings or who signed the charging documents, the relevant inquiry in deciding whether an official is entitled to absolute prosecutorial immunity is whether the official's conduct was comparable

[13] Mr. Jones' 42 USC § 1983 due process claim is premised on the allegation that the individual defendants "violated Jones's civil rights by initiating disciplinary proceedings that they knew or should have known were unreasonable and violated Jones's procedural due process rights..." CP at 474, 509.

to that of a prosecutor. Mr. Jones himself alleged in the Amended Complaint that Williams made the decisions to file a statement of charges and motion for summary suspension, and it is undisputed that these allegations are the factual basis for Mr. Jones' § 1983 claims against Williams. CP at 474, 509. Those allegations were, in fact, confirmed by Williams in his declaration, which was un-rebutted on summary judgment. CP at 267-68, 273, 276. The trial court erred in refusing to confer Executive Director Williams with absolute immunity, and all claims against Williams must be dismissed as a matter of law.

C. The Trial Court's Failure to Confer Qualified Immunity to All of the Individual Defendants Was Error

In this case, Mr. Jones' § 1983 claim is premised on his assertion that he was denied procedural due process under the Fourteenth Amendment, because he was not afforded a pre-deprivation hearing when the Pharmacy Board summarily suspended his pharmacy licenses. Qualified immunity shields governmental officials performing discretionary functions from civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known. *Harlow v. Fitzgerald*, 457 U.S. 800, 818, 102 S. Ct. 2727, 73 L. Ed. 2d 396 (1982).

In order to determine whether qualified immunity applies, the court must determine whether the facts, when taken in the light most favorable to the plaintiff, show the defendant's conduct violated the plaintiff's constitutional right. *Saucier v. Katz,* 121 S. Ct. 2156 (2001) (citing *Siegert v. Gilley*, 500 U.S 226, 232, 111 S. Ct. 1789, 114 L. Ed. 2d 277 (1991)). Only if the answer to this threshold question is affirmative must the court consider whether the right was "clearly established" at the time of the events in question. *Conn v. Gabbet*, 526 U.S. 286, 290, 119 S. Ct. 1292, 143 L. Ed. 2d 399 (1999). A right is "clearly established" if its contours are sufficiently clear that a reasonable official would understand that what he is doing violates that right. *Bator v. State of Hawaii*, 39 F.3d 1021, 1027 (9th Cir. 1994). Even where a constitutional violation has occurred, whether an official asserting qualified immunity may be held liable generally turns on the objective legal reasonableness of the action, assessed in light of the legal rules that were clearly established at the time it was taken. *Kwai Fun Wong v. United States*, 373 U.S. F.3d 952, 976 (9th Cir. 2004); *Butler v. Elle*, 281 F.3d 1014, 1021 (9th Cir. 2002). Once a defendant has raised the defense of qualified immunity in a motion for summary judgment, the plaintiff bears the burden of showing the defendant's conduct violated a clearly established constitutional right. *Robinson v. City of Seattle*, 119 Wn.2d 34, 65-66, 830 P.2d 318 (1992).

1. No Evidence that Investigators Wene or Jeppesen Committed a Constitutional Violation

Mr. Jones claims that his right to procedural due process under the Fourteenth Amendment was violated, because he was not afforded a pre-deprivation hearing when his professional licenses were summarily suspended. However, Mr. Jones failed to produce any evidence that Investigators Wene and Jeppesen, by simply inspecting his pharmacy and completing inspection reports for Executive Director Williams' consideration, violated any clearly established procedural due process right. Once the defendant has raised qualified immunity, the plaintiff bears the burden of identifying the right allegedly violated and showing that the right was clearly established. *Robinson v. City of Seattle*, 119 Wn.2d at 65-66; *Sorrels v. McKee*, 290 F.3d 965, 969 (9th Cir. 2002). "Even if the plaintiff's complaint adequately alleges the commission of acts that violated clearly established law, the defendant is entitled to summary judgment if discovery fails to uncover evidence sufficient to create a genuine issue as to whether the defendant in fact committed those acts." *Robinson,* 119 Wn.2d at 66 (quoting *Mitchell v. Forsyth,* 472 U.S.

11, 526, 105 S. Ct. 2806, 86 L. Ed. 2d 411 (1985)).[14] Mr. Jones failed to satisfy this burden.

As reflected in the Amended Complaint, the basis for Mr. Jones' § 1983 procedural due process claim is that the defendants initiated disciplinary proceedings against him. Yet, the only specific factual allegations Mr. Jones made about Wene and Jeppesen in the Amended Complaint concern their inspection and investigation of his pharmacy in July and August of 1999, and Wene's prior investigation of the pharmacy in 1998 and 1999. CP at 471-73, 506-08. As the State argued in its summary judgment reply brief, Mr. Jones failed to produce any evidence to show that the investigators initiated disciplinary proceedings against him, or that they even had the authority to do so. CP at 157-58.

All of the evidence submitted in support of and in opposition to the State's summary judgment motion confirmed that the investigators' only involvement in the disciplinary proceedings were their investigations of Mr. Jones' pharmacy and the completion of inspection reports. Thus, Executive Director Williams, not Inspectors Wene and Jeppesen, filed the motion for summary suspension and initiated the disciplinary action against Mr. Jones. Mr. Jones cited no authority to establish that an

[14] When the State moved for summary judgment, Mr. Jones made no motion pursuant to CR 56 (f) requesting a continuance for additional discovery to respond to the motion.

investigator, by conducting an investigation in any manner, violates an individual's right to procedural due process under the Fourteenth Amendment.[15] The court's decision in *Hannum* again provides proper guidance and requires the dismissal of Mr. Jones' claims against Investigators Wene and Jeppesen. In affirming summary judgment, the court held that a § 1983 due process claim could not be stated against an investigator for conduct that is virtually identical to the conduct Mr. Jones alleges against Wene and Jeppesen:

> The proper inquiry is whether Gerrish, by investigating Hannum's transactions, deprived Hannum of property without due process of law. Hannum fails to specify how Gerrish's investigative actions deprived him of property without due process of law. The complaints allege that "the actions of Defendants to summarily suspend Mr. Hannum's license violates his due process rights under the United States and State of Washington Constitutions." Hannum's due process claim focuses on the defendants' actions of summarily suspending his vehicle dealer license. Personal participation in the alleged violation is an essential allegation in a Sec. 1983 claim. Gerrish did not personally participate in the filing of charges against Hannum or in the summary suspension of Hannum's vehicle dealer license.

Id. at 890-91 (citations omitted).

There is no evidence that Investigators Wene or Jeppesen were involved in the decision to charge Mr. Jones or to initiate disciplinary

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[15] The State also argued that even if Mr. Jones had asserted a 42 USC § 1983 claim against the investigators premised on a Fourth Amendment violation, which he did not, he still failed to meet his burden to overcome the assertion of qualified immunity. CP 158-59.

proceedings. Their conduct was investigative in nature, just as the investigator's conduct in *Hannum* was, and it implicates no procedural due process violation. Because Mr. Jones failed to satisfy his burden of showing that Investigators Wene and Jeppesen committed a constitutional violation, the trial court erred in holding that they are not qualifiedly immune.

2. All of the Defendants are Qualifiedly Immune, Because a Reasonable Public Official Could Have Believed an Emergency Existed, Such that a Post-Deprivation Hearing, Which Mr. Jones Received, Was Adequate Due Process

In responding to the assertion of qualified immunity, Mr. Jones also bears the burden of showing that the right he alleges was violated was clearly established and that Williams, Wene, and Jeppesen's conduct was not objectively reasonable. *Robinson*, 119 Wn.2d at 66-67. Mr. Jones cited no authority in the trial court establishing that a pharmacist has a clearly established right to a pre-deprivation hearing. Furthermore, under the legal "objective reasonableness" standard, all three individual defendants are entitled to qualified immunity, because the summary suspension was authorized by statute and Mr. Jones admitted in declarations submitted to the Pharmacy Board to serious violations of laws pertaining to health and public safety. In this situation, a post-deprivation hearing, which it is undisputed that Mr. Jones received, satisfies the

requirements of procedural due process. In light of the admissions Mr. Jones made, a reasonable public official could have believed that invoking RCW 18.130.050(7), which specifically authorizes summary suspension proceedings against pharmacists, was not only justified, but necessary.

Where an individual possesses a constitutional property interest, due process requires that he be given notice and a meaningful opportunity to be heard before being finally deprived that interest. *Mathews v. Eldridge*, 424 US 319, 333, 96 S. Ct. 893, 47 L. Ed. 2d 18 (1976). In this case, Mr. Jones does not dispute that he received notice of the order of summary suspension the same day it was entered, nor does he dispute that he received notice of all subsequent actions by the State with respect to his professional licenses. Nor does Mr. Jones dispute that, while represented by counsel, he was heard by a full thee-member panel of the Pharmacy Board on his motion to stay and modify the summary suspension order just twenty-one (21) days after the order was entered. Moreover, the order was not a final disposition of the disciplinary action against Mr. Jones, but rather only a suspension of his licenses "pending further disciplinary proceedings by the Board." CP at 325. It is undisputed that, had he not voluntarily stipulated to a five-year suspension, an even more extensive hearing was available. Thus, Mr. Jones does not contend that he was given no due process. Rather, Mr. Jones' § 1983 due process claim is thus

premised strictly on his contention that he was not given sufficient due process, because he was afforded a post-deprivation hearing rather than a pre-deprivation hearing.

"The hearing required by the Due Process Clause must be 'meaningful' and 'appropriate to the nature of the case.'" *Bell v. Burson*, 402 U.S. 535, 541-42, 91 S. Ct. 1586, 29 L. Ed. 2d 90 (1971) (citations omitted). The specific procedural protections required depends on a balancing of three factors: (1) the gravity of the private interest affected; (2) the risk of erroneous deprivation under the current procedure, and the probable value, if any, of additional procedural safeguards; and (3) the interest of the government, including the burdens of additional or substitute procedures. *Mathews*, 424 US. at 335.

Public health and safety is implicated in nearly every transaction that a pharmacist, who is responsible for dispensing drugs and controlled substances, has with his customers. Not surprisingly, pharmacists are highly regulated. *See Murphy v. State*, 115 Wn. App. 297, 62 P.3d 533 (2003) (recognizing that pharmacy records are open for inspection to regulators and law enforcement); *State v. Mark*, 23 Wn. App. 392, 597 P.2d 406 (1979). Thus, evaluating the last factor in the *Mathews* analysis, the State undeniably has a great and substantial interest in regulating licensed pharmacists to ensure their compliance with high professional

standards to protect public health and safety. *See, e.g., Virginia State Bd. Of Pharmacy v. Virginia*, 425 U.S. 748, 766, 96 S. Ct. 1817, 48 L. Ed. 2d 346 (1976) (recognizing the government's interest in pharmacists' professional standards).

This interest by the State justifies its power to utilize summary action in appropriate situations. While a pre-deprivation hearing is the norm, "[t]he Court has often acknowledged...that summary administrative action may be justified in emergency situations." *Hodel v. Virginia Surface Mining and Reclamation Assoc.*, 452 U.S. 264, 299-300, 101 S. Ct. 2352, 69 L. Ed. 2d 1 (1981); *see also Clausing v. State*, 90 Wn. App. 863, 955 P.2d 394 (1998) (summary suspension of osteopath's license); *Hannum v. Friedt*, 88 Wn. App. 881, 947 P.2d 760 (1997) (summary suspension of automobile dealer's license). "Protection of the health and safety of the public is a paramount governmental interest which justifies summary administrative action." *Hodel,* 452 U.S. at 300. In these situations, due process is satisfied so long there is an opportunity for a hearing and a judicial determination at some stage in the proceedings. *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S.594, 599, 70 S. Ct. 870, 94 L. Ed. 1088 (1950).

Consistent with this principle, here the Board granted the motion summarily suspending Mr. Jones' professional licenses, because it found

that there was an immediate danger to the public health, safety, or welfare, and that summary action was the least restrictive action justified by the dangers posed. CP at 324-25. The Legislature has specifically conferred the Board with the authority to effect summary suspensions under these circumstances in RCW 18.130.050(7). Furthermore, WAC 246-11-300 provides that "[n]o notice to any person potentially affected by a summary action shall be required prior to issuance of a summary action." Thus, the summary suspension of Mr. Jones' professional licenses was authorized and completely consistent with state law.[16] Mr. Jones has never challenged the statute or regulations under which the State summarily suspended his licenses.

Under *Mathews*, the specific type and timing of the hearing guaranteed by the Fourteenth Amendment depends on a balancing of factors. Mr. Jones has not established, after weighing these factors in the case at bar, that the summary suspension violated any clearly established right under *Mathews*. As the Ninth Circuit has recognized, where a right

[16] Many courts have held that qualified immunity should be conferred where an individual defendant has complied with a facially valid statute. *See, e.g., Sherman v. Four County Counseling Center*, 987 F.2d 397, 402 (7th Cir. 1993); *Lytle v. Brewer*, 77 F. Supp.2d 730, 739-40 (E.D. Va. 1999); *Riley v. Wooton*, 1994 WL 374204 (E.D. La. 1994); *Carman v. City of Eden Prairie*, 622 F. Supp. 963, 967 (D.C. Minn. 1985); *See also Lugar v. Edmondson Oil Co., Inc.*, 457 U.S. 922, 942 fn. 23 (1982); *Johnson v. Duffy*, 588 F.2d 740, 745 (9th Cir. 1978).

depends on an ad hoc balancing test such as *Mathews*, the right is rarely clearly established and qualified immunity will ordinarily apply:

> While the right to due process is "clearly established" by the Due Process Clause, this level of generality was not intended to satisfy the qualified immunity standard. Rather, courts must look to the *Mathews* test. And...**because procedural due process analysis essentially boils down to an ad hoc balancing inquiry, the law regarding procedural due process claims "can rarely be considered 'clearly established' at least in the absence of closely corresponding factual and legal precedent.'"**...Not only does the *Mathews* inquiry require a delicate balancing of several competing interests, it requires that balancing at several separate stages of the procedural due process analysis.

Brewster v. Board of Education of Lynwood Unified School Dist., 149 F.3d 971, 983 (9th Cir. 1998) (emphasis added; citations omitted).

Thus, although Mr. Jones, as the holder of a professional license, may have a constitutional interest, he cited no authority showing that a pharmacist's interest is of such a magnitude that it would entitle him to a pre-deprivation hearing and outweigh the State's interest in public safety. The magnitude of his interest, especially under the facts of this case, is at best not well settled. Although Mr. Jones admittedly had a procedural due process interest in his professional license under the first factor in *Mathews*, the risk of an erroneous deprivation was offset by the extensive hearing process and availability of both administrative and judicial review within a short time period, a reasonable public official could have believed

that the second and third *Mathews* factors outweighed Mr. Jones' interest in a pre-deprivation hearing, especially in light of the fact that ample post-deprivation process was available.

Furthermore, the State's interest in taking immediate action was undeniably augmented in the factual context of this case. The admissions Mr. Jones made when he moved to stay and modify the summary suspension order, at a minimum, establish that qualified immunity must be granted under the facts of this case. Qualified immunity protects all but the plainly incompetent or those who knowingly violate the law, and if reasonable officials could disagree regarding the lawfulness of the defendant's conduct, immunity still applies. *Malley v. Briggs*, 475 U.S. 335, 341, 106 S. Ct. 1092, 89 L. Ed. 2d 271 (1986). The objective reasonableness of a defendant's action should be decided on summary judgment, and the court decides the issue as a matter of law. *Sintra v. City of Seattle*, 119 Wn.2d 1, 26-27, 829 P.2d 7654 (1992).

Here, Mr. Jones' admissions indicated that the balance of the factors under *Mathews* weighed in favor of an immediate action by the State, because of the threat to public health or safety. If the court simply considers the undisputed admissions that Mr. Jones made to the Pharmacy Board, it must find, at a minimum, that a reasonable public official could have believed that there was an immediate danger to the public health,

safety, or welfare such that summary suspension, as authorized by RCW 18.130.050 (8), was justified. Thus, Mr. Jones' admissions establish the individual defendants' qualified immunity.

First, Mr. Jones demonstrated a stunning lack of familiarity with the computer system that he should have been utilizing both to ensure that patients would not experience adverse allergic reactions or adverse drug interactions and to track changes in patients' prescription records. Mr. Jones verified in a declaration submitted to the Pharmacy Board that the feature of this system designed to provide detect and warn of patients' adverse drug reactions and drug interactions was not even turned on. As Executive Director Williams indicated in his declaration, without this function operating, Mr. Jones would not have been able to detect potentially fatal allergic reactions of his patients. Patients have died and suffered serious injuries as a result of similarly neglectful pharmacist's failure to utilize these warning systems properly. *See, e.g., Baker v. Arbor Drugs, Inc.*, 215 Mich. App. 198, 544 N.W. 2d 727 (Mich. App. 1996) (patient of pharmacy suffered stroke after pharmacist filled prescriptions for two incompatible drugs, because pharmacist failed to properly utilize computer system that provided a warning for this adverse drug interaction); *Dooley v. Everett*, 805 S.W.2d 380 (Tenn. App. 1990) (patient stated claim against pharmacy for failure to detect adverse drug

interaction, which caused patient to suffer cerebral seizures from resulting toxic levels of theophylline in her blood).

Mr. Jones also indicated that only after the August 1999 inspection did he speak with the technical support personnel from his computer system's vendor to confirm that the system was capable of performing an "audit trail," as required by WAC 246-875-001, which is a track of changes to a patient's prescription record. Thus, during both inspections in the summer of 1999, Mr. Jones was admittedly unable to utilize his computer system either to receive critical warnings regarding patient reactions or to document changes to patient prescription records.

Mr. Jones also admitted to being unable to demonstrate that he was properly dispensing drugs to patients in child-resistant caps (CRC's). At the inspections, he could not locate authorizations for patients to whom he had administered drugs in containers with non-child resistant caps. Other cases document that children who have ingested harmful substances that were improperly dispensed by pharmacists in non-child resistant containers have suffered serious injuries and death. *See, e.g., Wahba v. H&N Prescription Center, Inc.*, 539 F. Supp. 352 (1982) (two year-old died after ingesting 20 pills prescribed to mother, which were improperly dispensed by pharmacy in non-child resistant container). Given the

potential threat to the public and particularly children, this admitted violation would have appeared emergent to any reasonable public official.

Mr. Jones' admissions also established serious record-keeping deficiencies with respect to controlled substances. He was unable to locate required records of prescription record inventories, offering the excuses that they were misfiled or missing, later speculating that they had been stolen. Mr. Jones admitted that he was missing some of the required DEA drug order forms pertaining to Schedule II drugs, which are highly addictive and dangerous. The purpose of record-keeping requirements imposed on pharmacies is "to regulate behavior by those dispensing and using prescription drugs..." *Murphy*, 115 Wn. App. at 306. Courts are "committed to allow the maximum scope of police power in the control of the illegal use of narcotic drugs." *State v. Lee*, 62 Wn.2d 228, 233, 382 P.2d 491 (1963). Thus, pharmacists have been prosecuted under the Controlled Substances Act for the type of insufficient Schedule II records that Mr. Jones acknowledged. *See, e.g., United States v. Poulin*, 926 F. Supp. 246 (D. Mass. 1996) (pharmacy and owner liable in civil prosecution under Controlled Substances Act for, *inter alia*, defective DEA forms that were not properly signed or that did not reflect quantity of controlled substances received and failure to keep required biennial inventory); *United States v. Bycer*, 593 F.2d 549 (3d Cir. 1979)

(pharmacist convicted of faulty recordkeeping). Again, the numerous admitted recordkeeping violations support a reasonable belief by the individual defendants that RCW 18.130.050 (8) could properly be invoked to effect a summary suspension by the Board.

Mr. Jones' declaration further acknowledged that there were outdated prescriptions on his shelves at the inspections, admitting that he subsequently removed numerous outdated items. His attorney verified that these outdated prescription items had "slipped through the cracks." Again, keeping out-of-date and unstable drugs on the shelves, where they could potentially be sold to customers of the pharmacy, entails serious public health and safety concerns.

Last, Mr. Jones had a history of disciplinary misconduct with the Board. As Mr. Jones admitted, he previously failed an inspection of his pharmacy in December 1998, then corrected some of the deficiencies and secured a passing score at an inspection in February of 1999. CP at 212-13. Mr. Jones' license had also previously been placed on probation for a year in 1994. CP at 298, 415. The Board considered this history when it denied his motion to stay the summary suspension, and was concerned with his history of violating pharmacy law and then bringing his pharmacy into compliance once discovered. CP at 357. It was consequently not convinced that he had rectified the violations. CP at 357. The fact that Mr.

Jones was a repeat violator would also have intensified any reasonable public official's concerns with these numerous violations.

Where a threat to public health and safety is implicated, summary action satisfies procedural due process. A reasonable public official could have determined that cumulatively these violations reflected that Mr. Jones' pharmacy was in disarray and represented a threat to public health and safety justifying summary action. Mr. Jones failed to cite any case clearly establishing his right to a pre-deprivation hearing in circumstances where summary action was taken pursuant to a statute specifically authorizing it and where the license-holder himself admitted to serous health and safety violations. Consequently, Mr. Jones failed to meet his burden of showing that any clearly established right was violated, and the individual defendants are all entitled to qualified immunity on Mr. Jones' § 1983 due process claim. The trial court erred in holding that the individual defendants were not entitled to qualified immunity, and this court should reverse its decision.

D. Mr. Jones' Voluntary Stipulation to an Order Agreeing to the Suspension of His Licenses and Waiving the Available Administrative Hearing Precludes His State Law Tort Causes of Action

Mr. Jones' remaining state law causes of action for negligent supervision and intentional interference with a business expectancy are

barred, because he stipulated to the entry of an agreed order, voluntarily forgoing the full-blown hearing available during which he could have contested the suspension of his licenses. Once summary action is taken against a pharmacist's license, the pharmacist may request a prompt adjudicative proceeding, which must occur within twenty (20) days of the summary action if requested. WAC 246-11-330; WAC 246-11-340. Alternatively, the pharmacist may waive the right to a prompt adjudicative proceeding and request a regularly scheduled adjudicative proceeding. WAC 246-11-330. All of the Board's decisions, including summary actions, may be appealed to the Superior Court pursuant to the provisions of the Administrative Procedures Act (APA). RCW 18.64.200; RCW 18.130; WAC 246-11-310 (4); *See also* RCW 34.05, *et. seq.*

Here, Mr. Jones could have demanded a "prompt hearing," which would have been required to occur within 20 days of the summary suspension. WAC 246-11-330. Instead, Mr. Jones chose to waive his right to a "prompt hearing," electing to instead challenge the summary suspension by written motion. Mr. Jones' written motion to stay the summary suspension order was heard and denied by the Board just twenty-one (21) days after the summary suspension order was entered. Even after this unsuccessful motion, Mr. Jones still had the right to a full adjudicative "regularly scheduled" hearing. However, prior to any full

hearing taking place, Mr. Jones entered into a stipulated order in which he agreed to the suspensions of his licenses.

Because he voluntarily chose to settle the disciplinary action against him by entering into an agreed order providing for a five-year suspension of his professional licenses, Mr. Jones never availed himself of the full-blown hearing on the Statement of Charges that was available. While represented by counsel, Mr. Jones knowingly indicated in the stipulated order that he was waiving his right to the available hearing, and the Board, relying on that waiver, the Board signed the order. CP at 414, 430.

A plaintiff must exhaust administrative remedies prior to filing a lawsuit when: (1) a claim is cognizable in the first instance by the agency; (2) the agency's authority sets out clearly defined processes for resolving the aggrieved party's complaint; and (3) the relief sought can be obtained through an exclusive or adequate remedy. *Phillips v. King County*, 87 Wn. App. 468, 479, 943 P.2d 306 (1997). "The doctrine is founded on the principle that the judiciary should give proper deference to that body possessing expertise in areas outside the conventional experience of judges, so that the administrative process will not be interrupted prematurely, so that the agency can develop the necessary factual background on which to reach its decision, so that the agency will have the opportunity to exercise its

expertise and to correct its own errors, and so as not to encourage individuals to ignore administrative procedures by restoring to the courts prematurely." *Id.* at 479-80.

Thus, in *Laymon v. Wash. Dep't. of Natural Resources*, 99 Wn. App. 518, 994 P.2d 232 (2000), the court dismissed a tort action based on the plaintiff's failure to take advantage of the administrative remedies available to him. There, the Department of Natural Resources (DNR) had issued a stop work order requiring the plaintiff, Laymon, cease logging on his property, because a bald eagle's nest had been reported nearby. *Id.* at 522. Just as the order of summary suspension in this case had the effect of requiring Mr. Jones to cease the practice of pharmacy without a hearing first, the stop work order in *Laymon* was effective immediately and required that work be stopped without any prior hearing. *Id.* The stop work order could have been challenged by Laymon if he had filed a timely appeal with the Forest Practices Appeals Board. *Id.* 522-23. The Court of Appeals upheld dismissal of Laymon's state law tort lawsuit, because "Where, as here, the aggrieved party fails to show that it attempted to use the appropriate administrative appeals process, the trial court may properly dismiss the claim. *Id.* at 524-35 (quoting *CLEAN v. City of Spokane*, 133 Wn.2d 455, 465, 947 P.2d 1169 (1997)).

Mr. Jones not only failed to appeal the Board's order, he agreed to it. He could have proceeded to a full hearing before the Pharmacy Board, and its administrative findings could in turn have been reviewed by the Superior Court. The order of summary suspension was similarly subject to judicial review. His claims in this case should be dismissed just as the plaintiff's claims in *Laymon* were.

In addition, this court has applied judicial estoppel in situations where a party attempts to gain an advantage by asserting one position in a court proceeding and later seeking an advantage by taking a clearly inconsistent position in a different court proceeding. *See, e.g., Cunningham v. Reliable Concrete Pumping, Inc,* 126 Wn. App. 222, 108 P.3d 147 (2005) (applying judicial estoppel to bar plaintiff's claims where plaintiff failed to disclose them in bankruptcy). Mr. Jones derived a benefit when he agreed to a five-year suspension of his licenses and the Pharmacy Board, a quasi-judicial entity, accepted and relied on his agreement when it signed the order. Mr. Jones should not now be permitted to take an inconsistent position in this action, especially in light of the extensive adjudicative process that he elected to disregard. The trial court's decision holding that Mr. Jones' state law claims are not barred by his voluntary agreement to the suspensions and waiver of the extensive administrative remedies available was error and should be reversed.

E. The Court Committed Error to the Extent it Determined that Genuine Issues of Material Fact Existed Based on Portions of Mr. Jones' Declaration that Were Hearsay or that Impermissibly Contradicted Prior Declarations by Mr. Jones and His Attorney in Violation of the Doctrine of Judicial Estoppel

Mr. Jones' declaration submitted in opposition to the State's motion for summary judgment contained hearsay statements. For example, Mr. Jones recounted statements by Claudia Tomlinson and Sharla Keeling, two non-party witnesses, regarding their interactions with Pharmacy Board officials. CP at 175-76. The State filed a motion to strike these portions of his declaration. CP at 165-78. Mr. Jones, apparently conceding that these portions of his declaration were inadmissible hearsay, filed no response to the State's motion to strike. Nevertheless, the trial court's order reflected that it admitted the hearsay, but "for background purposes only" and "not for the truth of the matter asserted." CP at 132-33.

When opposing summary judgment, the non-moving party may not rely on hearsay to create a genuine issue of material fact. *Barrie v. Hosts of America, Inc.*, 94 Wn.2d 640, 643-44, 618 P.2d 96 (1980). There is no distinction made in the Rules of Evidence between considering evidence for "background purposes" and considering it "for the truth of the matter asserted." If anything, this ruling reflects that the court was somehow

offered in Mr. Jones' declaration was irrelevant, to the extent the trial court found it to be relevant and relied on it in denying summary judgment, it erred.

Furthermore, as previously described in Section III.B. *supra*, Mr. Jones admitted to many of the health and safety violations alleged against him in declarations that he and his attorney submitted to the Pharmacy Board in an effort to stay the Board's summary suspension order. Yet, Mr. Jones attempted to create an issue of fact by submitting a declaration in opposition to the State's summary judgment motion contradicting many of these admissions.[17] CP at 340-46. The State argued to the trial court that Mr. Jones is judicially estopped from contradicting statements he made under penalty of perjury, which were relied upon by the Pharmacy Board, a quasi-judicial entity, in ruling on his motion to lift the summary suspension order. CP at 149-53.

Judicial estoppel prevents a party from taking a factual position that is inconsistent with his factual position in previous litigation.

[17] For example, Mr. Jones admitted to the Pharmacy Board that he failed to activate the function in his computerized patient records system that would alert him to adverse drug interactions and reactions until the investigators had left for lunch on the day of his second failing inspection in August of 1999. CP at 341. Mr. Jones contradicted this admission in his summary judgment declaration by stating that this problem had already been corrected by the investigators' second investigation. CP at 214. Mr. Jones' declaration in opposition to the State's motion for summary judgment was replete with further impermissible contradictions, which are described in the State's summary judgment reply brief. CP at 149-53.

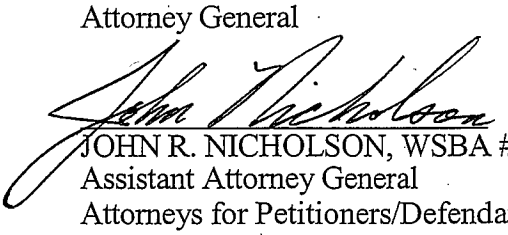
Judicial estoppel prevents a party from taking a factual position that is inconsistent with his factual position in previous litigation. *Holst v. Fireside Realty*, 89 Wn. App. 245, 259, 948 P.2d 858 (1997). This court should not permit Mr. Jones to create a genuine issue of fact by contradicting statements he made to the Pharmacy Board simply because it is advantageous for him to do so now. If this court considers Mr. Jones' admissions, which the Board relied on, then it must conclude that the defendants' conduct was objectively reasonable and that Mr. Jones' claims fail as a matter of law.

V. CONCLUSION

The trial court erred by denying absolute and qualified immunity to the individual defendants below. Furthermore, Mr. Jones' voluntary decision not to avail himself of the administrative remedies, require that his state law tort claims be dismissed. This court should reverse the trial court's partial denial of the State's motion for summary judgment and order that all Mr. Jones' claims must be dismissed as a matter of law.

RESPECTFULLY SUBMITTED this 29th day of August, 2006.

ROB MCKENNA
Attorney General



JOHN R. NICHOLSON, WSBA #30499
Assistant Attorney General
Attorneys for Petitioners/Defendants

CERTIFICATE OF SERVICE

I certify under penalty of perjury in accordance with the laws of the State of Washington that the original of the preceding Petitioner's Opening Brief was filed by legal messenger in Division I of the Court of Appeals at the following address:

Court of Appeals of Washington, Division I
One Union Square
600 University Street
Seattle, WA 98101

And that a copy of the preceding Petitioner's Opening Brief was served on appellants' counsel at the following address by legal messenger:

Murphy Evans
Brownlie, Evans, & Wolf, LLP
100 Central Avenue
Bellingham, Washington 98225

DATED this 29th day of August, 2006 at Seattle, Washington.

Valerie Tucker
VALERIE TUCKER

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Appendix A

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF EX PARTE ORDER OF SUMMARY ACTION

This matter came before the Board of Pharmacy (the Board) on August 17, 1999, on an Ex Parte Motion for Order of Summary Action brought by the Department of Health (the Department) by and through its attorneys, Christine O. Gregoire, Attorney General, and David M. Hankins, Assistant Attorney General. The Presiding Officer for the Board was Eric B. Schmidt, Senior Health Law Judge. The Board members deciding the Ex Parte Motion for Order of Summary Action were: Sharron Sellers, Public Member; Donna Docktor, R.Ph.; and C.A. Leon Alzola, R.Ph. The Board, having reviewed the motion and the documents submitted in support of the motion, hereby enters the following:

Section 1: ALLEGATIONS

1.1 Respondent Michael S. Jones was issued a license to practice pharmacy in the state of Washington in June 1980. Respondent's license to practice pharmacy in the state of Washington expires on October 29, 1999.

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1.2 Respondent Medicine Shoppe Pharmacy located at 9430 State Street in Marysville, Washington was issued a location license to operate as a Pharmacy in the state of Washington in October 1996. The current location license expires on June 1, 2000.

1.3 Respondent Michael Jones is the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

1.4 On March 1, 1994, a Statement of Charges was issued against Respondent Michael Jones related to a prescription filling error while Respondent was working as a pharmacist at Safeway Pharmacy # 497 in Seattle, Washington

1.5 On July 6, 1994, the Board entered Findings of Fact, Conclusions of Law and Order placing Respondent's license to practice pharmacy in the state of Washington on probation for a period of one year and imposing certain terms and conditions. One of the conditions imposed on Respondent was a requirement that Respondent create and submit a plan to avoid violations of pharmacy law related to the filling of prescriptions.

1.6 On December 7, 1995, Respondent's license to practice pharmacy in the state of Washington was fully reinstated.

1.7 On December 17, 1998, Respondent Medicine Shoppe received a failing inspection grade of 79 from Board of Pharmacy Investigator Wene while conducting a routine inspection of the pharmacy. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations observed during the inspection may be seen in detail in the Statement of Charges and on the Inspection sheet and report attached as Exhibit 1 to the Ex Parte Motion for Summary Action.

1.8 An inspection score of 90-100 is classified as a passing pharmacy inspection score. An inspection score of 80-89 is classified as a conditional pharmacy inspection score. An inspection score of 0-79 is classified as an unsatisfactory (failing) inspection score.

1.9 On February 3, 1999, Board of Pharmacy Investigator Wene conducted a re-inspection in relation to the December 1998 failing score. During the February 3, 1999 inspection, the pharmacy received a passing score of 94. The deducted points were related to inaccurate, incomplete or missing records required by state or federal law. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington The report of this inspection is attached as Exhibit 2 to the Ex Parte Motion for Summary Action.

1.10 On July 12, 1999, Board of Pharmacy Investigators Wene and Jeppesen conducted a routine inspection of the Medicine Shoppe Pharmacy in Marysville. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The pharmacy received an unsatisfactory extremely low failing grade of 48. The violations observed during the inspection may be seen in detail in the Statement of Charges and on the Inspection sheet and report attached as Exhibit 3 to the Ex Parte Motion for Summary Action.

1.11 On July 13, 1999, Investigator Jeppesen returned to the pharmacy to retrieve documents promised by Respondent Jones. At that time Respondent Jones stated he could not located the documents. Respondent stated that his computer could generate the required reports but that he, Respondent, did not know how to generate them. Investigator Jeppesen's report of this matter is attached as Exhibit 4 to the Ex Parte Motion for Summary Action.

1.12 On August 10, 1999, Investigators Wene and Jeppesen returned to the Medicine Shop Pharmacy in Marysville, Washington, to conduct the re-inspection in relation to the July 12, 1999 unsatisfactory (failing) score. This inspection again resulted in an extremely low failing score of 56. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations observed during the

inspection may be seen in detail in the Statement of Charges and on the Inspection sheet and report attached as Exhibit 5 to the Ex Parte Motion for Summary Action.

1.13 Respondent Michael S. Jones operated the Medicine Shoppe Pharmacy in a manner below the standard of care for the operation of a pharmacy in the state of Washington and therefore placed the patients of his pharmacy at serious risk of significant harm.

1.14 Due to the condition of the pharmacy, especially the violations related to record-keeping, summary suspension of both Respondent Jones and the Medicine Shoppe Pharmacy is the least restrictive means of protecting the pharmacy. The pharmacy is not in an operable condition to allow another pharmacist to operate the Pharmacy in Respondent Jones' absence.

Section 2: FINDINGS OF FACT

2.1 Respondent Jones was licensed as a pharmacist by the State of Washington at all times applicable to this matter.

2.2 Respondent Medicine Shoppe Pharmacy was licensed as a pharmacy by the State of Washington at all times applicable to this matter.

2.3 The Board issued a Statement of Charges alleging Respondents violated RCW 18.64.160(5), RCW 18.64.165(2), RCW 18.64.245, RCW 18.64.246, RCW 18.64.270, RCW 18.130.180(4), (6), (7), RCW 69.04.450, RCW 69.05.510, RCW 69.41.042, RCW 69.41.050, RCW 69.50.306, WAC 246-863-095, WAC 246-863-110, WAC 246-869-130, WAC 246-869-150, WAC 246-869-160(4) and (5), WAC 246-869-190, WAC 246-869-210, WAC 246-869-230, WAC 246-875-020, WAC 246-875-040, WAC 246-875-080(2), WAC 246-901-090 and WAC 246-901-100(3). The Statement of Charges was accompanied by all other documents required by WAC 246-11-250.

2.4 The Board finds that the public health, safety and welfare imperatively require emergency action pending further proceedings due to the nature of the allegations as stated above and in the Statement of Charges.

2.5 The alleged conduct, as set forth in the Allegations above and as supported by the documents attached to the Ex Parte Motion for Order of Summary Action, is directly related to Respondent Jones's ability to practice as a pharmacist, and Respondent Medicine Shoppe Pharmacy's ability to operate as a pharmacy, in the state of Washington. The Board finds, based on the declarations and evidence submitted with the Ex Parte Motion for Order of Summary Action, that summary suspension of Respondent Jones's license to practice as a pharmacist and of Respondent Medicine Shoppe Pharmacy's license to operate as a pharmacy are the least restrictive actions necessary to prevent or avoid immediate danger to the public health, safety, or welfare.

Section 3: CONCLUSIONS OF LAW

3.1 The Board has jurisdiction over Respondent Jones's license to practice as a pharmacist in the state of Washington.

3.2 The Board has jurisdiction over Respondent Medicine Shoppe Pharmacy's license to operate as a pharmacy in the state of Washington.

3.3 The Board has authority to take emergency adjudicative action to address an immediate danger to the public health, safety, or welfare. RCW 34.05.422(4), RCW 34.05.479, RCW 18.130.050(7); and WAC 246-11-300.

3.4 The above Findings of Fact and Allegations establish:

(a) The existence of an immediate danger to the public health, safety, or welfare;

(b) That the requested summary action adequately addresses the danger to the public health, safety, or welfare; and

(c) The requested summary action is necessary to address the danger to the public health, safety, or welfare.

3.5 The requested summary action is the least restrictive agency action justified by the danger posed by Respondent Jones's continued practice as a pharmacist and by Respondent Medicine Shoppe Pharmacy's continued operation as a pharmacy in the state of Washington.

3.6 The above Findings of Fact and Allegations establish conduct which warrants summary action to protect the public health, safety, or welfare.

Section 4: ORDERS

Based on the above Findings of Fact, Allegations and Conclusions of Law, the Board enters the following orders:

4.1 IT IS HEREBY ORDERED that the license issued to Respondent Michael S. Jones, R.Ph., to practice as a pharmacist in the state of Washington is SUMMARILY SUSPENDED pending further disciplinary proceedings by the Board.

4.2 IT IS HEREBY ORDERED that the license issued to Respondent Medicine Shoppe Pharmacy, located at 9430 State Street in Marysville, Washington, to operate as a pharmacy in the state of Washington is SUMMARILY SUSPENDED pending further disciplinary proceedings by the Board.

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4.3 Respondents shall immediately surrender both portions of their licenses to practice to a representative from the Board of Pharmacy upon demand.

DATED THIS 17th DAY OF AUGUST, 1999.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

C.A. LEON ALZOLA, R.Ph.
Panel Chair

FOR INTERNAL USE ONLY. INTERNAL TRACKING NUMBERS:
99010002, 99010013
CPS No. 99-03-14-0799

Appendix B

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF DECLARATION OF MICHAEL S. JONES

I, Michael S. Jones, R.Ph., do hereby declare as follows:

I am the Respondent herein and make this Declaration regarding facts and information about which I have personal knowledge and information.

I want to preface this statement by saying that I sincerely regret the fact that my pharmacy was considered to be below the accepted minimum standard for pharmacies in Washington when it was last inspected on August 10, 1999. Since that time, I have spent a great deal of time addressing the concerns of the investigators. I believe that the following discussion, which addresses each of the concerns raised in the Statement of Charges (S.O.C.) as well as by the inspectors, will show that all of the concerns had simple explanations, were not violations, and/or were quickly and easily rectified. I am truly sorry that the following matters had not been completely taken care of by August 10, 1999, so as to alleviate the concerns of the investigators:

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1. Although information regarding allergies and chronic conditions has always been obtained from all patients, there was a question as to whether it was being properly inputted into the computer. Further, the disease state-drug interaction fields were thought (by the inspectors) to have been turned off. Therefore, while the inspectors were at lunch on August 10th, I contacted my computer vender to discuss these problems. I was informed, much to my surprise, that these features were left off by the company (i.e., never turned on by them), unless they were specifically requested to do so. I had no idea that these features were not functioning and told them to activate them immediately, which they did. This explained why I could not explain their functioning to the inspectors and why they thought I had turned it off, which I had not done. Nevertheless, this function was operational by the time they returned from lunch. I even showed this to Mrs. Wene, so I am at a loss to understand why this is included in the S.O.C., especially when I was not marked down for this on the Inspection Report. Lastly, all patients have been updated regarding chronic conditions and allergy information. If there is no such information in the computer for a patient, that is because the patient has no allergies or chronic conditions.

2. Many of the prescriptions that were randomly selected and described as having products in them that did not match the NDC numbers were ones that were still there from the prior inspection and had not been picked up by the customers by the time of the August 10th inspection. Consequently, I was cited for them twice (double jeopardy) even though they were not new infractions. I should not have lost points a second time for the same prescriptions.

Nevertheless, I had already instituted a new system prior to the last inspection to make sure that the NDC numbers matched the product, and the necessary changes were

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being made, and have been made, in the computer. Henceforth, there will be no variance. However, at the time of the August 10th inspection, I had not had time to make all the necessary changes. This is an ongoing process and does not take place overnight. We now use checkmarks to double check and make sure the product matches the NDC. If it doesn't, the NDC is changed. I do not expect to have any further problems in this regard.

3. With respect to the CRC/NCRC issue, this has already been explained. It is a fact that at least 95 percent of my customers have specifically requested that I use NCRC lids on their containers and I have signatures for every one of them! There is no rule or regulation that mandates a maximum percentage of NCRC's that can be used. Anyone can request NCRC containers and it is not limited to the elderly. The only qualification is that they sign a record indicating this request and I did that with all my customers. While my records may not have been organized for ease of reference, it was wrong to single me out simply because the percentage of NCRC's is high. It was also my understanding that Mrs. Wene approved of my system when I received a 94 on February 3, 1999. That was the same system that was in place in July and August.

Nevertheless, as a result of the difficulties that this has caused me, I have already changed my system for recording these signatures. They will now be filed alphabetically on index cards so that they can be easily retrieved, in addition to this request being indicated in the computer. Everyone, including those who have already signed my signature book, will sign my new index cards. Further, everyone working in the pharmacy will be vigilant to make sure that no NCRC's are used without the necessary signatures. Further, no prescription will be dispensed without a CRC unless the receipt says "NRC".

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4. All outdated legend and OTC products have been removed from my shelves. In order to avoid any problems with this in the future, we will now do a monthly review instead of quarterly, for outdates. This will ensure that no outdates remain on the shelves. I also had "Returns by Howard" come out, inspect for outdates, too, and process our returns.

5. With regard to the "inaccurate, incomplete or unavailable" records, I have already rectified these concerns. Signatures have been provided, where needed, on controlled substance inventories. CII invoices have been separated from all other invoices and will continue to be filed separately. They are also being stapled to DEA 222 forms per the inspector's recommendation.

I also had an employee spend a week going through all of our prescription files to make sure they were in proper order and otherwise in compliance. The records and prescription hard copies that could not be located at the time of the inspection have since been located. They had simply been misfiled. We will, hereafter, be cognizant of this problem and vigilant to make sure that this doesn't happen. One plan for avoiding this problem is to organize these records and files on as nearly a daily basis as possible.

One of the primary reasons I had a problem with missing information at the last inspection was because of a lack of knowledge and information as to exactly what was expected or required. I would be told at one inspection that e.g. I was missing signatures. Having been made aware of this, I complied. However, nothing else was pointed out as being deficient. Then, at the next inspection, something else, e.g., DEA numbers, would be pointed out. If I had simply been advised, all at one time, what I needed to do, I would not have had a problem with these requirements on a piecemeal basis. However, I think I now

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know what is required and I can assure you that my records will be in full compliance hereafter.

6. All records, invoices, etc. that were of concern to the inspectors have been located, organized, and separated per their instructions and recommendations.

7. There were three DEA 222 forms that were in question at the time of the inspection regarding the quantities and dates. With one, the order had not yet been received at the pharmacy. Another blank had been lost between my pharmacy and the wholesaler. I verified this with them, and the fact that the order had not been received or filled by them. With respect to the third form, the order had not been checked in yet. I subsequently checked the quantity and dated the form. We now staple the CII invoice to the blue 222 form. We had never been advised, or instructed, to do this before, but we are doing it now.

8. Lastly, the inspectors were concerned that our QS-1 system was inadequate for the minimum procedures for utilization of the patient medication system and for creating an accurate and complete audit trail for changes made to the prescriptions after filling. These concerns were unfounded. I have spoken with the QS-1 technical support personnel, the system is fully capable of performing these functions, and I am able to utilize these functions. The process is too lengthy to describe, but I would gladly show an inspector how it is done.

I believe the foregoing fully and completely addresses all matters and concerns raised by the inspectors and alleged in the S.O.C. that have affected the licenses of myself and my pharmacy. I feel very strongly about the fact that none of these concerns have ever had even the potential for adversely affecting the health, safety or welfare of any of my customers. The health, safety and welfare of my customers has always been of paramount

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importance and I would never do anything to compromise this, nor have I. I take great pride in my professionalism and will continue to do so.

I do not believe that the summary suspensions of both mine and my pharmacy's licenses were necessary or justified. The action of the Board has very likely ruined me, financially, and it is doubtful that I will ever be able to recover. At the very least, I will never recoup my substantial losses. The Board has also caused me to suffer, unnecessarily, a great deal of personal humiliation and trauma.

I have done everything possible to bring my pharmacy into compliance and to satisfy the concerns of the Board. Further, I steadfastly resolve to maintain this compliance and to maintain my pharmacy's rating at the highest level.

I have been punished, and made an example of, long enough. Nothing more can possibly be gained by continuing the Board's course of action. I have been penalized in virtually every possible way. The punishment should fit the "crime", not exceed it, as it has in my case. It is time to stop the bleeding.

I respectfully request that the summary suspensions of my license and Medicine Shoppe's license be stayed immediately so that I can attempt to pull my business and my livelihood out of the ashes. In addition to the preservation of one of a dying breed of community pharmacies, it is imperative to open the pharmacy immediately so that I can service the medical needs of my customers. They, too, have been seriously affected by the board's action which has been counterproductive to the stated goal of "protecting" them.

There is absolutely no need, or justification, for preventing me from returning to my pharmacy immediately as the responsible pharmacist pending the resolution of any other matters with the Board, if any. I am the only one who knows the QS-1 system and I am

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perfectly capable, and competent, of continuing to operate my pharmacy in a very professional manner, and of continuing to provide my customers with the excellent care they have come to expect from me and my staff. Once again, I ask that, before I am ruined completely, the licenses be reinstated and my pharmacy reopened immediately.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my information, knowledge and belief.

EXECUTED this 27th day of August, 1999, at Bothell, Washington.

MICHAEL S. JONES

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF DECLARATION OF W. BERNARD BAUMAN IN SUPPORT OF RESPONDENTS' MOTION TO MODIFY AND TO STAY SUMMARY SUSPENSIONS

I, W. Bernard Bauman, do hereby declare as follows:

I am the attorney for the Respondents herein and make this Declaration regarding facts and information about which I have personal knowledge.

I have reviewed the Declaration of Michael S. Jones and confirm and agree with the statements made therein. Mr. Jones is quite accurate in his position that the Board's action has very nearly, if not completely, ruined him financially. The continued viability of his pharmacy after this lengthy closure is in serious jeopardy and the only possibility of resurrecting it and reversing the irreparable harm being caused by the Board's closure is to reinstate both licenses and re-open the pharmacy under the control of Mr. Jones no later than Tuesday, August 31, 1999.

It should be clear from Mr. Jones' Declaration that the only thing he is really "guilty" of is disorganization and this does not constitute unprofessional conduct nor does it

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represent any threat to the health, safety and welfare of his customers. To summarize the concerns of the Board and Mr. Jones' responses:

1. Medical Information. Mr. Jones has always obtained allergy and medical condition information from his patients and, when available, inputted it into his computer. His QS-1 computer has the capability of recognizing and alerting the user to drug interaction and disease date information and Mr. Jones logically assumed this feature was operating. However, QS-1 had not activated it and, when he learned this, he had them do it immediately. Obviously, this was not his fault, he has corrected the problem, and he has also gone over his patient files and updated this information.

2. NDC Numbers. Mr. Jones was already in the process of correcting this problem when the inspectors returned on August 10, 1999. However, he was penalized a second time for the same prescriptions because they had not been picked up by the customers. Since the August 10th inspection, Mr. Jones has instituted a new system that is designed to make sure that, henceforth, all products dispensed match the NDC numbers in the computer. Nevertheless, this type of infraction does not jeopardize the safety of his customers.

3. CRC/Non-CRC. Mr. Jones has, at all times, been in complete compliance with regard to the caps used on his prescription bottles. The worst thing that can be said is that his record-keeping system for the signatures did not allow for one to readily verify specific signatures. However, this was not pointed out to him as a problem during his inspection in February 1999! Further, the high percentage of non-CRC caps used is not a violation of any regulation. Nevertheless, in order to avoid any further questions in this regard, Mr. Jones has voluntarily changed his system as he has described. This was,

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apparently, a big concern of the inspectors but this, too, did not present a safety concern to "the public".

4. Outdates. In light of the fact that a few products slipped through the cracks, Mr. Jones has changed his procedure for discovering and removing outdated products. Nevertheless, the few items that were missed and inadvertently not pulled did not pose a health risk to "the public".

5. Records and Files. These issues were fully addressed by Mr. Jones in his Declaration, the situation has been corrected and it will not happen again due to the institution of new record-keeping procedures. Here, again, the record-keeping problems, posed absolutely no risk to "the public".

6. QS-1 Computer Functions. As stated in Mr. Jones' Declaration, his computer system is capable of performing all the functions that are necessary and required for any pharmacy to adequately monitor the medical and pharmaceutical information for their patients, including, but not limited to, drug interactions and audit trails.

It should be abundantly clear to all concerned that Mr. Jones is a capable and concerned Pharmacist. He has, at all times, provided professional care to his customers and has done nothing to jeopardize the health, safety, and welfare of "the public". The foregoing discussion makes this very clear. None of the Board's concerns, alone or even in combination, rise to the level of concern professed by the inspectors and the Board. This matter could, and should, have been handled in a much more constructive, pharmacist-friendly and customer-friendly manner, regardless of the results of his last two inspections. It is presumably the function of the Board to not only protect the public but to also assist pharmacists throughout the state to improve the level of their practice.

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It should not be the purpose of the Board to hinder and intimidate pharmacists in their practice, or to plunge ahead with sanctions without giving any thought to the seriousness of the consequences and ramifications of their actions. These are precisely the things that have occurred in this case. Instead of assisting Mr. Jones to improve the level of his practice, the inspectors descended on him with the intention of finding fault, intimidating him and disrupting his business. Their noticeable presence throughout the entire day was disruptive and intimidating, especially when an inspector stood directly behind him, looking over his shoulder, for an entire day. His intent was obvious and this type of conduct is completely inappropriate. Further, instead of trying to determine the truth as to what violations/infractions really occurred, by discussing their concerns and giving him the time and opportunity necessary to show that, for the most part, the real problem was simply disorganization, they treated him like a criminal instead of a fellow professional.

This attitude and approach led directly to the ex-parte summary suspensions for which there was absolutely no justification, not even under the circumstances described by the Board. The Board's action was clearly excessive and unwarranted and served to destroy a pharmacist and the business he has worked so hard to build. The Board has destroyed years of hard work overnight! There is no rational reason or justification for sending a man into bankruptcy for the violations discussed herein!

The time has come to lift the suspensions of both licenses, put an end to the financial and emotional damage that he is suffering, and allow him to try and salvage what is left of his business. He deserves this consideration. He does not deserve the damage the Board has caused him. And he has faithful customers standing behind him, waiting for him to re-open. They deserve to have their needs met, too, and the Board should be concerned about that.

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Mr. Jones is prepared to have the inspectors come out immediately so that his pharmacy can receive their approval. He must open his doors for business within the next 48 hours or the damage will be irreversible, if it isn't already. We request, and look forward to, the immediate consideration of this Motion and an immediate stay of the suspensions.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my information, knowledge and belief.

EXECUTED this 27th day of August, 1999, at Seattle, Washington.

W. BERNARD BAUMAN, WSBA #8849
Attorney for Respondents

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Appendix C

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice as a Pharmacist of: MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of Pharmacy Location License of: The Medicine Shoppe Pharmacy, License No. 55751 Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF ORDER ON MOTION TO MODIFY EX PARTE ORDER OF SUMMARY ACTION

This matter came before Health Law Judge Arthur E. DeBusschere, Presiding Officer for the Board of Pharmacy (the Board), on a Motion to Modify Ex Parte Order of Summary Action, brought by the Respondent, Michael S. Jones, R.Ph., by and through his counsel, W. Bernard Bauman, Attorney at Law. Lori Lebon Salo, Assistant Attorney General, represents the Department of Health (the Department). The Board members deciding this motion were Sharron Sellers, Public Member; Donna Docktor, R.Ph.; and C.A. Leon Alzola, R.Ph., Panel Chair.

The Board having reviewed the motion and the documents submitted in support of this motion, hereby enters the following:

I. PROCEDURAL HISTORY

1.1 On August 17, 1999, the following documents were served upon the Respondent: (1) Statement of Charges; (2) Notice and Opportunity for Prompt Hearing, Regularly Scheduled Hearing or Settlement; (3) Answer to Statement of Charges and

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Request for Prompt Hearing or Settlement and Regularly Scheduled Hearing; and (4) Ex Parte Order of Summary Action. In the Ex Parte Order of Summary Action, the Board ordered that the Respondent's license to practice as a pharmacist in the state of Washington be summarily suspended. The Board also ordered that the license issued to Respondent Medicine Shoppe Pharmacy, located at 9430 State Street in Marysville, Washington, to operate as a pharmacy be summarily suspended

1.2 On August 17, 1999, the Respondent filed an Answer to Statement of Charges. In his Answer, the Respondent indicated that he would file a motion to contest the summary action.

1.3 On August 30, 1999, the Respondent filed a Motion to Modify Ex Parte Order of Summary Action and a Declaration of Bernard Bauman in Support of his Motion. Also filed was a Declaration of Michael Jones, R.Ph.

1.4 On September 1, 1999, the Department filed a Response to Respondent's Motion to Modify Order of Summary Action and attached Department's Exhibits 1-5.

1.5 On September 2, 1999, the Respondent filed a Declaration of Bernard Bauman in Reply to Department's Response, which was also signed by the Respondent. Attached were Respondent's Exhibits 1-6.

1.6 On September 2, 1999, the Presiding Officer conducted a telephone conference with the parties. In regards to his motion to modify, the Respondent elected not to present oral argument on his motion to modify on September 10, 1999. Instead, the Respondent requested to have the Board consider his Motion to Modify as soon as a meeting time could be arranged. The Presiding Officer informed the Respondent that

if he received a decision to his disfavor, he may make a motion to have an expedited hearing, but that he has waived his right to a prompt hearing, which was scheduled for September 10, 1999.

1.7 On September 3, 1999, the Presiding Officer conducted a second telephone conference with the parties. The Presiding Officer heard oral argument on the issue of timeliness. The Presiding Officer ruled that the Motion to Modify was timely filed. The Respondent had filed his Answer to Statement of Charges on August 27, 1999, and timely stated that he would be filing a Motion to Modify. Further, the Respondent had not requested a prompt hearing within 10 days of service, which was required under the rules, WAC 246-11-340(3). Next, the Presiding Officer ruled on the Department's objections to Respondent's Exhibits No. 1, No. 2 and No. 6, which were attached to Respondent's Reply Declaration. During a second prehearing conference conducted on September 3, 1999, the Presiding Officer provided clarification on how the corrected exhibits should be filed.

1.8 On September 7, 1999, the Respondent filed corrections to Respondent's Exhibit No. 2 and No. 6, and filed an additional exhibit, Respondent's Exhibit No. 7, which was a declaration by W. Bernard Bauman.

1.9 On September 7, 1999, the Board met to consider the Respondent's Motion to Modify Ex Parte Order of Summary Action.

II. FINDINGS ON RESPONDENT'S MOTION TO MODIFY

The Respondent moved for an order modifying the Ex Parte Order of Summary Action and staying the summary suspension of the licenses issued to Respondent and

Medicine Shoppe, located at 9430 State Street in Marysville, Washington. The Respondent requested that both licenses be reinstated. The Board considered the documents filed by the Respondent and reviewed the filed exhibits. The Board also considered the Department's arguments and the attached exhibits. The Board finds that the arguments and evidence provided by the Respondent inadequately addressed the existence of immediate danger to the public health, safety and welfare. The Respondent had committed serious violations of the pharmacy laws by operating the pharmacy below the standard of care. The Board could not be assured by the Respondent's assertions that he has corrected the problems and that he will remain in compliance. The Respondent has a history of committing violations of the pharmacy law, correcting the violations, but then violating the laws again. The Board finds that the concerns for the protection of the public outweigh the Respondent's assertions that the violations have been corrected.

III. CONCLUSIONS OF LAW

The Board has authority to take emergency adjudicative action to address an immediate danger to the public health, safety, or welfare. RCW 34.05.422(4), RCW 34.05.479, RCW 18.130.050(7); and WAC 246-11-300. In this case, the Board considered the Respondent's arguments to modify the Ex Parte Order of Summary Action. The Board affirms that the existence of immediate danger to the public health, safety, or welfare remains. The Respondent's request to modify the Ex Parte Order of Summary Action did not adequately address the danger to the public health, safety or welfare. The Ex Parte Order of Summary Action, which was ordered on August 17,

1999, is necessary to address this danger to the public and is the least restrictive action justified by the danger posed. The Respondent's Motion to Modify Ex Parte Order of Summary Action should be denied.

IV. ORDER

Based upon the above, the Board hereby ORDERS that the Respondent's Motion to Modify Ex-Parte Order of Summary Action in this matter is DENIED.

DATED THIS 7th DAY OF SEPTEMBER, 1999.

BOARD OF PHARMACY

Sharron P Sellers

SHARRON SELLERS, Public Member, for
C.A. LEON ALZOLA, R.Ph., Panel Chair

Appendix D

State of Washington
Department of Health
Board of Pharmacy

In the Matter of the License to Practice Pharmacy of: MICHAEL S. JONES, R.Ph., License No. 10993 In the Matter of the Pharmacy Location License of: The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	)	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER

The State of Washington Board of Pharmacy, by and through David M. Hankins, Assistant Attorney General Prosecutor and Michael S. Jones, R.Ph., represented by W. Bernard Bauman stipulate and agree to the following:

Section 1: Procedural Stipulations

1.1 Michael S. Jones, Respondent, was issued a license to practice pharmacy in the state of Washington in June 1980. Respondent's license to practice pharmacy in the state of Washington expires on October 24, 1999.

1.2 On October 25, 1999 the Board of Pharmacy issued an Amended Statement of Charges against Respondent.

1.3 The Statement of Charges alleges that Respondent violated RCW 18.64.160(5), .165(2), .245, .246, 270, 18.130.180(1),(4), (6), (7), (12), (13), 69.04.450, .490, .510, 69.41.030,

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.042, .050, 69.50.306, .308(d)(e), .401(1)(d); WAC 246-863-095(f), -110, 246-869-100(1)(2)(a)-(c), -130, -150, -160(4)(5), -190, -210, -230, 246-875-001, -020, -040, 246-901-080(2), -090, -100(3).

1.4 Respondent understands that the State is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.5 Respondent understands that he has the right to defend himself against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.6 Respondent understands that, should the State prove at a hearing the allegations in the Statement of Charges, the Board of Pharmacy has the power and authority to impose sanctions pursuant to RCW 18.130.160.

1.7 Respondent and the Board of Pharmacy agree to expedite the resolution of this matter by means of this Stipulated Findings of Fact, Conclusions of Law, and Agreed Order (Agreed Order).

1.8 Respondent waives the opportunity for a hearing on the Statement of Charges contingent upon signature and acceptance of this Agreed Order by the Board of Pharmacy.

1.9 This Agreed Order is not binding unless and until it is signed and accepted by the Board of Pharmacy.

1.10 Should this Agreed Order be signed and accepted it will be subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any applicable interstate/national reporting requirements.

1.11 Should this Agreed Order be rejected, Respondent waives any objection to the participation at hearing of all or some of the Board members who heard the Agreed Order presentation.

Section 2: Stipulated Facts

While Respondent does not admit to the following conduct, Respondent acknowledges that the evidence is sufficient to justify the following findings:

2.1 Respondent Medicine Shoppe Pharmacy located at 9430 State Avenue, Marysville, Washington was issued a location license to operate as a pharmacy in the state of Washington in October 1996. The current location license expires on June 1, 2000.

2.2 Respondent Michael Jones is the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

2.3 On March 1, 1994, a Statement of Charges was issued against Respondent Michael Jones related to a prescription filling error while Respondent was working as a pharmacist at Safeway Pharmacy # 497 in Seattle, Washington

2.4 On July 6, 1994, the Board entered a Findings of Fact, Conclusions of Law and Order placing Respondent's license to practice pharmacy in the state of Washington on probation for a period of one year and imposing certain terms and conditions. One of the conditions imposed on Respondent was a requirement that he create and submit a plan to avoid violations of pharmacy law related to the filling of prescriptions.

2.5 On December 7, 1995, Respondent's license to practice pharmacy in the state of Washington was fully reinstated.

2.6 In approximately October 1996, Respondent Jones purchased and operated The Medicine Shoppe in Marysville, Washington.

2.7 On December 17, 1998, Respondent Medicine Shoppe received a failing inspection grade of 79 from Board of Pharmacy Investigator Wene while conducting a routine inspection of the pharmacy. An inspection score of 90-100 is classified as a passing pharmacy

inspection score. An inspection score of 80-89 is classified as a conditional pharmacy inspection score. An inspection score of 0-79 is classified as an unsatisfactory pharmacy inspection score. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations included but were not limited to:

2.7.1 Failing to obtain chronic conditions on patients of the pharmacy;

2.7.2 Dispensing the majority of prescriptions in non child-resistant containers without a written request from either the patient or the prescriber;

2.7.3 Various required records required by state and federal law were either inaccurate, incomplete or not available;

2.7.4 There was a box of filled prescription containers, many unlabeled, on the floor of the pharmacy.

2.7.5 Investigator Wene discovered a prescription filling error in the will call area. A prescription for [redacted] was incorrectly filled with [redacted]

2.7.6 Many of the prescriptions in the will-call area had labeled expiration dates exceeding the manufacturer's expiration date;

2.7.7 Most of the prescriptions in the will call area contained the incorrect NDC number for the product in the prescription container;

2.8 On February 3, 1999, Board of Pharmacy Investigator Wene conducted a re-inspection in relation to the December 1998 failing score. During the February 3, 1999 inspection, the pharmacy, received a passing score of 94. The deducted points were related to

inaccurate, incomplete or missing records required by state or federal law. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

2.9 On July 12, 1999, Board of Pharmacy Investigators Wene and Jeppesen conducted a routine inspection of the Medicine Shoppe Pharmacy in Marysville. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The pharmacy received an extremely low failing grade of 48. At that time the violations included but were not limited to:

2.9.1 Failing to obtain chronic conditions and allergies on patients of the pharmacy. Disease state management is coded in ICD-9 codes and provides the information in coded form, not readily readable by the Pharmacist.

2.9.2 Numerous (greater than 10) prescriptions were labeled with a different generic product than indicated on the label or NDC Code. Several of these prescriptions were dispensed in the presence of the Board of Pharmacy Investigators.

2.9.3 Dispensing the majority (in excess of 90%) of prescriptions in non-child- resistant containers without a written request from either the patient or the prescriber for non child-resistant packaging.;

2.9.4 Thirty-eight (38) drug products were outdated. Of those, 18 drugs were legend or controlled substances and 20 were OTC products.

2.9.5 Various records required by federal law (DEA) were either inaccurate, incomplete or not available. DEA order forms and invoices could not be reconciled. Respondent was unable to locate several required DEA forms. There was poor organization of DEA inventory records,

including non-sequential filing. Several DEA records did not include date and amount received on DEA 222 forms.

2.9.6 DEA Inventory incomplete, DEA inventory for Schedules III-V was missing. Respondent was unable to generate reports for Schedule II drugs. The daily refill reports were not signed, stored in various locations, out of sequence, with several months not located.

2.9.7 Facts and Comparisons, the only reference source in the pharmacy, had not been updated for at least nine (9) months.

2.9.8 Pharmacy Assistant did not have a name badge and none had been ordered. No Pharmacy Assistant certificate had been generated or signed. Modifications to the Pharmacy Assistant Utilization Plan were in place without Board approval.

2.9.9 The prescription records were inaccurate, missing and poorly organized. Examples include prescription files with non-sequential order. Several prescriptions, both C-II and other drugs were unaccounted for. Prescription files were kept with no organization. Respondent Jones was unable to locate files in a timely manner.

2.9.10 Minimum procedures for utilization of the patient medication system were inadequate.

2.9.11 During the inspection, a patient returned a prescription so that Respondent Jones could correct the instructions for use. The correction was made but no audit trail of the change was entered in the pharmacy computer

2.9.12 The pharmacy was generally disorganized and dirty. The pharmacy sink and immediate area were dirty and with numerous dirty food dishes.

2.10 On July 13, 1999, Investigator Jeppesen returned to the pharmacy to retrieve documents promised by Respondent Jones. At that time Respondent Jones stated he could not locate the documents. Respondent stated that his computer could generate the required reports but that he, (Respondent) did not know how to generate them.

2.11 On August 10, 1999, Investigators Wene and Jeppesen returned to the Medicine Shop Pharmacy in Marysville, Washington, to conduct the re-inspection in relation to the July 12, 1999 failing score. This inspection again resulted in an extremely low failing score of 56. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. At that time the violations included but were not limited to:

2.11.1 Six prescriptions selected randomly in the will call area did not have allergy or chronic conditions noted in the patient profile. The disease state - drug interaction fields had been turned off. Respondent Jones was unable to explain the purpose or the clinical significance of the clinical interaction levels that appeared for drug interaction messages.

2.11.2 Three prescriptions selected randomly from the will call area were labeled with a different generic product than indicated on the label and/or NDC Code.

2.11.3 Forty-one (41) prescriptions were located in the will call area. Of those, forty (40) were packaged in non child-resistant containers and the one that was in a child resistant container was in a container supplied by the manufacturer.

2.11.4 Eleven legend or controlled substances on the shelf were beyond the manufacturer's expiration date.

2.11.5 As in the July 12, 1999 inspection, various records required by federal law (DEA) were either inaccurate, incomplete or not available. The invoices for the C II drugs were not filed separately. Several DEA records did not include date and amount received on DEA 222 forms.

2.11.6 DEA Inventory records incomplete. There was no signature on the C-II, C-III - C-V inventories. Requested records could not be located.

2.11.7 Five prescriptions which had been filled and returned to the stock area were checked for accuracy of product on the label and against correct NDC numbers. All five prescriptions failed to comply with state and/or federal law.

2.11.8 Minimum procedures for utilization of the patient medication system were inadequate. The pharmacy QS-1 system was not able to create an accurate and complete audit trail for changes made to the prescriptions after filling including directions for use and drug dispensed.

2.11.9 During the period August 4, 1999 through August 5, 1999, forty-eight prescriptions were processed in the pharmacy. Of those forty-eight prescriptions, twenty-one did not have a hard copy in the prescriptions.

2.12 Respondent Michael S. Jones operated the Medicine Shoppe Pharmacy in a manner below the standard of care for the operation of a pharmacy and therefore placed the patients of his pharmacy at serious risk of significant harm.

2.13 That on or about 4-1-99, respondent refilled a prescription for patient A for [redacted] controlled substance. Respondent misfilled the prescription by filling it with [redacted] Patient A consumed [redacted] over [redacted] period. Respondent had to be taken to the [redacted] at [redacted] Everett, Washington for treatment for a [redacted]

2.14 That on or about 2-8-99, patient C was prescribed [redacted] by [redacted] physician and phoned in to respondent's pharmacy. The original prescription permitted substitution, but did not permit refills. Respondent failed to note in his phone prescription if substitution was permitted.

2.15 On or about 2-8-99, respondent filled the prescription for patient C with [redacted] Respondent without authorization from the physician refilled [redacted] prescription, and misfilled and mislabeled the medication with an increase in dosage strength on 3-1-99 and on 3-7-99 with [redacted]

2.16 Respondent failed to maintain the prescription hardcopy, failed to maintain accurate records and/or altered or manipulated the computer records by:

2.16.1 On 5-7-99, the pharmacy investigator obtained records from respondent's pharmacy. Patient C's medication profile record indicate respondent filled the prescription for [redacted] with a generic substitute [redacted] on 2-8-99, 3-1-99 and 3-7-99. The patient's [redacted] indicated that they never received the medication on 3-7-99. Respondent's daily audit log for 2-8-99 indicates he filled the prescription with [redacted] The investigator also received a previous copy of respondent's daily audit log for 2-8-99 which indicates that on 2-8-99, respondent filled the medication with [redacted]

2.17 That on or about 9-14-98, patient D obtained a prescription of [redacted] [redacted] blets and had the prescription filled by respondent. The patient indicated [redacted] did not obtain a refill of the medication. The prescription authorized only one refill. Respondent's records indicate that he refilled the [redacted] on 1-8-99, 2-16-99, and 3-27-99 without authorization from the prescriber and/or billed the state for prescriptions never obtained by the patient.

2.18 That on or about 10-23-98 patient D had respondent fill a prescription for [redacted] The patient's physician only prescribed [redacted] Respondent's records indicate that he filled a prescription for [redacted] and [redacted] He refilled the [redacted] on 11-19-98, 11-30-98, and 3-27-98. Respondent's records indicate he also refilled the [redacted] on 11-19-98, 11-30-98, 12-5-98, 1-8-99, 2-16-99 and 3-27-99. The patient indicated that [redacted] never received any [redacted] Respondent failed to maintain a hardcopy of the prescription and filled a prescription without authorization from the physician and/or billed the state for medication that a patient did not receive.

2.19 That on or about 2-15-99, respondent filled a prescription for patient D for [redacted] a controlled substance. Respondent's medication profile records for patient D show that respondent filled the prescription as [redacted] and also filled a prescription for [redacted] Respondent filled and refilled the [redacted] prescription without the physician's authorization on 2-15-99, 2-25-99 and 3-22-99. Respondent also refilled on 3-22-99, the patient's prescription for [redacted] The investigator was unable to locate a hard copy of the prescription for [redacted] The patient indicated to the pharmacy investigator that [redacted] received the [redacted] but not the [redacted]

2.20 That on or about December 1998, patient D observed respondent provide an unlabeled prescription vial containing large white caplet shaped tablets, which appear to be [redacted] tablets, a controlled substance, to a person in exchange for respondent's car repair.

2.21 That respondent without the physician's authorization or approval refilled a prescription for [redacted] tablets for patient B on 4-3-99 and 4-29-99.

2.22 That respondent misfilled patient F's prescription for [redacted] with [redacted] instead of [redacted] as prescribed by the physician.

Section 3: Conclusions of Law

The State and Respondent agree to the entry of the following Conclusions of Law:

3.1 The Board of Pharmacy has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 The above facts constitute unprofessional conduct in violation of RCW 18.64.160(5),.165(2),.245,.246,270, 18.130.180(1),(4),(6),(7),(12),(13), 69.04.450,.490,.510, 69.41.030,.042,.050, 69.50.306,.308(d)(e),.401(1)(d); WAC 246-863-095(f),-110, 246-869-100(1)(2)(a)-(c),-130,-150,-160(4)(5),-190,-210,-230, 246-875-001,-020,-040, 246-901-080(2),-090,-100(3).

3.3 For purposes of settlement, the state withdraws allegation 1.15 in the amended statement of charges and the violations outlined in paragraph 2.30.

3.4 The above violations are grounds for the imposition of sanctions under RCW 18.130.160.

Section 4: Agreed Order

Based on the preceding Stipulated Facts and Conclusions of Law, Respondent agrees to entry of the following Order:

4.1 The Pharmacy location license of Medicine Shoppe Pharmacy, license No. 55751 shall be REVOKED. Respondent shall have no right to re-apply for a pharmacy location license for at least five (5) years from the date of this order. Respondent shall promptly deliver to the Board the original license and current registration.

4.2 The license to practice pharmacy issued to Michael S. Jones, shall be SUSPENDED WITHOUT STAY effective from the date of August 17, 1999.

4.3 The respondent is prohibited from functioning in a pharmacy or any other drug-related employment during the respondent's suspension. The respondent will not make public appearances representing himself as a pharmacist.

4.4 Respondent's license to practice pharmacy shall be Suspended With Stay for at least 5 years from the date of January 13, 2000.

4.5 Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.6 Respondent shall assume all costs of complying with this Order.

4.7 If Respondent violates any provision of this Order in any respect, the Board of Pharmacy may take further action against Respondent's license.

4.8 Respondent shall inform the Board of Pharmacy, in writing, of changes in his residential address.

4.9 In the event respondent should leave Washington to reside or to practice outside the state, respondent must notify in writing the Board of Pharmacy of the date of departure and return. Periods of residency or practice outside Washington will not apply to the reduction of this probationary or suspension period.

4.10 The respondent shall submit written notification to the Board of Pharmacy, addressed to the Program Manager, of any employment or residence address changes. The notification shall include the complete new address and telephone number. The notification must be made within twenty (20) days of the change in employment or residence address.

4.11 The respondent shall submit periodic declarations under penalty of perjury stating whether there has been compliance with all conditions of this Order. Failure to submit information and/or to make true statements may subject the respondent to referral for prosecution under RCW 9A.76.020 and/or RCW 9A.72.030.

4.12 The respondent shall advise any employer who hires him or her, to function in the capacity of a health care practitioner, of the terms of this Order imposed by the Board of Pharmacy. The Respondent's employer must submit written notification to the Board indicating he or she has seen the Board's Order.

4.13 The respondent shall submit a quarterly declaration under penalty of perjury stating whether there has been compliance with all conditions of this Order. The first report is due 30 days, and on the first day of April, July, Oct and Jan and thereafter until —/—, —/— unless otherwise ordered by the Board of Pharmacy.

4.14 Respondent shall notify Board of Pharmacy of any employment in the health care field, including any change in employment or practice status. Respondent shall, within twenty (20) days of the effective date of this Order, or as soon thereafter as deemed by the Board of Pharmacy, submit to the Board of Pharmacy for the Board of Pharmacy's approval, a job description or description of practice and clinical privilege of respondent's present practice or position. Thereafter respondent shall submit a job description or description of practice and clinical privilege of respondent's practice or position to the Board of Pharmacy for their approval prior to making the contemplated change.

4.15 Respondent shall cause the respondent's employer to submit quarterly performance reports directly to the Board of Pharmacy on forms provided by the Board of Pharmacy. The first report is due 30 days and on the first day of April, July, Oct and Jan.

and thereafter. The respondent shall ensure that the respondent's employer has been given a copy of this Order and the employer understands the decision of the Board of Pharmacy in this case. The respondent shall ensure that the employer makes reference to Board of Pharmacy decision in the reports to the Board of Pharmacy.

4.16 The respondent is hereby placed on notice that it is the responsibility of the respondent to ensure that all required reports are submitted to the Board of Pharmacy in a timely manner.

4.17 Within thirty (30) days of the effective date of this Order, or as soon thereafter as deemed by the Board of Pharmacy, respondent shall make an appointment to undergo a psychological evaluation by a psychologist designated by the Board of Pharmacy who shall furnish a report to the Board of Pharmacy according to the following protocol adopted by the Board of Pharmacy:

Please perform a psychological examination to assess:

1. Psychological diagnosis, if any.
2. Treatment recommendations, if any.

The evaluation should consist of the following components:

1. A complete social, past medical, developmental and psychological history.
2. A review of this Agreed Order.
3. Any other physical examinations, psychological or laboratory studies deemed necessary by the evaluator.

The report of examination should discuss fully and with specificity the basis for the diagnosis, if any, conclusions and recommendations made pursuant to items 1-3 in the first paragraph above. The report of examination should be sent to:

Board of Pharmacy
PO Box 47863
Olympia WA 98504-7863

A copy shall be provided to the Respondent.

4.18 Within sixty (60) days of the effective date of this decision, or as soon thereafter as deemed by the Board of Pharmacy, respondent shall submit to the Board of Pharmacy for its prior approval, a program of remedial education, related to the violations found in the decision. The exact number of hours and the specific content of the program shall be determined by the Board of Pharmacy and shall not total less than twenty-five (25). This program shall be in addition to the Continuing Education requirement for re-licensure. The Board of Pharmacy may also require respondent to pass an examination related to the content of the program.

4.19 Respondent shall submit to the Board of Pharmacy for its prior approval, a clinical education program related to the violations found in the decision. The exact number of hours and the specific content of the program shall be determined by the Board of Pharmacy and shall total not less than four (4) nor more than twenty (20) hours per week. Respondent shall complete the clinical training program prior to seeking modification. The Board of Pharmacy may require the respondent to pass an examination related to the content of the program.

4.20 Respondent shall take and pass the MPJE examination within 60 days from the date of this order. Failure to pass the examination may result in the suspension of the license until such time as a passing score is achieved. Respondent shall not engage in the practice of the profession until respondent has passed the examination and has been so notified by the Board in writing.

4.21 Respondent is prohibited from serving as the responsible manager of a pharmacy or supervising pharmacy interns.

4.22 **SUPERVISING PHARMACIST AGREEMENT**

The supervising pharmacists signs an agreement that they:

1. Have reviewed, are aware of, and understands the terms of the Order.

2. Agree to be a supervising pharmacist and provide quarterly reports concerning:
   a. obey the laws and rules of practice of pharmacy;
   b. obey rules of employment and job performance;
   c. relationship with other employees and customers;
   d. any other relevant matters.

LEVELS OF SUPERVISION

X Specific Percentage Supervision requires that a supervising pharmacist have contact with and/or personally be present for supervision at least forty (40) percent of the time or 2 ½ hours – 3 ½ hours per day;

This percentage may be decreased by the reviewing board member upon submission of an employment description to 40 percent the first year, 30 percent the second year, and 20 the third year or less as the discretion of the reviewing board member.

4.23 The respondent shall submit to the Board of Pharmacy, within thirty (30) days of the effective date of the Order, policy and procedures relating to:

the process of receiving written and telephone prescriptions, filling the prescriptions, and checking the label and the product to prevent errors;

disposition of prescription filling errors which shall include, but not be limited to: documentation of filling errors, description of filling errors, explanation of how filling errors occurred, notification of patient and physician, and steps to be taken to prevent future errors;

error reports shall be kept for two (2) years;

A Pharmacy Board Investigator will contact the respondent to determine if the respondent is in compliance with the policy and procedures.

4.24 The respondent must implement a quality assurance program with thirty (30) days of receipt of the Order.

The quality assurance program is directed at prescription filling and misfilling and the number of errors in filling or labeling prescriptions. The respondent shall maintain a log of all errors in prescription filling. The log shall be maintained at the pharmacy and made available to Pharmacy Board Investigators and Staff at their request.

___ Develop an effective quality assurance set of criteria or guidelines by which to monitor patient profiles for inappropriate, excessive or non-therapeutic quantities of medications. An outline of the process and screening questions must be submitted to the Disciplinary Authority for approval.

A Pharmacy Board Investigator will contact the Respondent to determine if the respondent is in compliance with the quality assurance program.

4.25 The Respondent shall comply with the Board's probation surveillance program including appearing in person for interviews upon request at various intervals and with reasonable notice.

4.26 Respondent may submit a written request for modification of the Board's Order for his pharmacist license only, no sooner than three years from the date of this order. Respondent, at the Board's discretion shall personally appear before the Board of Pharmacy

4.27 At the conclusion of the stayed suspension, Respondent, if requested by the Board, shall appear before the Board of Pharmacy prior to seeking reinstatement of his license to practice pharmacy.

4.28 Respondent shall assume all costs associated with the compliance of this Order.

4.29 If the respondent violates any provision of this Order in any respect, the Board of Pharmacy, after giving the respondent notice and the opportunity to be heard, may **SET ASIDE THE STAY ORDER AND IMPOSE THE SUSPENSION OF THE RESPONDENT'S LICENSURE OR MAY** impose any sanction as appropriate under RCW 18.130.160 to protect the public, or may take emergency action ordering summary suspension or restriction or limitation of the respondent's practice as authorized by RCW 18.130.050.

4.30 Within 10 days of the effective date of this order, Respondent shall thoroughly complete the attached Healthcare Integrity and Protection Data Bank Reporting Form (Section 1128E of the Social Security Act) and return it to the disciplining authority.

IT IS FURTHER ORDERED that all parties shall be bound by the terms and conditions of this Order. Any failure to comply with the terms and conditions of this Order will subject the respondent's license to practice as a pharmacist to further disciplinary action.

I, Michael S. Jones, Respondent, certify that I have read this Stipulated Findings of Fact, Conclusions of Law and Agreed Order in its entirety; that my counsel of record, if any, has fully explained the legal significance and consequence of it; that I fully understand and agree to all of it; and that it may be presented to the Board of Pharmacy without my appearance. If the Board accepts the Stipulated Findings of Fact, Conclusions of Law and Agreed Order, I understand that I will receive a signed copy.

Michael S. Jones, R.Ph.
Respondent

January 14, 2000
Date

W. Bernard Bauman
WSBA #8849
Attorney for Respondent

January 11, 2000
Date

Section 5: Order

The Board of Pharmacy accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED this 4 day of February, 2005.

State of Washington
Department of Health
Board of Pharmacy

C. ALZOLA, R.PH
Panel Chair

Presented by:

DAVID M. HANKINS
WSBA #19194
Assistant Attorney General Prosecutor

Notice of Presentation Waived and Approved
As to Form:

W. Bernard Bauman
WSBA #8849
Attorney for Respondent

Appendix E

CHAPTER 39A—SPECIAL PACKAGING OF HOUSEHOLD SUBSTANCES FOR PROTECTION OF CHILDREN

Sec.
1471. Definitions.
1472. Special packaging standards.
(a) Establishment.
(b) Considerations.
(c) Publication of findings, reasons, and citation of statutory authorizations.
(d) Limitation.
1473. Conventional packages, marketing.
(a) Noncomplying packages for elderly or handicapped persons; labeling statements.
(b) Noncomplying packages for substances dispensed pursuant to orders of medical practitioners.
(c) Exclusive use of special packaging; necessary circumstances.
1474. Regulations for special packaging standards.
(a) Rule making procedure; election and application of procedure under section 371 of Title 21; publication of election and proposal.
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1475. Repealed.
1476. Preemption of Federal standards.
(a) Exception for identical State standards.
(b) Federal or State standards which afford a higher degree of protection.
(c) Exemption for State standards; requirements; determination of burden on interstate commerce; notice and hearing.

CROSS REFERENCES

Authority of Administrator of Environmental Protection Agency to establish standards for package, container, or wrapping in which pesticide is enclosed, see 7 USCA § 136w.
Transfer of functions to Consumer Product Safety Commission, see 15 USCA § 2079.

LIBRARY REFERENCES

Administrative Law

Agency activities, see 16 CFR § 1011.1 et seq.
Banned hazardous substances, see 16 CFR § 1500.17.
Commission organization and functions, see 16 CFR § 1000.2.
Conditions for the use of narcotic drugs, see 21 CFR § 291.505.
Consumer litigation, see 28 CFR § 0.45.
Information disclosure, see 16 CFR § 1101.2.
Meetings policy, see 16 CFR § 1012.1 et seq.
Poison prevention packaging, see 16 CFR § 1700.1 et seq.
Policies and procedures for information disclosure, see 16 CFR § 1016.1 et seq.
Policy on imported products, importers, and foreign manufacturers, see 16 CFR § 1009.3.
Procedure for petitioning for rulemaking, see 16 CFR § 1051.1.

Procedures for export of misbranded or banned products, see 16 CFR § 1019.1.
Reporting of information, see 16 CFR § 1116.7.
Substantial product hazard, see 16 CFR § 1115.2.

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§ 1471. Definitions

For the purpose of this Act—

(1) The term "Commission" means the Consumer Product Safety Commission.

(2) The term "household substance" means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is—

(A) a hazardous substance as that term is defined in section 1261(f) of this title;

(B) a food, drug, or cosmetic as those terms are defined in section 321 of Title 21; or

(C) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

(3) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of section 1473(a)(2) of this title, also means any outer container or wrapping used in the retail display of any such substance to consumers. Such term does not include—

(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) The term "labeling" means all labels and other written, printed, or graphic matter (A) upon any household substance or its package, or (B) accompanying such substance.

(Pub.L. 91–601, § 2, Dec. 30, 1970, 84 Stat. 1670; Pub.L. 92–516, § 3(2), Oct. 21, 1972, 86 Stat. 998; Pub.L. 92–573, § 30(a), Oct. 27, 1972, 86 Stat. 1231; Pub.L. 94–284, § 3(a), May 11, 1976, 90 Stat. 503.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91–1642 and Conference Report No. 91–1755, see 1970 U.S. Code Cong. and Adm. News, p. 5326.

1972 Acts. Senate Report Nos. 92–838 and 92–970 and Conference Report No. 92–1540, see 1972 U.S. Code Cong. and Adm. News, p. 3993.

Senate Report No. 92–835 and House Conference Report No. 92–1593, see 1972 U.S. Code Cong. and Adm. News, p. 4573.

1976 Acts. Senate Report No. 94–251 and House Conference Report No. 94–1022, see 1976 U.S. Code Cong. and Adm. News, p. 993.

References in Text

"This Act", referred to in text, means Pub.L. 91–601 which enacted this chapter, § 136(z)(2)(i) of Title 7, Agriculture, and §§ 343(n), 352(p), and 362(f) of Title 21, Food and Drugs, amended § 1261(p) of this title and § 353(b)(2) of Title 21, and enacted provisions set out as a note under this section. For complete classification of this Act to the Code, see Short Title note below and Tables.

Amendments

1976 Amendments. Par. (2). Pub.L. 94–284 struck out subpar. (B) which included pesticide as defined in § 136(u) of Title 7 within the meaning of "household substance", and redesignated subpars. (C) and (D) as (B) and (C), respectively.

1972 Amendments. Par. (2)(B). Pub.L. 92–516 substituted "a pesticide" for "an economic poison".

Effective Dates

1972 Acts. For effective date of amendment by Pub.L. 92–516, see § 4 of Pub.L. 92–516, set out as an Effective Date note under § 136 of Title 7, Agriculture.

1970 Acts. Section 8, formerly § 9, of Pub.L. 91–601, as amended Pub.L. 92–573, § 30(a), Oct. 27, 1972, 86 Stat. 1231, and renumbered by Pub.L. 97–35, title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716, provided that: "This Act [see Short Title note set out below] shall take effect on the date of its enactment [Dec. 30, 1970]. Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which date shall not be sooner than one hundred and eighty days or later than one year from the date such regulation is final, unless the Commission, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply. No such standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation."

Transfer of Functions

"Commission" substituted for "Secretary" and "Consumer Product Safety Commission" substituted for "Secretary of Health, Education, and Welfare" in par. (1) pursuant to section 30(a) of Pub.L. 92–573, which is classified to section 2079(a) of this title and which transferred functions of Secretary of Health, Education, and Welfare under this chapter to Consumer Product Safety Commission.

Short Title

1970 Acts. Section 1 of Pub.L. 91–601 provided that: "This Act [enacting this chapter, section 135(z)(2)(i) of Title 7, and sections 343(n), 352(p), and 362(f) of Title 21, enacting section 1261(p) of this title and section 353(b)(2) of Title 21, and enacting provisions set out as a note under this section] may be cited as the 'Poison Prevention Packaging Act of 1970'."

CROSS REFERENCES

Misbranded hazardous substance in relation to household substance, see 15 USCA § 1261.

LIBRARY REFERENCES

Administrative Law

Petition procedures and requirements, see 16 CFR § 1702.1 et seq.
Poison prevention packaging standards, see 16 CFR § 1700.15.
Procedures for disclosure or production of information, see 16 CFR § 1015.1 et seq.
Statements of policy, see 16 CFR § 1009.3 et seq., § 1701.1 et seq.
Substances requiring special packaging, see 16 CFR § 1700.14.

American Digest System

Trade Regulation ⇐870.

Encyclopedias

C.J.S. Trade-Marks, Trade-Names, and Unfair Competition § 238.

Law Review and Journal Commentaries

Long-range planning in environmental and health regulatory agencies. Richard N.L. Andrews, 20 Ecology L.Q. 515 (1993).

WESTLAW ELECTRONIC RESEARCH

See WESTLAW guide following the Explanation pages of this volume.

NOTES OF DECISIONS

Package 1
Private right of action 2

1. Package

Even though the Consumer Products Safety Commission is authorized to regulate disposable lighters as a "package" containing a "hazardous substance," the Commission is without authority to regulate under the Poison Prevention Packaging Act (PPPA) against designs which would too easily allow children to operate lighter, so that there was no cause of action against manufacturer under the Consumer Products Safety Act for violation of PPPA regulations. Carlson v. Bic Corp., E.D.Mich.1993, 840 F.Supp. 457.

Disposable cigarette lighter is not a "package" for butane, so that the Poison Prevention Packaging Act does not apply to a cigarette lighter. Bondie v. BIC Corp., E.D.Mich.1990, 739 F.Supp. 346.

2. Private right of action

No implied private right of action exists under either Federal Food, Drug, and Cosmetic Act or Poison Prevention Packaging Act. Deck by Deck v. McBrien, C.D.Ill.1991, 759 F.Supp. 454.

§ 1472. Special packaging standards

(a) Establishment

The Commission,[1] may establish in accordance with the provisions of this Act, by regulation, standards for the special packaging of any household substance if it finds that—

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) Considerations

In establishing a standard under this section, the Commission shall consider—

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by this Act; and

(4) the nature and use of the household substance.

(c) Publication of findings, reasons, and citation of statutory authorizations

In carrying out this Act, the Commission shall publish its findings, its reasons therefor, and citation of the sections of statutes which authorize its action.

(d) Limitation

Nothing in this Act shall authorize the Commission to prescribe specific packaging designs, product content, package quantity, or with the exception of authority granted in section 1473(a)(2) of this title labeling. In this case of a household substance for which special packaging is required pursuant to a regulation under this section, the Commission may in such regulation prohibit the packaging of such substance in packages which it determines are unnecessarily attractive to children.

(Pub.L. 91–601, § 3, Dec. 30, 1970, 84 Stat. 1670; Pub.L. 92–573, § 30(a), Oct. 27, 1972, 86 Stat. 1231; Pub.L. 97–414, § 9(k), Jan. 4, 1983, 96 Stat. 2065.)

[1] Comma retained in amendment by Pub.L. 97–414.

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91–1642 and Conference Report No. 91–1755, see 1970 U.S. Code Cong. and Adm. News, p. 4126.

1972 Acts. Senate Report No. 92–835 and House Conference Report No. 92–1593, see 1972 U.S. Code Cong. and Adm. News, p. 4573.

1983 Acts. House Report No. 97–840, see 1982 U.S. Code Cong. and Adm. News, p. 3577.

References in Text

For classification to the Code of "this Act", referred to in text, see References in Text note set out under section 1471 of this title.

Amendments

1983 Amendments. Subsec. (a), Pub.L. 97–414 struck out ", after consultation with the technical advisory committee provided for in section 1475 of this title" after "The Commission".

Transfer of Functions

"Commission" substituted for "Secretary", "it" substituted for "he", and "its" substituted for "his" wherever appearing in text pursuant to section 30(a) of Pub.L. 92–573, which is classified to section 2079(a) of this title and which transferred functions of Secretary of Health, Education, and Welfare under this chapter to Consumer Product Safety Commission.

CROSS REFERENCES

Misbranded in relation to packaging or labeling regulations—
Cosmetics, see 21 USCA § 362.
Drug or device, see 21 USCA § 352.
Food, see 21 USCA § 343.
Hazardous substance, see 15 USCA § 1261.
Report to Congressional committees of proposed consumer product safety regulations, see 15 USCA § 2076.

LIBRARY REFERENCES

Administrative Law

Petition procedures and requirements, see 16 CFR § 1702.1 et seq.
Promulgation of standards, see 16 CFR § 1700.1 et seq.
Statements of policy, see 16 CFR § 1701.1 et seq.

American Digest System

Consumer Protection ⇐11.

Encyclopedias

C.J.S. Trade-Marks, Trade-Names, and Unfair Competition § 237.

WESTLAW ELECTRONIC RESEARCH

See WESTLAW guide following the Explanation pages of this volume.

§ 1473. Conventional packages, marketing

(a) Noncomplying packages for elderly or handicapped persons; labeling statements

For the purpose of making any household substance which is subject to a standard established under section 1472 of this title readily available to elderly or handicapped persons unable to use such substance when packaged in compliance with such standard, the manufacturer or packer, as the case may be, may package any household substance, subject to such a standard, in packaging of a single size which does not comply with such standard if—

(1) the manufacturer (or packer) also supplies such substance in packages which comply with such standard; and

(2) the packages of such substance which do not meet such standard bear conspicuous labeling stating: "This package for households without young children"; except that the Commission may by regulation prescribe a substitute statement to the same effect for packaging too small to accommodate such labeling.

(b) Noncomplying packages for substances dispensed pursuant to orders of medical practitioners

In the case of a household substance which is subject to such a standard and which is dispensed pursuant to an order of physician, dentist, or other licensed medical practitioner authorized to prescribe, such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser.

(c) Exclusive use of special packaging; necessary circumstances

In the case of a household substance subject to such a standard which is packaged under subsection (a) of this section in a noncomplying package, if the Commission determines that such substance is not also being supplied by a manufacturer (or packer) in popular size packages which comply with such standard, it may, after giving the manufacturer (or packer) an opportunity to comply with the purposes of this Act, by order require such substance to be packaged by such manufacturer (or packer) exclusively in special packaging complying with such standard if it finds, after opportunity for hearing, that such exclusive use of special packaging is necessary to accomplish the purposes of this Act.

(Pub.L. 91–601, § 4, Dec. 30, 1970, 84 Stat. 1671; Pub.L. 92–573, § 30(a), Oct. 27, 1972, 86 Stat. 1231.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91–1642 and Conference Report No. 91–1755, see 1970 U.S. Code Cong. and Adm. News, p. 5326.

1972 Acts. Senate Report No. 92–835 and House Conference Report No. 92–1593, see 1972 U.S. Code Cong. and Adm. News, p. 4573.

References in Text

For classification to the Code of "this Act", referred to in subsec. (c), see References in Text note set out under section 1471 of this title.

Transfer of Functions

"Commission" substituted for "Secretary" in subsecs. (a) and (c) and "it" substituted for "he" in subsec. (c) pursuant to section 30(a) of Pub.L. 92–573 which is classified to section 2079(a) of this title and which transferred functions of Secretary of Health, Education, and Welfare under this chapter to Consumer Product Safety Commission.

CROSS REFERENCES

Misbranded in relation to packaging or labeling regulations—
Cosmetics, see 21 USCA § 362.
Drug or device, see 21 USCA § 352.
Food, see 21 USCA § 343.
Hazardous substance, see 15 USCA § 1261.

LIBRARY REFERENCES

Administrative Law

Adjudicatory providing exceptions, see 16 CFR § 1101.45.
Statements of policy, see 16 CFR § 1701.1 et seq.

WESTLAW ELECTRONIC RESEARCH

See WESTLAW guide following the Explanation pages of this volume.

§ 1474. Regulations for special packaging standards

(a) Rule making procedure; election and application of procedure under section 371 of Title 21; publication of election and proposal

Proceedings to issue, amend, or repeal a regulation prescribing a standard under section 1472 of this title shall be conducted in accordance with the procedures prescribed by section 553 (other than paragraph (3) (B) of the last sentence of subsection (b) of such section) of Title 5 unless the Commission elects the procedures prescribed by subsection (e) of section 371 of Title 21, in which event such subsection and subsections (f) and (g) of such section 371 shall apply to such proceedings. If the Commission makes such election, it shall publish that fact with the proposal required to be published under paragraph (1) of such subsection (e).

(b) Judicial review; petition; record; additional evidence; jurisdiction of court of appeals; scope of review; relief pending review; finality of judgment; review by Supreme Court

(1) In the case of any standard prescribed by a regulation issued in accordance with section 553 of Title 5, any person who will be adversely affected by such a standard may, at any time prior to the 60th day after the regulation prescribing such standard is issued by the Commission, file a petition with the United States Court of Appeals for the circuit in which such person resides or has his principal place of business for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Commission or other officer designated by it for that purpose. The Commission shall file in the court the record of the proceedings on which the Commission based its standard, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there was no opportunity to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Commission in a hearing or in such other manner, and upon such terms and conditions, as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, and its recommendation, if any, for the modification or setting aside of its original standard, with the return of such additional evidence.

(3) Upon the filing of the petition under paragraph (1) of this subsection the court shall have jurisdiction to review the standard of the Commission in accordance with subparagraphs (A), (B), (C), and (D) of paragraph (2) of section 706 of Title 5. If the court ordered additional evidence to be taken under paragraph (2) of this subsection, the court shall also review the Commission's standard to determine if, on the basis of the entire record before the court pursuant to paragraphs (1) and (2) of this subsection, it is supported by substantial evidence. If the court finds the standard is not so supported, the court may set it aside.

(4) With respect to any standard reviewed under this subsection, the court may grant appropriate relief pending conclusion of the review proceedings, as provided in section 705 of such Title 5.

(5) The judgment of the court affirming or setting aside, in whole or in part, any such standard of the Commission shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

(Pub.L. 91–601, § 5, Dec. 30, 1970, 84 Stat. 1671; Pub.L. 92–573, § 30(a), Oct. 27, 1972, 86 Stat. 1231.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91–1642 and Conference Report No. 91–1755, see 1970 U.S. Code Cong. and Adm. News, p. 5326.

1972 Acts. Senate Report No. 92–835 and House Conference Report No. 92–1593, see 1972 U.S. Code Cong. and Adm. News, p. 4573.

Transfer of Functions

In subsec. (a), "Commission" substituted for "Secretary" and "it" substituted for "he"; in subsec. (b), "Commission" substituted for "Secretary", "it" substituted for "him" and "he", "its" substituted for "his", and "Commission's" substituted for "Secretary's" pursuant to section 30(a) of Pub.L. 92–573, which is classified to section 2079(a) of this title and which transferred functions of Secretary of Health, Education, and Welfare under this chapter to Consumer Product Safety Commission.

LIBRARY REFERENCES

Administrative Law

Exemption from poison prevention requirements, see 16 CFR § 1702.1 et seq.
Meetings policy, see 16 CFR § 1012.1 et seq.
Notice of agency activities, see 16 CFR § 1011.1 et seq.
Poison prevention packaging standards, see 16 CFR § 1700.15.
Procedures for evidentiary public hearing, see 16 CFR § 1502.1 et seq.
Statements of policy, see 16 CFR § 1701.1 et seq.
Substances requiring special packaging, see 16 CFR § 1700.14.

Texts and Treatises

Statutory foundations of Supreme Court jurisdiction, see Wright, Miller, Cooper & Gressman, Federal Practice and Procedure: Jurisdiction § 4002.

WESTLAW ELECTRONIC RESEARCH

See WESTLAW guide following the Explanation pages of this volume.

§ 1475. Repealed. Pub.L. 97–35, Title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716

HISTORICAL AND STATUTORY NOTES

Section, Pub.L. 91–601, § 6, Dec. 30, 1970, 84 Stat. 1672, provided for appointment of a technical advisory committee to assist the Secretary in carrying out the purposes of the Poison Prevention Packaging Act of 1970.

Effective Date of Repeal

Repeal of section effective Aug. 13, 1981, see § 1215 of Pub.L. 97–35, set out as an Effective Date of 1981 Amendment note under § 2052 of this title.

§ 1476. Preemption of Federal standards

(a) Exception for identical State standards

Except as provided in subsections (b) and (c) of this section, whenever a standard established by the Commission under this Act applicable to a household substance is in effect, no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the standard established under section 1472 of this title (and any exemption therefrom and requirement related thereto) of this Act.

(b) Federal or State standards which afford a higher degree of protection

The Federal Government and the government of any State or political subdivision of a State may establish and continue in effect, with respect to a household substance for its own use, a standard for special packaging or related requirement which is designed to protect against a risk of illness or injury with respect to which a standard for special packaging or related requirement is in effect

under this Act and which is not identical to such standard or requirement if the Federal, State, or political subdivision standard or requirement provides a higher degree of protection from such risk of illness or injury than the standard or requirement in effect under this Act.

(c) **Exemption for State standards; requirements; determination of burden on interstate commerce; notice and hearing**

(1) Upon application of a State or political subdivision of a State the Commission may, by regulation promulgated in accordance with paragraph (2), exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, any standard for special packaging or related requirement of such State or political subdivision applicable to a household substance subject to a standard or requirement in effect under this Act if—

(A) compliance with the State or political subdivision standard or requirement would not cause the household substance to be in violation of the standard or requirement in effect under this Act, and

(B) the State or political subdivision standard or requirement (i) provides a significantly higher degree of protection from the risk of illness or injury with respect to which the Federal standard or requirement is in effect, and (ii) does not unduly burden interstate commerce.

In determining the burden, if any, of a State or political subdivision standard or requirement on interstate commerce the Commission shall consider and make appropriate (as determined by the Commission in its discretion) findings on the technological and economic feasibility of complying with such standard or requirement, the cost of complying with such standard or requirement, the geographic distribution of the household substance to which the standard or requirement would apply, the probability of other States or political subdivisions applying for an exemption under this subsection for a similar standard or requirement, and the need for a national uniform standard or requirement under this Act for such household substance.

(2) A regulation under paragraph (1) granting an exemption for a standard or requirement of a State or political subdivision of a State may be promulgated by the Commission only after it has provided, in accordance with section 553(b) of Title 5, notice with respect to the promulgation of the regulation and has provided opportunity for the oral presentation of views respecting its promulgation.

(Pub.L. 91-601, § 7, formerly § 8, Dec. 30, 1970, 84 Stat. 1673; Pub. 92-573, § 30(a), Oct. 27, 1972, 86 Stat. 1231; Pub.L. 94-284, § 17(c), 11, 1976, 90 Stat. 513; renumbered § 7, Pub.L. 97-35, Title XII, § 1205, Aug. 13, 1981, 95 Stat. 716.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91-1642 and Conference Report No. 91-1755, see 1970 U.S. Code Cong. and Adm. News, p. 4326.

1972 Acts. Senate Report No. 92-835 and House Conference Report No. 92-1593, see 1972 U.S. Code Cong. and Adm. News, p. 4573.

1976 Acts. Senate Report No. 94-251 and House Conference Report No. 94-1022, see 1976 U.S. Code Cong. and Adm. News, p. 993.

1981 Acts. Senate Report No. 97-139 and House Conference Report No. 97-208, see 1981 U.S. Code Cong. and Adm. News, p. 396.

References in Text

For classification to the Code of "this Act", referred to in text, see References in Text note set out under section 1471 of this title.

Amendments

1976 Amendments. Pub.L. 94-284 substituted "(a) Except as provided in subsections (b) and (c) of this section, whenever" for "Whenever" in existing provision, and added subsecs. (b) and (c).

Transfer of Functions

"Commission" substituted for "Secretary" in subsec. (a) pursuant to section 30(a) of Pub.L. 92-573, which is classified to section 2079(a) of this title and which transferred functions of Secretary of Health, Education, and Welfare under this chapter to Consumer Product Safety Commission.

LIBRARY REFERENCES

Administrative Law

Applications for exemption from preemption, see 16 CFR § 1061.1 et seq.

WESTLAW ELECTRONIC RESEARCH

See WESTLAW guide following the Explanation pages of this volume.

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Anyone who does business within the ach of this chapter is under an absolute ›ligation to comply with the law at all nes. U. S. v. Bodine Produce Co., C.Ariz.1962, 206 F.Supp. 201.

If this chapter is too broad and needs nending in the public interest to guard against the possibility of the destruction of wholesome food by the United States, the remedy is to call the matter to the attention of Congress. U. S. v. 233 Tins, More or Less, Grove Brand*** Whole Blakemore Strawberries, W.D.Ark.1959, 175 F.Supp. 694.

SUBCHAPTER II—DEFINITIONS

LIBRARY REFERENCES

dministrative Law
Enforcement of provisions, see 21 CFR § 1.1 et seq.
General policy or interpretation statements, see 21 CFR § 3.1 et seq.

321. Definitions; generally

For the purposes of this chapter—

(a)(1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph. A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of

the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this

chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 348(h)(6) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this chapter other than sections 342(a)(2)(B) and 346a of this title.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958 pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C.A. § 601 et seq.];

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(w) The term "animal feed", as used in paragraph (w) of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of Title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 355(j) of this title for the approval of a drug that relies on the approved application of another drug

with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of Title 42.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 355 of this title, or licensed as a biologic under section 262 of Title 42, and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of Title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has

issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

Except for purposes of paragraph (g), a dietary supplement shall be deemed to be a food within the meaning of this chapter.

(ii) The term "compounded positron emission tomography drug"—

(1) means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(June 25, 1938, c. 675, § 201, 52 Stat. 1041; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 22, 1954, c. 559, § 1, 68 Stat. 511; Sept. 6, 1958, Pub.L. 85–929, § 2, 72 Stat. 1784; July 12, 1960, Pub.L. 86–618, Title I, § 101, 74 Stat. 397; Oct. 10, 1962, Pub.L. 87–781, Title I, § 102(a), Title III, § 307(a), 76 Stat. 781, 796; July 15, 1965, Pub.L. 89–74, §§ 3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, Pub.L. 90–399, § 102, 82 Stat. 351; Oct. 24, 1968, Pub.L. 90–639, §§ 1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, Pub.L. 91–513, Title II, § 701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, Pub.L. 92–516, § 3(3), 86 Stat. 998; Apr. 22, 1976, Pub.L. 94–278, Title V, § 502(a)(2)(A), 90 Stat. 411; May 28, 1976, Pub.L. 94–295, § 3(a)(1)(A), (2), 90 Stat. 575; Nov. 23, 1977, Pub.L. 95–203, § 4(b)(3), 91 Stat. 1453; Sept. 26, 1980, Pub.L. 96–359, § 3, 94 Stat. 1193; Nov. 16, 1988, Pub.L. 100–670, Title I, § 107(a)(1), 102 Stat. 3984; Nov. 8, 1990, Pub.L. 101–535, § 5(b), 104 Stat. 2362; Nov. 28, 1990, Pub.L. 101–629, § 16(b), 104 Stat. 4526; May 13, 1992, Pub.L. 102–282, § 6, 106 Stat. 161; June 16, 1992, Pub.L. 102–300, § 6(a), (b), 106 Stat. 240; Oct. 29, 1992, Pub.L. 102–571, Title I, § 107(1), 106 Stat. 4499; Aug. 13, 1993, Pub.L. 103–80, §§ 3(b), (dd)(1), 4(b), 107 Stat. 775, 779; Oct. 25, 1994, Pub.L. 103–417, §§ 3(a), (b), 10(a), 108 Stat. 4327, 4332; Aug. 3, 1996, Pub.L. 104–170, Title IV, § 402, 110 Stat. 1513; Nov. 21, 1997, Pub.L. 105–115, Title I, §§ 121(a), 125(b)(2)(A), (e), 111 Stat. 2320, 2325, 2327; Oct. 30, 1998, Pub.L. 105–324, § 2(a), (c), 112 Stat. 3035, 3037.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1954 Acts. Senate Report No. 1635, see 1954 U.S. Code Cong. and Adm. News, p. 2626.

1958 Acts. Senate Report No. 2422, see 1958 U.S. Code Cong. and Adm. News, p. 5300.

1960 Acts. House Report No. 1761, see 1960 U.S. Code Cong. and Adm. News, p. 2887.

1962 Acts. Senate Report No. 1744 and Conference Report No. 2526, see 1962 U.S. Code Cong. and Adm. News, p. 2884.

1965 Acts. Senate Report No. 337, see 1965 U.S. Code Cong. and Adm. News, p. 1895.

1968 Acts. Senate Report No. 1308, see 1968 U.S. Code Cong. and Adm. News, p. 2607.

Senate Report No. 1609 and Conference Report No. 1958, see 1968 U.S. Code Cong. and Adm. News, p. 4594.

1970 Acts. House Report No. 91–1444 and Conference Report No. 91–1603, see 1970 U.S. Code Cong. and Adm. News, p. 4566.

1972 Acts. Senate Report Nos. 92–838 and 92–970 and Conference Report No. 92–1540, see 1972 U.S. Code Cong. and Adm. News, p. 3993.

1976 Acts. House Report No. 94–498 and House Conference Report No. 94–1005, see 1976 U.S. Code Cong. and Adm. News, p. 709.

Senate Report No. 94–33 and House Conference Report No. 94–1090, see 1976 U.S. Code Cong. and Adm. News, p. 1070.

1977 Acts. Senate Report Nos. 95–353, 95–369 and House Conference Report No. 95–810, see 1977 U.S. Code Cong. and Adm. News, p. 3921.

1980 Acts. Senate Report No. 96–916, see 1980 U.S. Code Cong. and Adm. News, p. 2858.

1988 Acts. House Report No. 100–972(Parts I and II), see 1988 U.S. Code Cong. and Adm. News, p. 5659.

1990 Acts. House Report No. 101–538 and Statement by President, see 1990 U.S. Code Cong. and Adm. News, p. 3336.

House Report No. 101–808 and House Conference Report No. 101–959, see 1990 U.S. Code Cong. and Adm. News, p. 6305.

1992 Acts. House Report No. 102–272, see 1992 U.S. Code Cong. and Adm. News, p. 103.

1994 Acts. Agreement Statement, see 1994 U.S. Code Cong. and Adm. News, p. 3523.

1996 Acts. House Report No. 104–669(Parts I and II), see 1996 U.S. Code Cong. and Adm. News, p. 1208.

1997 Acts. House Conference Report No. 105–399, see 1997 U.S. Code Cong. and Adm. News, p. 2881.

References in Text

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in text, is Act June 25, 1947, c. 125, as amended generally by Pub.L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (section 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the

bodied in this section empowering Attorney General to modify schedules of controlled substances and narcotics, alleged impermissible delegation of legislative power would not be considered. U. S. v. Westlake, C.A.5 (Fla.) 1973, 480 F.2d 1225.

13. Over the counter sales

Drug defendants convicted of manufacturing methamphetamine were not deprived of due process, though statutory scheme allowed for exemption for manufacturer of over-the-counter product containing methamphetamine; regulatory scheme was not so ambiguous that it failed to give defendants sufficient notice that their activity was deemed criminal, and defendants had made no showing that their product was eligible for exemption or that they had attempted to obtain exemption. U.S. v. Sherrod, C.A.5 (Tex.) 1992, 964 F.2d 1501, certiorari denied 113 S.Ct. 832, 506 U.S. 1041, 121 L.Ed.2d 701, certiorari dismissed 113 S.Ct. 834, 506 U.S. 1041, 122 L.Ed.2d 111, certiorari denied 113 S.Ct. 1367, 507 U.S. 953, 122 L.Ed.2d 745, rehearing denied 113 S.Ct. 1834, 507 U.S. 1025, 123 L.Ed.2d 461, certiorari denied 113 S.Ct. 1422, 507 U.S. 975, 122 L.Ed.2d 791.

Food and Drug Administration's approval of product containing methamphetamine with potency of .11 grams per 50 milliliters for sale over the counter without a prescription did not require Attorney General to remove methamphetamine from the schedule of controlled substances. U.S. v. Caperell, C.A.9 (Nev.) 1991, 938 F.2d 975.

Approval for over the counter sale of specified products containing methamphetamine did not result in exclusion of methamphetamine from Schedule II. U.S. v. Housley, D.Nev.1990, 751 F.Supp. 1446, affirmed 955 F.2d 622, certiorari denied 113 S.Ct. 394, 506 U.S. 946, 121 L.Ed.2d 301.

14. Motion to dismiss

Where reclassification of marijuana by Drug Enforcement Agency subsequent to date of defendant's alleged involvement in conspiracy to import marijuana would, in no way, relieve defendant of criminal responsibility for his acts, defendant's claim that he was entitled to dismissal of indictment for failure of agency Administrator to reclassify marijuana upon petition of reform organization had to be interpreted either as claim that any reclassification should be retroactive to period of time encompassed on charge as contained in indictment or as claim that as of such date amendment by agency was mandated, and since nothing in papers filed on motion suggested that reform organization had ever made such an argument, defendant could not raise it. U. S. v. Creswell, E.D.N.Y.1981, 515 F.Supp. 1268.

Where defendant has submitted numerous affidavits in support of his motion to dismiss under rule 12, Federal Rules of Civil Procedure, Title 28, on the ground that the classification of cocaine as "narcotic drug" is arbitrary and irrational and consequently violates due process and equal protection under U.S.C.A.Const. Amend. 14, no evidentiary hearing is required for disposition of the motion. U. S. v. DiLaura, D.C.Mass. 1974, 394 F.Supp. 770.

15. Rules and regulations—Generally

Duty of administrator of Drug Enforcement Administration to respond to all petitions for issuance, amendment, or repeal of rules required administrator to respond to petition to allow religious use of marijuana and to inform petitioners that rule they sought fell outside scope of statute [21 U.S.C.A. § 811(c)], providing that any interested party may petition to have substance added, removed, or transferred between schedules of controlled substances. Olsen v. Drug Enforcement Admin., C.A.11 (Fla.) 1985, 776 F.2d 267, certiorari denied 106 S.Ct. 1236, 475 U.S. 1030, 89 L.Ed.2d 344.

16. —— Publication requirements, rules and regulations

Administrator of Drug Enforcement Administration's (DEA) use of eight-factor test to evaluate evidence on petition to reschedule marijuana from Schedule I to Schedule II of Controlled Substances Act (CSA), without giving petitioners notice prior to close of evidence of use of factors did not violate Freedom of Information Act (FOIA); petitioners failed to demonstrate that they were adversely affected by lack of notice. Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., C.A.D.C.1994, 15 F.3d 1131, 304 U.S.App.D.C. 400.

Drug Enforcement Agency did not circumvent publication requirements for promulgation of rules regarding scheduling of controlled substances by filing notice 30 days early and placing notice in Federal Register while Secretary of Health and Human Services was still free to make comments and encouraged to do so in 30-day waiting period. U.S. v. Pees, D.Colo.1986, 645 F.Supp. 697.

§ 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970 and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.[2]
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.

(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Proheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-dimethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.

(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

Schedule II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.

(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine.

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(18) Phenazocine.

(19) Piminodine.

(20) Racemethorphan.

(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.

(3) Glutethimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids

Schedule IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

Schedule V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(Pub.L. 91–513, Title II, § 202, Oct. 27, 1970, 84 Stat. 1247; Pub.L. 95–633, Title I, § 103, Nov. 10, 1978, 92 Stat. 3772; Pub.L. 98–473, Title II, §§ 507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub.L. 99–570, Title I, § 1867, Oct. 27, 1986, 100 Stat. 3207–55; Pub.L. 99–646, § 84, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 101–647, Title XIX, § 1902(a), Nov. 29, 1990, 104 Stat. 4851.)

[1] Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

[2] So in original. Probably should be "Alphacetylmethadol".

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1970 Acts. House Report No. 91–1444 and Conference Report No. 91–1603, see 1970 U.S. Code Cong. and Adm. News, p. 4566.

1978 Acts. House Report No. 95–1193, see 1978 U.S. Code Cong. and Adm. News, p. 9496.

1984 Acts. House Report No. 98–1030 and House Conference Report No. 98–1159, see 1984 U.S. Code Cong. and Adm. News, p. 3182.

1986 Acts. Statement by President, see 1986 U.S. Code Cong. and Adm. News, p. 5393.

House Report No. 99–797, see 1986 U.S. Code Cong. and Adm. News, p. 6138.

1990 Acts. House Report Nos. 101–681(Parts I and II) and 101–736, Senate Report No. 101–460, and Statement by President, see 1990 U.S. Code Cong. and Adm. News, p. 6472.

Amendments

1990 Amendments. Subsec. (c), Pub.L. 101–647, § 1902(a), in schedule III added (e).

1986 Amendments. Subsec. (c), Pub.L. 99–646 in schedule II(a)(4) substituted "coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph" for "Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine".

Subsec. (c), Pub.L. 99–570, § 1867, in subsec. (a)(4) of schedule II substituted "Coca leaves (except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed); cocaine, its salts, optical and geometric isomers, and salts of isomers; and ecgonine, its derivatives, their salts, isomers, and salts of isomers" for "Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine".

1984 Amendments. Subsec. (c), Pub.L. 98–473, § 507(c), in schedule II(a)(4) added applicability to cocaine and ecgonine and their salts, isomers, etc.

Subsec. (d). Pub.L. 98–473, § 509(b), struck out subsec. (d), which related to authority of Attorney General to except stimulants or depressants containing active medicinal ingredients.

1978 Amendments. Subsec. (d), Pub.L. 95–633 added cl. (3).

Effective Dates

1990 Acts. Amendment by Pub.L. 101–647 effective 90 days after Nov. 29, 1990, see section 1902 of Pub.L. 101–647, set out as a note under section 802 of this title.

1978 Acts. Amendment by Pub.L. 95–633 effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see § 112 of Pub.L. 95–633, set out as a note under § 801a of this title.

1970 Acts. Section effective Oct. 27, 1970, see § 704(b) of Pub.L. 91–513, set out as a note under § 801 of this title.

Placement of Pipradrol and SPA in Schedule IV to Carry Out Obligation Under Convention on Psychotropic Substances

Section 102(c) of Pub.L. 95–633 provided that: "For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 201 and 202 of the Controlled Substances Act [this section and section 811 of this title], place such drugs in schedule IV of such Act [see subsec. (c) of this section]."

Texts and Treatises

Food, Drugs, and Cosmetics, 13 Fed Proc L Ed §§ 35:580-581.

WESTLAW ELECTRONIC RESEARCH

Drugs and Narcotics cases: 138k[add key number].
See WESTLAW guide following the Explanation pages of this volume.

Notes of Decisions

Data considered 4
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1. Reduction of quotas

Although trimming the whole pipeline is a permissible method of combatting the problem of diversion of controlled substances there might be situations in which, because of the interest in serving the nation's legitimate medical needs, reducing procurement quotas to make the pipeline more lean could be too crude an instrument; legislative history of the controlled substances legislation and concern of Congress over the diversion problem suggests that for such a situation to arise there would have to be, at the very least, a clear and definite showing that legitimate medical needs were not being satisfied. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

2. Reconsideration of quotas

Compliance Investigation Division of Drug Enforcement Administration did not act improperly in adhering to its original decision following reconsideration of manufacturing and procurement quotas for drug phenmetrazine after acting administrator returned the matter for redetermination following his exclusion, as unreliable, of certain data purporting to show a large increase in drugstore purchases where Compliance Investigation Division did not rely on the tainted data, was operating under considerable time restraints and was not presented with any evidence that its original judgment was in error. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

Acting administrator's order requiring redetermination of manufacturing and procurement quotas for drug phenmetrazine was not defective by reason of inadequate findings and reasons since in specifically approving Compliance Investigation Division's formula and impliedly approving reliance on prescription audit figure to implement congressional policy of dealing with diversion problem by reducing inventories the administrative law judge, whose report was accepted by the administrator, had clearly manifested his reasoning; in any event, remand would have been pointless since increase in inventory allowance would only cancel out the otherwise justified reduction of amount by which prior year sales exceeded prescriptions. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

3. Duty of Drug Enforcement Administration

Preludin, being a controlled substance, the Drug Enforcement Administration had the obligation, when it found substantial evidence of broad scale diversion, to attempt to achieve a more spartan pipeline, even though it might cause inconvenience to manufacturer and distributor. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

4. Data considered

Where administrative law judge found that certain data purporting to show large increase in purchases by drugstores of the drug phenmetrazine were unreliable, such data, which was received by the Compliance Investigation Division of the Drug Enforcement Administration after its quota letter and which did not affect the initial decision although it played a part in Compliance Investigation Division's reassessment, was properly excluded by the judge in any reconsideration. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

5. Determination of amount sold

Reliance on stratified random sampling of some 800 pharmacies in fixing individual manufacturing and procurement quotas for 1975 for the drug phenmetrazine was not misplaced on ground that the sampling, which revealed a 616 kg. excess of wholesale sales over prescriptions, was unreliable since audit had a reliability factor of ±5.1 percent; although sampling did not include prescriptions dispensed by hospitals, clinics, government installations or physicians, the drug was overwhelmingly sold by retail pharmacies and exclusion of 982 retail stores in Alaska, Hawaii and Puerto Rico, being 1.8 percent of the total, did not adversely affect reliability. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

Although reliance on a leaner pipeline was one way of meeting problem of diversion of the drug phenmetrazine, there were limits to such method; in order not to run the risk that legitimate consumers might, for substantial periods, be unable to purchase a drug, the Drug Enforcement Administration is advised to attempt to ascertain more directly the state of inventories at the wholesale and retail level. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

6. Judicial review

The substantial evidence test governs judicial review of legality of quota established by the Compliance Investigation Division of the Drug Enforcement Administration for the drug phenmetrazine, which in dosage form bears the trade name "Preludin." Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

Substantial evidence supported Drug Enforcement Administration's limiting inventory allowances of the drug phenmetrazine to 50 percent of sales, notwithstanding that sole manufacturer of the basic ingredient produced it only during month of each year and that the manufacturing process normally required some six months for each batch of the main dosage form. Western Fher Laboratories v. Levi, C.A.1 1976, 529 F.2d 325.

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c) of this section—

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of

by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply—

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

(d) Periodic reports to Attorney General

Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

(e) Reporting and recordkeeping requirements of drug conventions

In addition to the reporting and recordkeeping requirements under any other provision of this subchapter, each manufacturer registered under section 823 of this title shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this subchapter on manufacturers subject to the requirements of this subsection.

(f) Investigational uses of drugs; procedures

Regulations under sections 355(i) and 360b(j) of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(g) Change of address

Every registrant under this subchapter shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(Pub.L. 91–513, Title II, § 307, Oct. 27, 1970, 84 Stat. 1258; Pub.L. 93–281, § 5, May 14, 1974, 88 Stat. 125; Pub.L. 95–633, Title I, §§ 104, 110, Nov. 10, 1978, 92 Stat. 3772, 3773; Pub.L. 98–473, Title II, §§ 514, 515, Oct. 12, 1984, 98 Stat. 2074.)

its package, or accompanying such substance.

(Pub. L. 92-573, sec. 30(a), 86 Stat. 1231; (15 U.S.C. 2079(a)))

[38 FR 21247, Aug. 7, 1973, as amended at 41 FR 22266, June 2, 1976; 48 FR 57480, Dec. 30, 1983]

§ 1700.2 Authority.

Authority under the Poison Prevention Packaging Act of 1970 is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

§ 1700.3 Establishment of standards for special packaging.

(a) Pursuant to section 3 of the act, the Commission, after consultation with the technical advisory committee provided for by section 6 of the act, may establish by regulation standards for the special packaging of any household substance if the Commission finds:

(1) That the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) That the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing such a standard, the Commission shall consider:

(1) The reasonableness of such standard;

(2) Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) The manufacturing practices of industries affected by the act; and

(4) The nature and use of the household substance.

(c) In the process of establishing such a standard, the Commission shall publish its findings and reasons therefor and shall cite the sections of the act that authorize its action.

(d) In establishing such standards, the Commission shall not prescribe specific packaging designs, product content, package quantity, or labeling except for labeling under section 4(a)(2) of the act. Regarding a household substance for which special packaging is required by regulation, the Commission can prohibit the packaging of such substance in a package which the Commission determines is unnecessarily attractive to children.

(e) Promulgations pursuant to section 3 of the act shall be in accordance with section 5 of the act as to procedure.

§ 1700.4 Effective date of standards.

(a) The FR document promulgating a regulation establishing a child protection packaging standard shall indicate the standard's effective date. Section 3 of the act specifies that the effective date shall not be sooner than 180 days or later than 1 year from the date the standard is promulgated in the FEDERAL REGISTER unless the Commission, for good cause found, determines that an earlier effective date is in the public interest and publishes in the FEDERAL REGISTER the reason for such finding, in which case such earlier effective date shall apply.

(b) Upon becoming effective, a child protection packaging standard shall apply only to household substances packaged on and after its effective date.

§ 1700.5 Noncomplying package requirements.

To make household substances that are subject to requirements for special packaging readily available to elderly or handicapped persons who are unable to use those substances in special packaging, section 4(a) of the act authorizes manufacturers and packers to package such substances in noncomplying packaging of a single size provided that complying packaging is also supplied and the noncomplying packages are conspicuously labeled to indicate that they should not be used in households where young children are present. The purpose of this § 1700.5 is to implement section 4(a) of the act by prescribing requirements for the labeling of noncomplying packages.

(a) *Labeling statement.* (1) The statement "This Package for Households Without Young Children" shall appear conspicuously, and in accordance with all of the requirements of paragraph (b) of this section, on the package of any household substance subject to the special packaging requirements of this part 1700 that is supplied in noncomplying packaging under section 4(a) of the act, unless the package bears the substitute labeling statement in accordance with all of the requirements in paragraph (b) of this section.

(2) The statement required by paragraph (a)(1) of this section shall appear on the principal display panel of the immediate container as well as on the principal display panel of any outer container or wrapping used in the retail display of the substance. If a package bears more than one principal display panel, the required statement shall appear on each principal display panel of the immediate container as well as on each principal display panel of any outer container or wrapping used in the retail display of the substance. The principal display panel is the part of the labeling most likely to be displayed, presented, shown, or examined.

(3) The required labeling statement shall appear within the borderline of a square or rectangle on the principal display panel in conspicuous and easily legible capital letters, shall be in distinct contrast, by typography, layout, color, or embossing, to other matter on the package, and shall appear in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(4) The declaration shall be in letters of type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type-size specifications:

(i) Not less than 1/16 inch in height on packages the principal display panel of which has an area of 7 square inches or less.

(ii) Not less than 3/32 inch in height on packages the principal display panel of which has an area of more than 7 but not more than 15 square inches.

(iii) Not less than 1/8 inch in height on packages the principal display panel of which has an area of more than 15 but not more than 25 square inches.

(iv) Not less than 3/16 inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(v) Not less than 1/4 inch in height on packages the principal display panel of which has an area of more than 100 square inches.

(5)(i) For the purpose of obtaining uniform type size for the required statement for all packages of substantially the same size, the area of the principal display panel is the area of the side or surface that bears the principal display panel, which shall be:

(A) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel, the product of the height times the width of that side.

(B) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference.

(C) In the case of any other shape of container, 40 percent of the total surface of the container; however, if such container presents an obvious principal display (such as the top of a triangular or circular package), the area shall consist of the entire area of such obvious principal display panel.

(ii) In determining the area of the principal display panel exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, the labeling statement required by this section to appear on the principal display panel shall appear within that 40 percent of the circumference most likely to be displayed, presented, shown, or examined.

(b) *Substitute labeling statement.* If the area of the principal display panel, as determined in accordance with paragraph (a)(5) of this section, is too small to accommodate the statement required by paragraph (a)(1) using the type size required by paragraph (a)(4), the substitute statement "Package Not Child-Resistant" may be used. This substitute statement must comply with all of the requirements for size, placement, and conspicuousness prescribed by paragraph (a) of this section.

[40 FR 4650, Jan. 31, 1975]

(ii) Is prominently placed on the package; and

(iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing.

(2) If the tamper-evident feature chosen to meet the requirements in paragraph (b) of this section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck."

(d) *Request for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this chapter and should be clearly identified on the envelope as a "Request for Exemption from the Tamper-Evident Packaging Rule." The petition is required to contain the following:

(1) The name of the drug product or, if the petition seeks an exemption for a drug class, the name of the drug class, and a list of products within that class.

(2) The reasons that the drug product's compliance with the tamper-evident packaging or labeling requirements of this section is unnecessary or cannot be achieved.

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product or drug class will be the subject of malicious adulteration.

(4) Other information justifying an exemption.

(e) *OTC drug products subject to approved new drug applications.* Holders of approved new drug applications for OTC drug products are required under § 314.70 of this chapter to provide the agency with notification of changes in packaging and labeling to comply with the requirements of this section. Changes in packaging and labeling required by this regulation may be made before FDA approval, as provided under § 314.70(c) of this chapter. Manufacturing changes by which capsules are to be sealed require prior FDA approval under § 314.70(b) of this chapter.

(f) *Poison Prevention Packaging Act of 1970.* This section does not affect any requirements for "special packaging" as defined under § 310.3(l) of this chapter and required under the Poison Prevention Packaging Act of 1970.

(Approved by the Office of Management and Budget under OMB control number 0910–0149)

[54 FR 5228, Feb. 2, 1989, as amended at 63 FR 59470, Nov. 4, 1998]

§ 211.134 Drug product inspection.

(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label.

(b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling.

(c) Results of these examinations shall be recorded in the batch production or control records.

§ 211.137 Expiration dating.

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

(e) Homeopathic drug products shall be exempt from the requirements of this section.

(f) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section.

(g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or

specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product.

(h) Pending consideration of a proposed exemption, published in the FEDERAL REGISTER of September 29, 1978, the requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data.

[43 FR 45077, Sept. 29, 1978, as amended at 46 FR 56412, Nov. 17, 1981; 60 FR 4091, Jan. 20, 1995]

Subpart H—Holding and Distribution

§ 211.142 Warehousing procedures.

Written procedures describing the warehousing of drug products shall be established and followed. They shall include:

(a) Quarantine of drug products before release by the quality control unit.

(b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.

§ 211.150 Distribution procedures.

Written procedures shall be established, and followed, describing the distribution of drug products. They shall include:

(a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

(b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.

Subpart I—Laboratory Controls

§ 211.160 General requirements.

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(1) Determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

(3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified.

(4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions,

schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

§ 211.165 Testing and release for distribution.

(a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.

(b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms.

(c) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed.

(d) Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels.

(e) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

(f) Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant critieria.

§ 211.166 Stability testing.

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

(b) An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.

(c) For homeopathic drug products, the requirements of this section are as follows:

(1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product

for the normal or expected period of use.

(2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.

(d) Allergenic extracts that are labeled "No U.S. Standard of Potency" are exempt from the requirements of this section.

[43 FR 46077, Sept. 29, 1978, as amended at 46 FR 56412, Nov. 17, 1981]

§ 211.167 Special testing requirements.

(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed.

(b) For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed.

(c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed.

§ 211.170 Reserve samples.

(a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows:

(1) For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient.

(2) For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or

(ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days.

(3) For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under § 211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient.

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with § 211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows:

(1) For a drug product other than those described in paragraphs (b) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the drug product.

(2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(Authority: 21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5320, Feb. 13, 1986; 62 FR 13959, Mar. 24, 1997]

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA.

[68 FR 37410, June 24, 2003]

INVENTORY REQUIREMENTS

§ 1304.11 Inventory requirements.

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable.

In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by §1301.13 or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each

person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) *Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

[62 FR 13959, Mar. 24, 1997, as amended at 68 FR 41228, July 11, 2003]

Continuing Records

§ 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is registered, except as provided in § 1304.22(d).

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13960, Mar. 24, 1997]

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by § 1301.13(e) or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(ix) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iii) The number of containers of each such commercial finished form

the Registration Unit of the Administration. All requisition forms (DEA Form 222a) shall be submitted to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to §1305.07.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Unit of the Administration by returning the forms with notification of the error.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 53 FR 4963, Feb. 19, 1988; 62 FR 13964, Mar. 24, 1997]

§1305.06 Procedure for executing order forms.

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed shall be noted on that form at the bottom of the form, in the space provided. Order forms for carfentanil, etorphine hydrochloride, and diprenorphine shall contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.

(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

[62 FR 13963, Mar. 24, 1997]

§1305.07 Power of attorney.

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. The form for the power of attorney and notice of revocation shall be similar to the following:

Power of Attorney for DEA Order Forms

_____ (Name of registrant)
_____ (Address of registrant)
_____ (DEA registration number)

I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____
(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____
(Signature of attorney-in-fact)

Witnesses:
1. _____.
2. _____.

Signed and dated on the _____ day of _____, (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____
(Signature of person revoking power)

Witnesses:
1. _____.
2. _____.

Signed and dated on the _____ day of _____, (year), at _____.

[62 FR 13963, Mar. 24, 1997]

§1305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he/she is discontinuing business or if his/her registration is expiring without reregistration, may dispose of any controlled substances listed in Schedule I or II in his/her possession pursuant to order forms in accordance with §1307.14 of this chapter;

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he/she obtained the substance, to the manufacturer of the substance, or to a registered reverse distributor pursuant to the order form of the latter person;

(c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, §1307.11 of this chapter; and

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a controlled substance listed in Schedule I or II to another person registered or authorized to conduct chemical analysis, instructional activities, or research with such substances pursuant to the order form of the latter person, if such distribution is for the purpose of furthering such chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to off-site narcotic treatment programs only.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971; 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1305.08, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§1305.09 Procedure for filling order forms.

(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the

supplier, and retain Copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he/she desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form, except as specified in paragraph (f) of this section.

(d) The supplier shall retain Copy 1 of the order form for his/her own files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982; 62 FR 13964, Mar. 24, 1997]

§ 1305.10 Procedure for endorsing order forms.

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.09 may be endorsed to another supplier for filling. The endorsement shall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of Copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he/she desires to do so, in accordance with § 1305.09 (b), (c), and (d), including shipping all substances directly to the purchaser.

(b) Distributions made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13964, Mar. 24, 1997]

§ 1305.11 Unaccepted and defective order forms.

(a) No order form shall be filled if it:

(1) Is not complete, legible, or properly prepared, executed, or endorsed; or

(2) Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this section, the supplier shall return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with § 1305.13.

defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

§ 1305.12 Lost and stolen order forms.

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with Copy 3 of the order form first executed. A copy of the statement shall be attached to Copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return Copies 1 and 2 to the purchaser, who shall attach it to Copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen or lost (otherwise than in the course of transmission) by any purchaser or supplier, he/she shall immediately upon discovery of such theft or loss, report the same to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he/she shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he/she shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located shall immediately be notified.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 62 FR 13964, Mar. 24, 1997]

§ 1305.13 Preservation of order forms.

(a) The purchaser shall retain Copy 3 of each order form which has been filled. He/She shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain Copy 1 of each order form which he/she has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 years. If a purchaser has several registered locations, he/she must retain Copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to § 1305.06(d)) at the registered location printed on the order form.

(d) The supplier of carfentanil etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 17839, May 21, 1974; 54 FR 33674, Aug. 16, 1989; 62 FR 13964, Mar. 24, 1997]

§ 1305.14 Return of unused order forms.

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to § 1301.36 of this chapter as to all controlled substances listed in Schedules I and II for which he/she is registered, he/she shall return

Some trade and other names: N,N-Diethyltryptamine; DET
(18) Dimethyltryptamine 7435
Some trade or other names: DMT
(19) 5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT) 7439
(20) Ibogaine 7260
Some trade and other names: 7-Ethyl-6,6β,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga
(21) Lysergic acid diethylamide 7315
(22) Marihuana 7360
(23) Mescaline 7381
(24) Parahexyl—7374; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl.
(25) Peyote 7415
Meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts
(Interprets 21 USC 812(c), Schedule I(c) (12))
(26) N-ethyl-3-piperidyl benzilate 7482
(27) N-methyl-3-piperidyl benzilate 7484
(28) Psilocybin 7437
(29) Psilocyn 7438
(30) Tetrahydrocannabinols 7370
Meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:
1 cis or trans tetrahydrocannabinol, and their optical isomers
6 cis or trans tetrahydrocannabinol, and their optical isomers
3, 4 cis or trans tetrahydrocannabinol, and its optical isomers
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)
(31) Ethylamine analog of phencyclidine 7455
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE
(32) Pyrrolidine analog of phencyclidine 7458
Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP
(33) Thiophene analog of phencyclidine 7470
Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP
(34) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine 7473
Some other names: TCPy

(e) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate) 2010
(2) Mecloqualone 2572
(3) Methaqualone 2565

(f) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex (Some other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenly-2-oxazolamine) 1585
(2) N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine) 7493
(3) Cathinone 1235
Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone
(4) Fenethylline 1503
(5) Methcathinone (Some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; *N*-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR1432), its salts, optical isomers and salts of optical isomers 1237
(6) (±)*cis*-4-methylaminorex ((±)*cis*-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) 1590
(7) N-ethylamphetamine 1475
(8) *N,N*-dimethylamphetamine (also known as *N,N*-alpha-trimethyl-benzeneethanamine; *N,N*-alpha-trimethylphenethylamine) 1480

(g) *Temporary listing of substances subject to emergency scheduling.* Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers 9818
(2) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isolers, salts and salts of isomers 9834

[39 FR 22141, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 1308.12 Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) *Substances, vegetable origin or chemical synthesis.* Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

(1) Raw opium 9600
(2) Opium extracts 9610
(3) Opium fluid 9620
(4) Powdered opium 9639
(5) Granulated opium 9640
(6) Tincture of opium 9630
(7) Codeine 9050
(8) Dihydroetorphine 9334
(9) Ethylmorphine 9190
(10) Etorphine hydrochloride 9059
(11) Hydrocodone 9193
(12) Hydromorphone 9150
(13) Metopon 9260
(14) Morphine 9300
(15) Oxycodone 9143
(16) Oxymorphone 9652
(17) Thebaine 9333

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy), 9670.

(c) *Opiates.* Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil 9737
(2) Alphaprodine 9010
(3) Anileridine 9020
(4) Bezitramide 9800
(5) Bulk dextropropoxyphene (non-dosage forms) 9273
(6) Carfentanil 9743
(7) Dihydrocodeine 9120
(8) Diphenoxylate 9170
(9) Fentanyl 9801
(10) Isomethadone 9226
(11) Levo-alphacetylmethadol 9648
[Some other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM]
(12) Levomethorphan 9210
(13) Levorphanol 9220
(14) Metazocine 9240
(15) Methadone 9250
(16) Methadone-intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane 9254
(17) Moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid 9802
(18) Pethidine (meperidine) 9230
(19) Pethidine-intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine 9232
(20) Pethidine-intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate 9233
(21) Pethidine-intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid 9234
(22) Phenazocine 9715
(23) Piminodine 9730
(24) Racemethorphan 9732
(25) Racemorphan 9733
(26) Remifentanil 9739
(27) Sufentanil 9740

(d) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100
(2) Methamphetamine, its salts, isomers, and salts of its isomers 1105
(3) Phenmetrazine and its salts 1631
(4) Methylphenidate 1724

(e) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including

its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital 2125
(2) Glutethimide 2550
(3) Pentobarbital 2270
(4) Phencyclidine 7471
(5) Secobarbital 2315

(f) *Hallucinogenic substances.*

(1) Nabilone 7379
[Another name for nabilone: (±)-*trans*-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one]

(g) *Immediate precursors.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(i) Phenylacetone 8501
Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

(2) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine 7460
(ii) 1-piperidinocyclohexanecarbonitrile (PCC) 8603

[39 FR 22142, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.12, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 1308.13 Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous sxstem, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances 1405
(2) Benzphetamine 1228
(3) Chlorphentermine 1645
(4) Clortermine 1647
(5) Phendimetrazine 1615

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:
(i) Amobarbital 2126
(ii) Secobarbital 2316
(iii) Pentobarbital 2271
or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
(2) Any suppository dosage form containing:
(i) Amobarbital 2126
(ii) Secobarbital 2316
(iii) Pentobarbital 2271
or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof 2100
(4) Chlorhexadol 2510
(5) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act 2012
(6) Ketamine, its salts, isomers, and salts of isomers .. 7285
[Some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone]
(7) Lysergic acid 7300
(8) Lysergic acid amide 7310
(9) Methyprylon 2575
(10) Sulfondiethylmethane 2600
(11) Sulfonethylmethane 2605
(12) Sulfonmethane 2610
(13) Tiletamine and zolazepam or any salt thereof 7295
Some trade or other names for a tiletamine-zolazepam combination product:
Telazol..
Some trade or other names for tiletamine:
2-(ethylamino)-2-(2-thienyl)-cyclohexanone..
Some trade or other names for zolazepam:
4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-*e*] [1,4]-diazepin-7(1*H*)-one, flupyrazapon..

(d) Nalorphine 9400.

(e) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule:

(1) Any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
(i) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803
(ii) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804
(iii) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium 9805
(iv) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts 9806
(v) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts ... 9807
(vi) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ... 9808
(vii) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ... 9809
(viii) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810
(2) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below:
(i) Buprenorphine 9064
(ii) [Reserved].

(f) *Anabolic steroids.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids 4000

(g) *Hallucinogenic substances.* (1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369.

[Some other names for dronabinol: (6a*R*-*trans*)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo [*b*,*d*]pyran-1-ol] or (-)-delta-9-(*trans*)-tetrahydrocannabinol]

(2) [Reserved]

[39 FR 22142, June 20, 1974, as amended at 41 FR 43401, Oct. 1, 1976; 43 FR 3359, Jan. 25, 1978; 44 FR 40888, July 13, 1979; 46 FR 52334, Oct. 27, 1981; 51 FR 5320, Feb. 13, 1986; 52 FR 2222, Jan. 21, 1987; 52 FR 5952, Feb. 27, 1987; 56 FR 5754, Feb. 13, 1991; 56 FR 11932, Mar. 21, 1991; 62 FR 13968, Mar. 24, 1997; 64 FR 35930, July 2, 1999; 64 FR 37675, July 13, 1999; 65 FR 13238, Mar. 13, 2000; 65 FR 17440, Apr. 3, 2000; 67 FR 62370, Oct. 7, 2002]

§ 1308.14 Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit 9167
(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) 9278

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam 2882
(2) Barbital 2145
(3) Bromazepam 2748
(4) Camazepam 2749
(5) Chloral betaine 2460
(6) Chloral hydrate 2465
(7) Chlordiazepoxide 2744
(8) Clobazam 2751
(9) Clonazepam 2737
(10) Clorazepate 2768
(11) Clotiazepam 2752
(12) Cloxazolam 2753
(13) Delorazepam 2754
(14) Diazepam 2765
(15) Dichloralphenazone 2467
(16) Estazolam 2756
(17) Ethchlorvynol 2540
(18) Ethinamate 2545

Appendix F

47; 1991 c 229 § 7; 1989 1st ex.s. c 9 § 421; 1984 c 153 § 11; 1979 c 90 § 12; 1971 ex.s. c 201 § 6; 1963 c 38 § 9; 1949 c 153 § 2; 1935 c 98 § 5; 1899 c 121 § 11; Rem. Supp. 1949 § 10136. Formerly RCW 18.64.140 and 18.64.150.]

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Severability—1971 ex.s. c 201: See note following RCW 18.64.040.

18.64.160 Disciplinary action against pharmacist's and intern's licenses—Grounds. In addition to the grounds under RCW 18.130.170 and 18.130.180, the board of pharmacy may take disciplinary action against the license of any pharmacist or intern upon proof that:

(1) His or her license was procured through fraud, misrepresentation, or deceit;

(2) In the event that a pharmacist is determined by a court of competent jurisdiction to be mentally incompetent, the pharmacist shall automatically have his or her license suspended by the board upon the entry of the judgment, regardless of the pendency of an appeal;

(3) He or she has knowingly violated or permitted the violation of any provision of any state or federal law, rule, or regulation governing the possession, use, distribution, or dispensing of drugs, including, but not limited to, the violation of any provision of this chapter, Title 69 RCW, or rule or regulation of the board;

(4) He or she has knowingly allowed any unlicensed person to take charge of a pharmacy or engage in the practice of pharmacy, except a pharmacy intern or pharmacy assistant acting as authorized in this chapter or chapter 18.64A RCW in the presence of and under the immediate supervision of a licensed pharmacist;

(5) He or she has compounded, dispensed, or caused the compounding or dispensing of any drug or device which contains more or less than the equivalent quantity of ingredient or ingredients specified by the person who prescribed such drug or device: PROVIDED, HOWEVER, That nothing herein shall be construed to prevent the pharmacist from exercising professional judgment in the preparation or providing of such drugs or devices. [1993 c 367 § 13; 1985 c 7 § 60; 1984 c 153 § 12; 1979 c 90 § 13; 1963 c 38 § 10; 1909 c 213 § 10; RRS § 10143. Formerly RCW 18.64.160 through 18.64.190.]

18.64.163 Uniform Disciplinary Act. The Uniform Disciplinary Act, chapter 18.130 RCW, governs unlicensed practice, the issuance and denial of licenses of pharmacists and pharmacy interns, and the discipline of licensed pharmacists and pharmacy interns under this chapter. [1993 c 367 § 14.]

18.64.165 Refusal, suspension, and revocation of other licenses. The board shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor upon proof that:

(1) The license was procured through fraud, misrepresentation, or deceit;

(2) The licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the board of pharmacy or has been convicted of a felony. [1995 c 319 § 5. Prior: 1989 1st ex.s. c 9 § 404; 1989 c 352 § 4; 1979 c 90 § 14; 1963 c 38 § 15.]

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Violation of chapter 69.50 RCW, the Uniform Controlled Substances Act—Suspension of license: RCW 69.50.413.

18.64.200 Refusal, suspension, and revocation of other licenses—Appeal procedure. In any case of the refusal, suspension or revocation of a license by said board under the provisions of this chapter, appeal may be taken in accordance with the Administrative Procedure Act. [1963 c 38 § 11; 1909 c 213 § 11; RRS § 10144. Formerly RCW 18.64.200 through 18.64.240.].

Administrative Procedure Act: Title 34 RCW.

18.64.205 Retired active license status. The board may adopt rules pursuant to this section authorizing a retired active license status. An individual licensed pursuant to this chapter, who is practicing only in emergent or intermittent circumstances as defined by rule established by the board, may hold a retired active license at a reduced renewal fee established by the secretary under RCW 43.70.250 and 43.70.280. Such a license shall meet the continuing education requirements, if any, established by the board for renewals, and is subject to the provisions of the uniform disciplinary act, chapter 18.130 RCW. Individuals who have entered into retired status agreements with the disciplinary authority in any jurisdiction shall not qualify for a retired active license under this section. [1996 c 191 § 48; 1991 c 229 § 2.]

18.64.245 Prescription records—Penalty. (1) Every proprietor or manager of a pharmacy shall keep readily available a suitable record of prescriptions which shall preserve for a period of not less than two years the record of every prescription dispensed at such pharmacy which shall be numbered, dated, and filed, and shall produce the same in court or before any grand jury whenever lawfully required to do so. The record shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy. All record-keeping requirements for controlled substances must be complied with. Such record of prescriptions shall be for confidential use in the pharmacy, only. The record of prescriptions shall be open for inspection by the board of pharmacy or any officer of the law, who is authorized to enforce chapter 18.64, 69.41, or 69.50 RCW.

(2) A person violating this section is guilty of a misdemeanor. [2003 c 53 § 135. Prior: 1989 1st ex.s. c 9 § 402; 1989 c 352 § 2; 1979 c 90 § 15; 1939 c 28 § 1; RRS § 6154-1. Formerly RCW 18.67.090.]

Intent—Effective date—2003 c 53: See notes following RCW 2.48.180.

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

(3) In addition to the authority to discipline license holders, the disciplining authority has the authority to grant or deny licenses based on the conditions and criteria established in this chapter and the chapters specified in subsection (2) of this section. This chapter also governs any investigation, hearing, or proceeding relating to denial of licensure or issuance of a license conditioned on the applicant's compliance with an order entered pursuant to RCW 18.130.160 by the disciplining authority.

(4) All disciplining authorities shall adopt procedures to ensure substantially consistent application of this chapter, the Uniform Disciplinary Act, among the disciplining authorities listed in subsection (2) of this section. [2004 c 38 § 2. Prior: 2003 c 275 § 2; 2003 c 258 § 7; prior: 2002 c 223 § 6; 2002 c 216 § 11; 2001 c 251 § 27; 1999 c 335 § 10; 1998 c 243 § 16; prior: 1997 c 392 § 516; 1997 c 334 § 14; 1997 c 285 § 13; 1997 c 275 § 2; prior: 1996 c 200 § 32; 1996 c 81 § 5; prior: 1995 c 336 § 2; 1995 c 323 § 16; 1995 c 260 § 11; 1995 c 1 § 19 (Initiative Measure No. 607, approved November 8, 1994); prior: 1994 sp.s. c 9 § 603; 1994 c 17 § 19; 1993 c 367 § 4; 1992 c 128 § 6; 1990 c 3 § 810; prior: 1988 c 277 § 13; 1988 c 267 § 22; 1988 c 243 § 7; prior: 1987 c 512 § 22; 1987 c 447 § 18; 1987 c 415 § 17; 1987 c 412 § 15; 1987 c 150 § 1; prior: 1986 c 259 § 3; 1985 c 326 § 29; 1984 c 279 § 4.]

Effective date—2004 c 38: See note following RCW 18.155.075.

Effective date—2003 c 275 § 2: "Section 2 of this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect July 1, 2003." [2003 c 275 § 4.]

Severability—Effective date—2003 c 258: See notes following RCW 18.79.330.

Severability—Effective date—2002 c 216: See RCW 18.230.900 and 18.230.901.

Severability—2001 c 251: See RCW 18.225.900.

Effective dates—1998 c 243: See RCW 18.205.900.

Short title—Findings—Construction—Conflict with federal requirements—Part headings and captions not law—1997 c 392: See notes following RCW 74.39A.009.

Effective dates—1997 c 334: See note following RCW 18.89.010.

Intent—Purpose—1997 c 285: See RCW 18.200.005.

Severability—1997 c 285: See RCW 18.200.901.

Severability—1996 c 200: See RCW 18.35.902.

Effective date—1996 c 81: See note following RCW 70.128.120.

Effective date—1995 c 336 §§ 2 and 3: "Sections 2 and 3 of this act are necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and shall take effect immediately [May 11, 1995]." [1995 c 336 § 11.]

Effective date—1995 c 260 §§ 7-11: "Sections 7 through 11 of this act shall take effect July 1, 1996." [1995 1st sp.s. c 18 § 116; 1995 c 260 § 12.]

Short title—Severability—1995 c 1 (Initiative Measure No. 607): See RCW 18.30.900 and 18.30.901.

Severability—Headings and captions not law—Effective date—1994 sp.s. c 9: See RCW 18.79.900 through 18.79.902.

Index, part headings not law—Severability—Effective dates—Application—1990 c 3: See RCW 18.155.900 through 18.155.902.

Severability—1987 c 512: See RCW 18.19.901.

Severability—1987 c 447: See RCW 18.36A.901.

Severability—1987 c 415: See RCW 18.89.901.

Effective date—Severability—1987 c 412: See RCW 18.84.901 and 18.84.902.

Severability—1987 c 150: See RCW 18.122.901.

Severability—1986 c 259: See note following RCW 18.130.010.

18.130.045 Massage practitioners—Procedures governing convicted prostitutes. RCW 18.108.085 shall govern the issuance and revocation of licenses issued or applied for under chapter 18.108 RCW to or by persons convicted of violating RCW 9A.88.030, 9A.88.070, 9A.88.080, or 9A.88.090 or equivalent local ordinances. [1995 c 353 § 3.]

18.130.050 Authority of disciplining authority. The disciplining authority has the following authority:

(1) To adopt, amend, and rescind such rules as are deemed necessary to carry out this chapter;

(2) To investigate all complaints or reports of unprofessional conduct as defined in this chapter and to hold hearings as provided in this chapter;

(3) To issue subpoenas and administer oaths in connection with any investigation, hearing, or proceeding held under this chapter;

(4) To take or cause depositions to be taken and use other discovery procedures as needed in any investigation, hearing, or proceeding held under this chapter;

(5) To compel attendance of witnesses at hearings;

(6) In the course of investigating a complaint or report of unprofessional conduct, to conduct practice reviews;

(7) To take emergency action ordering summary suspension of a license, or restriction or limitation of the licensee's practice pending proceedings by the disciplining authority;

(8) To use a presiding officer as authorized in RCW 18.130.095(3) or the office of administrative hearings as authorized in chapter 34.12 RCW to conduct hearings. The disciplining authority shall make the final decision regarding disposition of the license unless the disciplining authority elects to delegate in writing the final decision to the presiding officer;

(9) To use individual members of the boards to direct investigations. However, the member of the board shall not subsequently participate in the hearing of the case;

(10) To enter into contracts for professional services determined to be necessary for adequate enforcement of this chapter;

(11) To contract with licensees or other persons or organizations to provide services necessary for the monitoring and supervision of licensees who are placed on probation, whose professional activities are restricted, or who are for any authorized purpose subject to monitoring by the disciplining authority;

(12) To adopt standards of professional conduct or practice;

(13) To grant or deny license applications, and in the event of a finding of unprofessional conduct by an applicant or license holder, to impose any sanction against a license applicant or license holder provided by this chapter;

(14) To designate individuals authorized to sign subpoenas and statements of charges;

(15) To establish panels consisting of three or more members of the board to perform any duty or authority within the board's jurisdiction under this chapter;

(16) To review and audit the records of licensed health facilities' or services' quality assurance committee decisions in which a licensee's practice privilege or employment is terminated or restricted. Each health facility or service shall produce and make accessible to the disciplining authority the

appropriate records and otherwise facilitate the review and audit. Information so gained shall not be subject to discovery or introduction into evidence in any civil action pursuant to RCW 70.41.200(3). [1995 c 336 § 4. Prior: 1993 c 367 § 21; 1993 c 367 § 5; 1987 c 150 § 2; 1984 c 279 § 5.]

Severability—1987 c 150: See RCW 18.122.901.

18.130.060 Additional authority of secretary. In addition to the authority specified in RCW 18.130.050, the secretary has the following additional authority:

(1) To employ such investigative, administrative, and clerical staff as necessary for the enforcement of this chapter;

(2) Upon the request of a board, to appoint pro tem members to participate as members of a panel of the board in connection with proceedings specifically identified in the request. Individuals so appointed must meet the same minimum qualifications as regular members of the board. Pro tem members appointed for matters under this chapter are appointed for a term of no more than one year. No pro tem member may serve more than four one-year terms. While serving as board members pro tem, persons so appointed have all the powers, duties, and immunities, and are entitled to the emoluments, including travel expenses in accordance with RCW 43.03.050 and 43.03.060, of regular members of the board. The chairperson of a panel shall be a regular member of the board appointed by the board chairperson. Panels have authority to act as directed by the board with respect to all matters concerning the review, investigation, and adjudication of all complaints, allegations, charges, and matters subject to the jurisdiction of the board. The authority to act through panels does not restrict the authority of the board to act as a single body at any phase of proceedings within the board's jurisdiction. Board panels may make interim orders and issue final decisions with respect to matters and cases delegated to the panel by the board. Final decisions may be appealed as provided in chapter 34.05 RCW, the Administrative Procedure Act;

(3) To establish fees to be paid for witnesses, expert witnesses, and consultants used in any investigation and to establish fees to witnesses in any agency adjudicative proceeding as authorized by RCW 34.05.446;

(4) To conduct investigations and practice reviews at the direction of the disciplining authority and to issue subpoenas, administer oaths, and take depositions in the course of conducting those investigations and practice reviews at the direction of the disciplining authority;

(5) To have the health professions regulatory program establish a system to recruit potential public members, to review the qualifications of such potential members, and to provide orientation to those public members appointed pursuant to law by the governor or the secretary to the boards and commissions specified in RCW 18.130.040(2)(b), and to the advisory committees and councils for professions specified in RCW 18.130.040(2)(a). [2001 c 101 § 1; 1995 c 336 § 5; 1991 c 3 § 269; 1989 c 175 § 68; 1987 c 150 § 3; 1984 c 279 § 6.]

Effective date—1989 c 175: See note following RCW 34.05.010.

Severability—1987 c 150: See RCW 18.122.901.

18.130.065 Rules, policies, and orders—Secretary's role. The secretary of health shall review and coordinate all proposed rules, interpretive statements, policy statements, and declaratory orders, as defined in chapter 34.05 RCW, that are proposed for adoption or issuance by any health profession board or commission vested with rule-making authority identified under RCW 18.130.040(2)(b). The secretary shall review the proposed policy statements and declaratory orders against criteria that include the effect of the proposed rule, statement, or order upon existing health care policies and practice of health professionals. Within thirty days of the receipt of a proposed rule, interpretive statement, policy statement, or declaratory order from the originating board or commission, the secretary shall inform the board or commission of the results of the review, and shall provide any comments or suggestions that the secretary deems appropriate. Emergency rule making is not subject to this review process. The secretary is authorized to adopt rules and procedures for the coordination and review under this section. [1995 c 198 § 26.]

18.130.070 Rules requiring reports—Court orders—Immunity from liability—Licensees required to report. (1) The disciplining authority may adopt rules requiring any person, including, but not limited to, licensees, corporations, organizations, health care facilities, impaired practitioner programs, or voluntary substance abuse monitoring programs approved by the disciplining authority and state or local governmental agencies, to report to the disciplining authority any conviction, determination, or finding that a license holder has committed an act which constitutes unprofessional conduct, or to report information to the disciplining authority, an impaired practitioner program, or voluntary substance abuse monitoring program approved by the disciplining authority, which indicates that the license holder may not be able to practice his or her profession with reasonable skill and safety to consumers as a result of a mental or physical condition. To facilitate meeting the intent of this section, the cooperation of agencies of the federal government is requested by reporting any conviction, determination, or finding that a federal employee or contractor regulated by the disciplinary authorities enumerated in this chapter has committed an act which constituted unprofessional conduct and reporting any information which indicates that a federal employee or contractor regulated by the disciplinary authorities enumerated in this chapter may not be able to practice his or her profession with reasonable skill and safety as a result of a mental or physical condition.

(2) If a person fails to furnish a required report, the disciplining authority may petition the superior court of the county in which the person resides or is found, and the court shall issue to the person an order to furnish the required report. A failure to obey the order is a contempt of court as provided in chapter 7.21 RCW.

(3) A person is immune from civil liability, whether direct or derivative, for providing information to the disciplining authority pursuant to the rules adopted under subsection (1) of this section.

(4) The holder of a license subject to the jurisdiction of this chapter shall report to the disciplining authority any conviction, determination, or finding that the licensee has com-

mitted unprofessional conduct or is unable to practice with reasonable skill or safety. Failure to report within thirty days of notice of the conviction, determination, or finding constitutes grounds for disciplinary action. [1998 c 132 § 8; 1989 c 373 § 19; 1986 c 259 § 4; 1984 c 279 § 7.]

Finding—Intent—Severability—1998 c 132: See notes following RCW 18.71.0195.

Severability—1989 c 373: See RCW 7.21.900.

Severability—1986 c 259: See note following RCW 18.130.010.

18.130.075 Temporary practice permits—Penalties. (1) If an individual licensed in another state that has licensing standards substantially equivalent to Washington applies for a license, the disciplining authority shall issue a temporary practice permit authorizing the applicant to practice the profession pending completion of documentation that the applicant meets the requirements for a license and is also not subject to denial of a license or issuance of a conditional license under this chapter. The temporary permit may reflect statutory limitations on the scope of practice. The permit shall be issued only upon the disciplining authority receiving verification from the states in which the applicant is licensed that the applicant is currently licensed and is not subject to charges or disciplinary action for unprofessional conduct or impairment. Notwithstanding RCW 34.05.422(3), the disciplining authority shall establish, by rule, the duration of the temporary practice permits.

(2) Failure to surrender the temporary practice permit is a misdemeanor under RCW 9A.20.010 and shall be unprofessional conduct under this chapter.

(3) The issuance of temporary permits is subject to the provisions of this chapter, including summary suspensions. [2003 c 53 § 140; 1991 c 332 § 2.]

Intent—Effective date—2003 c 53: See notes following RCW 2.48.180.

Application to scope of practice—Captions not law—1991 c 332: See notes following RCW 18.130.010.

18.130.080 Unprofessional conduct—Complaint—Investigation—Immunity of complainant. A person, including but not limited to consumers, licensees, corporations, organizations, health care facilities, impaired practitioner programs, or voluntary substance abuse monitoring programs approved by disciplining authorities, and state and local governmental agencies, may submit a written complaint to the disciplining authority charging a license holder or applicant with unprofessional conduct and specifying the grounds therefor or to report information to the disciplining authority, or voluntary substance abuse monitoring program, or an impaired practitioner program approved by the disciplining authority, which indicates that the license holder may not be able to practice his or her profession with reasonable skill and safety to consumers as a result of a mental or physical condition. If the disciplining authority determines that the complaint merits investigation, or if the disciplining authority has reason to believe, without a formal complaint, that a license holder or applicant may have engaged in unprofessional conduct, the disciplining authority shall investigate to determine whether there has been unprofessional conduct. A person who files a complaint or reports information under this section in good faith is immune from suit in any civil action related to the filing or contents of the complaint or report. [1998 c 132 § 9; 1986 c 259 § 5; 1984 c 279 § 8.]

Finding—Intent—Severability—1998 c 132: See notes following RCW 18.71.0195.

Severability—1986 c 259: See note following RCW 18.130.010.

18.130.085 Communication with complainant. If the department communicates in writing to a complainant regarding his or her complaint, the communication shall not include the address or telephone number of the health care provider against whom he or she has complained. The department shall inform all applicants for a health care provider license of the provisions of this section and RCW 42.17.310 regarding the release of address and telephone information. [1993 c 360 § 1.]

Effective date—1993 c 360: "This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and shall take effect immediately [May 15, 1993]." [1993 c 360 § 3.]

18.130.090 Statement of charge—Request for hearing. (1) If the disciplining authority determines, upon investigation, that there is reason to believe a violation of RCW 18.130.180 has occurred, a statement of charge or charges shall be prepared and served upon the license holder or applicant at the earliest practical time. The statement of charge or charges shall be accompanied by a notice that the license holder or applicant may request a hearing to contest the charge or charges. The license holder or applicant must file a request for hearing with the disciplining authority within twenty days after being served the statement of charges. If the twenty-day limit results in a hardship upon the license holder or applicant, he or she may request for good cause an extension not to exceed sixty additional days. If the disciplining authority finds that there is good cause, it shall grant the extension. The failure to request a hearing constitutes a default, whereupon the disciplining authority may enter a decision on the basis of the facts available to it.

(2) If a hearing is requested, the time of the hearing shall be fixed by the disciplining authority as soon as convenient, but the hearing shall not be held earlier than thirty days after service of the charges upon the license holder or applicant. [1993 c 367 § 1; 1986 c 259 § 6; 1984 c 279 § 9.]

Severability—1986 c 259: See note following RCW 18.130.010.

18.130.095 Uniform procedural rules. (1)(a) The secretary, in consultation with the disciplining authorities, shall develop uniform procedural rules to respond to public inquiries concerning complaints and their disposition, active investigations, statement of charges, findings of fact, and final orders involving a licensee, applicant, or unlicensed person. The uniform procedural rules adopted under this subsection apply to all adjudicative proceedings conducted under this chapter and shall include provisions for establishing time periods for initial assessment, investigation, charging, discovery, settlement, and adjudication of complaints, and shall include enforcement provisions for violations of the specific time periods by the department, the disciplining authority, and the respondent. A licensee must be notified upon receipt of a complaint, except when the notification would impede an effective investigation. At the earliest point of time the lic-

ensee must be allowed to submit a written statement about that complaint, which statement must be included in the file. Complaints filed after July 27, 1997, are exempt from public disclosure under chapter 42.17 RCW until the complaint has been initially assessed and determined to warrant an investigation by the disciplining authority. Complaints determined not to warrant an investigation by the disciplining authority are no longer considered complaints, but must remain in the records and tracking system of the department. Information about complaints that did not warrant an investigation, including the existence of the complaint, may be released only upon receipt of a written public disclosure request or pursuant to an interagency agreement as provided in (b) of this subsection. Complaints determined to warrant no cause for action after investigation are subject to public disclosure, must include an explanation of the determination to close the complaint, and must remain in the records and tracking system of the department.

(b) The secretary, on behalf of the disciplining authorities, shall enter into interagency agreements for the exchange of records, which may include complaints filed but not yet assessed, with other state agencies if access to the records will assist those agencies in meeting their federal or state statutory responsibilities. Records obtained by state agencies under the interagency agreements are subject to the limitations on disclosure contained in (a) of this subsection.

(2) The uniform procedures for conducting investigations shall provide that prior to taking a written statement:

(a) For violation of this chapter, the investigator shall inform such person, in writing of: (i) The nature of the complaint; (ii) that the person may consult with legal counsel at his or her expense prior to making a statement; and (iii) that any statement that the person makes may be used in an adjudicative proceeding conducted under this chapter; and

(b) From a witness or potential witness in an investigation under this chapter, the investigator shall inform the person, in writing, that the statement may be released to the licensee, applicant, or unlicensed person under investigation if a statement of charges is issued.

(3) Only upon the authorization of a disciplining authority identified in RCW 18.130.040(2)(b), the secretary, or his or her designee, may serve as the presiding officer for any disciplinary proceedings of the disciplining authority authorized under this chapter. Except as provided in RCW 18.130.050(8), the presiding officer shall not vote on or make any final decision. All functions performed by the presiding officer shall be subject to chapter 34.05 RCW. The secretary, in consultation with the disciplining authorities, shall adopt procedures for implementing this subsection.

(4) The uniform procedural rules shall be adopted by all disciplining authorities listed in RCW 18.130.040(2), and shall be used for all adjudicative proceedings conducted under this chapter, as defined by chapter 34.05 RCW. The uniform procedural rules shall address the use of a presiding officer authorized in subsection (3) of this section to determine and issue decisions on all legal issues and motions arising during adjudicative proceedings. [1997 c 270 § 1; 1995 c 336 § 6; 1993 c 367 § 2.]

18.130.098 Settlement—Disclosure—Conference. (1) The settlement process must be substantially uniform for licensees governed by disciplining authorities under this chapter. The disciplinary authorities may also use alternative dispute resolution to resolve complaints during adjudicative proceedings.

(2) Disclosure of the identity of reviewing disciplining authority members who participate in the settlement process is available to the respondent or his or her representative upon request.

(3) The settlement conference will occur only if a settlement is not achieved through written documents. The respondent will have the opportunity to conference either by phone or in person with the reviewing disciplining authority member if the respondent chooses. The respondent may also have his or her attorney conference either by phone or in person with the reviewing disciplining authority member without the respondent being present personally.

(4) If the respondent wants to meet in person with the reviewing disciplining authority member, he or she will travel to the reviewing disciplining authority member and have such a conference with a department representative in attendance either by phone or in person. [1995 c 336 § 7; 1994 sp.s. c 9 § 604.]

Severability—Headings and captions not law—Effective date—1994 sp.s. c 9: See RCW 18.79.900 through 18.79.902.

18.130.100 Hearings—Adjudicative proceedings under chapter 34.05 RCW. The procedures governing adjudicative proceedings before agencies under chapter 34.05 RCW, the Administrative Procedure Act, govern all hearings before the disciplining authority. The disciplining authority has, in addition to the powers and duties set forth in this chapter, all of the powers and duties under chapter 34.05 RCW, which include, without limitation, all powers relating to the administration of oaths, the receipt of evidence, the issuance and enforcing of subpoenas, and the taking of depositions. [1989 c 175 § 69; 1984 c 279 § 10.]

Effective date—1989 c 175: See note following RCW 34.05.010.

18.130.110 Findings of fact—Order—Report. (1) In the event of a finding of unprofessional conduct, the disciplining authority shall prepare and serve findings of fact and an order as provided in chapter 34.05 RCW, the Administrative Procedure Act. If the license holder or applicant is found to have not committed unprofessional conduct, the disciplining authority shall forthwith prepare and serve findings of fact and an order of dismissal of the charges, including public exoneration of the licensee or applicant. The findings of fact and order shall be retained by the disciplining authority as a permanent record.

(2) The disciplining authority shall report the issuance of statements of charges and final orders in cases processed by the disciplining authority to:

(a) The person or agency who brought to the disciplining authority's attention information which resulted in the initiation of the case;

(b) Appropriate organizations, public or private, which serve the professions;

(c) The public. Notification of the public shall include press releases to appropriate local news media and the major news wire services; and

Appendix G

(a) Approve the application for full adjudicative procedure and issue and serve on the parties a scheduling order or other scheduling mechanism establishing timelines for discovery, settlement, and scheduled hearings; or

(b) Approve the application for a brief adjudicative procedure and issue and serve a notice of the date by which any additional written materials are to be submitted for consideration; or

(c) Deny the application according to RCW 34.05.416.

(2) If a scheduling order is issued:

(a) The scheduling order shall specify:

(i) The date, time, and place of a settlement conference, a prehearing conference, and the hearing;

(ii) The deadlines for completion of discovery and submission of prehearing motions; and

(iii) The name, address, and telephone number of the assistant attorney general or other department representative who will represent the state in the matter.

(b) The scheduling order may be modified by order of the presiding officer upon his/her own initiative or upon motion of a party. Any request for change of the scheduling mechanism or order shall be made by motion as provided in WAC 246-11-380.

(c) The presiding officer may waive establishing dates for the settlement conference, completion of discovery, submission of prehearing motions, and the prehearing conference, if, in the discretion of the presiding officer, those proceedings are not necessary or appropriate in a particular matter or type of case. However, either party may request by motion to the presiding officer that any or all of the dates be set.

(d) Dates contained in the scheduling order may be changed by the adjudicative clerk office upon written request of either party made within fifteen days of issuance of the first scheduling order. All other changes must be made by motion pursuant to WAC 246-11-380.

[Statutory Authority: RCW 18.155.040. 97-13-015, § 246-11-290, filed 6/6/97, effective 7/7/97. Statutory Authority: RCW 18.130.050(1) and 18.130.060(3). 94-04-078, § 246-11-290, filed 1/31/94, effective 3/3/94. Statutory Authority: RCW 18.130.050(1) and 34.05.419. 93-08-003 (Order 347), § 246-11-290, filed 3/24/93, effective 4/24/93.]

SECTION III
EMERGENCY ADJUDICATIVE PROCEEDINGS

WAC 246-11-300 Conduct of emergency adjudicative proceedings. (1) Summary action may be taken only after a review by the board of such evidence, including affidavits, if appropriate, to establish:

(a) The existence of an immediate danger to the public health, safety, or welfare;

(b) The board's ability to address the danger through a summary action, and

(c) The summary action necessary to address the danger.

(2) No notice to any person potentially affected by a summary action shall be required prior to issuance of a summary action.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3). 94-04-078, § 246-11-300, filed 1/31/94, effective 3/3/94. Statutory Authority: RCW 18.130.050(1), 34.05.422 and 34.05.479. 93-08-003 (Order 347), § 246-11-300, filed 3/24/93, effective 4/24/93.]

WAC 246-11-310 Effect of summary action. (1) Summary action takes effect upon entry of the order.

(2) No person shall be required to comply with a summary action until service has been made or the person has knowledge of the order, whichever occurs first.

(3) A summary action shall be served as promptly as practicable, in accordance with WAC 246-11-080.

(4) A summary action shall not be subject to the post hearing process provided in WAC 246-11-550 through 246-11-610, but a summary action may be appealed to superior court as provided by law.

[Statutory Authority: RCW 18.130.050(1), 34.05.422 and 34.05.479. 93-08-003 (Order 347), § 246-11-310, filed 3/24/93, effective 4/24/93.]

WAC 246-11-320 Form and content of summary actions. (1) A summary action shall be entered in the form of an order containing findings of fact, conclusions of law, and the summary action imposed, as well as a statement of policy reasons for the decision.

(2) A summary action imposed by emergency adjudicative proceeding shall be limited to those actions necessary to alleviate an immediate danger to the public health, safety, or welfare.

(3) Initiating documents, and all other documents required by WAC 246-11-250 shall accompany a summary action order when served.

[Statutory Authority: RCW 18.130.050(1), 34.05.473 and 34.05.479. 93-08-003 (Order 347), § 246-11-320, filed 3/24/93, effective 4/24/93.]

WAC 246-11-330 Adjudicative proceedings upon summary action. Following summary action taken by the board, the respondent may:

(1) Request a prompt adjudicative proceeding conducted in accordance with this chapter; or

(2) Waive the prompt adjudicative proceeding and request a regularly scheduled adjudicative proceeding conducted in accordance with this chapter;

(3) Waive the right to an adjudicative proceeding and submit a written statement to be considered prior to the entry of the final order; or

(4) Waive the opportunity to be heard.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3). 94-04-078, § 246-11-330, filed 1/31/94, effective 3/3/94. Statutory Authority: RCW 18.130.050(1) and 34.05.479. 93-08-003 (Order 347), § 246-11-330, filed 3/24/93, effective 4/24/93.]

WAC 246-11-340 Opportunity for prompt adjudicative proceeding. (1) Any respondent affected by a summary action shall be provided the opportunity to request a prompt adjudicative proceeding. Notice of the opportunity shall be provided in the notice of opportunity to defend against the allegations that are the basis for the summary action. The form for requesting an adjudicative proceeding shall include the option of requesting a prompt adjudicative proceeding.

(2) Any respondent affected by a summary action may request an prompt adjudicative proceeding, may elect a regularly scheduled adjudicative proceeding instead of a prompt adjudicative proceeding, or may waive the opportunity for adjudicative proceeding in accord with WAC 246-11-270.

WAC 246-11-270 Request for adjudicative proceeding. A respondent may respond to an initiating document by filing an application for an adjudicative proceeding or by waiving the opportunity for adjudicative proceeding.

(1) If the respondent wishes to file an application for an adjudicative proceeding:

(a) An application for adjudicative proceeding must be filed in accordance with the following time periods:

(i) For matters under chapter 18.130 RCW, the Uniform Disciplinary Act, within twenty days of service of the initiating documents unless and extension has been granted as provided in subsection (3) of this section; and

(ii) For all other matters, within twenty days of service of the initiating documents, unless otherwise provided by statute.

(b) The application for adjudicative proceeding shall be made on the Request for Adjudicative Proceeding form accompanying the initiating documents or by a written document including substantially the same information.

(c) By filing a request for adjudicative proceeding, the responding party agrees to appear personally at the adjudicative proceeding or, if otherwise approved by the presiding officer, by telephone, unless appearance is waived as authorized in WAC 246-11-130(4).

(d) The application for adjudicative proceeding shall contain a response to the initiating documents, indicating whether each charge is admitted, denied or not contested, and responses shall be subject to the following conditions:

(i) Once admitted or not contested, an allegation may not be denied; and

(ii) An allegation denied or not contested may later be admitted.

(e) When an allegation is admitted or not contested, it shall be conclusively deemed to be true for all further proceedings. No proof of the allegation need be submitted.

(f) The application for adjudicative proceeding shall specify the representative, if any, designated pursuant to WAC 246-11-070 and any request for interpreter. The responding party shall amend the name of the representative and need for interpreter immediately if circumstances change prior to the hearing.

(g) The application for adjudicative proceeding shall be filed at the adjudicative clerk office.

(2) A respondent may waive an adjudicative proceeding and submit a written statement and other documents in defense or in mitigation of the charges. Such waiver and documents shall be filed:

(a) In accordance with the timelines in subsection (1)(a) of this section; and

(b) At the address indicated in subsection (1)(g) of this section.

(3) For matters under RCW 18.130.180, if the twenty-day limit for filing an application for adjudicative proceeding results in a hardship to the respondent, the respondent may request an extension of not more than sixty days upon a showing of good cause.

(a) The request for extension shall be filed within the twenty-day limit and shall include:

(i) The reason for the request and the number of days for which the extension is requested; and

(ii) Documentation of the circumstances creating the hardship.

(b) The request shall be granted for a period not to exceed sixty days upon showing of:

(i) Illness of the respondent; or

(ii) Absence of the respondent from the county of residence or employment; or

(iii) Emergency in the respondent's family; or

(iv) Other good cause as determined by the presiding officer.

(c) If a request for extension is denied, the respondent shall have ten days from service of the order denying the extension or twenty days from service of the initiating documents, whichever is longer, to file an application for adjudicative proceeding.

[Statutory Authority: RCW 18.155.040. 97-13-015, § 246-11-270, filed 6/6/97, effective 7/7/97. Statutory Authority: RCW 18.130.050(1) and 18.130.060(3). 94-04-078, § 246-11-270, filed 1/31/94, effective 3/3/94. Statutory Authority: RCW 18.130.050(1) and 34.05.220. 93-08-003 (Order 347), § 246-11-270, filed 3/24/93, effective 4/24/93.]

WAC 246-11-280 Default. (1) If a party fails to respond to initiating documents according to WAC 246-11-270, that party will be deemed to have waived the right to a hearing, and the board shall enter a final order without further contact with that party.

(2) If a party requests an adjudicative proceeding but fails to appear, without leave to do so, at a scheduled prehearing conference, the presiding officer may issue an order of default. The order shall include notice of opportunity to request that the default order be vacated pursuant to RCW 34.05.440(3). Unless vacated, a default order under this subsection shall be grounds for the board to proceed to decide the matter in the absence of the respondent and without additional notice to the respondent and to issue a final order.

(3) If a party requests an adjudicative proceeding but fails to appear at the hearing, the presiding officer may issue an order of default in the same manner as subsection (2) of this section, or may proceed to hear the matter in the absence of the party and issue a final order.

(4) Final orders entered under this section shall contain:

(a) Findings of fact and conclusions of law based upon prima facie proof of the allegations contained in the initiating documents;

(b) Proof of service of or a good faith attempt to serve initiating documents and appropriate notices;

(c) A finding that there is no reason to believe that the party in default is in active military service;

(d) The penalties or conditions imposed by the order; and

(e) Notice of the opportunity to request reconsideration pursuant to RCW 34.05.470.

(5) Final and default orders entered under this section shall be served upon the parties in accordance with WAC 246-11-080.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3). 94-04-078, § 246-11-280, filed 1/31/94, effective 3/3/94. Statutory Authority: RCW 18.130.050(1), 34.05.220, 34.05.440 and 34.05.470. 93-08-003 (Order 347), § 246-11-280, filed 3/24/93, effective 4/24/93.]

WAC 246-11-290 Scheduling orders. (1) Within thirty days after receipt of the application for adjudicative proceeding, the board or designee thereof, shall:

(2) A pharmacist who is not being investigated by the board or subject to current disciplinary action or currently being monitored by the board for substance abuse may voluntarily participate in the approved substance abuse monitoring program without being referred by the board. Such voluntary participants shall not be subject to disciplinary action under RCW 18.64.160 for their substance abuse and shall not have their participation known to the board if they meet the requirements of the approved monitoring program:

(a) The pharmacist shall undergo a complete physical and psychosocial evaluation before entering the approved monitoring program. This evaluation will be performed by a health care professional with expertise in chemical dependency. The person(s) performing the evaluation shall not also be the provider of the recommended treatment.

(b) The pharmacist shall enter into a contract with the approved substance abuse monitoring program to comply with the requirements of the program which shall include, but not be limited to:

(i) The pharmacist will undergo intensive substance abuse treatment in an approved treatment facility.

(ii) The pharmacist will agree to abstain from the use of all mind-altering substances, including alcohol, except for medications prescribed by an authorized prescriber, as defined in RCW 69.41.030 and 69.50.101. Said prescriber shall notify the monitoring program of all drugs prescribed within fourteen days of the date care was provided.

(iii) The pharmacist must cause the treatment counselor(s) and authorized prescriber(s) to provide reports to the approved monitoring program at specified intervals. Reports shall include treatment prognosis, goals, drugs prescribed, etc.

(v) The pharmacist shall submit to random drug screening, with observed specimen collection, as specified by the approved monitoring program.

(vi) The pharmacist will attend pharmacist support groups facilitated by a pharmacist and/or twelve-step group meetings as specified by the contract.

(vii) The pharmacist will comply with specified employment conditions and restrictions as defined by the contract.

(viii) The pharmacist shall sign a waiver allowing the approved monitoring program to release information to the board if the pharmacist does not comply with the requirements of this contract.

(c) The pharmacist is responsible for paying the costs of the physical and psychosocial evaluation, substance abuse treatment, random urine screens, and other personal expenses incurred in compliance with this contract.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-867-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 90-03-054 (Order 025), § 360-15-060, filed 1/17/90, effective 2/17/90.]

WAC 246-867-060 Confidentiality. (1) The treatment and pretreatment records of license holders referred to or voluntarily participating in approved monitoring programs shall be confidential, shall be exempt from RCW 42.17.250 through 42.17.450 and shall not be subject to discovery by subpoena or admissible as evidence except for monitoring records reported to the disciplinary authority for cause as defined in WAC 246-867-050 (1) and (2). Records held by the board under this section shall be exempt from RCW 42.17.250 through 42.17.450 and shall not be subject to discovery by subpoena except by the license holder.

(2) Notwithstanding subsection (1) of this section, board orders shall be subject to RCW 42.17.250 through 42.17.450.

[Statutory Authority: RCW 18.64.005 and 18.130.050. 92-12-035 (Order 277B), § 246-867-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-867-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 90-03-054 (Order 025), § 360-15-070, filed 1/17/90, effective 2/17/90.]

Chapter 246-869 WAC
PHARMACY LICENSING

WAC

246-869-020 Pharmacies and differential hours.
246-869-030 Pharmacy license notice requirements.
246-869-040 New pharmacy registration.
246-869-060 Employers to require evidence of pharmacist's qualifications.
246-869-070 Responsible manager—Appointment.
246-869-080 Clinic dispensaries.
246-869-090 Prescription transfers.
246-869-095 Facsimile transmission of prescription orders.
246-869-100 Prescription record requirements.
246-869-110 Refusal to permit inspection.
246-869-120 Mechanical devices in hospitals.
246-869-130 Return or exchange of drugs.
246-869-140 Prescription department—Conversing with pharmacist prohibited.
246-869-150 Physical standards for pharmacies—Adequate stock.
246-869-160 Physical standards for pharmacies—Adequate facilities.
246-869-170 Physical standards for pharmacies—Sanitary conditions.
246-869-180 Physical standards for pharmacies—Adequate equipment.
246-869-190 Pharmacy inspections.
246-869-200 Poison control.
246-869-210 Prescription labeling.
246-869-220 Patient counseling required.
246-869-230 Child-resistant containers.
246-869-235 Prescription drug repackaging—Definitions.
246-869-250 Closing a pharmacy.
246-869-255 Customized patient medication packages.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-869-050 Pharmacy license renewal. [Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 88-14-041 (Order 215), § 360-16-025, filed 6/30/88. Statutory Authority: RCW 18.64.043, 84-12-019 (Order 186), § 360-16-025, filed 5/25/84.] Repealed by 98-05-060, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.280.

246-869-240 Pharmacist's professional responsibilities. [Statutory Authority: RCW 18.64.005. 92-08-058 (Order 260B), § 246-869-240, filed 3/26/92, effective 4/26/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-240, filed 8/30/91, effective 9/30/91; Order 129, § 360-16-290, filed 7/13/76; Order 127, § 360-16-290, filed 12/1/75.] Repealed by 96-03-016, filed 1/5/96, effective 2/5/96. Statutory Authority: RCW 18.64.005.

246-869-260 Pharmacist supervised sales—General. [Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-260, filed 8/30/91, effective 9/30/91; Regulation 15, filed 3/23/60.] Repealed by 97-20-165, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

WAC 246-869-020 Pharmacies and differential hours. (1) A pharmacy must provide adequate security for its drug supplies and records and in the absence of a pharmacist the pharmacy must be closed and access limited to persons authorized by the pharmacist; for example, janitorial services, inventory services, etc. If a pharmacy is located within a larger mercantile establishment which is open to the public for business at times when a pharmacist is not present then the pharmacy must be enclosed by solid partitions at least seven feet in height, from the floor, which are sufficient to provide adequate security for the pharmacy. In the absence of a pharmacist such pharmacies must be locked and secured so that only persons authorized by the pharmacist can gain access, provided however that employees of the mercantile establishment cannot be authorized to enter the closed pharmacy during those hours that the mercantile establishment is open to the public for business.

(2) All equipment and records referred to in WAC 246-869-180 and all drugs, devices, poisons and other items or products which are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area.

(3) Written prescription orders and refill request can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription orders must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drop box" such that the prescription order is stored in the pharmacy area. The times that the pharmacy is open for business must be so displayed that they are prominently visible to the person depositing the prescription orders.

(4) Prescriptions shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient; person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place.

(5) No drugs, devices, poisons and other items or products which are restricted to sale either by or under the personal supervision of a pharmacist can be sold or delivered without a pharmacist being present in the pharmacy.

(6) Any pharmacy having hours differing from the remainder of an establishment shall have a separate and distinct telephone number from that business establishment. The phone shall not be answerable in the remainder of the establishment unless all conversations, when the pharmacist is absent, are recorded and played back by the pharmacist.

(7) Oral prescriptions cannot be taken if a pharmacist is not present unless it is taken on a recording which must inform the caller as to the times the pharmacy is open.

(8) A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the times that it is open for business. If a pharmacy is located within a larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being open for business shall be prominently displayed in a permanent manner at the pharmacy area and on or adjacent to the entrance to the mercantile establishment.

(9) Any advertising by the mercantile establishment which makes reference to the pharmacy or those products which are sold only in the pharmacy which in such advertising sets forth the days and hours that the mercantile establishment is open to the public for business must also indicate the days and hours that the pharmacy is open to the public for business.

(10) Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy must notify the board of pharmacy at least thirty days prior to commencing such differential hours. In order to constitute notification the applicant must complete the file forms provided by the board providing the required information. Board inspection and approval must be completed prior to the commencing of such differential hours. Such inspection and approval or disapproval shall be within 10 days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and pharmacy standards under chapter 246-869 WAC.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-020, filed 8/30/91, effective 9/30/91; Order 106, § 360-16-005, filed 9/11/70.]

WAC 246-869-030 Pharmacy license notice requirements. (1) Applications for a new pharmacy license must be submitted at least thirty days prior to the next regularly scheduled board meeting and the board shall require the submission of proof of the applicant's identity, and qualifications and such other information as may be necessary to properly evaluate the application, and, at its option, the board may require a personal interview at the next scheduled board meeting.

(2) In case of change of ownership or location of a pharmacy, the original license comes void and must be returned with a new application, as set forth in paragraph (1) above, and the statutorily required fees.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-030, filed 8/30/91, effective 9/30/91; Order 114, § 360-16-011, filed 6/28/73.]

WAC 246-869-040 New pharmacy registration. The state board of pharmacy shall issue no new pharmacy registrations after December 1, 1976 unless:

(1) The pharmacy will operate a bona fide prescription department, with such equipment, facilities, supplies and pharmaceuticals as are specified by state board regulations;

(2) The pharmacy passes inspection with a minimum of an "A" grade;

(3) The pharmacy in a new or remodeled building can produce evidence of being built or remodeled in accordance with all building, health and fire codes required for the particular area.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-040, filed 8/30/91, effective 9/30/91; Order 130, § 360-16-020, filed 11/10/76; Regulation 10, filed 3/23/60.]

WAC 246-869-060 Employers to require evidence of pharmacist's qualifications. It shall be the duty of every employer to require suitable evidence of qualifications to practice pharmacy before they permit anyone to be in charge, compound or dispense drugs on their premises.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-060, filed 8/30/91, effective 9/30/91; Regulation 19 (part), filed 3/23/60.]

WAC 246-869-070 Responsible manager—Appointment. Every nonlicensed proprietor of one or more pharmacies shall place in charge of each pharmacy a licensed pharmacist who shall be known as the "responsible manager." The nonlicensed proprietor shall immediately report to the state board of pharmacy the name of the "responsible manager," who shall ensure that the pharmacy complies with all the laws, rules and regulations pertaining to the practice of pharmacy. Every portion of the establishment coming under the jurisdiction of the pharmacy laws shall be under the full and complete control of such responsible manager. A now-licensed proprietor shall at once notify the board of pharmacy of the termination of employment of a responsible manager. Please refer to WAC 246-863-060 for additional information.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 79-10-007 (Order 151, Resolution No. 9/79), § 360-16-050, filed 9/6/79; Regulation 6, filed 3/23/60.]

WAC 246-869-080 Clinic dispensaries. The clinics of this state shall place their dispensaries in charge of a registered pharmacist, or the dispensing must be done by each prescribing physician in person.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-080, filed 8/30/91, effective 9/30/91; Regulation 9, filed 3/23/60.]

WAC 246-869-090 Prescription transfers. The transfer of original prescription information for a noncontrolled substance legend drug for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(a) Record in the patient medication record system that a copy has been issued.

(b) Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(2) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(a) Write the word "TRANSFER" on the face of the transferred prescription.

(b) Provide all information required to be on the prescription - patient's name and address; doctor's name and address, and also include:

(i) Date of issuance of original prescription.

(ii) Number of valid refills remaining and date of last refill.

(iii) The pharmacy's name, address, and original prescription number from which the prescription information was transferred.

(iv) Name of transferor pharmacist.

(c) Both the original and transferred prescription must be maintained as if they were original prescriptions.

(d) A transferred prescription may not be refilled after one year from the date the original was issued.

(e) The above subsections apply to the transfer of prescription information for noncontrolled substances. The transfer of controlled substance prescription information must conform to the requirements of 21 CFR 1306.26.

(3) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.

(4) If two or more pharmacies utilize a common electronic data base for prescription recordkeeping, prescriptions may be refilled at any of these pharmacies as long as there is provided an audit trail which documents the location of each filling and provisions are made to assure that the number of authorized refills are not exceeded.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 88-23-058 (Order 221), § 360-16-094, filed 11/15/88.]

WAC 246-869-095 Facsimile transmission of prescription orders. Prescription orders may be transmitted to pharmacies from prescriber's offices and health care facilities using facsimile transmission devices subject to the following requirements:

(1) The order contains the date, time, and telephone number and location of the transmitting device.

(2) Transmission of orders for Schedule II drugs are not allowed provided that, when an emergency exists, an order for Schedule II controlled substances may be dispensed and delivered to a patient pursuant to a facsimile transmission subject to the requirements of WAC 246-887-020(7). And further provided that, in a nonemergent situation, an order for Schedule II controlled substances may be prepared for delivery to a patient pursuant to a facsimile transmission but may not be delivered to the patient except upon presentation of a written order.

(3) The transmitted order shall be filed in the same manner as any other prescription. However, the pharmacist is responsible for assuring that the quality of the order is sufficient to be legible for at least two years pursuant to the records retention requirements of WAC 246-869-100.

(4) Refill authorizations for prescriptions may be transmitted using a facsimile device.

(5) The pharmacist is responsible for assuring that each facsimile prescription is valid and shall verify authenticity with the prescriber whenever there is a question.

(6) No agreement between a prescriber and a pharmacy shall require that prescription orders be transmitted by facsimile machine from the prescriber to only that pharmacy.

[Statutory Authority: RCW 18.64.005. 92-14-032 (Order 283B), § 246-869-095, filed 6/23/92, effective 7/24/92.]

WAC 246-869-100 Prescription record requirements. (1) Records for the original prescription and refill records shall be maintained on the filled prescription or in a separate record book or patient medication record. Such records must be maintained for a period of at least two years and shall be made available for inspection to representatives of the board of pharmacy.

(2) The pharmacist shall be required to insure that the following information be recorded:

(a) Original prescription—At the time of dispensing, a serial number, date of dispensing, and the initials of the responsible pharmacist shall be placed on the face of the prescription. The patient's address must be readily available to the pharmacist, either from the face of the prescription, a record book, patient medication record, or hospital or clinic record.

(b) Refill prescription authorization—Refills for prescription for legend drugs must be authorized by the prescriber prior to the dispensing of the refill prescription.

(c) Refill prescription—At the time of dispensing, the date of refilling, quantity of the drug (if other than original), the name of authorizing person (if other than original), and the initials of the responsible pharmacist shall be recorded on the back side of the prescription, or in a separate record book or patient medication record.

(d) Prescription refill limitations—No prescription may be refilled for a period longer than one year from the date of the original prescription. "PRN" prescriptions shall expire at the end of one year. Expired prescriptions require authorization before filling. If granted a new prescription shall be written and placed in the files.

(e) Prescription copies—Prescription copies and prescription labels presented for filling must be considered as informational only, and may not be used as the sole document. The prescriber shall be contacted for complete information and authorization. If granted, a new prescription shall be written and placed on file. Copies of prescriptions must be clearly identified as such on the face of the prescription. The transfer of original prescription information is permitted if the provisions of WAC 246-869-090 are met.

(f) Emergency refills—If the prescriber is not available and in the professional judgment of the pharmacist an emergency need for the medication has been demonstrated, the pharmacist may dispense enough medication to last until a prescriber can be contacted - but not to exceed 72 hours' supply. The prescriber shall be promptly notified of the emergency refill.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-100, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 89-22-046, § 360-16-096, filed 10/30/89, effective 11/30/89; 88-23-058 (Order 221), § 360-16-096, filed 11/15/88; Order 131, § 360-16-096, filed 2/4/77; Order 126, § 360-16-096, filed 5/21/75; Order 117, § 360-16-096, filed 11/9/73; Regulation 49, filed 12/1/65.]

WAC 246-869-110 Refusal to permit inspection. The refusal to permit an authorized representative of the Washington state board of pharmacy to examine during normal business hours the premises, inventory and/or records relating to drugs of licensed wholesalers, manufacturers, pharmacies and shopkeepers constitutes grounds for the suspension or revocation of the establishment's license and/or that of the pharmacist refusing such requested examination.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-110, filed 8/30/91, effective 9/30/91; Order 109, § 360-16-098, filed 5/23/72; Order 103, § 360-16-098, filed 12/5/69.]

WAC 246-869-120 Mechanical devices in hospitals. Mechanical devices for storage of floor stock, shall be limited to hospitals and shall comply with all the following provisions:

(1) All drugs and medicines to be stocked in the device shall be prepared for use in the device by or under the direct supervision of a registered pharmacist in the employ of the hospital and shall be prepared in the hospital from the hospital stock in which the drug is to be administered. "Hospital" shall mean any hospital licensed by the state department of health or under the direct supervision of the state department of institutions.

(2) Such device shall be stocked with drugs and medicines only by a registered pharmacist in the employ of the hospital.

(3) A registered pharmacist in the employ of the hospital shall be personally responsible for the inventory and stocking of drugs and medicines in the device and he shall be personally responsible for the condition of the drugs and medicines stored in the device.

(4) A registered pharmacist in the employ of the hospital shall be the only person having access to that portion, section, or part of the device in which the drugs or medicines are stored.

(5) All containers of drugs or medicines to be stored in the device shall be correctly labeled to include: Name, strength, route of administration and if applicable, the expiration date.

(6) At the time of the removal of any drug or medicine from the device, the device shall automatically make a written record showing the name, strength, and quantity of the drug or medicine removed, the name of the patient for whom the drug or medicine was ordered, and the identification of the nurse removing the drug or medicine from the device. The record must be maintained for two years by the hospital and shall be accessible to the pharmacist.

(7) Medical practitioners authorized to prescribe, pharmacists authorized to dispense, or nurses authorized to administer such drugs shall be the only persons authorized to remove any drug or medicine from the device and such removal by a nurse or medical practitioner shall be made only pursuant to a chart order. An identification mechanism, required to operate the device shall be issued permanently to each operator while the operator is on the staff of, or employed by the hospital. Such mechanism must imprint the operator's name or number if it permits the device to operate.

(8) The device shall be used only for the furnishing of drugs or medicines for administration in the hospital to registered in-patients or emergency patients in the hospital.

(9) Every hospital seeking approval to use any device shall, prior to installation of the device, register with the board by filing an application. Such application shall contain: The name and address of the hospital; the name of the registered pharmacist who is to be responsible for stocking the device; the manufacturer's name and model, description, and the proposed location of each device in the hospital.

(10) No such device shall be used until approval has been granted by the board, and no change in the location of the device or in the registered pharmacist responsible for stocking the device shall be made without prior written notice

to the board. No such device shall be removed from the licensed premises without prior approval of the board.

(11) As used in this section, a "pharmacist in the employ of the hospital" shall not include any pharmacist who is, or is employed by, a manufacturer, wholesaler, distributor, or itinerant vendor of drugs or medicines.

(12) Each and every device approved by the board shall be issued a certificate of location. Such certificate must be conspicuously displayed on the device and contain the following:

(a) Name and address of the hospital

(b) Name of the registered pharmacist who is to be responsible for stocking the device

(c) Location of the device in the hospital

(d) Manufacturer's name of the device and the serial number of the device.

(13) Upon any malfunction the device shall not be used until the malfunction has been corrected.

(14) A copy of this regulation shall be attached to each and every device certified by the board of pharmacy.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-120, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-120, filed 8/30/91, effective 9/30/91; Regulation 47, filed 12/1/65.]

WAC 246-869-130 Return or exchange of drugs. Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

(1) Those drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials in which the pharmacist can readily determine that entry or attempted entry by any means has not been made and which, in the pharmacist's professional judgment, meet the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability may be returned.

(2) Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria;

(a) The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made;

(b) In the pharmacist's professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability;

(c) The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;

(d) The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;

(e) The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable.

(f) If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug.

(3) This rule shall not include items such as orthopedic appliances, crutches, canes, wheelchairs and other similar items unless otherwise prohibited.

(4) Controlled substances shall not be returned to a pharmacy except for destruction in accordance with rules of the drug enforcement administration or the Washington state board of pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-12-020 (Order 187), § 360-16-150, filed 5/25/84; Regulation 28, filed 3/23/60.]

WAC 246-869-140 Prescription department—Conversing with pharmacist prohibited. Henceforth the prescription department of every licensed pharmacy in the state of Washington shall be protected against trespass by the lay public. No person shall be permitted to converse with a registered pharmacist while he or she is engaged in compounding a prescription, except nothing in this promulgation shall prevent one pharmacist from consulting with another pharmacist, a physician, a dentist or a veterinary surgeon, regarding the contents or technique connected with or pertaining to, the prescription being compounded.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-140, filed 8/30/91, effective 9/30/91; Regulation 37, filed 11/23/60.]

WAC 246-869-150 Physical standards for pharmacies—Adequate stock. (1) The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients.

(2) Dated items—All merchandise which has exceeded its expiration date must be removed from stock.

(3) All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration.

(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations.

(5) Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock.

(6) All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-150, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 85-11-066 (Order 194), § 360-16-200, filed 5/21/85; Order 131, § 360-16-200, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 246-869-160 Physical standards for pharmacies—Adequate facilities. (1) The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles).

(2) The prescription department shall be well ventilated. There shall be a constant flow of air through the area.

(3) There shall be a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(4) The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon. (Profile systems are excepted.)

(5) There shall be a sink with hot and cold running water in the prescription compounding area.

(6) There shall be refrigeration facilities with a thermometer in the prescription compounding area for the storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A locked refrigerator in the immediate vicinity of the prescription department will meet the requirements of this paragraph.

(7) The prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items are stored, compounded or dispensed.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-160, filed 8/30/91, effective 9/30/91; Order 131, § 360-16-210, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 246-869-170 Physical standards for pharmacies—Sanitary conditions. (1) The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.

(2) Adequate trash receptacles shall be available, both in the prescription compounding and in the retail areas.

(3) If a restroom is provided, there must be a sink with hot and cold running water, soap and towels, and the toilet must be clean and sanitary.

(4) All equipment must be kept in a clean and orderly manner. That equipment used in the compounding of prescriptions (counting, weighing, measuring, mixing and stirring equipment) must be clean and in good repair.

(5) All professional personnel and staff, while working in the pharmacy, shall keep themselves and their apparel neat and clean.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-170, filed 8/30/91, effective 9/30/91; Order 131, § 360-16-220, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 246-869-180 Physical standards for pharmacies—Adequate equipment. (1) All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(2) All pharmacies will have in their possession:

(a) One up-to-date copy of the state of Washington statutes, rules and regulations governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines maintained in a binder.

(3) All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-180, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 85-11-066 (Order 194), § 360-16-230, filed 5/21/85; 84-03-015 (Order 180), § 360-16-230, filed 1/9/84; Order 131, § 360-16-230, filed 2/4/77; Order 118, § 360-16-230, filed 1/2/74; Order 51 (part), filed 8/15/67.]

WAC 246-869-190 Pharmacy inspections. (1) All pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.

(2) Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards.

(3) There shall be three rating classifications:

(a) "Class A" - for inspection scores of 90 to 100;

(b) "Conditional" - for inspection scores of 80 to 89; and,

(c) "Unsatisfactory" - for inspection scores below 80.

(4) Any pharmacy receiving a conditional rating shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

(5) Any pharmacy receiving an unsatisfactory rating shall have fourteen days to raise its inspection score rating to 90 or better. If upon reinspection after fourteen days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

(6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.

(7) Noncompliance with the provisions of chapter 18.64A RCW (Pharmacy assistants) and, chapter 246-901 WAC (Pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.

(8) Pharmacies receiving an unsatisfactory rating which represent a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-190, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-190, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 87-08-031 (Order 205), § 360-16-235, filed 3/27/87.]

WAC 246-869-200 Poison control. (1) The telephone number of the nearest poison control center shall be readily available.

(2) Each pharmacy shall maintain at least one ounce bottle of Ipecac syrup in stock at all times.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-200, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 87-08-031 (Order 205), § 360-16-245, filed 3/27/87; Order 120, § 360-16-245, filed 3/11/74.]

WAC 246-869-210 Prescription labeling. To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:

(a) The nature of the drug;

(b) The container in which it was packaged by the manufacturer and the expiration date thereon;

(c) The characteristics of the patient's container, if the drug is repackaged for dispensing;

(d) The expected conditions to which the article may be exposed;

(e) The expected length of time of the course of therapy; and

(f) Any other relevant factors.

The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.

(2) The quantity of drug dispensed, for example the volume or number of dosage units.

(3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-210, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-210, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.246. 85-06-010 (Order 193), § 360-16-255, filed 2/22/85. Statutory Authority: RCW 18.64.005. 84-22-027 (Order 191), § 360-16-255, filed 11/1/84.]

WAC 246-869-220 Patient counseling required. The purpose of this counseling requirement is to educate the public in the use of drugs and devices dispensed upon a prescription.

(1) The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices.

(2) For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist.

(3) For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription.

(4) This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional authorized to administer medications.

[Statutory Authority: RCW 18.64.005(7). 01-04-055, § 246-869-220, filed 2/5/01, effective 3/8/01. Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-869-220, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-220, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 89-04-016 (Order 223), § 360-16-265, filed 1/23/89.]

WAC 246-869-230 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including CFR Part 1700 of Title 16, unless:

(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.

(b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant.

(2) Authorization from the patient to the pharmacist to use a regular container (nonchild-resistant) shall be verified in one of the following ways:

(a) The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant.

(b) The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant.

(c) The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant.

(3) No pharmacist or pharmacy employee may designate himself or herself as the patient's agent.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-230, filed 8/30/91, effective 9/30/91; Order 126, § 360-16-270, filed 5/21/75.]

WAC 246-869-235 Prescription drug repackaging—Definitions. (1) "Unit-dose" means the ordered amount of a drug in an individually sealed package and in a dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

(2) "Unit-of-use" means a sufficient quantity of a drug for one normal course of therapy.

(3) "Lot number," "control number" means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which a complete history of the manufacturer, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

(4) "Med-pack" means any package prepared under the immediate supervision of a pharmacist for a specific patient comprising a series of containers and containing one or more prescribed solid oral dosage forms including multifill blister packs.

[Statutory Authority: RCW 18.64.005. 93-01-051 (Order 320B), § 246-869-235, filed 12/10/92, effective 1/10/93.]

WAC 246-869-250 Closing a pharmacy. (1) Whenever a pharmacy ceases to operate, the owner shall notify the pharmacy board of the pharmacy's closing not later than fifteen days prior to the anticipated date of closing. This notice shall be submitted in writing and shall contain all of the following information:

(a) The date the pharmacy will close;

(b) The names and addresses of the persons who shall have custody of the prescription files, the bulk compounding

records, the repackaging records, and the controlled substances inventory records of the pharmacy to be closed;

(c) The names and addresses of any persons who will acquire any of the legend drugs from the pharmacy to be closed, if known at the time the notification is filed.

(2) Not later than 15 days after the pharmacy has closed, the owner shall submit to the pharmacy board the following documents:

(a) The license of the pharmacy that closed; and

(b) A written statement containing the following information;

(i) Confirmation that all legend drugs have been transferred to an authorized person (or persons) or destroyed. If the legend drugs were transferred, the names and addresses of the person(s) to whom they were transferred;

(ii) If controlled substances were transferred, a list of the names and addresses to whom the substances were transferred, the substances transferred, the amount of each substance transferred, and the date on which the transfer took place;

(iii) Confirmation that the drug enforcement administration (DEA) registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(iv) Confirmation that all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed;

(v) Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-869-250, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. 83-10-013 (Order 174), § 360-16-300, filed 4/26/83.]

WAC 246-869-255 Customized patient medication packages. The board approves the use of med-pack containers in the dispensing of prescription drugs within the same pharmacy, provided that:

(1) The pharmacy must maintain custody of the original prescription container at the pharmacy;

(2) No more than a thirty-one day supply of drugs is packaged;

(3) The signature of the patient or the patient's agent is obtained for dispensing in a nonchild resistant container;

(4) The container's label bear the following information:

(a) Pharmacy name and address;

(b) Patient's name;

(c) Drug name, strength, quantity;

(d) Directions;

(e) Serial prescription numbers; date

(f) Prescriber's name, and pharmacist's initials.

[Statutory Authority: RCW 18.64.005. 93-01-051 (Order 320B), § 246-869-255, filed 12/10/92, effective 1/10/93.]

Chapter 246-870 WAC
ELECTRONIC TRANSMISSION OF PRESCRIPTION INFORMATION

WAC

246-870-010 Purpose.
246-870-020 What definitions do I need to know to understand these rules?
246-870-030 What is included in the electronic transmission and transfer of prescription information?
246-870-040 Can all prescriptions be transmitted electronically?
246-870-050 What are the requirements for fax machines?
246-870-060 What are the board requirements for electronic prescription transmission systems?
246-870-070 What are the board requirements for pharmacies using electronic prescription transmission systems?
246-870-080 Can prescription records be stored electronically?
246-870-090 Can electronic mail systems be used to transmit patient information?

WAC 246-870-010 Purpose. The purpose of this chapter is to ensure compliance with the law on electronic transfer of prescription information and to provide guidance on how compliance can be achieved.

[Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. 03-24-070, § 246-870-010, filed 12/1/03, effective 1/1/04.]

WAC 246-870-020 What definitions do I need to know to understand these rules? (1) "Electronic transmission of prescription information" means the communication from an authorized prescriber to a pharmacy or from one pharmacy to another pharmacy, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with state and federal law.

(2) "Confidential patient information" means information maintained in the patient's health care records or individually identifiable health care records. Confidential information must be maintained and protected from release in accordance with chapter 70.02 RCW and applicable federal law.

(3) "Digital signature" means an electronic identifier that provides for message integrity, nonrepudiation, user authentication, and encryption and is intended to have the force and effect of a manual signature.

(4) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription.

(5) "Security" means a system to maintain the confidentiality and integrity of patient records including:

(a) Documented formal procedures for selecting and executing security measures;

(b) Physical safeguards to protect computer systems and other pertinent equipment from intrusion;

(c) Processes to protect, control and audit access to confidential patient information; and

(d) Processes to prevent unauthorized access to the data when transmitted over communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives or CD media.

[Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. 03-24-070, § 246-870-020, filed 12/1/03, effective 1/1/04.]

WAC 246-870-030 What is included in the electronic transmission and transfer of prescription information? The electronic transfer of prescription information includes the communication of prescription information by computer, fax, or other electronic means. It includes the transfer of orig-

WAC 246-873-110 Additional responsibilities of pharmacy service. (1) General. The pharmacy service shall participate in other activities and committees within the hospital affecting pharmaceutical services, drugs and drug use.

(2) Quality assurance. The pharmaceutical service shall establish a pharmacy quality assurance program.

(3) Clinical activities. The director of pharmacy should develop clinically oriented programs, including but not limited to obtaining and recording comprehensive drug histories and participation in discharge planning to affect appropriate drug use, a formal drug information service, prescribing, and administration of drugs.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-100, filed 7/29/81.]

Chapter 246-875 WAC
PHARMACY—PATIENT MEDICATION RECORD SYSTEMS

WAC

246-875-001	Purpose.
246-875-010	Definitions.
246-875-020	Minimum required information in an automated patient medication record system.
246-875-030	Minimum required information in a manual patient medication record system.
246-875-040	Minimum procedures for utilization of a patient medication record system.
246-875-050	Auxiliary recordkeeping procedure.
246-875-060	Retrieval of information from an automated system.
246-875-070	Confidentiality and security of data.
246-875-080	Extension of time for compliance.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-875-090 Effective date. [Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-100, filed 1/9/84.] Repealed by 92-12-035 (Order 277B), filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005.

WAC 246-875-001 Purpose. The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. This system will consist of certain patient and prescription information, and shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy. It shall be designed to provide adequate safeguards against the improper manipulation or alteration of records, and to provide an audit trail. It may be either a manual system or an automated data processing system for the storage and retrieval of prescription and patient information. If an automated data processing system is utilized, an auxiliary recordkeeping procedure shall be available for documentation of new and refill prescriptions in case the automated system is inoperative for any reason. Establishment of a patient medication record system is intended to insure that the information it contains will be reviewed by the pharmacist in a manner consistent with sound professional practice when each prescription is filled.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-010, filed 1/9/84.]

WAC 246-875-010 Definitions. Terms used in this chapter shall have the meaning set forth in this section unless the context clearly indicates otherwise:

(1) "Address" means the place of residence of the patient.

(2) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.

(3) "Auxiliary recordkeeping procedure" means a back-up procedure used to record medication record system data in case of scheduled or unscheduled down-time of an automated data processing system.

(4) "Hard copy of the original prescription" shall include the prescription as defined in RCW 18.64.011(8) and/or the medical records or chart.

(5) "Therapeutic duplication" means two or more drugs in the same pharmacological or therapeutic category which when used together may have an additive or synergistic effect.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-020, filed 1/9/84.]

WAC 246-875-020 Minimum required information in an automated patient medication record system. An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system.

(1) All automated patient medication record systems must maintain the following information with regard to ambulatory patients:

(a) Patient's full name and address.

(b) A serial number assigned to each new prescription.

(c) The date of all instances of dispensing a drug.

(d) The identification of the dispenser who filled the prescription.

(e) The name, strength, dosage form and quantity of the drug dispensed.

(f) Any refill instructions by the prescriber.

(g) The prescriber's name, address, and DEA number where required.

(h) The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050.

(i) Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(j) Authorization for other than child-resistant containers pursuant to WAC 246-869-230, if applicable.

(2) All automated patient medication record systems must maintain the following information with regard to institutional patients:

(a) Patient's full name.

(b) Unique patient identifier.

(c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(d) Patient location.

(e) Patient status, for example, active, discharge, or on-pass.

(f) Prescriber's name, address, and DEA number where required.

(g) Minimum prescription data elements:

(i) Drug name, dose, route, form, directions for use, prescriber.

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

(h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.

(i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.-005. 84-03-016 (Order 181), § 360-19-030, filed 1/9/84.]

WAC 246-875-030 Minimum required information in a manual patient medication record system. A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.

(1) All manual patient medication record systems must maintain the following information with regard to ambulatory patients:

(a) Patient's full name and address.

(b) A serial number assigned to each new prescription.

(c) The date of all instances of dispensing a drug.

(d) The identification of the dispenser who filled the prescription.

(e) The name, strength, dosage form and quantity of the drug dispensed.

(f) The prescriber's name, address and DEA number where appropriate.

(g) Any patient allergies, idiosyncrasies or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(2) All manual patient medication record systems must maintain the following information with regard to institutional patients:

(a) Patient's full name.

(b) Unique patient identifier.

(c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(d) Patient location.

(e) Patient status, for example, active, discharge, or on-pass.

(f) Prescriber's name, address and DEA number where required.

(g) Minimum prescription data elements:

(i) Drug name, dose, route, form, directions for use, prescriber.

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

(h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.

(i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-040, filed 1/9/84.]

WAC 246-875-040 Minimum procedures for utilization of a patient medication record system. Upon receipt of a prescription or drug order, a dispenser must examine visually or via an automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed. Any order modified in the system must carry in the audit trail the unique identifier of the person who modified the order. Any change in drug name, dose, route, dose form or directions for use which occurs after an initial dose has been given requires that a new order be entered into the system and the old order be discontinued, or that the changes be accurately documented in the record system, without destroying the original record or its audit trail.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-050, filed 1/9/84.]

WAC 246-875-050 Auxiliary recordkeeping procedure. If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system interruption. The auxiliary

recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. Upon restoration of operation of the automated system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. This section does not require that a permanent dual recordkeeping system be maintained.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-060, filed 1/9/84.]

WAC 246-875-060 Retrieval of information from an automated system. All automated patient medication record systems must provide within 72 hours, via CRT or hard copy printout, the information required by WAC 246-875-020 and by 21 CFR § 1306.22(b) as amended July 1, 1980. Any data purged from an automated patient medication record system must be available within 72 hours.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-070, filed 1/9/84.]

WAC 246-875-070 Confidentiality and security of data. (1) Information contained in patient medication record systems shall be considered to be a part of prescription records maintained in accordance with RCW 18.64.245 and shall be maintained for a period of at least two years in the same manner as provided for all prescription records (see WAC 246-869-100).

(2) The information in the patient medication record system which identifies the patient shall be deemed confidential and may be released to persons other than the patient or a pharmacist, or a practitioner authorized to prescribe only on written release of the patient. If in the judgment of the dispenser, the prescription presented for dispensing is determined to cause a potentially harmful drug interaction or other problem due to a drug previously prescribed by another practitioner, the dispenser may communicate this information to the prescribers.

(3) Security codes or systems must be established on automated medication record systems to prevent unauthorized modification of data.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-080, filed 1/9/84.]

WAC 246-875-080 Extension of time for compliance. The rules regarding patient medication record systems contained in chapter 246-875 WAC shall apply to all pharmacists practicing pharmacy in the state of Washington upon the effective date of the chapter unless an extension is granted by the board pursuant to this rule. In order to seek an extension that will allow compliance with this chapter to be delayed, good cause for granting such extension must be shown. The board shall consider requests for extensions and if, in the board's judgment good cause is shown, the board may grant an extension for a period of time, specifying those portions of the rules with respect to which an extension is being granted.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-090, filed 1/9/84.]

Chapter 246-877 WAC
PHARMACEUTICAL—SALES PROHIBITED

WAC

246-877-020 Drug sample prohibitions.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-877-030 Unsealed hard gelatin capsule restrictions. [Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-877-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 86-21-033 (Order 202), § 360-20-210, filed 10/9/86.] Repealed by 97-20-166, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

WAC 246-877-020 Drug sample prohibitions. (1) The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby prohibited.

(2) This shall not apply to any pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request of an authorized practitioner pursuant to RCW 69.45.050.

(3) A health care entity means any organization or business entity that provides diagnostic, medical, surgical, or dental treatment and/or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-877-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 89-22-047, § 360-20-100, filed 10/30/89, effective 11/30/89; Order 114, § 360-20-100, filed 6/28/73.]

Chapter 246-878 WAC
GOOD COMPOUNDING PRACTICES

WAC

246-878-010 Definitions.
246-878-020 Compounded drug products—Pharmacist.
246-878-030 Organization and personnel.
246-878-040 Facilities.
246-878-050 Sterile pharmaceutical.
246-878-060 Radiopharmaceuticals.
246-878-070 Special precaution products.
246-878-080 Equipment.
246-878-090 Control of components and drug product containers and closures.
246-878-100 Drug compounding controls.
246-878-110 Labeling control of excess products.
246-878-120 Records and reports.

WAC 246-878-010 Definitions. (1) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(2) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the com-

WAC 246-886-060 Responsible individuals. (1) Each agency or society registered in accordance with WAC 246-887-050 shall name a designated individual as the person who shall be responsible for maintaining all records and submitting all reports required by applicable federal or state law or regulation, including chapter 246-887 WAC.

(2) This designated individual shall also be responsible for the ordering, possession, safe storage, and utilization of the sodium pentobarbital and approved legend drugs.

[Statutory Authority: RCW 69.41.080. 92-12-035 (Order 277B), § 246-886-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-886-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 91-04-056 (Order 140B), § 360-35-070, filed 2/4/91, effective 3/7/91.]

WAC 246-886-070 Notification. Each humane society and animal control agency shall promptly notify the board of its designated individual, of all employees authorized to purchase, possess, or administer approved legend drugs, and of any change in the status of these individuals.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-886-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 91-04-056 (Order 140B), § 360-35-080, filed 2/4/91, effective 3/7/91.]

WAC 246-886-080 Recordkeeping and reports. (1) A bound log book with consecutively numbered pages shall be used to record the receipt, use, and disposition of approved legend drugs. No more than one drug shall be recorded on any single page. The record shall be in sufficient detail to allow an audit to be performed.

(2) All invoices, record books, disposition records, and other records regarding approved legend drugs shall be maintained in a readily retrievable manner for no less than two years.

(3) All records shall be available for inspection by the state board of pharmacy or any officer who is authorized to enforce this chapter.

(4) A physical inventory of approved legend drugs shall be performed and reconciled with the log book no less frequently than every six months.

(5) Any discrepancy in the actual inventory of approved legend drugs shall be documented in the log book and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy which has not been corrected within seven days shall be reported to the board of pharmacy in writing.

(6) Any approved legend drug which has become unfit for use due to contamination or having passed its expiration date shall be destroyed by a supervisor and another staff member. Record of such destruction shall be made in the log book which shall be signed and dated by the individuals involved.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-886-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 91-04-056 (Order 140B), § 360-35-090, filed 2/4/91, effective 3/7/91.]

WAC 246-886-090 Drug storage. All approved legend drugs shall be stored in a substantially constructed locked cabinet or drawer. Keys to the storage area shall be restricted to those persons authorized to administer the drugs. Specifically designated agents and employees of the registrant may possess a supply of approved legend drugs for emergency field use. Such emergency supply shall be stored in a locked metal box securely attached to the vehicle.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-886-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 91-04-056 (Order 140B), § 360-35-100, filed 2/4/91, effective 3/7/91.]

WAC 246-886-100 Violations. The board may suspend or revoke a registration issued under chapter 69.50 RCW if the board determines that any agent or employee of a registered humane society or animal control agency has purchased, possessed, or administered legend drugs in violation of RCW 69.41.080 or this chapter or has otherwise demonstrated inadequate knowledge in the administration of legend drugs. The board's revocation or suspension of a registration as provided herein would restrict the registered entity's ability to use both approved legend drugs and sodium pentobarbital.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-886-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 91-04-056 (Order 140B), § 360-35-110, filed 2/4/91, effective 3/7/91.]

Chapter 246-887 WAC

PHARMACY—REGULATIONS IMPLEMENTING THE UNIFORM CONTROLLED SUBSTANCES ACT

WAC

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WAC 246-887-020 Uniform Controlled Substances Act. (1) Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 CFR), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306. Although those regulations are automatically applicable to registrants in this state, the board is nevertheless adopting as its own regulations the existing regulations of the federal government published in the Code of Federal Regulations revised as of April 1, 1991, and all references made therein to

the director or the secretary shall have reference to the board of pharmacy, and the following sections are not applicable: Section 1301.11-.13, section 1301.31, section 1301.43-.57, section 1303, section 1308.41-.48, and section 1316.31-.67. The following specific rules shall take precedence over the federal rules adopted herein by reference, and therefore any inconsistencies shall be resolved in favor of the following specific rules.

(2) A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed. Application for registration must be made on forms supplied by the pharmacy board, and all information called for thereon must be supplied unless the information is not applicable, in which case it must be indicated. An applicant for registration must hold the appropriate wholesaler, manufacturer or pharmacy license provided for in chapter 18.64 RCW.

(3) Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include:

(a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;

(b) Distribution records; i.e., invoices, etc. from wholesalers and manufacturers and prescriptions records for dispensers;

(c) In the event of a loss by theft or destruction, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the board;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to and from whom. Said record must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to section 1307.11 (federal rules).

(4) The records must be maintained separately for Schedule II drugs. The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable from the business records of the registrant. Prescription records will be deemed readily retrievable if the prescription has been stamped in red ink in the lower right hand corner with the letter "C" no less than one inch high, and said prescriptions are filed in a consecutively numbered prescription file which includes prescription and noncontrolled substances.

(5) A federal order form is required for each distribution of a Schedule I or II controlled substance, and said forms along with other records required to be kept must be made readily available to authorized employees of the board.

(6) Schedule II drugs require that a dispenser have a signed prescription in his possession prior to dispensing said drugs. An exception is permitted in an "emergency." An emergency exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the physician to provide a written prescription for the drug at that time. If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within 72 hours, and further he must note on the prescription that it was filled on an emergency basis.

[Statutory Authority: RCW 43.70.280. 98-05-060, § 246-887-020, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. 92-04-029 (Order 239B), § 246-887-020, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-010, filed 8/8/89, effective 9/8/89. Statutory Authority: RCW 69.50.301. 87-10-029 (Order 206), § 360-36-010, filed 5/1/87. Statutory Authority: RCW 18.64.005(4). 85-06-010 (Order 193), § 360-36-010, filed 2/22/85. Statutory Authority: RCW 69.50.301. 80-05-074 (Order 154, Resolution No. 4/80), § 360-36-010, filed 4/28/80; 79-10-007 (Order 151, Resolution No. 9/79), § 360-36-010, filed 9/6/79. Statutory Authority: RCW 69.50.301 and chapter 69.50 RCW. 78-02-070 (Order 140), § 360-36-010, filed 1/25/78; Order 132, § 360-36-010, filed 5/4/77; Order 108, § 360-36-010, filed 10/26/71.]

WAC 246-887-030 Dispensing Schedule V controlled substances. (1) Those drugs classified in Schedule V of the Uniform Controlled Substances Act (RCW 69.50.212) which can be dispensed without a prescription can be so distributed only for the medical purpose(s) indicated on the manufacturer's label (e.g., cough syrups may only be dispensed for the treatment of coughs) and shall be dispensed in accordance with the following rules.

(2) Only a licensed pharmacist or a pharmacy intern may dispense a Schedule V drug. The pharmacist or pharmacy intern making the sale is responsible for the recording of the required information in the Schedule V register book. The pharmacist or pharmacy intern shall not sell a Schedule V drug to a person below the age of 21 and shall require the purchaser to supply identification so that the purchaser's true name, address and age can be verified. The pharmacist must keep the Schedule V drugs in a safe place not accessible to members of the public. The name and address of the pharmacy must be placed on the bottle or vial of each Schedule V drug sold and the pharmacist or pharmacy intern dispensing the product must place the date of sale and his/her initials on the label at the time of sale. The pharmacist or pharmacy intern is required to show every purchaser of a Schedule V product a copy of subsections (3) and (4) of this rule (sections relating to purchaser(s) of Schedule V drugs).

(3) No person shall obtain a Schedule V drug without a practitioner's prescription unless he/she complies with the following:

(a) The product must be purchased as a medicine for its indicated medical use only;

(b) The purchaser must sign the Schedule V register book with his/her true name and address and supply proof of identification.

(c) The purchaser cannot purchase more than 120 mls (four fluid ounces) of Schedule V cough preparations, nor more than 240 mls (eight fluid ounces) of Schedule V antidiarrheal preparations.

(4) In the absence of a practitioner's prescription, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain, within a ninety-six hour period, more than the maximum quantity set forth in subsection (3)(c) of this rule. Further, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain more than twice the maximum quantity set forth in (3)(c) above in any sixty-day period.

(5)(a) Every pharmacy handling Schedule V drugs must keep a Schedule V register book in which the following statement must appear at the top of each page: "I have not obtained any Schedule V preparations within the last ninety-six hours, nor obtained Schedule V preparations more than twice within the last sixty days. This is my true name and address." All sales of Schedule V preparations without a practitioner's prescription shall be recorded in the Schedule V register book and the following information must be recorded therein:

(i) Printed name of purchaser

(ii) Signature of purchaser

(iii) Address of purchaser

(iv) Name of the Schedule V preparation sold

(v) Quantity of Schedule V preparation sold

(vi) Date of sale

(vii) Initials or name of pharmacist or pharmacy intern who sold the Schedule V drug

(viii) Proof of identification: A unique identification number from a driver's license or from other state or federally issued photo identification card.

(b) All register books used to record the sale of Schedule V preparations shall conform to the following standards:

(i) The book shall be 8 1/2 inches wide, 11 inches long.

(ii) The book shall be securely bound, not loose leaf or spiral bound.

(iii) The book shall have its pages consecutively numbered with a unique number assigned to each book and identified on each page.

(iv) Each page shall consist of an original and duplicate. If any sales are recorded, the duplicate sheet must be mailed to the board of pharmacy when completed or on the last day of each month, whichever is earlier.

(3) All pharmacy records relating to Schedule V drugs shall be open to examination by state board of pharmacy investigators during normal business hours. The refusal to permit such examination shall constitute grounds for the suspension or revocation of the pharmacist's license.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-36-020, filed 12/17/82. Statutory Authority: RCW 18.64.005 and 69.41.075. 82-19-022 (Order 169), § 360-36-020, filed 9/8/82; Order 108, § 360-36-020, filed 10/26/71.]

WAC 246-887-040 Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402 (a)(3). The board of pharmacy hereby designates, the following Schedule II controlled substances as nonnarcotic stimulants for purposes of RCW 69.50.402 (a)(3):

(1) Amphetamine sulfate in any of its generic forms.

(2) Dextroamphetamine sulfate in any of its generic forms and under the following brand names:

(a) Dexedrine (SKF);

(b) Dexedrine spansules (SKF).

(3) Dextroamphetamine HCL in any of its generic forms.

(4) Dextroamphetamine tannate in any of its generic forms.

(5) Methamphetamine HCL (Desoxyephedrine HCL) in any of its generic forms and under the following brand name:

Desoxyn (Abbott).

(6) Amphetamine complex in any of its generic forms and under the following brand names:

(a) Biphetamine 12 1/2 (Pennwalt);

(b) Biphetamine 20 (Pennwalt).

(7) Combined amphetamines sold under the following brand names:

Obetrol-10 and 20 (Obetrol).

(8) Phenmetrazine HCL in any of its generic forms and under the following brand name:

(a) Preludin (Boehringer-Ingelheim).

(9) Methylphenidate HCL in any of its generic forms and under the following brand name:

(a) Ritalin (Ciba).

[Statutory Authority: RCW 18.64.005. 92-04-029 (Order 239B), § 246-887-040, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 79-08-069 (Order 148, Resolution No. 7-79), § 360-36-115, filed 7/24/79.]

WAC 246-887-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants. The Schedule II stimulants listed in WAC 246-887-040 may be prescribed, dispensed, or administered to patients for the following disease states or conditions:

(1) Disease states or conditions listed in RCW 69.50.402 (3)(ii);

(2) Multiple sclerosis.

[Statutory Authority: RCW 69.50.402 and 18.64.005(7). 03-04-045, § 246-887-045, filed 1/28/03, effective 2/28/03.]

WAC 246-887-050 Sodium pentobarbital for animal euthanasia. (1) Registration eligibility. Any humane society or animal control agency who designates a responsible individual under WAC 246-887-070 may apply to the Washington state board of pharmacy for a limited registration under chapter 69.50 RCW (Controlled Substances Act) to purchase, possess and administer sodium pentobarbital. The sodium pentobarbital will be used only to euthanize injured, sick, homeless or unwanted domestic pets and domestic or wild animals.

(2) Sodium pentobarbital restrictions. Sodium pentobarbital obtained under this limited registration shall be labeled "For veterinary use only." The board will make available a list of approved products.

(3) Sodium pentobarbital storage. The registered location supply of sodium pentobarbital shall be kept or stored in a safe or a substantial well-built double-locked drawer or cabinet.

(a) Registrants may designate only the following agents to possess and administer sodium pentobarbital at locations other than the registered location:

(i) Humane officer;

(ii) Animal control enforcement officer;

(iii) Animal control authority;

(iv) Peace officer authorized by police chief, sheriff or county commissioners.

(b) Specially designated agents of the registrant may possess a supply of sodium pentobarbital for emergency field use. Such emergency supply shall be stored in a locked metal box securely attached to the vehicle. The designated agent

shall be responsible to insure that the sodium pentobarbital is present at the beginning and is present or accounted for at the end of each shift. A log book shall be kept in which all receipts and use of sodium pentobarbital from the emergency supply shall be recorded.

[Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. 92-12-035 (Order 277B), § 246-887-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-210, filed 8/8/89, effective 9/8/89; Order 138, § 360-36-210, filed 11/8/77.]

WAC 246-887-060 Sodium pentobarbital administration. All agencies registered under WAC 246-887-050 will establish written policies and procedures to insure that any of their agents or personnel which administer sodium pentobarbital for animal euthanasia have received sufficient training in its handling and administration, and have demonstrated adequate knowledge of the potentials and hazards, and proper techniques to be used in administering the drug. A copy of the written policies and procedures shall be filed with the board at the time of initial application for registration. The board shall be notified in writing of any individuals who have qualified to administer sodium pentobarbital or of any amendments or deletions to the policies and procedures.

[Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. 92-12-035 (Order 277B), § 246-887-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-250, filed 8/8/89, effective 9/8/89; Order 138, § 360-36-250, filed 11/8/77.].

WAC 246-887-070 Sodium pentobarbital records and reports. (1) Each agency or society registered in accordance with WAC 246-887-050 shall designate an individual as the registrant who shall be responsible for maintaining all records and submitting all reports required by applicable federal or state law or regulation, including chapter 246-887 WAC.

(2) This designated individual shall also be responsible for the ordering, possession, safe storage and utilization of the sodium pentobarbital.

[Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. 92-12-035 (Order 277B), § 246-887-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-260, filed 8/8/89, effective 9/8/89; Order 138, § 360-36-260, filed 11/8/77.]

WAC 246-887-080 Sodium pentobarbital registration disciplinary action. In addition to any criminal or civil liabilities that may occur, the board may deny, suspend, or revoke registration upon determination that (1) the registration was procured through fraud or misrepresentation, (2) the registrant or any agent or employee of the registrant has violated any of the federal or state laws related to drugs, or has violated any of the rules or regulations of the board of pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-270, filed 8/8/89, effective 9/8/89; Order 138, § 360-36-270, filed 11/8/77.]

WAC 246-887-090 Authority to control. Pursuant to the authority granted to the board of pharmacy in RCW 69.50.201, the board has considered the following factors with regards to each of the substances listed in this chapter and in chapter 69.50 RCW:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The risk to the public health;

(7) The potential of the substance to produce psychic or psychological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under the Uniform Controlled Substances Act (chapter 69.50 RCW).

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-400, filed 11/7/84.]

WAC 246-887-100 Schedule I. The board finds that the following substances have high potential for abuse and have no accepted medical use in treatment in the United States or that they lack accepted safety for use in treatment under medical supervision. The board, therefore, places each of the following substances in Schedule I.

(a) The controlled substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name, are included in Schedule I.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

(2) Acetylmethadol;

(3) Allylprodine;

(4) Alphacetylmethadol; [(except for levo-alphacetylmethadol - also known as levo-alpha-acetylmethadol, levomethadyl acetate or LAAM);].

(5) Alphameprodine;

(6) Alphamethadol;

(7) Alpha-methylfentanyl (N-[1-alpha-methyl-beta-phenyl) ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(8) Benzethidine;

(9) Betacetylmethadol;

(10) Betameprodine;

(11) Betamethadol;

(12) Betaprodine;

(13) Clonitazene;

(14) Dextromoramide;

(15) Diampromide;

(16) Diethylthiambutene;

(17) Difenoxin;

(18) Dimenoxadol;
(19) Dimepheptanol;
(20) Dimethylthiambutene;
(21) Dioxaphetyl butyrate;
(22) Dipipanone;
(23) Ethylmethylthiambutene;
(24) Etonitazene;
(25) Etoxeridine;
(26) Furethidine;
(27) Gamma-hydroxybutyric Acid (other names include: GHB);
(28) Hydroxypethidine;
(29) Ketobemidone;
(30) Levomoramide;
(31) Levophenacylmorphan;
(32) 3-Methylfentanyl (N-[3-Methyl-1-(2-phenylethyl)-4-piperidyl)]-N-phenylpropanamide);
(33) Morpheridine;
(34) MPPP (1-Methyl-4-phenyl-4-propionoxypiperidine);
(35) Noracymethadol;
(36) Norlevorphanol;
(37) Normethadone;
(38) Norpipanone;
(39) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);
(40) Phenadoxone;
(41) Phenampromide;
(42) Phenomorphan;
(43) Phenoperidine;
(44) Piritramide;
(45) Proheptazine;
(46) Properidine;
(47) Propiram;
(48) Racemoramide;
(49) Tilidine;
(50) Trimeperidine.

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;
(2) Acetyldihydrocodeine;
(3) Benzylmorphine;
(4) Codeine methylbromide;
(5) Codeine-N-Oxide;
(6) Cyprenorphine;
(7) Desomorphine;
(8) Dihydromorphine;
(9) Drotebanol;
(10) Etorphine (except hydrochloride salt);
(11) Heroin;
(12) Hydromorphinol;
(13) Methyldesorphine;
(14) Methyldihydromorphine;
(15) Morphine methylbromide;
(16) Morphine methylsulfonate;
(17) Morphine-N-Oxide;
(18) Myrophine;
(19) Nicocodeine;
(20) Nicomorphine;
(21) Normorphine;
(22) Pholcodine;
(23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of paragraph (d) of this section, only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 4-bromo-2,5-dimethoxy-amphetamine: Some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA;

(2) 2,5-dimethoxyamphetamine: Some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA;

(3) 2,5-dimethoxy-4-ethylamphetamine (DOET)

(4) 4-methoxyamphetamine: Some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine, PMA;

(5) 5-methoxy-3,4-methylenedioxy-amphetamine;

(6) 4-methyl-2,5-dimethoxy-amphetamine: Some trade and other names: 4-methyl-2,5-dimethoxy-a-methylphenethylamine; "DOM"; and "STP";

(7) 3,4-methylenedioxy amphetamine;

(8) 3,4-methylenedioxymethamphetamine (MDMA);

(9) 3,4,5-trimethoxy amphetamine;

(10) Bufotenine: Some trade or other names: 3-(beta-Dimethylaminoethyl)-5-hydroxindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;

(11) Diethyltryptamine: Some trade or other names: N,N-Diethyltryptamine; DET;

(12) Dimethyltryptamine: Some trade or other names: DMT;

(13) Ibogaine: Some trade or other names: 7-Ethyl-6,6 beta,7,8,9,10,12,13,-octahydro-2-methoxy-6,9methano-5H-pyndo (1',2':1,2) azepino (5,4-b) indole; Tabernanthe iboga;

(14) Lysergic acid diethylamide;

(15) Marihuana;

(16) Mescaline;

(17) Parahexyl-7374; some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo[b,d]pyran; synhexyl;

(18) Peyote, meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds, or extracts; (interprets 21 USC § 812 (c), Schedule I (c)(12))

(19) N-ethyl-3-piperidyl benzilate;

(20) N-methyl-3-piperidyl benzilate;

(21) Psilocybin;

(22) Psilocyn;

(23) Tetrahydrocannabinols, synthetic equivalents of the substances contained in the plant, or in the resinous extrac-

tives of Cannabis, sp., and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

(i) Delta 1 - cis - or transtetrahydrocannabinol, and their optical isomers, excluding tetrahydrocannabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration;

(ii) Delta 6 - cis - or transtetrahydrocannabinol, and their optical isomers;

(iii) Delta 3,4 - cis - or transtetrahydrocannabinol, and its optical isomers;

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(24) Ethylamine analog of phencyclidine: Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE;

(25) Pyrrolidine analog of phencyclidine: Some trade or other names: 1-(1-phencyclohexyl)pyrrolidine; PCPy; PHP;

(26) Thiophene analog of phencyclidine: Some trade or other names: 1-(1-[2-thenyl]-cyclohexly)-pipendine; 2-thienylanalog of phencyclidine; TPCP; TCP;

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(i) Mecloqualone;

(ii) Methaqualone.

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers;

(i) Cathinone (also known as 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone and norephedrone)

(ii) Fenethylline;

(iii) N-ethylamphetamine;

(iv) 4-methylaminorex;

(v) N,N-dimethylamphetamine.

[01-03-108, § 246-887-100, filed 1/22/01, effective 1/22/01. Statutory Authority: RCW 18.64.005. 94-08-098, § 246-887-100, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.65.005 and 18.64.005. 94-07-105, § 246-887-100, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 18.64.005. 92-04-029 (Order 239B), § 246-887-100, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-410, filed 8/8/89, effective 9/8/89; 86-16-057 (Order 200), § 360-36-410, filed 8/1/86. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-410, filed 11/7/84.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

Reviser's note: RCW 34.05.395 requires the use of underlining and deletion marks to indicate amendments to existing rules, and deems ineffectual changes not filed by the agency in this manner. The bracketed material in the above section does not appear to conform to the statutory requirement.

Reviser's note: Under RCW 34.05.030 (1)(c), as amended by section 103, chapter 288, Laws of 1988, the above section was not adopted under the Administrative Procedure Act, chapter 34.05 RCW, but was published in the Washington State Register and codified into the Washington Administrative Code exactly as shown by the agency filing with history notes added by the code reviser's office.

WAC 246-887-110 Adding MPPP to Schedule I. The Washington state board of pharmacy finds that 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-411, filed 9/4/85.]

WAC 246-887-120 Adding PEPAP to Schedule I. The Washington state board of pharmacy finds that 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-120, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-412, filed 9/4/85.]

WAC 246-887-130 Adding MDMA to Schedule I. The Washington state board of pharmacy finds that 3,4-methylenedioxymethamphetamine (MDMA) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-413, filed 9/4/85.]

WAC 246-887-131 Adding Methcathinone to Schedule I. The Washington state board of pharmacy finds that Methcathinone (also called 2-methylamino-1-phenylpropan-1-one, ephedrone, Monomethylpropion, UR 1431) its salts, optical isomers and salts of optical isomers has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005. 92-23-059 (Order 318B), § 246-887-131, filed 11/17/92, effective 12/18/92.]

WAC 246-887-132 Adding Aminorex to Schedule I. The Washington state board of pharmacy finds that Aminorex (also called aminoxaphen, 2-amino-5-phenyl-2-oxazoline or 4,5-dihydro-5-phenyl-2-oxazolamine) its salts, optical isomers and salts of optical isomers has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under

medical supervision and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005. 93-14-037 (Order 375B), § 246-887-132, filed 6/29/93, effective 7/30/93.]

WAC 246-887-133 Adding Alpha-ethyltryptamine to Schedule I. The Washington state board of pharmacy finds that Alpha-ethyltryptamine has been classified as both a central nervous system stimulant and as a tryptamine hallucinogen. The DEA used its emergency scheduling authority to place this under Schedule I after finding that immediate CSA control was necessary to avoid an imminent hazard to public safety. The substance has been found by DEA in clandestine laboratories and on the illicit drug market. Therefore the Washington State Board of Pharmacy places Alpha-ethyltryptamine under control of Schedule I of the Controlled Substances Act.

[Statutory Authority: RCW 18.64.005. 94-08-098, § 246-887-133, filed 4/6/94, effective 5/7/94.]

WAC 246-887-140 Schedule II. The board finds that the following substances have a high potential for abuse and have currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions and that the abuse of the following substances may lead to severe psychic or psychological dependence. The board, therefore, places each of the following substances in Schedule II.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule II.

(b) Substances. (Vegetable origin or chemical synthesis.) Unless specifically excepted, any of the following substances, except those listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, naloxone, and naltrexone, and their respective salts, but including the following:

(i) Raw opium;
(ii) Opium extracts;
(iii) Opium fluid;
(iv) Powdered opium;
(v) Granulated opium;
(vi) Tincture of opium;
(vii) Codeine;
(viii) Ethylmorphine;
(ix) Etorphine hydrochloride;
(x) Hydrocodone;
(xi) Hydromorphone;
(xii) Metopon;
(xiii) Morphine;
(xiv) Oxycodone;
(xv) Oxymorphone; and
(xvi) Thebaine.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b)(1) of this section, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Methylbenzoylecgonine (cocaine—its salts, optical isomers, and salts of optical isomers).

(6) Concentrate of poppy straw (The crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy.)

(c) Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil;
(2) Alphaprodine;
(3) Anileridine;
(4) Bezitramide;
(5) Bulk dextropropoxyphene (nondosage forms);
(6) Carfentanil;
(7) Dihydrocodeine;
(8) Diphenoxylate;
(9) Fentanyl;
(10) Isomethadone;
(11) Levo-alphacetylmethadol - also known as levo-alpha-acetylmethadol, levomethadyl acetate or LAAM;
(12) Levomethorphan;
(13) Levorphanol;
(14) Metazocine;
(15) Methadone;
(16) Methadone—Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane;
(17) Moramide—Intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid;
(18) Pethidine (meperidine);
(19) Pethidine—Intermediate—A,4-cyano-1-methyl-4-phenylpiperidine;
(20) Pethidine—Intermediate—B,ethyl-4-phenylpiperidine-4-carboxylate;
(21) Pethidine—Intermediate—C,1-methyl-4-phenylpiperidine-4-carboxylic acid;
(22) Phenazocine;
(23) Piminodine;
(24) Racemethorphan;
(25) Remifentanil;
(26) Racemorphan;
(27) Sufentanil.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) Methamphetamine, its salts, optical isomers, and salts of optical isomers;

(3) Phenmetrazine and its salts;

(4) Methylphenidate.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital;

(2) Glutethimide;

(3) Pentobarbital;

(4) Phencyclidine;

(5) Secobarbital.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(2) Phenylacetone: Some trade or other names phenyl-2-propanone, P2P, benzyl methyl ketone, methyl benzyl ketone.

(3) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile (PCC).

(g) Hallucinogenic substances.

(1) Nabilone. (Another name for nabilone: (±)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one.)

[00-01-075, § 246-887-140, filed 12/13/99. 97-21-054, § 246-887-140, filed 10/13/97, effective 11/13/97. Statutory Authority: RCW 18.65.005 and 18.64.005. 94-07-105, § 246-887-140, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 18.64.005. 92-04-029 (Order 239B), § 246-887-140, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-140, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-420, filed 8/8/89, effective 9/8/89; 86-16-057 (Order 200), § 360-36-420, filed 8/1/86. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-420, filed 11/7/84.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

Reviser's note: Under RCW 69.50.201 (2)(e), the above section was not adopted under the Administrative Procedure Act, chapter 34.05 RCW, but was published in the Washington State Register and codified into the Washington Administrative Code exactly as shown by the agency filing with history notes added by the code reviser's office.

WAC 246-887-150 Schedule II immediate precursors. (1) The board finds and designates the following substances as being the principal compound used or produced primarily for use and which are an immediate chemical intermediary used or likely to be used, in the manufacture of a Schedule II controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(2) Unless specifically excepted or listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances or their salts or isomers having potential for abuse associated with the preparation of controlled substances shall be a Schedule II controlled substance.

(a) Anthranilic acid.

(b) Ephedrine.

(c) Hydriodic acid.

(d) Methylamine.

(e) Phenylacetic acid.

(f) Pseudoephedrine.

(g) Methephedrine.

(h) Lead acetate.

(i) Methyl formamide.

Provided: That any drug or compound containing Ephedrine, or any of its salts or isomers, or Pseudoephedrine, or any of its salts or isomers that are prepared for dispensing or over-the-counter distribution and are in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations are not controlled substances for the purpose of this section: And Provided Further, That any cosmetic containing lead acetate that is distributed in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations are not controlled substances.

[Statutory Authority: RCW 18.65.005 and 18.64.005. 94-07-105, § 246-887-150, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-150, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 88-11-007 (Order 214), § 360-36-425, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). 88-06-060 (Order 211), § 360-36-425, filed 3/2/88.]

WAC 246-887-160 Schedule III. The board finds that the following substances have a potential for abuse less than the substances listed in Schedules I and II, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to moderate or low physical dependency or high psychological dependency. The board, therefore, places each of the following substances in Schedule III.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations are referred to as excepted compounds in Schedule III as published in 21 CFR 1308.13 (b)(1) as of April 1, 1984, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(5) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:
(i) Amobarbital;
(ii) Secobarbital;
(iii) Pentobarbital;
or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing:
(i) Amobarbital;
(ii) Secobarbital;
(iii) Pentobarbital;
or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid;

(4) Chlorhexadol;

(5) Ketamine, its salts, isomers, and salts of isomers—some other names for ketamine: (<plus-minus>)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone;

(6) Lysergic acid;

(7) Lysergic acid amide;

(8) Methyprylon;

(9) Sulfondiethylmethane;

(10) Sulfonethylmethane;

(11) Sulfonmethane;

(12) Tiletamine and zolazepam or any salt thereof—some trade or other names for a tiletamine-zolazepam combination product: Telazol some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl) cyclohexanone—some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e] [1,4] diazepin 7 (1H)-one flupyrazapon.

(d) Nalorphine.

(e) Anabolic steroids. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

(1) Boldenone;
(2) Chlorotestosterone;
(3) Clostebol;
(4) Dehydrochlormethyltestosterone;
(5) Dihydrotestosterone;
(6) Drostanolone;
(7) Ethylestrenol;
(8) Fluoxymesterone;
(9) Formebulone (Formebolone);
(10) Mesterolone;
(11) Methandienone;
(12) Methandranone;
(13) Methandriol;
(14) Methandrostenolone;
(15) Methenolone;
(16) Methyltestosterone;
(17) Mibolerone;
(18) Nandrolone;
(19) Norethandrolone;
(20) Oxandrolone;
(21) Oxymesterone;
(22) Oxymetholone;
(23) Stanolone;
(24) Stanozolol;
(25) Testolactone;
(26) Testosterone;
(27) Trenbolone; and

(28) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of health and human services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

The following are implants or pellets which are exempt:

Ingredients	Trade Name	Company
Testosterone Propionate, Oestradiol Benzoate	F-TO	Animal Health Div. Upjohn International Kalamazoo, MI
Trenbolone Acetate	Finaplix-H	Hoechst-Roussel Agri-Vet Co., Somerville, NJ
Trenbolone Acetate	Finaplix-S	Hoechst-Roussel Agri-Vet Co., Somerville, NJ
Testosterone Propionate, Estradiol Benzoate	Heifer-oid	Anchor Division Boehringer Ingelheim St. Joseph, MO
Testosterone Propionate, Estradiol Benzoate	Heifer-oid	Bio-Ceutic Division Boehringer Ingelheim St. Joseph, MO
Testosterone Propionate, Estradiol Benzoate	Heifer-oid	Ivy Laboratories, Inc. Overland Park, KS
Testosterone Propionate, Estradiol Benzoate	Implus	The Upjohn Co. Kalamazoo, MI
Trenbolone Acetate, Estradiol	Revalor-s	Hoechst-Roussel Agri-Vet Co., Somerville, NJ
Testosterone Propionate, Estradiol Benzoate	Synovex H	Syntex Laboratories Palo Alto, CA

(f) The following anabolic steroid products containing compounds, mixtures, or preparations are exempt from the recordkeeping, refill restrictions, and other Controlled Substances Act requirements:

Ingredients	Trade Name	Company
Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml	Androgyn L.A.	Forest Pharmaceuticals St. Louis, MO
Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml	Andro-Estro 90-4	Rugby Laboratories Rockville Centre, NY
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	depANDROGYN	Forest Pharmaceuticals St. Louis, MO
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	DEPO-T.E.	Quality Research Laboratories Carmel, IN

Ingredients	Trade Name	Company
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	depTESTROGEN	Martica Pharmaceuticals Phoenix, AZ
Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml	Duomone	Wintec Pharmaceutical Pacific, MO
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	DURATESTRIN	W.E. Hauck Alpharetta, GA
Testosterone cypionate 50 mg/ml Esterified cypionate 2 mg/ml	DUO-SPAN II	Primedics Laboratories Gardena, CA
Esterified estrogens 1.25 mg. Methyltestosterone 2.5 mg.	Estratest	Solvay Pharmaceuticals Marietta, GA
Esterified estrogens 0.525 mg. Methyltestosterone 1.25 mg.	Estratest HS	Solvay Pharmaceuticals Marietta, GA
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	PAN ESTRA TEST	Pan American Labs Covington, LA
Conjugated estrogens 1.25 mg. Methyltestosterone 10 mg.	Premarin with Methyltestosterone	Ayerst Labs, Inc. New York, NY
Conjugated estrogens 0.625 mg. Methyltestosterone 5 mg.	Premarin with Methyltestosterone	Ayerst Labs, Inc. New York, NY
Testosterone propionate 25 mg Estradiol benzoate 2.5 mg	Synovex H Pellets in process	Syntex Animal Health Palo Alto, CA
Testosterone propionate 10 parts Estradiol benzoate 1 part	Synovex H Pellets in process, granulation	Syntex Animal Health Palo Alto, CA
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	Testagen	Clint Pharmaceutical Nashville, TN
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	TEST-ESTRO Cypionates	Rugby Laboratories Rockville Centre, NY
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate Amityville, NY
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	Testosterone Cypionate-Estradiol Cypionate Injection	Best Generics No. Miami Beach, FL
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	Testosterone Cypionate-Estradiol Cypionate Injection	Goldline Labs Ft. Lauderdale FL
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	Testosterone Cypionate-Estradiol Cypionate Injection	Schein Pharmaceuticals Port Washington, NY
Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml	Testosterone Cypionate-Estradiol Cypionate Injection	Steris Labs, Inc. Phoenix, AZ
Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml	Testosterone Enanthate-Estradiol Valerate Injection	Goldline Labs Ft. Lauderdale FL
Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml	Testosterone Enanthate-Estradiol Valerate Injection	Schein Pharmaceuticals Port Washington, NY
Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml	Testosterone Enanthate-Estradiol Valerate Injection	Steris Labs, Inc. Phoenix, AZ

(g) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in paragraph (e) of this section:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(h) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below;

(1) Buprenorphine.

(i) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product. (Some other names for dronabinol [6aR-trans]-6a,7,8, 10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d] pyran-i-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.)

[Statutory Authority: RCW 18.64.005 and 69.50.201. 04-13-162, § 246-887-160, filed 6/23/04, effective 7/24/04. Statutory Authority: RCW

[...201 and 18.64.005(7). 03-02-021, § 246-887-160, filed 12/23/02, effective 1/23/03. 00-10-113, § 246-887-160, filed 5/3/00. 00-01-075, § 246-887-160, filed 12/13/99. Statutory Authority: RCW 18.64.005. 96-01-032, § 246-887-160, filed 12/12/95, effective 1/12/96; 94-08-098, § 246-887-160, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005. 93-14-[illegible] (Order 376B), § 246-887-160, filed 6/29/93, effective 7/30/93; 93-06-[illegible] (Order 343B), § 246-887-160, filed 3/3/93, effective 4/3/93; 92-04-029 [illegible] Order 239B), § 246-887-160, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order [illegible]B), recodified as § 246-887-160, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-430, filed 8/8/89, effective 9/8/89. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-430, filed 11/7/84.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-887-165 Adding Xyrem to Schedule III. The Washington state board of pharmacy finds that Xyrem, sodium oxybate, Gamma-hydroxybutyric (GHB), is approved for medical use by the Food and Drug Administration and hereby places that substance in Schedule III.

[Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. 03-09-064, § 246-887-165, filed 4/15/03, effective 5/16/03.]

WAC 246-887-170 Schedule IV. The board finds that the following substances have a low potential for abuse relative to substances in Schedule III and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III. The board, therefore, places each of the following substances in Schedule IV.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule IV.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-e-dimethylamino-1,2-diphenyl-3-methyl-2 propionoxybutane).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam;
(2) Barbital;
(3) Bromazepam;
(4) Camazepam;
(5) Chloral betaine;
(6) Chloral hydrate;
(7) Chlordiazepoxide;
(8) Clobazam;
(9) Clonazepam;
(10) Clorazepate;
(11) Clotiazepam;
(12) Cloxazolam;
(13) Delorazepam;
(14) Diazepam;
(15) Estazolam;
(16) Ethchlorvynol;
(17) Ethinamate;
(18) Ethyl loflazepate;
(19) Fludiazepam;
(20) Flunitrazepam;
(21) Flurazepam;
(22) Halazepam;
(23) Haloxazolam;
(24) Ketazolam;
(25) Loprazolam;
(26) Lorazepam;
(27) Lormetazepam;
(28) Mebutamate;
(29) Medazepam;
(30) Meprobamate;
(31) Methohexital;
(32) Methylphenobarbital (mephobarbital);
(33) Midazolam;
(34) Nimetazepam;
(35) Nitrazepam;
(36) Nordiazepam;
(37) Oxazepam;
(38) Oxazolam;
(39) Paraldehyde;
(40) Petrichloral;
(41) Phenobarbital;
(42) Pinazepam;
(43) Prazepam;
(44) Quazepam;
(45) Temazepam;
(46) Tetrazepam;
(47) Triazolam.
(48) Zolpidem

(d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position or geometric), and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible.

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cathine ((+) - norpseudoephedrine);
(2) Diethylpropion;
(3) Fencamfamin;
(4) Fenproporex;
(5) Mazindol;
(6) Mefenorex;
(7) Pemoline (including organometallic complexes and chelates thereof);
(8) Phentermine;
(9) Pipradrol;
(10) SPA ((-)-1-dimethylamino-1, 2-dephenylethane.

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine;

(2) Butorphanol.

[98-02-084 § 246-887-170, filed 1/7/98, effective 1/7/98. Statutory Authority: RCW 18.64.005. 94-08-098, § 246-887-170, filed 4/6/94, effective 5/7/94; 92-04-029 (Order 239B), § 246-887-170, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-170, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-440, filed 8/8/89, effective 9/8/89. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-440, filed 11/7/84.]

Reviser's note: Under RCW 69.50.221 (2)(e), the above section was not adopted under the Administrative Procedure Act, chapter 34.05 RCW, but was published in the Washington State Register and codified into the Washington Administrative Code exactly as shown by the agency filing with history notes added by the code reviser's office.

WAC 246-887-180 Schedule V. The board finds that the following substances have low potential for abuse relative to substances in Schedule IV and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. The board, therefore, places each of the following substances in Schedule V.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in this section, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-180, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-450, filed 11/7/84.]

WAC 246-887-190 Adding buprenorphine to Schedule V. The Washington state board of pharmacy finds that buprenorphine has a low potential for abuse relative to substances in Schedule IV; has currently accepted medical use in treatment in the United States; and the substance has limited physical dependence or psychological dependence liability relative to the substances in Schedule IV, and hereby places that substance in Schedule V.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-190, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-451, filed 9/4/85.]

WAC 246-887-200 Other controlled substance registrants—Requirements. (1) All persons and firms, except persons exempt from registration, shall register with the board in order legally to possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers shall be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-887-150.

(3) The applicant for a controlled substance registration shall complete and return an application form supplied by the board. Either on the form or on an addendum, the applicant shall list the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances.

(4) All controlled substances shall be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. An inventory of all controlled substances in the possession of the registrant shall be completed every two years on the anniversary of the issuances of the registration and shall be maintained for two years. Unwanted, outdated, or unusable controlled substances shall be returned to the source from which obtained or surrendered to the Federal Drug Enforcement Administration.

[Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. 92-12-03 (Order 277B), § 246-887-200, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-887-200, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. 89-17-023 (Order 226), § 360-36-500, filed 8/8/89, effective 9/8/89.]

WAC 246-887-210 Standards for transmission of controlled substances sample distribution reports. These standards describe the format for transmission of data regarding distribution of controlled substance samples by manufacturers or distributors to licensed practitioners in the state of Washington.

(1) Each report shall contain the following information regarding the firm distributing controlled substance samples:

(a) Name of firm.

(b) DEA number of firm.

(c) Complete address of firm including zip code.

(d) Name and phone number of contact person.

(2) Each report shall contain the following information regarding the licensed practitioner to whom samples are distributed:

(a) First and last name of practitioner.

(b) DEA number of practitioner.

(c) Professional designation of practitioner. (E.g., MD, DO, DDS.)

(d) Complete address of practitioner including zip code.

(3) Each report shall contain the following information regarding the controlled substance(s) distributed:

(a) Name of controlled substance(s) distributed.

(b) Dosage units of controlled substance(s) distributed.

(c) Quantity distributed.

(d) Date distributed.

(4) Each report shall be submitted in alphabetical order by practitioner's last name.

(5) Each report shall be submitted quarterly.

[Statutory Authority: RCW 18.64.005. 92-09-071 (Order 265B), § 246-887-210, filed 4/14/92, effective 5/15/92.]

Chapter 246-888 WAC
MEDICATION ASSISTANCE

WAC

246-888-010 Purpose.

246-888-020 What is self-administration with assistance and how is it different from independent self-administration or medication administration?

246-888-030 How is self-administration with assistance initiated in a community-based care setting or an in-home setting?

246-888-045 What is an enabler?

246-888-050 How can medications be altered to assist with self-administration?

246-888-060 Can all medications be altered to facilitate self-administration?

246-888-070 What other type of assistance can a nonpractitioner provide?

246-888-080 Is oxygen covered under this rule?

246-888-090 If a individual/resident is able to administer his or her own oral medication through a gastrostomy or "g-tube," can a nonpractitioner provide assistance as outlined in these rules?

246-888-100 Are there any other requirements I need to be aware of?

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-888-040 What if there is a change in the individual's situation? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-040, filed 12/17/99, effective 1/17/00.] Repealed by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005.

246-888-050 What is an enabler? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-050, filed 12/17/99, effective 1/17/00.] Decodified by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-045.

246-888-060 How can medications be altered to assist with self-administration? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-060, filed 12/17/99, effective 1/17/00.] Decodified by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-050.

246-888-070 Can all medications be altered to facilitate self-administration? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-070, filed 12/17/99, effective 1/17/00.] Decodified and amended by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-060.

246-888-080 What other type of assistance can a nonpractitioner provide? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-080, filed 12/17/99, effective 1/17/00.] Decodified by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-070.

246-888-090 Is oxygen covered under this rule? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-090, filed 12/17/99, effective 1/17/00.] Decodified by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-080.

246-888-100 If a individual/resident is able to administer his or her own oral medication through a gastrostomy or "g-tube," can a nonpractitioner provide assistance as outlined in these rules? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-100, filed 12/17/99, effective 1/17/00.] Decodified by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-090.

246-888-110 Are there any other requirements I need to be aware of? [Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-110, filed 12/17/99, effective 1/17/00.] Decodified by 04-18-095, filed 9/1/04, effective 10/2/04. Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. Recodified as WAC 246-888-100.

WAC 246-888-010 Purpose. The legislature recognizes that individuals residing in community-based care settings or in-home settings may need assistance self-administering their legend drugs and controlled substances, due to physical or mental limitations.

Community-based care settings include: Community residential programs for the developmentally disabled, certified by the department of social and health services under chapter 71A.12 RCW; adult family homes licensed under chapter 70.128 RCW; and boarding homes licensed under chapter 18.20 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

In-home settings include: An individual's place of temporary and permanent residence, but does not include acute care or skilled nursing facilities, and does not include community-based care settings. The following rules provide guidance to the individual/resident and caregiver on medication assistance and administration.

[Statutory Authority: Chapter 69.41 RCW, RCW 18.64.005. 04-18-095, § 246-888-010, filed 9/1/04, effective 10/2/04. Statutory Authority: RCW 18.64.005 and 69.41.085. 00-01-123, § 246-888-010, filed 12/17/99, effective 1/17/00.]

WAC 246-888-020 What is self-administration with assistance and how is it different from independent self-administration or medication administration? Self-administration with assistance means assistance with legend drugs and controlled substances rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the medication container, using an enabler, or placing the medication in the hand of the individual/resident. The individual/resident must be able to put the medication into his or her mouth or apply or instill the medication. The individual/resident does not necessarily need to state the name of the medication, intended effects, side effects, or other details, but must be aware that he/she is receiving medications. Assistance may be provided with prefilled insulin syringes. Assistance is limited to handing the prefilled insulin syringe to an individual/resident. Assistance with the administration of any other intravenous and/or injectable medication is specifically

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Appendix A: Declaration of Michael Jones in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment with exhibit (Snohomish County Superior Court Cause No. 02-2-08819-6)

Appendix B: Inspection Report from July 12, 1999 Inspection

Appendix C: Inspection Report from August 10, 1999 Inspection

Appendix D: August 10, 1999 Respondent Written Notice signed by Michael Jones

Appendix E: Respondent Statement Instructions

Appendix F: Declaration of Donald Williams with Exhibits 4-5, 18 (Snohomish County Superior Court Cause No. 02-2-08819-6)

Appendix G: Declaration of W. Bernard Bauman in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment (Snohomish County Superior Court Cause No. 02-2-08819-6)

Appendix H: Declaration of Murphy Evans in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment with Exhibits 7-17

Appendix I: First Amended Complaint (Snohomish County Superior Court Cause No. 02-2-10037-4)

APPENDIX A

IN THE SUPERIOR COURT OF WASHINGTON FOR SNOHOMISH COUNTY

MICHAEL S. JONES, R. Ph., Plaintiff, vs. STATE OF WASHINGTON AND ITS DEPARTMENT OF HEALTH; WASHINGTON STATE BOARD OF PHARMACY; PHYLLIS WENE and STAN JEPPESEN, individually and as investigators for the Washington State Board of Pharmacy, Defendants	**Case No.: 02-2-08819-6** **DECLARATION OF MICHAEL JONES IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

I, MICHAEL JONES, declare as follows, based on my personal knowledge:

1. I am the plaintiff in this action.

2. I have had a professional license to practice pharmacy in Washington since 1980.

3. In 1995, I purchased The Medicine Shoppe franchise in Marysville, WA. In addition to my professional license, I secured a location license for the pharmacy that same year. On October 30, 1996, inspectors with the Board of Pharmacy conducted an inspection of his pharmacy, and Jones's pharmacy received a passing score of 95. On December 17, 1998, Phyllis Wene conducted another inspection of my pharmacy. The pharmacy received a failing score of

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COPY

79. On February 3, 1999, Phyllis Wene performed a re-inspection, and the pharmacy received a passing score of 96.

4. In my experience, inspectors perform inspections approximately once every two to three years. I have experienced numerous inspections by the state Board of Pharmacy since I started practicing pharmacy in Washington. Until July 1999, they had always performed their inspections in a quiet, professional manner, with minimum disruption to the operation of my pharmacy. Until July 1999, their inspections had always taken approximately one hour. In July 1999, that all changed.

5. On July 12, 1999, inspectors Phyllis Wene and Stan Jeppesen arrived unannounced at my pharmacy and informed me that Jeppesen was a new inspector and that they had come to my pharmacy to conduct a training exercise for Jeppesen's benefit. I thought this was strange. Because I was very busy at the time, I objected and asked them to conduct their training elsewhere. Phyllis Wene ignored my objection and pushed past me into the pharmacy.

6. For four hours that morning – and again for three hours in the afternoon after they returned from a lunch break -- I was subjected to non-stop harassment by Wene and Jeppesen. Jeppesen would crowd me and interrupt me while I tried to fill prescriptions. Jeppesen stood directly behind me – within six inches – and interrupted me while I entered information on the computer system and attempted to intimidate me while I filled prescriptions or spoke with customers. Wene and Jeppesen stood on either side of me and made repeated demands in rapid-fire succession that I access computer records or answer their independent inquiries. Wene repeatedly returned to my photocopy machine and ran photocopies of pharmacy records in an obvious attempt to intimidate me. On more than one occasion Jeppesen yelled at me and banged his hands on the pharmacy counter while I tried to select, count and prepare medications. I

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believe that he and Wene were intentionally trying to make me commit errors. My employees were shocked and intimidated. My customers were aghast.

7. On the morning of July 13, 1999, Jeppesen returned to my pharmacy. I asked Jeppesen why he had returned. Jeppesen said he was there for additional training. I told Jeppesen that I would not tolerate further harassment and intimidation. Jeppesen remained inside the pharmacy and outside the pharmacy for approximately one hour. He then handed me an inspection report with a failing grade of 48. I was shocked. Phyllis Wene had given my pharmacy a score of 96 on February 3, 1999 – only five months earlier, -- and I knew my pharmacy was in better shape now than it had been back then.

8. The inspection report contained numerous errors. Contrary to the inspection report, I did enter allergy and chronic disease information about customers into my computer record, but unbeknownst to me the QS-1 computer system was recording the information but not processing it. This was corrected by the second inspection. I did have written records of patients' requests for non-child resistant caps. I had a regular process for checking outdated medications and did not have 38 outdated items on the shelves. I did have the required DEA order forms and invoices but I kept them in different places.

9. On August 10, 1999, Stan Jeppesen and Phyllis Wene returned to my pharmacy and conducted a re-inspection. This time I received a failing grade of 56. The reinspection report contained numerous errors. I had contacted officials with the QS-1 computer system and they had turned on the part of the program which processed medical conditions. I did have records for authorization to use non-child resistant caps. I never substituted a drug that had been prescribed by a doctor. I did not have outdated medications on the shelf. I had matched DEA order forms with invoices. I did perform the inventory for Schedule II and Schedule III drugs

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prior to the second inspection. My prescriptions were in sequential order by prescription number. I believe the missing prescriptions were the result of theft by a former employee, Mary Berlin, whom I had fired for misconduct and who unbeknownst to me at the time was an informant for the state.

10. In addition to the numerous errors in each inspection report, I believe the scoring of the deficiencies was conducted in an arbitrary and capricious manner. For example, in numerous instances the inspector deducted five points (the maximum per deficiency) for minor discrepancies. Such arbitrary and capricious scoring accounts, in part, for how my pharmacy could go from a score of 96 in February 3, 1999, to a score of 48 on July 12, 1999, when the condition of the pharmacy – if anything – had improved. I have worked at numerous pharmacies and encountered numerous inspections by inspectors with the Board of Pharmacy. In July and August of 1999, my pharmacy was in greater compliance with the pharmacy rules and regulations than those other pharmacies which received passing scores.

11. I believe the false and capricious scoring of the inspection reports was part of a calculated effort by Board of Pharmacy officials to drive me out of business. In 1994, while I was working for a Safeway pharmacy in Shoreline, I got a call at home from a fellow pharmacist, Sharla Keeling, who asked me to come to the pharmacy because a Board of Pharmacy inspector, Joe Honda, was harassing her. I went to the pharmacy and saw Honda staring at Sharla for no reason. Sharla obviously appeared intimidated, and I confronted Honda and told him to leave if he'd finished his inspection.

12. Three weeks after this incident, I received a notice of a hearing before the Board of Pharmacy regarding my license to practice pharmacy. I attended the hearing and discovered that I had been charged with misfiling a prescription for proctocream with proctofoam. Both

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products contain the same amount of active ingredient and both were used internally. I admitted the mistake and the Board of Pharmacy put me on probation for one year. This seemed extremely harsh to me.

13. Approximately six months later, I ran into my "accuser," Claudia Tomlinson, and I apologized. She told me that she had initially contacted the Board of Pharmacy about the mistake, and about two months after reporting the incident a group of inspectors had showed up at her home and urged her to press charges against me. They had showed up at her home after the encounter with Joe Honda in the Safeway store.

14. After the pharmacy failed the second inspection, I was given written interrogatories by Phyllis Wene. I was told to answer the interrogatories and submit them. I was never told that there might be a hearing to determine whether my licenses should be revoked summarily. I was never told that the condition of my pharmacy constituted an emergency.

15. On August 17, 1999, I called my attorney, Bernie Bauman. I told him that I was having trouble answering the Board of Pharmacy's interrogatories. He said he would check with the Board of Pharmacy and get back to me. When he called me back, he said the Board of Pharmacy had said to keep working on the answers. They indicated that the timing was no big deal. They didn't say anything about an ex parte motion for an order to summarily suspend my licenses. Had the Board of Pharmacy contacted me, I could have appeared at the hearing on the motion to suspend my licenses. I think it's likely that my attorney could also have appeared on very short notice.

16. When Phyllis Wene delivered the order suspending my licenses and closed down my pharmacy on August 17, 1999, I was shocked. No one had told me that any of the problems reported in the inspection reports were so serious as to warrant the suspension of my licenses.

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My pharmacy had been allowed to remain open since July 12 – the date of the first inspection. Nothing had gotten worse since then; things had only gotten better. I believe that Wene, Jeppesen and the as-yet-unidentified official at the Board of Pharmacy who decided to seek the ex parte order (whom I believe to be Donald Williams, the executive director) knew that in fact the condition of my pharmacy did not constitute a public emergency.

17. The suspensions put me in a horrible financial bind. I tried desperately to have the summary suspensions lifted immediately so that I could keep the pharmacy open and save my business at least until a hearing could take place on the merits. The Board of Pharmacy refused to lift the summary suspensions.

18. Because of the summary suspensions I lost my franchise with The Medicine Shoppe International, Inc.. On August 31, 1999, The Medicine Shoppe International terminated my franchise effective immediately. *See a true and correct copy of the August 31, 1999 letter from The Medicine Shoppe International attached hereto as Exhibit 1.* But for the summary suspensions, I believe I could have saved my franchise. Because of the summary order, I ended up losing my franchise, losing my commercial lease, and losing my business.

19. I made numerous efforts to reach a settlement with the Board that might allow me to reopen the pharmacy and save the business, but the Board of Pharmacy refused to negotiate. Instead, they kept trumping up more charges against me.

20. By November, 1999, I had lost the business. I agreed to enter the stipulated order because I no longer had the financial means to pay for an attorney and to fight the Board of Pharmacy's charges. I had already lost my pharmacy. I agreed to the stipulated order because I could not afford to risk losing my professional license as well.

BROWNLIE & EVANS, LLP
119 N. Commercial St., Suite 1250
Bellingham, WA 98225
(360) 676-0306

21. I did not admit to any wrongdoing in the stipulated order. I never intended to waive my right to sue the Board of Pharmacy for what it had done to me. I always intended to pursue a lawsuit against the Board of Pharmacy once I could marshal the financial resources for a lawsuit. My understanding is that the stipulated order would have no impact on my right to sue the Board of Pharmacy. I would not have agreed to the stipulated order if it waived my right to sue.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Dated: November 11, 2003.
Bellingham, WA

By: Michael Jones
Michael Jones

BROWNLIE & EVANS, LLP
119 N. Commercial St., Suite 1250
Bellingham, WA 98225
(360) 676-0306

Kevin M. Barry
kbarry@medshoppe.com

Medicine Shoppe International, Inc.
A Cardinal Health Company

August 31, 1999

First Class Mail
and Facsimile

Michael S. Jones, R.Ph., P.S.
Michael S. Jones, President
9430 State Avenue
Marysville, WA 98270

Michael S. Jones
17330 S.E. 26th Ave.
Bothell, WA 98012

Re: ***The Medicine Shoppe® Pharmacy No. 0719***

Dear Mr. Jones:

You were advised of numerous material breaches of License Agreement dated October 5, 1996 (the "Agreement") between Michael S. Jones, R.Ph., P.S. and Medicine Shoppe International, Inc. ("MSI") on August 20, 1999. Based upon those events of default, the Agreement is terminated pursuant to section 12 for the failure of the licensee and guarantor to perform their obligations. The termination is effective immediately.

As you were also advised on August 20, 1999 you are in default of your numerous financial obligations to MSI. MSI demands immediate payment. As of July 31, 1999, MSI has calculated that you owe us $246,451.23. This figure represents the following balances as of that date. You owe MSI $139,957.05 under the Note. MSI has calculated that you owe $90,846.48 in license fees based upon actual and estimated net revenues because you have failed to meet the reporting requirements under the Agreement. Thus, MSI reserves the right to verify all amounts. You also owe MSI Advertising Fund contribution totaling $13,511.34. Additionally, you owe $2,136.36 for product purchased.

As a result of your conduct giving rise to a default and the resulting termination of the Agreement, pursuant to section 13 of the Agreement you are obligated to comply with all provisions thereunder including, but not limited to, the following:

(1) discontinue all use of our trademarks;

(2) immediately desist identifying your pharmacy as a Medicine Shoppe® Pharmacy including, but not limited to, your licensing of the pharmacy with any state regulatory body;

EXHIBIT 1

(3) provide all information required by subparagraph (c.) including your patient files/prescription records;

(4) return all of our manuals, and;

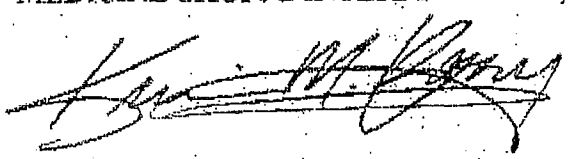
(5) honor the non-compete in subparagraph (e.).

Again, section 13 of the Agreement spells out your obligations in detail. Please refer to the Agreement to be sure you fully comply with all requirements. In the event that you have any questions, please contact counsel of your own choosing or you may contact me.

In particular, we note that you are expressly prohibited for operating a pharmacy licensed and/or in any way identified as a Medicine Shoppe® Pharmacy. Moreover, you are prohibited from having any "interest as an owner, partner, director, officer, employee, consultant, representative or agent, or in any other capacity, in any prescription pharmacy or prescription pharmacy department..." within your specified territory (copy enclosed). It is unfortunate that it is necessary for us to take this action. Your actions, however, leave us no choice.

Sincerely,

MEDICINE SHOPPE INTERNATIONAL, INC.



By: Kevin M. Barry
Corporate Counsel

Enc.

c. L. Moran, Esq. (by facsimile w/enc.)
D. Williams (by facsimile)
S. Somers, Esq. (by facsimile)
B. Bauman, Esq. (by facsimile)

APPENDIX B

07/20/1999 19:15 4256949 PHYLLIS WENE PAGE 01

The Medicine Shoppe

8439 STATE AVENUE
MARYSVILLE, WA 98270

Phone
(360) 653-4520

PHARMACY INSPECTION REPORT

DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
1300 QUINCE ST., S.E.; P. O. BOX 47863
OLYMPIA, WASHINGTON 98504-7863
TEL: 360/ 236-4825 FAX: 360/ 586-4359

INSPECTION PURPOSE
___ NEW
✓ PERIODIC
___ OWNER CHANGE
___ LOCATION CHANGE
___ REINSPECTION
___ SELF

7-12-1999
INSPECTION DATE

TELEPHONE NUMBER (Include Area Code)

MICHAEL S. JONES
RESPONSIBLE MANAGER

PH 10995
LICENSE NUMBER

LAST INSPECTED: 2-3-1995 CLASS A OWNERSHIP: ✓ C ___ P ___ S PHARMACY TYPE: ✓ C ___ H ___ P ___ I ___ N ___ O

A. GENERAL REQUIREMENTS (10 POINTS)

1. ✓ PHARMACY INSPECTION CERT. POSTED (WAC 246-902-190)
2. ✓ PERSONNEL LICENSES POSTED (RCW 18.64.140)
3. ✓ PHARMACY LICENSES POSTED (RCW 18.64.043)
4. ✓ DEA REGISTRATION (WAC 246-887-020)

LOCATION LICENSE NUMBER C.E. 55751
REGISTRATION NUMBER BTS1080941

PHARMACISTS	LICENSE #	PRECEPTOR	INTERNS & TECHNICIANS	CERTIFICATE #	INTERN OR TECH
			SHANNON Boston - Level "2"		

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY (USE ADDITIONAL PAGE IF NECESSARY) SECTION A TOTAL

B. PATIENT HEALTH & SAFETY REQUIREMENTS (30 POINTS)

1. -5 PATIENT MED. RECORDS (WAC 246-875)
2. ✓ PATIENT INFORMATION (WAC 246-866-220)
3. -5 DRUG PRODUCT SUBSTITUTION GENERIC SIGN (RCW 69.41 & WAC 246-869)
4. -5 QRC COMPLIANCE (WAC 246-887-230)
5. ✓ POISON REQUIREMENTS (WAC 246-887-200) PECAC SYR / POISON CONTROL #
6. -15 OUTDATED/DETERIORATED STOCK (WAC 246-884-150)

NUMBER OF OUTDATED ITEMS
00 TO 09 ITEMS = 00 POINTS
10 TO 17 ITEMS = 05 POINTS
18 TO 24 ITEMS = 10 POINTS
25 PLUS ITEMS = 15 POINTS (39)

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY SECTION B TOTAL -0-

C. PROFESSIONAL REQUIREMENTS (40 POINTS)

1. -2 DEA ORDER FORMS (WAC 246-887-020)
2. -5 DEA INVENTORY RECORD (WAC 246-887-020)
3. ___ SCHEDULE V CS REGISTER (WAC 246-887-030)
4. ✓ RESPONSIBLE RPH MANAGER (WAC 246-863-070)
5. ✓ LAWBOOK (WAC 246-886-100)
6. -2 REFERENCE SOURCE (WAC 246-886-100) Not 2 Years
7. -1 PHARMACY ANCILLARY STAFF (WAC 246-931)
8. ___ PROFESSIONAL RESPONSIBILITIES (WAC 246-863-095)
9. -1 ALL DRUGS PROPERLY LABELED (WAC 246-869-150)
10. -2 COMPLETED PRESCRIPTION LABELS (WAC 246-869-210)
11. -1 PRESCRIPTION FILES (WAC 246-869-160)
12. -1 REGULATION COMPLIANCE (RCW 18.64.150 & 148)

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY SECTION C TOTAL 19

D. FACILITIES (20 POINTS)

1. n/a DIFFERENTIAL HOURS (WAC 246-869-020)
2. ✓ RX AREA SECURE FROM PUBLIC (WAC 246-869-160)
3. ✓ APPEARANCE OF STAFF (WAC 246-869-170)
4. ✓ RX AREA WORKING SPACE (WAC 246-869-160)
5. -1 PRESCRIPTION AREA SINK (WAC 246-869-160)
6. ✓ REFRIGERATOR (WAC 246-869-160)
7. ✓ TRASH RECEPTACLES (WAC 246-869-170)
8. ✓ REST ROOMS (WAC 246-869-170)
9. ✓ GENERAL CLEANLINESS & SANITATION (WAC 246-869-150, 160, & 170)
10. ✓ NECESSARY EQUIPMENT (WAC 246-863-190)

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY SECTION D TOTAL 19

100 TO 90 POINTS = A | 89 TO 80 POINTS = CONDITIONAL (WAC 246-863-180) | BELOW 80 POINTS = UNSATISFACTORY

COMMENTS: YES NO Comments are set forth on the reverse side of this report.

GRADE TOTAL 48

Signature of Pharmacist

Signature of Investigator

DOH 640-012A (Rev. 6/97)

04131807

APPENDIX C

AFFIX STORE LABEL HERE
OR FILL IN INFORMATION

PHARMACY NAME The Medicine Shoppe Pharmacy
ADDRESS 9430 State Ave
CITY Marysville ZIP CODE 98270

PHARMACY INSPECTION REPORT #5

DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
1300 QUINCE ST., S.E.; P. O. BOX 47863
OLYMPIA, WASHINGTON 98504-7863
TEL: 360/ 236-4825 FAX: 360/ 586-4359

INSPECTION PURPOSE
___ NEW
___ PERIODIC
___ OWNER CHANGE
___ LOCATION CHANGE
✓ REINSPECTION
___ SELF

360 653-4520
TELEPHONE NUMBER (Include Area Code)

MICHAEL JONES
RESPONSIBLE MANAGER

8-10-99
INSPECTION DATE

PH 10993
LICENSE NUMBER

LAST INSPECTED: 7-12-99

CLASS Unsatisfactory OWNERSHIP: ___ C ___ P ___ S PHARMACY TYPE: ✓ C ___ H ___ P ___ L ___ N ___ O

A. GENERAL REQUIREMENTS (10 POINTS)

1. ✓ PHARMACY INSPECTION CERT. POSTED (WAC 246-869-190)
2. ✓ PERSONNEL LICENSES POSTED (RCW 18.64.140)
3. ✓ PHARMACY LICENSES POSTED (RCW 18.64.043)
4. ✓ DEA REGISTRATION (WAC 246-887-020)

LOCATION LICENSE NUMBER CF 55751
REGISTRATION NUMBER BT5108041

PHARMACISTS	LICENSE #	PRECEPTOR	INTERNS & TECHNICIANS	CERTIFICATE #	INTERN OR TECH
			SHANNON Boston 'Level B'		
			KRISTA BOLOBANIC 'LEVEL B'		

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY (USE ADDITIONAL PAGE IF NECESSARY)

SECTION A TOTAL 10

B. PATIENT HEALTH & SAFETY REQUIREMENTS (30 POINTS)

1. -5 PATIENT MED. RECORDS (WAC 246-875)
2. ✓ PATIENT INFORMATION (WAC 246-869-220)
3. -5 DRUG PRODUCT SUBSTITUTION GENERIC SIGN (RCW 69.41 & WAC 246-899)
4. -5 CRC COMPLIANCE (WAC 246-869-230)
5. ✓ POISON REQUIREMENTS (WAC 246-869-200)
6. -5 IPECAC SYR./ POISON CONTROL # OUTDATED/DETERIORATED STOCK (WAC 246-869-160)

NUMBER OF OUTDATED ITEMS
00 TO 09 ITEMS = 00 POINTS
10 TO 17 ITEMS = 05 POINTS
18 TO 23 ITEMS = 10 POINTS
24 PLUS ITEMS = 15 POINTS

N ITEMS FOUND

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY

SECTION B TOTAL 10

C. PROFESSIONAL REQUIREMENTS (40 POINTS)

1. -2 DEA ORDER FORMS (WAC 246-887-020)
2. -5 DEA INVENTORY RECORD (WAC 246-887-020)
3. N/A SCHEDULE V CS REGISTER (WAC 246-887-030)
4. ✓ RESPONSIBLE RPH MANAGER (WAC 246-869-070)
5. ✓ LAWBOOK (WAC 246-869-160)
6. ✓ REFERENCE SOURCE (WAC 246-869-160)
7. ✓ PHARMACY ANCILLARY STAFF (WAC 246-801)
8. ✓ PROFESSIONAL RESPONSIBILITIES (WAC 246-863-095)
9. -5 ALL DRUGS PROPERLY LABELED (WAC 246-869-150)
10. -5 COMPLETED PRESCRIPTION LABELS (WAC 246-869-210)
11. -5 PRESCRIPTION FILES (WAC 246-869-100)
12. -2 REGULATION COMPLIANCE (RCW 18.64.160 & 165)

UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY

SECTION C TOTAL 16

D. FACILITIES (20 POINTS)

1. N/A DIFFERENTIAL HOURS (WAC 246-869-020)
2. ✓ RX AREA SECURE FROM PUBLIC (WAC 246-869-180)
3. ✓ APPEARANCE OF STAFF (WAC 246-869-170)
4. ✓ RX AREA WORKING SPACE (WAC 246-869-180)
5. ✓ PRESCRIPTION AREA SINK (WAC 246-869-180)
6. ✓ REFRIGERATOR (WAC 246-869-180)
7. ✓ TRASH RECEPTACLES (WAC 246-869-170)
8. ✓ REST ROOMS (WAC 246-869-170)
9. ✓ GENERAL CLEANLINESS & SANITATION (WAC 246-869-150,160,& 170)
10. ✓ NECESSARY EQUIPMENT (WAC 246-869-180) TORSION #186592

UP TO 2 POINTS SUBTRACTED FOR EACH DEFICIENCY

SECTION D TOTAL 20

100 TO 90 POINTS = A

89 TO 80 POINTS = CONDITIONAL (WAC 246-863-190)

BELOW 80 POINTS = UNSATISFACTORY

COMMENTS: YES NO

GRADE TOTAL 56

Comments are set forth on the reverse side of this report.

Michael Jones RPh
Signature of Pharmacist

Stan Jorgensen
Signature of Investigator

DOH 660-012A (Rev. 6/99)

04131785

PHARMACY INSPECTION COMMENTS

The Medicine Shoppe Pharmacy — CF55751
Pharmacy Name — Location License Number

COMMENTS

B1 Six patients noted in computer system with no Allergy information. 2 of 5 patients without Disease State data. Drug-Disease State interaction module has been turned off. Pharmacist without knowledge of meaning of Drug-Drug interaction Levels or how to find definitions or meanings. PT pro fil do not Reflect what the patient Actually Received, with Additional Entries present due to billing Transactions.

B-3 Three prescriptions filled and labeled with a Manufacturer other than that Filed with. Computer Records Reflect incorrect MFR and NDC number.

B-4 41 Prescriptions on will-call shelves, only one with CRC cap. one Rx found with NON-CRC Authorization on file.

B6 Eleven items found in Prescription Shelves and Refrigerator past their expiration dates

TELEPHONE INFORMATION LIST

Washington State Board of Pharmacy
Olympia Office - (360) 236-4825
Donald H. Williams, Executive Director
Joseph M. Honda, Operations Manager
Shannon Walker, Program Manager, Facilities Licensing: (360) 236-4830
Susan Loutzenhiser, Program Manager, Individuals Licensing: (360) 236-4826

Washington State Pharmacists Association
Office - 1-800-222-WSPA (9772)

Washington Recovery Assistance Program for Pharmacy (WRAPP): 1-800-446-7220
Ruth Kerschbaum, Monitoring Program Manager

Pharmacy Board Investigator

Telephone

PHARMACY INSPECTION COMMENTS

THE MEDICINE SHOPPE PHARMACY
Pharmacy Name

Location License Number

COMMENTS

C-1 DEA forms not complete. Receiving dates not completed. New filing system improves filing sequence & Reduces Loss.

C-2 DEA Inventory for C-II drug not signed. C-II invoices filed with General Invoice Records and not ~~Readily Retrievable~~ filed separately. FIRM DEA number is not on the C-II inventory or the CIII-V inventory.

C-9 5 prescription bottles returned to prescription stock shelves, labeled with incorrect manufacturer

C-10 three prescriptions on will call shelf labeled with wrong manufacturer.

C-11 Numerous voids (Holes) found in prescription files, with 21 noted missing in two consecutive days. two prescriptions noted with a date of 00/00/00.

C-12, Computer System does not have the ability to track changes made to the prescription record. No tracking for audit purpose. poss. ble.

TELEPHONE INFORMATION LIST

Washington State Board of Pharmacy
Olympia Office - (360) 236-4825
Donald H. Williams, Executive Director
Joseph M. Honda, Operations Manager
Shannon Walker, Program Manager, Facilities Licensing: (360) 236-4830
Susan Loutzenhiser, Program Manager, Individuals Licensing: (360) 236-4826

Washington State Pharmacists Association
Office - 1-800-222-WSPA (9772)

Washington Recovery Assistance Program for Pharmacy (WRAPP): 1-800-448-7220
Ruth Kerschbaum, Monitoring Program Manager

Pharmacy Board Investigator

206-985-3715
Telephone

04131786

APPENDIX D

DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
1300 Quince Street S.E., P.O. Box 47863
Olympia, Washington 98504-7863
(360) 236-4825

for Sue Somers

RESPONDENT WRITTEN NOTICE

Date: August, 10 1999 Time: 8:15 pm

Michael S. Jones,

This notice is to inform you that the Washington State Board of Pharmacy has received a complaint alleging that:

On July 12, 1999 Investigators from the Board of Pharmacy conducted a routine periodic inspection of the Medicine Shoppe Pharmacy. At that time, the pharmacy received an extremely low, failing score of 48. Upon re-inspection on 08/10/99, the pharmacy received a failing grade of 56. You are now required to address the following issues thoroughly, completely and with sufficient detail to provide a clear response specifically directed at the questions below. Your failure to answer these questions may result in formal disciplinary action pursuant to RCW 18.130.180 (8) despite the disciplinary determination regarding the failure of the pharmacy for two successive inspections.

1. Were you aware that the pharmacy received a failing score of 48 on the previous inspection?

2. What specific actions did you take after that inspection to remedy the deficiencies noted during that inspection?

3. For what reason do you fill the majority of prescriptions in non child resistant containers, when there has been no written request by the patient or prescriber to do so?

4. Where were (are) the required records for schedule II through V Controlled substances? Include in your response the location of the schedule III-V Inventory, prescriptions, invoices, daily printouts of prescriptions filled and DEA 222 Forms.

5. Are both pharmacy and non-pharmacy related items, records, etc., stored in the storage area outside. How do you keep this area secure? Are pharmacy records stored in such a way in the storage area to protect them from damage by moisture etc. What other pharmacy related items are stored in the storage area? How do you assure that these items are stored under appropriate conditions?

page 2- Respondent Written Notice

6. Why are so many Rx hard copies missing? On 8-4-99 and 8-5-99 I compared the daily print out to the Rx file - 21 Rx numbers had no hard copy Rx. Why?

7. It appears that many patient profiles note both the date a Rx was dispensed and also the date it was billed. There are also profiles where the same Rx appears to be billed multiple times on the same day - not Why does the medication profile reflect what was actually dispensed? How can you do a Drug Utilization Review if you cannot determine when the patients actually received meds?

8. Why are there still so many outdated drugs on your stock shelves?

9. Why are you still unable to get the proper manufacturer (the one that was actually dispensed) on the Rx label and into the computer?

10. Why did you fail to go back and complete the DEA 222 forms and why did you fail to sign the CII inventory and include the pharmacy DEA # on either the CII or the CIII-V inventory?

An investigation has been initiated under the authority of the Uniform Disciplinary Act, Revised Code of Washington (RCW) Chapter 18.130.

You may consult with an attorney, at your expense, prior to making a written statement. Your statement may be used in a hearing if disciplinary action is deemed necessary in this matter.

Acknowledgment:

I received this notice from Phyllis Wene before providing my written statement.

Signed: [signature] RPh.
Respondent

APPENDIX E

RESPONDENT STATEMENT INSTRUCTIONS

Please be advised that you have the right to consult with an attorney at your expense before providing a response, and that any statement you make can be used in a hearing if disciplinary action is deemed necessary under RCW 18.130.

Under the provisions of RCW 18.130.180(8)(b), you are required to cooperate with the disciplining authority (licensing board) by furnishing in writing a full and complete explanation covering the matter contained in the complaint filed with the disciplining authority.

You may either hand write or type your statement. If there are any typo's or errors, please initial them. Begin the statement by filling in your name on the first line after: "I, _____".

Before you begin your narrative, you must identify who you are by providing your name, date of birth, where you work and live. You may do this by writing the following: "**I am (your name, date of birth). I am employed as a (your occupation & title) at (business name, address, telephone number). I reside at (home address, telephone number).**"

Then begin your statement. When supplying statements be as specific as you can. For example, supply specific names, dates, times, and circumstances when known. Keep in mind that the information you are providing will raise the questions of who, what, when, where, why, and how in the reader's mind. If you can supply answers to those questions, please do. Do not write on the back side of a page. **If you need more pages you may photocopy as many additional pages as you will need.**

Do not sign or complete any of the lines on the bottom of the statement forms until you are ready to have your signature witnessed. You may do this in one of three ways:

1. Any two individuals may witness your signature(s) and they must also sign on the appropriate lines.
2. Have your signature(s) witnessed by a notary and each page of the statement notarized.
3. Have your attorney or the investigator present to witness your signature(s).

You must sign each page, and initial where indicated, in the presence of your witness/es and have their signatures on each page.

Please provide a full and complete explanation concerning the following matter and/or allegation(s):

See Respondent written Notice

If you have any questions please give me, Phyllis Wene, a call at (425) 649-4359. If there are any other individuals who may have something to contribute, please provide them with copies of the statement forms and these instructions. I must ask that you return your statement to my office no later than 8-16-99.

STM-IN-R.FRM 3/96

APPENDIX F

RECEIVED
NOV 03 2005
BROWNLIE EVANS WOLF & LEE

STATE OF WASHINGTON
SNOHOMISH COUNTY SUPERIOR COURT

MICHAEL S. JONES, R.Ph., Plaintiff, v. STATE OF WASHINGTON; STATE OF WASHINGTON, DEPARTMENT OF HEALTH; STATE OF WASHINGTON, DEPARTMENT OF HEALTH, BOARD OF PHARMACY; PHYLLIS WENE; and STAN JEPPESEN, individually and as investigators for the Washington State Board of Pharmacy, and DONALD WILLIAMS, individually and as executive director of the Board of Pharmacy, Defendants.	NO. 02-2-08819-6 DECLARATION OF DONALD WILLIAMS

I, Donald Williams, declare as follows:

1. I am over the age of 18 years, am competent to testify, and have personal knowledge of the matters stated herein.

2. I am currently retired. From August 3, 1981 until July 31, 2004, I was employed by the State of Washington Board of Pharmacy as Executive Director. As Executive Director, it was my responsibility to review information obtained by pharmacy investigators to determine

COPY

ATTORNEY GENERAL OF WASHINGTON
Tort Claims Division
900 Fourth Avenue Ste 2200
Seattle, WA 98146-1012
(206) 464-7352

whether pharmacists had engaged in unprofessional conduct such that disciplinary action was necessary.

3. WAC 246-869-190 provides that all pharmacies in Washington shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy. Whenever a pharmacy is inspected, the investigator who performs the inspection completes a standard scoring form called a pharmacy inspection report. After completing the report, the investigator gives the pharmacy an inspection score between 0 and 100. The report lists the criteria that the investigator considers when inspecting the pharmacy and giving it an inspection score. These criteria are divided into four general sections. Section A consists of "general requirements," which account for 10 of the available 100 points the pharmacist may receive. Section B consists of requirements pertaining to "patient health and safety requirements," which account for 30 of the available 100 points. Section C consists of requirements pertaining to "professional requirements," which account for 40 of the available 100 points. Finally, Section D consists of requirements pertaining to "facilities," which accounts for 20 of the available 100 points.

4. On July 12, 1999, pharmacy investigator Stan Jeppesen and former pharmacy investigator Phyllis Wene conducted an inspection of the Medicine Shoppe pharmacy in Marysville, Washington, which was owned and operated by Michael Jones, the plaintiff in this lawsuit. Mr. Jeppesen completed a pharmacy inspection report regarding this July 1999 inspection and provided it to me for review. Attached hereto as Exhibit 1 is a true and correct photocopy of the pharmacy inspection report that Mr. Jeppesen authored regarding his and Ms. Wene's July 1999 inspection of Mr. Jones' pharmacy. Attached hereto as Exhibit 2 is a true and correct photocopy of a memorandum that Mr. Jeppesen wrote regarding the same inspection. Portions of Exhibit 2 that contain confidential information have been redacted.

5. The records in Exhibits 1 and 2 are created and maintained by the Department of Health in the ordinary course of business. These records document alleged violations

ATTORNEY GENERAL OF WASHINGTON
Tort Claims Division
900 Fourth Avenue Ste 2200
Seattle, WA 98146-1012
(206) 464-7352

committed by Mr. Jones of statutes and regulations governing the practice of pharmacy, including the following:

- CRC Compliance. WAC 246-869-230 and federal laws referenced therein require that all legend drugs be dispensed in a child-resistant container, unless an authorization is received by the pharmacist from the patient, the patient's representative, or the prescriber. According to Mr. Jeppesen's account, Mr. Jones could not locate Non-CRC authorizations for many patients to whom he was dispensing legend drugs in non-complying containers.
- Outdated/Deteriorated Stock. WAC 246-869-150 requires that any merchandise which has exceeded its expiration date must be removed from stock. Mr. Jeppesen's report indicated that there were 38 products, in Mr. Jones' prescription drug stock, with expiration dates that had passed.
- DEA Order Forms and Inventory and Prescription Records. WAC 246-887-020(3) requires every pharmacist who dispenses controlled substances to keep inventory records, including records of receipt and distribution of the controlled substances, for a period of two years from the date of purchase. In addition, WAC 246-869-100 requires that original prescription and refill records be maintained for a period of at least two years. Mr. Jeppesen indicated in his report that there were many holes in Mr. Jones' inventory and prescription records, and that many requested records could not be located, even after the investigators allowed Mr. Jones an additional day to find them.
- Pharmacy Ancillary Staff. WAC 246-901-090 requires that all pharmacy ancillary personnel having contact with patients or the general public must wear badges or name tags clearly identifying them as pharmacy assistants or technicians. Mr. Jeppesen indicated that Mr. Jones' Level-B assistant, Shannon Boston, was not wearing the required name badge.

ATTORNEY GENERAL OF WASHINGTON
Tort Claims Division
900 Fourth Avenue Ste 2200
Seattle, WA 98146-1012
(206) 464-7352

Based on these and other violations, Mr. Jones received a failing score of 48 at the July 1999 inspection of his pharmacy, as indicated in Exhibit 1.

6. WAC 246-869-190(5) provides that whenever a pharmacist receives an unsatisfactory inspection score (a score below 80), he must increase his score to a satisfactory score (a score of 90 or better) within 14 days. On August 10, 1999, Investigator Jeppesen conducted a reinspection of Mr. Jones' pharmacy. Attached hereto as Exhibit 3 is a true and correct photocopy of the pharmacy inspection report that Mr. Jeppesen authored regarding his August 1999 inspection of Mr. Jones' pharmacy. The records in Exhibit 3 are created and maintained by the Department of Health in the ordinary course of business.

7. The records in Exhibit 3 document alleged violations committed by Mr. Jones of statutes and regulations governing the practice of pharmacy, including the following:

- Patient Medical Records. WAC 246-875-001 requires that a pharmacist maintain either a manual or an automated patient medical record system. WAC 246-875-020 sets forth the minimum requirements for an automated system. It requires that an automated system maintain information on "[a]ny patient allergies, idiosyncarasies, or chronic condition which may relate to drug utilization." In addition, WAC 246-875-040 requires that an automated patient medication record system "determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication...". Mr. Jeppesen's report indicated that Mr. Jones was failing to obtain chronic conditions and allergies on patients of the pharmacy and that Mr. Jones was without knowledge of the meaning of drug-drug interaction levels and could not find definitions or meanings. Mr. Jeppesen also indicated in his report that the drug-disease state drug interaction checking module on the automated system Mr. Jones was utilizing was turned off. Also, Mr. Jeppesen indicated that the patient profiles on Mr. Jones' computer system did not reflect what drugs the patient actually received.

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- WAC 246-875-040 provides that a patient medication record system be able to document changes in drug name, dose, route, dose form or directions for use which occurs after an initial dose has been given without destroying the original record. It thus requires that such a system have an "audit trail" to document any such changes and the persons responsible for making them. Mr. Jeppesens' report indicated that Mr. Jones' computer system did not appear to have the ability to track changes made to a patient's prescription record. The report also indicated that it appeared no tracking for purposes of an audit trail was possible with Mr. Jones' system at the August 1999 inspection.
- Drug Product Substitution. RCW 69.41.200 requires proper labeling of legend drugs. In addition, WAC 246-899-020 provides that if a pharmacist dispenses a "therapeutically equivalent drug product" to the one actually prescribed by the patient's physician, the pharmacist must note the manufacturer or distributor of the drug product actually dispensed on the permanent record or patient medication record. Mr. Jeppesen's report indicated that three prescriptions dispensed by Mr. Jones were filled and labeled with a manufacturer that did not match the manufacturer reflected in Mr. Jones' computer records.
- CRC Compliance. WAC 246-869-230 and federal laws referenced therein require that all legend drugs be dispensed in a child-resistant container, unless an authorization is received by the pharmacist from the patient, the patient's representative, or the prescriber. Mr. Jeppesen's report indicates that he and Ms. Wene found 41 prescriptions that were on Mr. Jones' will-call shelf, that all but one of these were in non-CRC containers, and that Mr. Jones could locate a corresponding patient authorization for only one of these prescriptions.

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- Outdated/Deteriorated Stock. WAC 246-869-150 requires that any merchandise which has exceeded its expiration date must be removed from stock. Mr. Jeppesen's report indicated that he and Ms. Wene located eleven items on Mr. Jones' prescription shelves and in the refrigerator for which the expiration dates had passed.
- DEA Order Forms. WAC 246-887-020(3) requires every pharmacist who dispenses controlled substances to keep inventory records, including records of receipt and distribution of the controlled substances, for a period of two years from the date of purchase. Among the records covered by this regulation are DEA order forms. Mr. Jeppesen's report indicated that Mr. Jones' DEA forms were not complete. Specifically, the report indicated that the receiving dates were not completed on some of the forms.
- DEA Inventory Record. WAC 246-869-100 requires that original prescription and refill records be maintained for a period of at least two years. The DEA inventory for C-II drugs was not signed and that other records requested were not easily located due to Mr. Jones' filing system.
- All Drugs Properly Labeled and Completed Prescription Labels. WAC 246-869-150 requires that all stock and materials must be properly labeled according to federal and state statutes, rules and regulations. Accordingly, a prescription's container must indicate the correct manufacturer for the medication it contains. Mr. Jeppesen's report indicated that five prescription bottles on Mr. Jones' prescription stock shelves and three prescriptions on his will-call shelf had been labeled with incorrect manufacturer information.
- Prescription Files. WAC 246-869-100 provides that a pharmacist must maintain original prescription and refill records for at least two years. Mr. Jeppesen's report indicated that there were numerous holes found in Mr. Jones' prescription files. He noted 21 missing records in reviewing Mr. Jones' records for two consecutive days. In

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addition, he noted two records indicated 00/00/00 as a date when prescriptions had been dispensed, which is obviously an invalid date.

Based on these and other violations, Mr. Jones received a failing score of 56 at the August 1999 inspection of his pharmacy, as indicated in Exhibit 3.

8. Following Investigators Jeppesen and Wene's August 1999 reinspection of Mr. Jones' pharmacy, I reviewed the records that are attached to this declaration as Exhibits 1, 2, and 3. I concluded that the violations documented by the investigators warranted summary action against Mr. Jones' pharmacy license and pharmacy location license. Accordingly, on August 16, 1999, I filed an ex parte motion for summary action against Mr. Jones' licenses. A true and correct photocopy of the ex parte motion for summary action is attached to this declaration as Exhibit 4.

9. On August 16, 1999, I also filed a Statement of Charges against Mr. Jones. A true and correct photocopy of this Statement of Charges is attached to this declaration as Exhibit 5.

10. I did not sign any declaration or affidavit attesting to the truth of any facts supporting the summary suspension motion in Exhibit 4 or the Statement of Charges in Exhibit 5. Rather, I attached Mr. Jeppesen's July and August 1999 inspection reports regarding Mr. Jones' pharmacy to the summary suspension motion in Exhibit 4. The Statement of Charges in Exhibit 5 merely reflects that the allegations contained therein were supported by evidence contained in the case files against Mr. Jones.

11. On August 17, 1999, the Pharmacy Board granted my ex parte motion for a summary suspension of Mr. Jones' licenses. A true and correct photocopy of the Pharmacy Board's order granting this motion is attached to this declaration as Exhibit 6.

12. Attached to this declaration as Exhibit 7 is a true and correct photocopy of a Notice for Opportunity for Settlement and Hearing regarding the Statement of Charges I filed against Mr. Jones' licenses.

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13. Attached to this declaration as Exhibit 8 is a true and correct photocopy of a Declaration of Service by Personal Service, which is signed by Phyllis Wene. This Declaration indicates that Ms. Wene personally served Mr. Jones with copies of the Notice for Opportunity of Settlement and Hearing and the Order of Summary Suspension.

14. On August 30, 1999, Mr. Jones, through his attorney, Bernard Bauman, filed a motion to modify the Pharmacy Board's Order of Summary Suspension. A true and correct photocopy of Mr. Jones' motion to stay the Order of Summary Suspension is attached to this declaration as Exhibit 9. In support of the motion to modify the Order of Summary Suspension, Mr. Jones and his attorney filed declarations for the Pharmacy Board's consideration. A true and correct coy of Mr. Jones' declaration, dated August 27, 1999, is attached to this declaration as Exhibit 10. A true and correct copy of the declaration of Mr. Jones' attorney, Bernard Bauman, dated August 27, 1999, is attached to this declaration as Exhibit 11.

15. In Exhibits 10 and 11, Mr. Jones and Mr. Bauman confirmed many of the problems identified by the investigators in the July and August 1999 inspection reports, and they represented to the Pharmacy Board that Mr. Jones had corrected these problems. Among the issues Mr. Jones and Mr. Bauman acknowledged in their declarations are the following:

- Mr. Jones confirms in Paragraph 1 of Exhibit 10 that the disease state-drug interaction fields of his automated patient medical records system were indeed not turned on until the investigators brought the issue to his attention at the August 1999 inspection, prompting him to call the computer vendor to turn this function on. Mr. Bauman similarly confirmed this allegation in Paragraph 1 of Exhibit 11. Without this function being turned on, Mr. Jones would not receive warnings of potentially fatal allergic reactions of patients to whom he was dispensing prescription drugs.

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- Mr. Jones confirmed in Paragraph 2 of Exhibit 10 that many prescriptions on his shelves at the August 1999 inspection displayed incorrect National Drug Code (NDC) identifying numbers, and that these prescriptions had remained on his shelf since the inspectors' July 1999 inspection. Mr. Bauman similarly confirmed this allegation in Paragraph 2 of Exhibit 11, representing that Mr. Jones had been in the process of correcting this problem when the investigators conducted their August 1999 inspection.
- Mr. Jones also confirmed in Paragraph 3 of Exhibit 10 that he had been unable to locate authorization signatures for many patients to whom he was dispensing medications in non-CRC containers. While he maintained that he had obtained the authorizations, he had been unable to locate them because his records had previously not been organized for ease of reference. Similarly, Mr. Bauman confirmed in Paragraph 3 of Exhibit 11 that Mr. Jones' "record keeping system for the signatures did not allow for one to readily verify specific signatures." Both Mr. Jones and Mr. Bauman then represented to the Board in their declarations that this problem had been corrected.
- In Paragraph 4 of Exhibit 10, Mr. Jones acknowledged that there had been outdated legend and over-the-counter products on his shelves, and that he had had these outdated products removed. Similarly, in Paragraph 4 of Exhibit 11, Mr. Bauman acknowledged that with respect to the allegations that Mr. Jones had outdated drugs on his shelves that "a few products slipped through the cracks..." Again, they then represented to the Board that this issue had been corrected.
- Mr. Jones acknowledged in Paragraph 5 of Exhibit 10 that many records of controlled substance inventories, invoices, DEA forms, and other prescription records that were requested by the investigators could not be located at the time of his August 1999 inspection. He represented to the Board that the records were later located. Mr. Bauman similarly represented in Paragraph 5 of Exhibit 11 that "the situation has been

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corrected and it will not happen again due to the institution of new record-keeping procedures."

16. After considering the materials in Exhibits 9, 10, and 11, the Pharmacy Board denied Mr. Jones' motion to modify the Order of Summary Suspension on September 7, 1999. A true and correct photocopy of the Pharmacy Board's order denying Mr. Jones' motion to modify the Order of Summary Suspension is attached to this declaration as Exhibit 12.

17. On October 22, 1999, I completed an Amended Statement of Charges against Mr. Jones, and the Amended Statement of Charges was filed on October 26, 1999. A true and correct photocopy of the Amended Statement of Charges is attached to this declaration as Exhibit 13. Just as with the initial Statement of Charges, I again did not sign any declaration or affidavit attesting to the facts supporting the Amended Statement of Charges. Rather, the Amended Statement of Charges reflects that the allegations it contains are supported by evidence contained in the program case files pertaining to Mr. Jones.

18. On October 22, 1999, I also completed a new Notice of Opportunity for Hearing. A true and correct photocopy of the Notice of Opportunity for Hearing is attached to this declaration as Exhibit 14. Attached hereto as Exhibit 15 is a true and correct copy of a Declaration of Service signed by Georgia Robinson-Sage, an administrative assistant. Her declaration indicates that both the Amended Statement of Charges and the Notice of Opportunity for Settlement and Hearing were mailed to both Mr. Jones and his attorney, Mr. Bauman, on October 25, 1999.

19. Initially, Mr. Jones contested the allegations in the Statement of Charges and Amended Statement of Charges. A true and correct photocopy of Mr. Jones' answer to the initial Statement of Charges is attached to this declaration as Exhibit 16. A true and correct photocopy of Mr. Jones' answer to the Amended Statement of Charges is attached to this declaration as Exhibit 17.

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20. On January 11, 2000, Mr. Jones and his attorney, Bernard Bauman, both signed stipulated findings of fact, conclusions of law, and an agreed order, resolving the disciplinary actions relating to the July and August 1999 inspections of Mr. Jones' pharmacy. A true and correct photocopy of the findings of fact, conclusions of law, and agreed order is attached hereto as Exhibit 18.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

DATED this 10th day of October, 2005 at Bellevue, Washington

Donald Williams

DONALD WILLIAMS

ATTORNEY GENERAL OF WASHINGTON
Tort Claims Division
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DECLARATION OF SERVICE

I declare that I caused a copy of this document to be served on all parties or their counsel of record on the date below as follows:

☒ US Mail Postage Prepaid via Consolidated Mail Service to
Murphy Evans
Brownlie, Evans, & Wolf, LLP
100 Central Avenue
Bellingham, Washington 98225

☐ ABC/Legal Messenger

☐ State Campus Delivery

☐ Hand delivered by _____

I declare under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.

DATED this 2 day of November, 2005, at Seattle, WA.

Brittany Breese
BRITTANY BREESE

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Exhibit 4

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF EX PARTE MOTION FOR ORDER OF SUMMARY ACTION

The Executive Director of the Washington State Department of Health, Board of Pharmacy, by and through David M. Hankins, Assistant Attorney General, moves for an Order of Summary Action against Respondent based upon the facts alleged below. The Executive Director does not request oral argument in support of this motion. This motion is based on the following:

BASIS OF THE MOTION

The Board of Pharmacy is authorized under RCW 34.05.422(4) and RCW 34.05.479 of the Administrative Procedure Act and RCW 18.130.050(7) of the Uniform Disciplinary Act to issue an order of summary action.

1.1 Respondent Michael S. Jones was issued a license to practice pharmacy in the state of Washington in June 1980. Respondent's license to practice pharmacy in the state of Washington expires on October 29, 1999.

1.2 Respondent Medicine Shoppe Pharmacy located at 9430 State Street in Marysville, Washington was issued a location license to operate as a Pharmacy in the state of Washington in October 1996. The current location license expires on June 1, 2000.

1.3 Respondent Michael Jones is the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

1.4 On March 1, 1994, a Statement of Charges was issued against Respondent Michael Jones related to a prescription filling error while Respondent was working as a pharmacist at Safeway Pharmacy # 497 in Seattle, Washington

1.5 On July 6, 1994, the Board entered Findings of Fact, Conclusions of Law and Order placing Respondent's license to practice pharmacy in the state of Washington on probation for a period of one year and imposing certain terms and conditions. One of the conditions imposed on Respondent was a requirement that Respondent create and submit a plan to avoid violations of pharmacy law related to the filling of prescriptions.

1.6 On December 7, 1995, Respondent's license to practice pharmacy in the state of Washington was fully reinstated.

1.7 On December 17, 1998, Respondent Medicine Shoppe received a failing inspection grade of 79 from Board of Pharmacy Investigator Wene while conducting a routine inspection of the pharmacy. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations observed during the inspection may be seen in detail in the Statement of Charges and on the Inspection sheet and report attached as Exhibit 1.

1.8 An inspection score of 90-100 is classified as a passing pharmacy inspection score. An inspection score of 80-89 is classified as a conditional pharmacy inspection score. An inspection score of 0-79 is classified as an unsatisfactory (failing) inspection score.

1.9 On February 3, 1999, Board of Pharmacy Investigator Wene conducted a re-inspection in relation to the December 1998 failing score. During the February 3, 1999 inspection, the pharmacy received a passing score of 94. The deducted points were related to inaccurate, incomplete or missing records required by state or federal law. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington The report of this inspection is attached as Exhibit 2.

1.10 On July 12, 1999, Board of Pharmacy Investigators Wene and Jeppesen conducted a routine inspection of the Medicine Shoppe Pharmacy in Marysville. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The pharmacy received an unsatisfactory extremely low failing grade of 48. The violations observed during the inspection may be seen in detail in the Statement of Charges and on the Inspection sheet and report attached as Exhibit 3.

1.11 On July 13, 1999, Investigator Jeppesen returned to the pharmacy to retrieve documents promised by Respondent Jones. At that time Respondent Jones stated he could not located the documents. Respondent stated that his computer could generate the required reports but that he, Respondent, did not know how to generate them. Investigator Jeppesen's report of this matter is attached as Exhibit 4.

1.12 On August 10, 1999, Investigators Wene and Jeppesen returned to the Medicine Shop Pharmacy in Marysville, Washington, to conduct the re-inspection in relation to the July 12, 1999 unsatisfactory (failing) score. This inspection again resulted in an extremely low failing score of 56. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations observed during the inspection may be seen in detail in the Statement of Charges and on the Inspection sheet and report attached as Exhibit 5.

1.13 Respondent Michael S. Jones operated the Medicine Shoppe in a manner below the standard of care for the operation of a pharmacy in the state of Washington and therefore placed the patient of his pharmacy at serious risk of significant harm.

1.14 Due to the condition of the pharmacy, especially the violations related to record-keeping, Summary Suspension of both Respondent Jones and the Medicine Shoppe Pharmacy is the least restrictive means of protecting the pharmacy. The pharmacy is not in an operable condition to allow another pharmacist to operate the Pharmacy in respondent Jones' absence.

NECESSARY ACTION

Based on the above, the Executive Director respectfully requests the Board of Pharmacy issue an Order summarily suspending the Respondent's license to practice pharmacy and the pharmacy location license. This is the least restrictive action due to the number and type of violations in the pharmacy.

DATED this 16th day of August 1999.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

DONALD H. WILLIAMS
EXECUTIVE DIRECTOR

David M. Hankins, WSBA #19194
Assistant Attorney General Prosecutor

FOR INTERNAL USE ONLY. INTERNAL TRACKING NUMBERS:
99020003, 99040002, 99040004, 99050003, 99020071

Exhibit 5

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993 In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No.55751, Respondents.	)	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF STATEMENT OF CHARGES

Donald H. Williams, Executive Director of the Washington State Department of Health, Board of Pharmacy on designation by the Board of Pharmacy makes the allegations below which are supported by evidence contained in program case file(s) No. 99020071, 99020003, 99040002, 99040004, 99050003.

Section 1: ALLEGED FACTS

1.1 Respondent Michael S. Jones was issued a license to practice pharmacy in the state of Washington in June 1980. Respondent's license to practice pharmacy in the state of Washington expires on October 24, 1999.

1.2 Respondent Medicine Shoppe Pharmacy located at 9430 State Avenue, Marysville, Washington was issued a location license to operate as a pharmacy in the state of Washington in October 1996. The current location license expires on June 1, 2000.

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1.3 Respondent Michael Jones is the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

1.4 On March 1, 1994, a Statement of Charges was issued against Respondent Michael Jones related to a prescription filling error while Respondent was working as a pharmacist at Safeway Pharmacy # 497 in Seattle, Washington

1.5 On July 6, 1994, the Board entered a Findings of Fact, Conclusions of Law and Order placing Respondent's license to practice pharmacy in the state of Washington on probation for a period of one year and imposing certain terms and conditions. One of the conditions imposed on Respondent was a requirement that he create and submit a plan to avoid violations of pharmacy law related to the filling of prescriptions.

1.6 On December 7, 1995, Respondent's license to practice pharmacy in the state of Washington was fully reinstated.

1.7 In approximately November 1996, Respondent Jones purchased and operated The Medicine Shoppe in Marysville, Washington.

1.8 On December 17, 1998, Respondent Medicine Shoppe received a failing inspection grade of 79 from Board of Pharmacy Investigator Wene while conducting a routine inspection of the pharmacy. An inspection score of 90-100 is classified as a passing pharmacy inspection score. An inspection score of 80-89 is classified as a conditional pharmacy inspection score. An inspection score of 0-79 is classified as a failing pharmacy inspection score. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations included but were not limited to:

1.8.1 Failing to obtain chronic conditions on patients of the pharmacy;

1.8.2 Dispensing the majority of prescriptions in non child-resistant containers without a written request from either the patient or the prescriber;

1.8.3 Various required records required by state and federal law were either inaccurate, incomplete or not available;

1.8.4 There was a box of filled prescription containers, many unlabeled, on the floor of the pharmacy.

1.8.5 Investigator Wene discovered a prescription filling error in the will call area. A prescription for [redacted] was incorrectly filled with [redacted]

1.8.6 Many of the prescriptions in the will call area had labeled expiration dates exceeding the manufacturer's expiration date;

1.8.7 Most of the prescriptions in the will call area contained the incorrect NDC number for the product in the prescription container;

1.9 On February 3, 1999, Board of Pharmacy Investigator Wene conducted a re-inspection in relation to the December 1998 failing score. During the February 3, 1999 inspection, the pharmacy, received a passing score of 94. The deducted points were related to inaccurate, incomplete or missing records required by state or federal law. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

1.10 On July 12, 1999, Board of Pharmacy Investigators Wene and Jeppesen conducted a routine inspection of the Medicine Shoppe Pharmacy in Marysville. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The pharmacy received an extremely low failing grade of 48. At that time the violations included but were not limited to:

1.10.1 Failing to obtain chronic conditions and allergies on patients of the pharmacy. Disease state management is coded in ICD-9 codes and provides the information in coded form, not readily readable by the Pharmacist.

1.10.2 Numerous (greater than 10) prescriptions were labeled with a different generic product than indicated on the label or NDC Code. Several of these prescriptions were dispensed in the presence of the Board of Pharmacy Investigators.

1.10.3 Dispensing the majority (in excess of 90%) of prescriptions in non child- resistant containers without a written request from either the patient or the prescriber for non child-resistant packaging.;

1.10.4 Thirty eight (38) drug products were outdated. Of those, 18 drugs were legend or controlled substances and 20 were OTC products.

1.10.5 Various records required by federal law (DEA) were either inaccurate, incomplete or not available. DEA order forms and invoices could not be reconciled. Respondent was unable to locate several required DEA forms. There was poor organization of DEA inventory records, including non-sequential filing. Several DEA records did not include date and amount received on DEA 222 forms.

1.10.6 DEA Inventory incomplete, DEA inventory for Schedules III-V was missing. Respondent was unable to generate reports for Schedule II drugs. The daily refill reports were not signed, stored in various locations, out of sequence, with several months not located.

1.10.7 Facts and Comparisons, the only reference source in the pharmacy, had not been updated for at least nine (9) months.

1.10.8 Pharmacy Assistant did not have a name badge and none had been ordered. No Pharmacy Assistant certificate had been generated or signed. Modifications to the Pharmacy Assistant Utilization Plan were in place without Board approval.

1.10.9 The prescription records were inaccurate, missing and poorly organized. Examples include prescription files with non-sequential order. Several prescriptions, both C-II and other drugs were unaccounted for. Prescription files were kept with no organization. Respondent Jones was unable to locate files in a timely manner.

1.10.10 Minimum procedures for utilization of the patient medication system were inadequate.

1.10.11 During the inspection, a patient returned a prescription so that Respondent Jones could correct the instructions for use. The correction was made but no audit trail of the change was entered in the pharmacy computer

1.10.12 The pharmacy was generally disorganized and dirty. The pharmacy sink and immediate area were dirty and with numerous dirty food dishes.

1.11 On July 13, 1999, Investigator Jeppesen returned to the pharmacy to retrieve documents promised by Respondent Jones. At that time Respondent Jones stated he could not locate the documents. Respondent stated that his computer could generate the required reports but that he, (Respondent) did not know how to generate them.

1.12 On August 10, 1999, Investigators Wene and Jeppesen returned to the Medicine Shop Pharmacy in Marysville, Washington, to conduct the re-inspection in relation to the July 12, 1999 failing score. This inspection again resulted in an extremely low failing score of 56. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed

as working at the Medicine Shoppe in Marysville, Washington. At that time the violations included but were not limited to:

1.12.1 Six prescriptions selected randomly in the will call area did not have allergy or chronic conditions noted in the patient profile. The disease state - drug interaction fields had been turned off. Respondent Jones was unable to explain the purpose or the clinical significance of the clinical interaction levels that appeared for drug interaction messages.

1.12.2 Three prescriptions selected randomly from the will call area were labeled with a different generic product than indicated on the label and/or NDC Code.

1.12.3 Forty one (41) prescriptions were located in the will call area. Of those, forty (40) were packaged in non child-resistant containers and the one that was in a child resistant container was in a container supplied by the manufacturer.

1.12.4 Eleven legend or controlled substances on the shelf were beyond the manufacturer's expiration date.

1.12.5 As in the July 12, 1999 inspection, various records required by federal law (DEA) were either inaccurate, incomplete or not available. The invoices for the C II drugs were not filed separately. Several DEA records did not include date and amount received on DEA 222 forms.

1.12.6 DEA Inventory records incomplete. There was no signature on the C-II, C-III - C-V inventories. Requested records could not be located.

1.12.7 Five prescriptions which had been filled and returned to the stock area were checked for accuracy of product on the label and against correct NDC numbers. All five prescriptions failed to comply with state and/or federal law.

1.12.8 Minimum procedures for utilization of the patient medication system were inadequate. The pharmacy QS-1 system was not able to create an accurate and complete audit trail for changes made to the prescriptions after filling including directions for use and drug dispensed.

1.12.9 During the period August 4, 1999 through August 5, 1999, forty-eight prescriptions were processed in the pharmacy. Of those forty-eight prescriptions, twenty-one did not have a hard copy in the patient's files.

1.13 Respondent Michael S. Jones operated the Medicine Shoppe Pharmacy in a manner below the standard of care for the operation of a pharmacy and therefore placed the patients of his pharmacy at serious risk of significant harm.

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action pursuant to RCW 18.64.160 and RCW 18.130.180 and the imposition of sanctions under RCW 18.64.165 and RCW 18.130.160.

2.2 The allegations contained in paragraph 1.8 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(7); WAC 246-869-190.

2.3 The allegations contained in paragraph 1.8.1 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6),(7), RCW 18.64.165(2); WAC 246-875-020, WAC 246-875-040, WAC 246-863-095(f).

2.4 The allegations contained in paragraph 1.8.2 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-869-230, WAC 246-863-095(f).

2.5 The allegations contained in paragraph 1.8.3 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.64.165(2), RCW 18.64.245, RCW 69.50.306, RCW 18.130.180(4),(6), (7); WAC 246-863-110, WAC 246-875-020.

2.6 The allegations contained in paragraph s 1.8.4 through 1.8.7 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6),(7), RCW 18.64.165(2), RCW 18.64.246, RCW 18.64.270, RCW 69.04.450, RCW 69.04.490, RCW 69.04.510; RCW 69.41.042, RCW 69.41.050; WAC 246-863-095(f), WAC 246-869-130, WAC 246-869-150, WAC 246-869-210, WAC 246-875-020, WAC 246-875-040.

2.7 The allegations contained in paragraph 1.9 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(7), RCW 69.50.306; WAC 246-869-190, WAC 246-863-110.

2.8 The allegations contained in paragraph 1.10 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine

Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(7); WAC 246-869-190.

2.9 The allegations contained in paragraph 1.10.1 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4), (6), (7); RCW 18.64.165(2), RCW 18.64.245, RCW 18.64.246; WAC 246-863-095(f), WAC 246-875-020, WAC 246-875-040.

2.10 The allegations contained in paragraph s 1.10.2 through 1.10.7 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4), (6), (7), RCW 18.64.165(2), RCW 18.64.245, RCW 18.64.246, RCW 18.64.270, RCW 69.04.450, RCW 69.04.490, RCW 69.04.510, RCW 69.41.042, RCW 69.41.050, WAC 246-863-095(f), WAC 246-869-130, WAC 246-869-150, WAC 246-869-210, WAC 246-875-020, WAC 246-875-040.

2.11 The allegations contained in paragraph 1.10.3 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to WAC 246-869-230.

2.12 The allegations contained in paragraph s 1.10.5, 1.10.6, 1.10.9, 1.11, 1.12.5, 1.12.6 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 69.50.306, WAC 246-863-110.

2.13 The allegations contained in paragraph 1.10.8 and 1.10.9 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-901-080(2), WAC 246-901-090, WAC 246-901-100(3).

2.14 The allegations contained in paragraph 1.10.10 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-875-020.

2.15 The allegations contained in paragraph 1.10.11 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2),RCW 18.64.245, RCW 18.64.246, RCW 18.64.270, RCW 69.41.042, WAC 246-869-230, WAC 246-863-110.

2.16 The allegations contained in paragraph 1.10.12 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-869-160(5).

2.17 The allegations contained in paragraph 1.11 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-875-020, WAC 246-875-040.

2.18 The allegations contained in paragraph 1.12 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(7); WAC 246-869-190.

2.19 The allegations contained in paragraph 1.12.1 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-863-095(f).

2.20 The allegations contained in paragraph 1.12.2 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); RCW 18.64.246, RCW 18.64.270, RCW 69.04.450, RCW 69.04.490, RCW 69.04.510, RCW 69.41.042, RCW 69.41.050; WAC 246-836-095(f), WAC 246-869-130, WAC 246-869-150, WAC 246-869-210, WAC 246-869-230.

2.21 The allegations contained in paragraph 1.12.3 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2), WAC 246-863-095(f), WAC 246-869-230.

2.22 The allegations contained in paragraph 1.12.4 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington

pursuant to RCW 18.130.180(4), (6), (7), RCW 18.64.165(2); WAC 246-863-095(f), WAC 246-869-130, WAC 246-869-150.

2.23 The allegations contained in paragraph 1.12.5 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4), (6), (7), RCW 18.64.165(2).

2.24 The allegations contained in paragraph 1.12.6 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4), (6), (7), RCW 18.64.165(2).

2.25 The allegations contained in paragraph 1.12.7 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4), (6), (7), RCW 18.64.165(2), RCW 18.64.270, RCW 69.04.450, RCW 69.04.490, RCW 69.04.510, RCW 69.41.050, RCW 69.41.042; WAC 246-836-095(f).

2.26 The allegations contained in paragraph 1.12.8 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4), (6), (7), RCW 18.64.165(2).

2.27 The allegations contained in paragraph 1.12.9 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington

pursuant to RCW 18.130.180(4),(6), (7), RCW 18.64.165(2); WAC 246-875-020, WAC 246-875-040.

2.28 The allegations contained in paragraph 1.13 above constitute unprofessional conduct and are grounds for disciplinary action against Respondents' Michael Jones and the Medicine Shoppe licenses to practice pharmacy and/or as a pharmacy in the state of Washington pursuant to RCW 18.130.180(4),(6), (7).

> (5) He or she has compounded, dispensed, or caused the compounding or dispensing of any drug or device which contains more or less than the equivalent quantity of ingredient or ingredients specified by the person who prescribed such drug or device: PROVIDED, HOWEVER, That nothing herein shall be construed to prevent the pharmacist from exercising professional judgment in the preparation or providing of such drugs or devices.

RCW 18.64.160(5).

> The board shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor upon proof that:
> (2) The licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the board of pharmacy or has been convicted of a felony.

RCW 18.64.165(2).

> **Every proprietor or manager of a pharmacy shall keep readily available a suitable record of prescriptions which shall preserve for a period of not less than two years the record of every prescription dispensed at such pharmacy which shall be numbered, dated, and filed, and shall produce the same in court or before any grand jury whenever lawfully required to do so. The record shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy. All record-keeping requirements for controlled substances must be complied with. Such record of prescriptions shall be for confidential use in the pharmacy, only. The record of prescriptions shall be open for inspection by the board of pharmacy or any officer of the law, who is authorized to enforce chapter 18.64, 69.41, or 69.50 RCW.**

RCW 18.64.245.

> **To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the pharmacy wherein the prescription is compounded, the corresponding serial number of the prescription, the name of the prescriber, his directions, the name of the medicine and the strength**

per unit dose, name of patient, date, the expiration date, and initials of the licensed pharmacist who has compounded the prescription, and the security of the cover or cap on every bottle or jar shall meet safety standards promulgated by the state board of pharmacy: PROVIDED, That at the physician's request, the name and dosage of the drug need not be shown. If the prescription is for a combination drug product, the generic names of the drugs combined or the trade name used by the manufacturer or distributor for the product shall be noted on the label. This section shall not apply to the dispensing of medicines to in-patients in hospitals.

RCW 18.64.246.

Every proprietor of a wholesale or retail drug store shall be held responsible for the quality of all drugs, chemicals or medicines sold or dispensed by him except those sold in original packages of the manufacturer and except those articles or preparations known as patent or proprietary medicines. Any person who shall knowingly, willfully or fraudulently falsify or adulterate any drug or medicinal substance or preparation authorized or recognized by an official compendium or used or intended to be used in medical practice, or shall willfully, knowingly or fraudulently offer for sale, sell or cause the same to be sold for medicinal purposes, shall be deemed guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine in any sum not less than seventy-five nor more than one hundred and fifty dollars or by imprisonment in the county jail for a period of not less than one month nor more than three months, and any person convicted a third time for violation of any of the provisions of this section may suffer both fine and imprisonment. In any case he shall forfeit to the state of Washington all drugs or preparations so falsified or adulterated.

RCW 18.64.270.

The following conduct, acts, or conditions constitute unprofessional conduct for any certificate holder or applicant under the jurisdiction of this chapter:

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

. . . .

(6) The possession, use, prescription for use, or distribution of controlled substances or legend drugs in any way other than for legitimate or therapeutic purposes, diversion of controlled substances or legend drugs, the violation of any drug law, or prescribing controlled substances for oneself;

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

RCW 18.130.180(4)(6)(7).

Drugs-Misbranding by false labeling. A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.

RCW 69.04.450.

If a drug is not designated solely by a name recognized in an official compendium it shall be deemed to be misbranded unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamime, arsenic, digitalis, glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: PROVIDED, That to the extent that compliance with the requirements of clause (2) of this section is impracticable, exemptions shall be established by regulations promulgated by the director.

RCW 69.04.490.

A drug or device shall be deemed to be misbranded if it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: PROVIDED, That the method of packing may be modified with the consent of the director, as permitted under section 502(g) of the federal act. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States pharmacopoeia.

RCW 69.04.510.

A pharmaceutical manufacturer, wholesaler, pharmacy, or practitioner who purchases, dispenses, or distributes legend drugs shall maintain invoices or such other records as are necessary to account for the receipt and disposition of the legend drugs.

The records maintained pursuant to this section shall be available for inspection by the board and its authorized representatives and shall be maintained for two years.

RCW 69.41.042.

To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he determines that his patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.

RCW 69.41.050.

Persons registered, or exempted from registration under RCW 69.50.302(d), to manufacture, distribute, dispense, or administer controlled substances under this chapter shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the state board of pharmacy issues.

RCW 69.50.306.

(1) A pharmacist shall not delegate the following professional responsibilities:

(a) Receipt of a verbal prescription other than refill authorization from a prescriber.

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not preclude a pharmacy assistant from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.

(c) Consultation with the prescriber regarding the patient and the patient's prescription.

(d) Extemporaneous compounding of the prescription provided that bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a level A pharmacy assistant when supervised by a pharmacist.

(e) Interpretation of data in a patient medication record system.

(f) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

(g) Dispense prescriptions to patient with proper patient information as required by WAC 246-869-220.

(h) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW 69.38.030 and WAC 246-887-030 and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

(i) Professional communications with physicians, dentists, nurses and other health care practitioners.

(2) Utilizing personnel to assist the pharmacist.

(a) The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities.

(b) This does not preclude delegation to an intern or extern.

WAC 246-863-095.

The term "monitoring drug therapy" used in RCW 18.64.011(11) shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. Monitoring of drug therapy shall include, but not be limited to:

(1) Collecting and reviewing patient drug use histories;

(2) Measuring and reviewing routine patient vital signs including, but not limited to, pulse, temperature, blood pressure and respiration; and

(3) Ordering and evaluating the results of laboratory tests relating to drug therapy including, but not limited to, blood chemistries and cell counts, drug levels in blood, urine, tissue or other body fluids, and culture and sensitivity tests when performed in accordance with policies and procedures or protocols applicable to the practice setting, which have been developed by the pharmacist and prescribing practitioners and which include appropriate mechanisms for reporting to the prescriber monitoring activities and results.

WAC 246-863-110.

Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

(1) Those drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials in which the pharmacist can readily determine that entry or attempted entry by any means has not been made and which, in the pharmacist's professional judgment, meet the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability may be returned.

(2) Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria;

(a) The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made;

(b) In the pharmacist's professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability;

(c) The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;

(d) The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;

(e) The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable.

(f) If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug.

(3) This rule shall not include items such as orthopedic appliances, crutches, canes, wheelchairs and other similar items unless otherwise prohibited.

(4) Controlled substances shall not be returned to a pharmacy except for destruction in accordance with rules of the drug enforcement administration or the Washington state board of pharmacy.

WAC 246-869-130.

(1) The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients.

(2) Dated items--All merchandise which has exceeded its expiration date must be removed from stock.

(3) All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration.

(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations.

(5) Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock.

(6) All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed.

WAC 246-869-150.

(4) The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon. (Profile systems are excepted.)

(5) There shall be a sink with hot and cold running water in the prescription compounding area.

WAC 246-869-160 (4)(5).

(1) All pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.

(2) Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards.

(3) There shall be three rating classifications

(a) "Class A" - for inspection scores of 90 to 100;

(b) "Conditional" - for inspection scores of 80 to 89; and,

(c) "Unsatisfactory" - for inspection scores below 80.

(4) Any pharmacy receiving a conditional rating shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

(5) Any pharmacy receiving an unsatisfactory rating shall have fourteen days to raise its inspection score rating to 90 or better. If upon reinspection after fourteen days, the
pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

(6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.

(7) Noncompliance with the provisions of chapter 18.64A RCW (Pharmacy assistants) and, chapter 246-901 WAC (Pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.

(8) Pharmacies receiving an unsatisfactory rating which represent a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.

WAC 246-869-190.

To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:

(a) The nature of the drug;

(b) The container in which it was packaged by the manufacturer and the expiration date thereon;

(c) The characteristics of the patient's container, if the drug is repackaged for dispensing;

(d) The expected conditions to which the article may be exposed;

(e) The expected length of time of the course of therapy; and

(f) Any other relevant factors.

The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.

(2) The quantity of drug dispensed, for example the volume or number of dosage units.

(3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220.

WAC 246-869-210.

(1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including CFR Part 1700 of Title 16, unless:

(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.

(b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant.

(2) Authorization from the patient to the pharmacist to use a regular container (nonchild-resistant) shall be verified in one of the following ways:

(a) The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant.

(b) The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant.

(c) The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant.

(3) No pharmacist or pharmacy employee may designate himself or herself as the patient's agent.

WAC 246-869-230.

An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system.

(1) All automated patient medication record systems must maintain the following information with regard to ambulatory patients:

(a) Patient's full name and address.

(b) A serial number assigned to each new prescription.

(c) The date of all instances of dispensing a drug.

(d) The identification of the dispenser who filled the prescription.

(e) The name, strength, dosage form and quantity of the drug dispensed.

(f) Any refill instructions by the prescriber.

(g) The prescriber's name, address, and DEA number where required.

(h) The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050.

(i) Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(j) Authorization for other than child-resistant containers pursuant to WAC 246-869-230, if applicable.

(2) All automated patient medication record systems must maintain the following information with regard to institutional patients:

(a) Patient's full name.

(b) Unique patient identifier.

(c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(d) Patient location.

(e) Patient status, for example, active, discharge, or on-pass.

(f) Prescriber's name, address, and DEA number where required.

(g) Minimum prescription data elements:

(i) Drug name, dose, route, form, directions for use, prescriber.

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

(h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.

(i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

WAC 246-875-020.

> Upon receipt of a prescription or drug order, a dispenser must examine visually or via an automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed. Any order modified in the system must carry in the audit trail the unique identifier of the person who modified the order. Any change in drug name, dose, route, dose form or directions for use which occurs after an initial dose has been given requires that a new order be entered into the system and the old order be discontinued, or that the changes be accurately documented in the record system, without destroying the original record or its audit trail.

WAC 246-875-040.

> (2) Record of certifications. All pharmacies employing Level B pharmacy assistants shall complete a certification application on a form approved by the board, such form to include a declaration by the applicant that he or she has never been found guilty by any court of competent jurisdiction of any violation of any laws relating to drugs or the practice of pharmacy, for each Level B pharmacy assistant employed. The completed form will be witnessed by the responsible pharmacist for the pharmacy and will be produced for inspection on the request of the board or its agents. The fee for certification will be included in the fee for authorization to utilize the services of pharmacy assistants.

WAC 246-901-080(2).

> All Level A pharmacy assistants must wear badges or tags clearly identifying them as Level A pharmacy assistants while on duty. Those pharmacy assistants working within the pharmacy and having contact with patients or the general public shall wear badges or tags clearly identifying their status.

WAC 246-901-090.

> (3) Utilization plan for Level B pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant.

WAC 246-901-100(3).

Section 3: NOTICE TO RESPONDENT

IT IS FURTHER alleged that the allegations specified and conduct referred to in this Statement of Charges affect the public health, safety and welfare, and the Board of Pharmacy directs that a notice be issued and served on the Respondent as provided by law, giving the Respondent the opportunity to defend against the allegations of the Statement of Charges. If the

Respondent fails to defend against these allegations, the Respondent shall be subject to discipline as is appropriate under RCW 18.130.160.

DATED this 16th day of August, 1999.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

DONALD H. WILLIAMS
EXECUTIVE DIRECTOR

David M. Hankins, WSBA #19194
Assistant Attorney General Prosecutor

FOR INTERNAL USE ONLY. INTERNAL TRACKING NUMBERS:
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APPENDIX G

FILED
DEC 12 2005
PAM DANIELS
COUNTY CLERK
SNOHOMISH CO. WASH

IN THE SUPERIOR COURT OF WASHINGTON FOR SNOHOMISH COUNTY

MICHAEL S. JONES, R. Ph., Plaintiff, vs. STATE OF WASHINGTON AND ITS DEPARTMENT OF HEALTH; WASHINGTON STATE BOARD OF PHARMACY; PHYLLIS WENE and STAN JEPPESEN, individually and as investigators for the Washington State Board of Pharmacy, Defendants	**Case No.: 02-2-08819-6** **DECLARATION OF W. BERNARD BAUMAN IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

I, W. BERNARD BAUMAN, declare as follows, based on my personal knowledge:

1. I am a registered pharmacist licensed to practice pharmacy by the state of Washington. I am also a practicing attorney duly licensed to practice law by the state of Washington.

2. I represented Michael Jones regarding the disciplinary proceedings that led to the suspensions of his pharmacy and professional licenses. My first contact with anyone representing the Department or the Board of Pharmacy was with Phyllis Wene on August 16, 1999.

BROWNLIE EVANS WOLF & LEE, LLP
100 Central Avenue
Bellingham, WA 98225

3. On August 16, 1999, I received a phone call from Mr. Jones who indicated that he was having trouble answering the questions that he had been given and asked to answer by Phyllis Wene after his pharmacy had failed a reinspection on August 10, 1999. I told Mr. Jones that I would check with Phyllis Wene of the Board of Pharmacy and get back to him. Although I was in Nevada on that day, I placed a phone call to Phyllis Wene and informed her that Mr. Jones was having trouble answering the questions and would not be able to submit all of the answers by August 17, 1999. Additionally, he wanted the opportunity to discuss his responses with me before he sent them in. I was told that this was not a problem and that Mr. Jones could have more time to prepare his answers, review them with me, and submit them to her. She did not express any urgency whatsoever, nor did she indicate that his license, or that of his pharmacy, was in jeopardy in any way.

4. I was never told that they were preparing a motion for an ex parte hearing for the summary suspensions of Mr. Jones's professional and pharmacy licenses. I did not learn about this until after Mr. Jones was served and he contacted me about the hearing and the entry of the order for summary suspension. Had I been given notice and an opportunity to be heard on the motion, I would have been available to appear either in person or by phone at the hearing to defend the substantial rights of my client. I also believe that Mr. Jones would have been available to appear – either in person or by phone – on short notice.

I regret that I was unable to assist Mr. Jones and Mr. Evans before today in the preparation of this declaration due to my unavailability until today. It was not possible for me, or them, to prepare and send this declaration any earlier than late afternoon of today's date.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Dated: Dec. 8, 2005.
Seattle, WA

By:
W. Bernard Bauman

CERTIFICATION OF DELIVERY

I certify under penalty of perjury under the laws of the state of Washington that I faxed and mailed one copy of this document to John Nicholson, Assistant Attorney General, 900 – Fourth Avenue, Suite 2200, Seattle, WA 98164-1012, postage prepaid, on the 8th day of December, 2005.

Signed:
W. Bernard Bauman

APPENDIX H

IN THE SUPERIOR COURT OF WASHINGTON FOR SNOHOMISH COUNTY

MICHAEL S. JONES, R. Ph., Plaintiff, vs. STATE OF WASHINGTON AND ITS DEPARTMENT OF HEALTH; WASHINGTON STATE BOARD OF PHARMACY; PHYLLIS WENE and STAN JEPPESEN, individually and as investigators for the Washington State Board of Pharmacy, Defendants	**Case No.: 02-2-08819-6** **DECLARATION OF MURPHY EVANS IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

I, MURPHY EVANS, declare as follows, based on my personal knowledge:

1. I am one of the attorneys for the plaintiff in this action.

2. I have reviewed correspondence and pleadings submitted as part of the administrative disciplinary action taken by the Washington Board of Pharmacy against plaintiff that is the subject of this dispute.

3. Attached as Exhibit 1 is a true and correct copy of the Pharmacy Inspection Report relating to the inspection of plaintiff's pharmacy on or about July 12, 1999.

BROWNLIE & EVANS, LLP
119 N. Commercial St., Suite 1250
Bellingham, WA 98225
(360) 676-0306

COPY

4. Attached as Exhibit 2 is a true and correct copy of the Pharmacy Inspection Report relating to the reinspection of plaintiff's pharmacy on or about August 10, 1999.

5. Attached as Exhibit 3 is a true and correct copy of the Respondent Written Notice provided to Jones by inspector Wene on or about August 10, 1999.

6. Attached as Exhibit 4 is a true and correct copy of Respondent Statement Instructions provided to Jones by inspector Wene on or about August 10, 1999.

7. Attached as Exhibit 5 is a true and correct copy of the Statement of Charges prepared by Donald Williams, the executive director of the State of Washington Department of Health, Board of Pharmacy, on or about August 16, 1999.

8. Attached as Exhibit 6 is a true and correct copy of the Ex Parte Order of Summary Action dated August 17, 1999.

9. Attached as Exhibit 7 is a true and correct copy of Respondents' Motion to Modify Ex Parte Order of Summary Action.

10. Attached as Exhibit 8 is a true and correct copy of the Declaration of W. Bernard Bauman in Support of Respondents' Motion to Modify and to Stay Summary Suspensions.

11. Attached as Exhibit 9 is a true and correct copy of the Declaration of Michael Jones.

12. Attached as Exhibit 10 is a true and correct copy of Department's Response to Respondent's Motion to Modify Order of Summary Action.

13. Attached as Exhibit 11 is a true and correct copy of the Order on Motion to Modify Ex Parte Order of Summary Action.

14. Attached as Exhibit 12 is a true and correct copy of Letter of W. Bernard Bauman dated September 13, 1999 to Ms. Pam Mena of the Office of Professional Standards.

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15. Attached as Exhibit 13 is a true and correct copy of the State's Response to Motion for Expedited Trial.

16. Attached as Exhibit 14 is a true and correct copy of September 22, 1999, Letter of Bernard Bauman to Sue Somers.

17. Attached as Exhibit 15 is a true and correct copy of the Order on Motion to *(sic)* for Expedited Hearing.

18. Attached as Exhibit 16 is a true and correct copy of the Prehearing Order No. 4: Order Granting Motion for Continuance.

19. Attached as Exhibit 17 is a true and correct copy of the Stipulated Findings of fact, Conclusions of Law and Agreed Order.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Dated: November 11, 2003.
Bellingham, WA

By: _____
Murphy Evans

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF RESPONDENTS' MOTION TO MODIFY EX-PARTE ORDER OF SUMMARY ACTION

COME NOW the respondents herein, MICHELE S. JONES and the MEDICINE SHOPPE PHARMACY, by and through their attorney of record, W. Bernard Bauman, and move this court for an Order Modifying the Ex-Parte Order of Summary Action and STAYING the Summary Suspension of the licenses issued to Respondent Michael S. Jones, R.Ph. and Medicine Shoppe Pharmacy, located at 9430 State Street in Marysville, Washington, said licenses having been suspended on August 17, 1999. This Motion is based on the subjoined Declarations of W. Bernard Bauman and Michael S. Jones.

DATED this 27th day of August, 1999.

W. BERNARD BAUMAN, WSBA #8849
Attorney for Respondents

EXHIBIT 7

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF DECLARATION OF W. BERNARD BAUMAN IN SUPPORT OF RESPONDENTS' MOTION TO MODIFY AND TO STAY SUMMARY SUSPENSIONS

I, W. Bernard Bauman, do hereby declare as follows:

I am the attorney for the Respondents herein and make this Declaration regarding facts and information about which I have personal knowledge.

I have reviewed the Declaration of Michael S. Jones and confirm and agree with the statements made therein. Mr. Jones is quite accurate in his position that the Board's action has very nearly, if not completely, ruined him financially. The continued viability of his pharmacy after this lengthy closure is in serious jeopardy and the only possibility of resurrecting it and reversing the irreparable harm being caused by the Board's closure is to reinstate both licenses and re-open the pharmacy under the control of Mr. Jones no later than Tuesday, August 31, 1999.

It should be clear from Mr. Jones' Declaration that the only thing he is really "guilty" of is disorganization and this does not constitute unprofessional conduct nor does it

EXHIBIT 8

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represent any threat to the health, safety and welfare of his customers. To summarize the concerns of the Board and Mr. Jones' responses:

1. Medical Information. Mr. Jones has always obtained allergy and medical condition information from his patients and, when available, inputted it into his computer. His QS-1 computer has the capability of recognizing and alerting the user to drug interaction and disease date information and Mr. Jones logically assumed this feature was operating. However, QS-1 had not activated it and, when he learned this, he had them do it immediately. Obviously, this was not his fault, he has corrected the problem, and he has also gone over his patient files and updated this information.

2. NDC Numbers. Mr. Jones was already in the process of correcting this problem when the inspectors returned on August 10, 1999. However, he was penalized a second time for the same prescriptions because they had not been picked up by the customers. Since the August 10th inspection, Mr. Jones has instituted a new system that is designed to make sure that, henceforth, all products dispensed match the NDC numbers in the computer. Nevertheless, this type of infraction does not jeopardize the safety of his customers.

3. CRC/Non-CRC. Mr. Jones has, at all times, been in complete compliance with regard to the caps used on his prescription bottles. The worst thing that can be said is that his record-keeping system for the signatures did not allow for one to readily verify specific signatures. However, this was not pointed out to him as a problem during his inspection in February 1999! Further, the high percentage of non-CRC caps used is not a violation of any regulation. Nevertheless, in order to avoid any further questions in this regard, Mr. Jones has voluntarily changed his system as he has described. This was,

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apparently, a big concern of the inspectors but this, too, did not present a safety concern to "the public".

4. Outdates. In light of the fact that a few products slipped through the cracks, Mr. Jones has changed his procedure for discovering and removing outdated products. Nevertheless, the few items that were missed and inadvertently not pulled did not pose a health risk to "the public".

5. Records and Files. These issues were fully addressed by Mr. Jones in his Declaration, the situation has been corrected and it will not happen again due to the institution of new record-keeping procedures. Here, again, the record-keeping problems, posed absolutely no risk to "the public".

6. QS-1 Computer Functions. As stated in Mr. Jones' Declaration, his computer system is capable of performing all the functions that are necessary and required for any pharmacy to adequately monitor the medical and pharmaceutical information for their patients, including, but not limited to, drug interactions and audit trails.

It should be abundantly clear to all concerned that Mr. Jones is a capable and concerned Pharmacist. He has, at all times, provided professional care to his customers and has done nothing to jeopardize the health, safety, and welfare of "the public". The foregoing discussion makes this very clear. None of the Board's concerns, alone or even in combination, rise to the level of concern professed by the inspectors and the Board. This matter could, and should, have been handled in a much more constructive, pharmacist-friendly and customer-friendly manner, regardless of the results of his last two inspections. It is presumably the function of the Board to not only protect the public but to also assist pharmacists throughout the state to improve the level of their practice.

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It should not be the purpose of the Board to hinder and intimidate pharmacists in their practice, or to plunge ahead with sanctions without giving any thought to the seriousness of the consequences and ramifications of their actions. These are precisely the things that have occurred in this case. Instead of assisting Mr. Jones to improve the level of his practice, the inspectors descended on him with the intention of finding fault, intimidating him and disrupting his business. Their noticeable presence throughout the entire day was disruptive and intimidating, especially when an inspector stood directly behind him, looking over his shoulder, for an entire day. His intent was obvious and this type of conduct is completely inappropriate. Further, instead of trying to determine the truth as to what violations/infractions really occurred, by discussing their concerns and giving him the time and opportunity necessary to show that, for the most part, the real problem was simply disorganization, they treated him like a criminal instead of a fellow professional.

This attitude and approach led directly to the ex-parte summary suspensions for which there was absolutely no justification, not even under the circumstances described by the Board. The Board's action was clearly excessive and unwarranted and served to destroy a pharmacist and the business he has worked so hard to build. The Board has destroyed years of hard work overnight! There is no rational reason or justification for sending a man into bankruptcy for the violations discussed herein!

The time has come to lift the suspensions of both licenses, put an end to the financial and emotional damage that he is suffering, and allow him to try and salvage what is left of his business. He deserves this consideration. He does not deserve the damage the Board has caused him. And he has faithful customers standing behind him, waiting for him to re-open. They deserve to have their needs met, too, and the Board should be concerned about that.

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Mr. Jones is prepared to have the inspectors come out immediately so that his pharmacy can receive their approval. He must open his doors for business within the next 48 hours or the damage will be irreversible, if it isn't already. **We request, and look forward to, the immediate consideration of this Motion and an immediate stay of the suspensions.**

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my information, knowledge and belief.

EXECUTED this 27th day of August, 1999, at Seattle, Washington.

W. BERNARD BAUMAN, WSBA #8849
Attorney for Respondents

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF DECLARATION OF MICHAEL S. JONES

I, Michael S. Jones, R.Ph., do hereby declare as follows:

I am the Respondent herein and make this Declaration regarding facts and information about which I have personal knowledge and information.

I want to preface this statement by saying that I sincerely regret the fact that my pharmacy was considered to be below the accepted minimum standard for pharmacies in Washington when it was last inspected on August 10, 1999. Since that time, I have spent a great deal of time addressing the concerns of the investigators. I believe that the following discussion, which addresses each of the concerns raised in the Statement of Charges (S.O.C.) as well as by the inspectors, will show that all of the concerns had simple explanations, were not violations, and/or were quickly and easily rectified. I am truly sorry that the following matters had not been completely taken care of by August 10, 1999, so as to alleviate the concerns of the investigators:

EXHIBIT 9

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1. Although information regarding allergies and chronic conditions has always been obtained from all patients, there was a question as to whether it was being properly inputted into the computer. Further, the disease state-drug interaction fields were thought (by the inspectors) to have been turned off. Therefore, while the inspectors were at lunch on August 10th, I contacted my computer vender to discuss these problems. I was informed, much to my surprise, that these features were left off by the company (i.e., never turned on by them), unless they were specifically requested to do so. I had no idea that these features were not functioning and told them to activate them immediately, which they did. This explained why I could not explain their functioning to the inspectors and why they thought I had turned it off, which I had not done. Nevertheless, this function was operational by the time they returned from lunch. I even showed this to Mrs. Wene, so I am at a loss to understand why this is included in the S.O.C., especially when I was not marked down for this on the Inspection Report. Lastly, all patients have been updated regarding chronic conditions and allergy information. If there is no such information in the computer for a patient, that is because the patient has no allergies or chronic conditions.

2. Many of the prescriptions that were randomly selected and described as having products in them that did not match the NDC numbers were ones that were still there from the prior inspection and had not been picked up by the customers by the time of the August 10th inspection. Consequently, I was cited for them twice (double jeopardy) even though they were not new infractions. I should not have lost points a second time for the same prescriptions.

Nevertheless, I had already instituted a new system prior to the last inspection to make sure that the NDC numbers matched the product, and the necessary changes were

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being made, and have been made, in the computer. Henceforth, there will be no variance. However, at the time of the August 10th inspection, I had not had time to make all the necessary changes. This is an ongoing process and does not take place overnight. We now use checkmarks to double check and make sure the product matches the NDC. If it doesn't, the NDC is changed. I do not expect to have any further problems in this regard.

3. With respect to the CRC/NCRC issue, this has already been explained. It is a fact that at least 95 percent of my customers have specifically requested that I use NCRC lids on their containers and I have signatures for every one of them! There is no rule or regulation that mandates a maximum percentage of NCRC's that can be used. Anyone can request NCRC containers and it is not limited to the elderly. The only qualification is that they sign a record indicating this request and I did that with all my customers. While my records may not have been organized for ease of reference, it was wrong to single me out simply because the percentage of NCRC's is high. It was also my understanding that Mrs. Wene approved of my system when I received a 94 on February 3, 1999. That was the same system that was in place in July and August.

Nevertheless, as a result of the difficulties that this has caused me, I have already changed my system for recording these signatures. They will now be filed alphabetically on index cards so that they can be easily retrieved, in addition to this request being indicated in the computer. Everyone, including those who have already signed my signature book, will sign my new index cards. Further, everyone working in the pharmacy will be vigilant to make sure that no NCRC's are used without the necessary signatures. Further, no prescription will be dispensed without a CRC unless the receipt says "NRC".

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4. All outdated legend and OTC products have been removed from my shelves. In order to avoid any problems with this in the future, we will now do a monthly review instead of quarterly, for outdates. This will ensure that no outdates remain on the shelves. I also had "Returns by Howard" come out, inspect for outdates, too, and process our returns.

5. With regard to the "inaccurate, incomplete or unavailable" records, I have already rectified these concerns. Signatures have been provided, where needed, on controlled substance inventories. CII invoices have been separated from all other invoices and will continue to be filed separately. They are also being stapled to DEA 222 forms per the inspector's recommendation.

I also had an employee spend a week going through all of our prescription files to make sure they were in proper order and otherwise in compliance. The records and prescription hard copies that could not be located at the time of the inspection have since been located. They had simply been misfiled. We will, hereafter, be cognizant of this problem and vigilant to make sure that this doesn't happen. One plan for avoiding this problem is to organize these records and files on as nearly a daily basis as possible.

One of the primary reasons I had a problem with missing information at the last inspection was because of a lack of knowledge and information as to exactly what was expected or required. I would be told at one inspection that e.g. I was missing signatures. Having been made aware of this, I complied. However, nothing else was pointed out as being deficient. Then, at the next inspection, something else, e.g., DEA numbers, would be pointed out. If I had simply been advised, all at one time, what I needed to do, I would not have had a problem with these requirements on a piecemeal basis. However, I think I now

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know what is required and I can assure you that my records will be in full compliance hereafter.

6. All records, invoices, etc. that were of concern to the inspectors have been located, organized, and separated per their instructions and recommendations.

7. There were three DEA 222 forms that were in question at the time of the inspection regarding the quantities and dates. With one, the order had not yet been received at the pharmacy. Another blank had been lost between my pharmacy and the wholesaler. I verified this with them, and the fact that the order had not been received or filled by them. With respect to the third form, the order had not been checked in yet. I subsequently checked the quantity and dated the form. We now staple the CII invoice to the blue 222 form. We had never been advised, or instructed, to do this before, but we are doing it now.

8. Lastly, the inspectors were concerned that our QS-1 system was inadequate for the minimum procedures for utilization of the patient medication system and for creating an accurate and complete audit trail for changes made to the prescriptions after filling. These concerns were unfounded. I have spoken with the QS-1 technical support personnel, the system is fully capable of performing these functions, and I am able to utilize these functions. The process is too lengthy to describe, but I would gladly show an inspector how it is done.

I believe the foregoing fully and completely addresses all matters and concerns raised by the inspectors and alleged in the S.O.C. that have affected the licenses of myself and my pharmacy. I feel very strongly about the fact that none of these concerns have ever had even the potential for adversely affecting the health, safety or welfare of any of my customers. The health, safety and welfare of my customers has always been of paramount

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importance and I would never do anything to compromise this, nor have I. I take great pride in my professionalism and will continue to do so.

I do not believe that the summary suspensions of both mine and my pharmacy's licenses were necessary or justified. The action of the Board has very likely ruined me, financially, and it is doubtful that I will ever be able to recover. At the very least, I will never recoup my substantial losses. The Board has also caused me to suffer, unnecessarily, a great deal of personal humiliation and trauma.

I have done everything possible to bring my pharmacy into compliance and to satisfy the concerns of the Board. Further, I steadfastly resolve to maintain this compliance and to maintain my pharmacy's rating at the highest level.

I have been punished, and made an example of, long enough. Nothing more can possibly be gained by continuing the Board's course of action. I have been penalized in virtually every possible way. The punishment should fit the "crime", not exceed it, as it has in my case. It is time to stop the bleeding.

I respectfully request that the summary suspensions of my license and Medicine Shoppe's license be stayed immediately so that I can attempt to pull my business and my livelihood out of the ashes. In addition to the preservation of one of a dying breed of community pharmacies, it is imperative to open the pharmacy immediately so that I can service the medical needs of my customers. They, too, have been seriously affected by the board's action which has been counterproductive to the stated goal of "protecting" them.

There is absolutely no need, or justification, for preventing me from returning to my pharmacy immediately as the responsible pharmacist pending the resolution of any other matters with the Board, if any. I am the only one who knows the QS-1 system and I am

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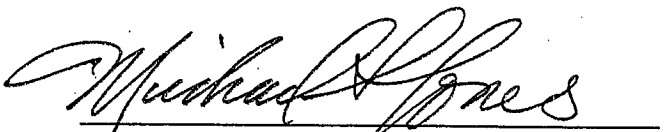
perfectly capable, and competent, of continuing to operate my pharmacy in a very professional manner, and of continuing to provide my customers with the excellent care they have come to expect from me and my staff. Once again, I ask that, before I am ruined completely, the licenses be reinstated and my pharmacy reopened immediately.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my information, knowledge and belief.

EXECUTED this 27th day of August, 1999, at Bothell, Washington.



MICHAEL S. JONES

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of	Docket No. 99-08-A-1016PH
	Docket No. 99-08-A-1017CF
MICHAEL S. JONES, R.Ph. License No. 10993	DEPARTMENT'S RESPONSE TO RESPONDENT'S MOTION TO MODIFY ORDER OF SUMMARY ACTION
In the Matter of the Pharmacy Location License of	
The Medicine Shoppe Pharmacy, License No. 55751, Respondents	

COMES NOW the State of Washington, Department of Health, Board of Pharmacy, by and through its attorneys, CHRISTINE O. GREGOIRE, Attorney General, and LORI LEBON SALO, Assistant Attorney General, and requests that Respondent's motion to modify the Board's summary action and requesting a stay of the summary suspensions be denied. The Department's response is based on the following argument and attached exhibits.

ARGUMENT

The Respondent's motion to modify the summary action and requesting a stay of the summary suspensions should be denied for three reasons. First the motion is untimely. The deadline for Respondent to file the motion was August 27, 1999. Respondent did not file the motion until August 30, 1999. Second, the condition of Respondent's pharmacy practice remains an immediate danger to the public health, safety or welfare. Respondent's assertions that he has made the necessary changes to his practice so that he can safely comply with the pharmacy laws

EXHIBIT 10

should be viewed with skepticism. The Respondent does not offer any evidence to support his assertions. Respondent has a history of committing violations of the pharmacy laws and then coming into compliance for awhile, only to violate again. Finally, if the court decides to hear the motion in spite of its untimeliness, the issue is moot because the Medicine Shoppe has terminated its franchise agreement with the Respondent. The Respondent currently does not have a pharmacy within which to practice.

First, Respondent's motion is untimely. Respondent was personally served with notice of the Department's summary action against his license on August 17, 1999. (See Exhibit 1, Declaration of Investigator Wene). Respondent was required to file his motion by August 27, 1999. WAC 246-11-340(3) gives a Respondent ten days from date of service of the summary action to request a prompt adjudicative hearing. This WAC can also be interpreted as establishing the timeframe for filing a motion to contest the summary action. The Respondent knew about this deadline because the Answer form filed by the Respondent on August 27, 1999 contains a check mark indicating he chose to proceed by filing a motion to contest the summary action. (See Exhibit 2, Respondent's Answer to the Statement of Charges). Next to Respondent's check mark are instructions for this procedure which indicate that his motion must be received by the adjudicative clerk office by August 27, 1999. The language of the instruction clearly states that the **motion itself** must be filed by August 27, 1999, so filing the Answer on August 27, 1999 does not satisfy this requirement. Timelines are created to establish certainty and finality in the legal process and should be enforced. Since the Respondent did not file his motion to contest the Department's summary action in this case on time, the court should not consider it at all.

If the Board is willing to overlook the Respondent's untimely filing of this motion, his motion should still be denied. The Respondent committed serious violations of the pharmacy laws by operating the pharmacy below the standard for care. Concerns remain that his operation of a pharmacy and practice as a pharmacist are a danger to public health, safety and welfare. Respondent's allegations that he has made the necessary corrections to operate the pharmacy safely

and in compliance with the pharmacy laws should be viewed with skepticism. Respondent does not offer any evidence to support his allegations. He has a history of going through a cycle of violating the pharmacy laws and then complying and then violating the laws again. Additionally, it is clear from Respondent's declaration that he is not taking responsibility for the nature of his violations. He minimizes the seriousness of the violations and blames the investigator for not instructing him in the law. As a result of his denial of his responsibility it is likely he will commit violations again.

First and foremost, the Board's role is to protect the public. Respondent's emphasis on the impact of the Board's decision to suspend him is inappropriate and the Board should disregard it. The Respondent's violations of the pharmacy laws are serious, in spite of Respondent's assertions to the contrary. Several of the charges involve activities that directly impact patients. The following are examples of these violations: filling prescriptions with a different labeled generic product than indicated on the label or NDC code; failing to obtain patient information about allergies; having legend or controlled substances on the shelf that were beyond the manufactured expiration date; and dispensing the majority of prescriptions in non child resistant containers without a written request form the patient of prescriber.

Additionally, Respondent's poor record keeping constitutes an immediate danger to the public because he is unable to retrieve either patient or drug records. Clearly all of these actions constitute an immediate danger to the public.

The Respondent claims to have made changes to his practice since August 10, 1999, but he has been suspended since August 17, 1999; is it believable that he made these changes in seven days when he was unable to make them in thirty days? He was given a month between inspections to make changes to his practice and he failed to make them. The inspectors visited his location on July 12, 1999 and then again on August 10, 1999. At the August 10, 1999 inspection the inspectors found many of the same problems still in existence at the Respondent's pharmacy. (See Exhibit 3, Affidavit of Susan M. Somers, and Exhibit 4, Statement of Charges paragraphs 1.10 – 1.12.9).

Additionally, Respondent's assertions that he has corrected the problems and will remain in compliance are questionable. Respondent has a history of committing violations of the pharmacy law, coming into compliance only to violate the laws again. The attached affidavit of Sue Sommers, Exhibit 3, and the Statement of Charges, Exhibit 4, support the following facts.

In March 1994, a Statement of Charges was issued against Respondent related to a prescription filling error. July 1994 the Board entered an Order placing Respondent's license on probation for one year and imposing conditions and terms. In December 1995, Respondent's pharmacy license was fully reinstated.

Then in December 1998, the Respondent committed violations of the pharmacy laws which resulted in his receiving a failing pharmacy inspection score of 79. Some of the December 1998 violations are identical to the violations alleged in our present Statement of Charges. For instance he violated the pharmacy laws by: failing to obtain chronic conditions on patients of the pharmacy; dispensing the majority of prescription in non child resistant containers without a written request from either the patient or prescriber, having prescription with expiration dates exceeding the manufacturer's expiration date. But by the next inspection in February 1999 he appeared to be in compliance with most of the pharmacy laws and received a passing score of 94.

Then in July 1999, the Respondent again violated the pharmacy laws so that he received an extremely low inspection score of 48. The July 1999 violations were similar to the December 1998 violations. He was given an opportunity to regain compliance with the pharmacy laws and another inspection was held in August 1999. However, the Respondent had not improved much and received a failing score of 56. Again many of the same violations were found. As a result of Respondent's history of violations, the respondent's assertions that he has corrected the problems and his promises to maintain the corrections should be viewed with skepticism.

Finally, the Respondent's motion should be denied because the issue of whether the summary suspension should be stayed so that Respondent can return to practice at the Medicine Shoppe located in Marysville is moot. The Medicine Shoppe formally terminated its franchise

agreement with the Respondent on August 31, 1999. (See Exhibit 5, letter from the Medicine Shoppe to Michael Jones, dated August 31, 1999).

Respondent's motion should be denied because, given the Respondent's history, and the lack of evidence to support his assertions, the public protection concerns outweigh the Respondent's promises.

RELIEF REQUESTED

The Respondent's motion to modify the Board's summary order and to stay the summary suspensions should be denied.

RESPECTFULLY SUBMITTED this 1st day of September, 1999.

CHRISTINE O. GREGOIRE
Attorney General

LORI LEBON SALO
Assistant Attorney General, WSBA #22518
1125 Washington Street S.E.
P.O. Box 40110
Olympia, Washington 98504-0110
(360) 586-2644

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice as a Pharmacist of: MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of Pharmacy Location License of: The Medicine Shoppe Pharmacy, License No. 55751 Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF ORDER ON MOTION TO MODIFY EX PARTE ORDER OF SUMMARY ACTION

This matter came before Health Law Judge Arthur E. DeBusschere, Presiding Officer for the Board of Pharmacy (the Board), on a Motion to Modify Ex Parte Order of Summary Action, brought by the Respondent, Michael S. Jones, R.Ph., by and through his counsel, W. Bernard Bauman, Attorney at Law. Lori Lebon Salo, Assistant Attorney General, represents the Department of Health (the Department). The Board members deciding this motion were Sharron Sellers, Public Member; Donna Docktor, R.Ph.; and C.A. Leon Alzola, R.Ph., Panel Chair.

The Board having reviewed the motion and the documents submitted in support of this motion, hereby enters the following:

I. PROCEDURAL HISTORY

1.1 On August 17, 1999, the following documents were served upon the Respondent: (1) Statement of Charges; (2) Notice and Opportunity for Prompt Hearing, Regularly Scheduled Hearing or Settlement; (3) Answer to Statement of Charges and

EXHIBIT 11

1999, is necessary to address this danger to the public and is the least restrictive action justified by the danger posed. The Respondent's Motion to Modify Ex Parte Order of Summary Action should be denied.

IV. ORDER

Based upon the above, the Board hereby ORDERS that the Respondent's Motion to Modify Ex-Parte Order of Summary Action in this matter is DENIED.

DATED THIS 7th DAY OF SEPTEMBER, 1999.

BOARD OF PHARMACY

SHARRON SELLERS, Public Member, for
C.A. LEON ALZOLA, R.Ph., Panel Chair

W. BERNARD BAUMAN
Attorney at Law
Suite 601, Pioneer Building
One Pioneer Square
Seattle, Washington 98104

Telephone
(206) 464-1860

FAXED

TO AVOID DELAY
AND SENT VIA MAIL

September 13, 1999

URGENT ACTION REQUESTED

Ms. Pam Mena
Office of Professional Standards
1107 Eastside St.
P.O. Box 47879
Olympia, WA. 98504-7879

RE: MICHAEL JONES, R.Ph. & MEDICINE SHOPPE PHARMACY
Docket Nos. 99-08-A-1016PH & 98-08-A-1017CF

Dear Ms. Mena:

Pursuant to our conversation of today's date, please consider this correspondence as my **PETITION FOR EXPEDITED HEARING** in the above matter.

As you know, I previously brought a Motion to Modify Summary Suspension that was considered by three Board members on the basis of the pleadings last week and denied. Prior to that, I had been assured by O.P.S. that if we did not prevail on that motion, we could request an expedited hearing, since we would no longer be able to have this heard on the prompt hearing calendar on September 10th. I was also assured that the Board would be convened as quickly as possible after September 10th.

It is imperative that this matter be heard in the very near future. Mr. Jones has been unable to operate his pharmacy or practice pharmacy for over a month! This has created serious financial hardship for him. We estimate his losses to be approaching $30,000 now, and he is in jeopardy of being unable to make his mortgage payments as well as the lease payments for the premises where his business is no longer even operating. There can be no delay in having this matter heard. Mr. Jones has suffered serious and irreversible financial harm and faces certain ruin if we don't act immediately.

Your assistance in this regard will be most appreciated, Pam. Please let me know if you need anything else from me. Thank you very much.

Very truly yours,

W. BERNARD BAUMAN

WBB:seh

EXHIBIT 12

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY

In the Matter of the License to Practice Pharmacy of MICHAEL S. JONES, R.Ph. License No. 10993 In the Matter of the Pharmacy Location License of The Medicine Shoppe Pharmacy, License No. 55751, Respondents	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF STATE'S RESPONSE TO MOTION FOR EXPEDITED TRIAL

COMES NOW, the State of Washington, Department of Health, Board of Pharmacy (Board) by and through its attorneys, CHRISTINE O. GREGOIRE, Attorney General and DAVID M. HANKINS, Assistant Attorney General and responds to respondent's petition for expedited hearing.

BACKGROUND

On or about August 17, 1999, the Board issued a Summary Suspension Order summarily suspending the license to practice pharmacy of the respondent and respondent's license to operate the pharmacy. On or about August 30, 1999 respondent through his attorney filed a motion to modify the summary action of the Board. The state responded to respondent's motion. On or about September 7, 1999, the Board reviewed the motion and denied respondent's motion. On or about September 14, 1999, respondent filed a faxed letter addressed to the Office of Professional Standards, requesting an expedited hearing date.

ARGUMENT

The State does not object to this matter being placed on the Board's regularly scheduled meeting dates, but does object to this matter being specially set outside the Board's regularly scheduled hearing dates. Respondent answered the statement of charges, by marking the following box:

EXHIBIT 13

☐ I will file a motion to contest the summary action. I understand that by doing so I waive my opportunity to a prompt hearing. [*but not my right to an expedited hearing]*
NOTE: IF YOU SELECT THIS OPTION, YOUR MOTION MUST BE RECEIVED BY THE ADJUDICATIVE CLERK OFFICE BY **August 27, 1999.**

Respondent's counsel altered the form by including the language, "but not my right to an expedited hearing." Respondent's altering of the form is not binding on the Board. The Administrative Procedures Act, chapter 34.05 RCW or the Uniform Disciplinary Act, chapter 18.130. RCW do not require an expedited hearing date, if the motion to modify the summary action has been denied. Respondent made his motion and was not successful. Respondent acknowledged that he waived his right to a prompt hearing. This waiver is absolute. Therefore, respondent should not be granted a prompt hearing, when he already, knowingly waived his right to a prompt hearing.

The state is not opposed to having this matter set on an expedited basis at the Board's next regularly scheduled meeting date, but is adamantly opposed to this matter being placed on a date outside the Board's regular meeting calendar.

CONCLUSION

The state requests the presiding officer deny respondent's request to have this matter set on an expedited basis outside the Board's regularly scheduled meeting dates. The state is not opposed to having this matter set at the Board's next available, regularly scheduled hearing date.

RESPECTFULLY SUBMITTED this 21st day of September, 1999.

CHRISTINE O. GREGOIRE
Attorney General

DAVID M. HANKINS, WSBA #19194
Assistant Attorney General

W. BERNARD BAUMAN
Attorney at Law
Suite 601, Pioneer Building
One Pioneer Square
Seattle, Washington 98104

Telephone
(206) 464-1860
FAXED
(360)586-4359

September 22, 1999

EXTREMELY URGENT
FAXED TO AVOID DELAY

Ms. Sue Somers, Esq.
Board of Pharmacy
P.O. Box 47863
Olympia, WA. 98504-7863

RE: LICENSES OF MICHAEL JONES & MEDICINE SHOPPE PHARMACY

Dear Sue:

Per our telephone conversation this morning, it is my understanding that you have not been given any authority to negotiate a settlement in this matter and that the only recommendation at the present time is the revocation of my client's license. Therefore, in accordance with our discussion, this is intended to serve as my formal request, on behalf of my client, Mr. Michael Jones, for an immediate settlement conference. This is extremely urgent and I respectfully request that this conference be set on an emergency basis with yourself, myself, my client, and the reviewing Board member present. As you are well aware of the emergent nature of this request and the dire need for an immediate conference, I will not undertake to outline these circumstances in this letter.

Please call me as soon as possible in this regard. I realize everyone is very busy, but this matter cannot linger another minute. I look forward to hearing from you later today.

Thank you very much for your kind attention to this extremely urgent matter.

Very truly yours,

W. BERNARD BAUMAN

WBB:seh

cc: Mr. Michael Jones

EXHIBIT 14

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF PROFESSIONAL STANDARDS

In the Matter of the License to Practice as a Pharmacist of: MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of Pharmacy Location License of: The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF ORDER ON MOTION TO FOR EXPEDITED HEARING

This matter came before Health Law Judge Arthur E. DeBusschere, Presiding Officer for the Board of Pharmacy (the Board), on a Petition for an Expedited Hearing filed by W. Bernard Bauman, Attorney at Law, representing Michael R. Jones, R.Ph. & the Medicine Shoppe Pharmacy (the Respondents). David M. Hankins and Lori Lebon Salo, Assistant Attorneys General, represent the Department of Health (the Department).

I. PROCEDURAL HISTORY AND MOTION FOR EXPEDITED HEARING

1.1 On August 17, 1999, the following documents were served upon the Respondent: (1) Statement of Charges; (2) Notice and Opportunity for Prompt Hearing, Regularly Scheduled Hearing or Settlement; (3) Answer to Statement of Charges and Request for Prompt Hearing or Settlement and Regularly Scheduled Hearing; and (4) Ex Parte Order of Summary Action. In the Ex Parte Order of Summary Action, the Board ordered that the Respondent's license to practice as a pharmacist in the state of

EXHIBIT 15
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Washington was summarily suspended. The Board also ordered that the license issued to Respondent Medicine Shoppe Pharmacy, located at 9430 State Street in Marysville, Washington, to operate as a pharmacy was summarily suspended

1.2 On August 27, 1999, the Respondent filed an Answer to Statement of Charges.

1.3 On August 30, 1999, the Respondent filed a Motion to Modify Ex-Parte Order of Summary Action and on September 1, 1999, the Department filed a Response. On September 2, 1999, the Respondent filed a reply. On September 2 & 3, 1999, the Presiding Officer conducted telephone conferences on the Motion to Modify.

1.4 On September 7, 1999, the Board issued an Order denying the Respondent's Motion to Modify Ex-Parte Order of Summary Action.

1.5 On September 15, 1999, the Respondent filed a Petition for Expedited Hearing in this matter. The Respondent requested that the hearing in this matter be held in the very near future and that there be no delay in having it heard.

1.6 On September 22, 1999, the Department filed a Response to Motion for Expedited Trial. The Department did not oppose this matter being set at the Board's next available regularly scheduled hearing date, but opposed this matter being set on an date outside the Board's regular meeting times. The Department had argued that the Respondent had already waived his right to a prompt hearing.

II. CONCLUSIONS OF LAW

The Scheduling Order may be modified by order of the Presiding Officer upon his/her own initiative or upon motion of a party. WAC 246-11-290(2)(b). In this case,

the Presiding Officer had informed the Respondent that he had waived his right to a prompt hearing when he selected in his Answer to Statement of Charges to file a motion to contest the summary action and waived his opportunity for a prompt hearing. The Presiding Officer also informed the Respondent that if the Board's ruling on his Motion to Modify Ex-Parte Order of Summary Action was to his disfavor, then he could file a motion to expedite the date for the hearing. Thus, the Respondent had filed such a motion. The Department did not object to expediting the hearing date as long as it was set at the Board's next available, regularly scheduled hearing date. The Presiding Officer concludes that the Scheduling Order/Notice of Hearing in this matter can be issued so that a hearing in this matter can be held when the Board convenes at its next regularly scheduled time, which is on October 21, 1999. Thus, this is expediting the hearing date and is allowing the Respondent an opportunity to have a hearing in this matter without delay. Further, a prehearing conference shall be scheduled in preparation for the hearing.

III. ORDER

Based upon the above, the Presiding Officer hereby issues the following ORDERS:

3.1 The Respondent's Petition for an Expedited Hearing is GRANTED as follows:

3.2 The hearing in this matter shall be held on **October 21, 1999**. The Adjudicative Clerk Office shall issue a Scheduling Order/Notice of Hearing providing the starting time and location of the hearing.

3.5 There shall be a telephonic prehearing conference in this matter on **October 13, 1999,** at **9:00 a.m.** The Presiding Officer will initiate the telephone conference call. FURTHER, no later than **October 12, 1999**, each party shall file with the Adjudicative Clerk Office a prehearing memorandum and their exhibits.

DATED THIS 29 DAY OF SEPTEMBER, 1999.

ARTHUR E. DeBUSSCHERE, Health Law Judge
Presiding Officer

DECLARATION OF SERVICE BY MAIL
I declare that today I served a copy of this document upon the following parties of record:
DAVID HANKINS AND W. BERNARD BAUMAN by mailing a copy properly addressed with postage prepaid.
DATED AT OLYMPIA, WASHINGTON THIS 30 DAY OF SEPTEMBER, 1999.

Adjudicative Clerk Office

cc: **GEORGIA ROBINSON-SAGE**

FOR INTERNAL USE ONLY: (Internal tracking numbers)
Program No. 99-02-0003, 99-04-0007, 99-04-0004, 99-05-0003, 99-02-0071

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF PROFESSIONAL STANDARDS

In the Matter of the License to Practice as a Pharmacist of: MICHAEL S. JONES, R.Ph., License No. 10993, In the Matter of Pharmacy Location License of: THE MEDICINE SHOPPE PHARMACY, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH and Docket No. 99-08-A-1017CF PREHEARING ORDER NO. 4: ORDER GRANTING MOTION FOR CONTINUANCE

A prehearing conference was held before Health Law Judge Arthur E. DeBusschere, Presiding Officer for the Board of Pharmacy (the Board), on October 18, 1999. Appearing by telephone and representing Michael R. Jones, R.Ph. & the Medicine Shoppe Pharmacy (the Respondents) was W. Bernard Bauman, Attorney at Law. Also appearing by telephone and representing the Department of Health (the Department) was David M. Hankins.

I. UPDATED PROCEDURAL HISTORY AND MOTION FOR A CONTINUANCE

1.1 On September 29, 1999, the Presiding Officer issued an Order on Motion for Expedited Hearing. The Presiding Officer ordered that the hearing in this matter shall be on October 21, 1999. The Presiding Officer also ordered a telephonic prehearing conference on October 13, 1999, at 9:00 a.m., and parties were to file prehearing statements.

EXHIBIT 16

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1.2 On October 6, 1999, the Adjudicative Clerk Office served the Notice of Hearing notifying the parties of the date, starting time and location of the hearing.

1.3 During the prehearing conference on October 13, 1999, the Presiding Officer scheduled another prehearing conference for October 18, 1999. Mr. Hankins had reported that the Department planned to amend the Statement of Charges prior to the hearing date. Further, Mr. Bauman needed to review the new charges to determine whether to elect to go forward with the hearing as scheduled. Prehearing Order No. 3.

1.4 During the prehearing conference on October 18, 1999, the Department moved for a continuance of the hearing. Mr. Hankins argued that the Department will be filing an amendment to the Statement of Charges before the hearing. Mr. Hankins asserted that the additional charges are significant in nature. He asserted that it would not be a judicious use of time to have the hearing on the present changes and then have another hearing regarding the additional charges. Mr. Hankins argued that the new charges will most likely require additional exhibits and witnesses and most likely the Department will be seeking revocation of the Respondent's license. Mr. Hankins also stated that the Corporation for the Medicine Shoppe Pharmacy has issued a preliminary injunction prohibiting him from going back to this store. Mr. Hankins requested to reschedule the hearing to December 2, 1999, when the Board has its next regularly scheduled meeting.

1.5 Mr. Bauman stated that if the Statement of Charges are not amended before the hearing, then he would oppose the motion and would want to go forward with the hearing as scheduled. He stated that his client is not working and is having a

difficult time meeting his expenses. Mr. Bauman pointed out that this matter has been delayed long enough and has not met his client's expectations to have an expedited hearing.

II. CONCLUSIONS OF LAW

2.1 The Presiding Officer shall rule on motions. Continuances may be granted by the Presiding Officer for good cause. WAC 246-11-380. The hearing in this case was expedited by the setting of the hearing at the Board's next regularly scheduled meeting and by request of the Respondent. However at this time, to go forward with this hearing without also considering the amendments would be of no benefit to either party, because the parties would know that this matter would not have been resolved until the additional allegations have been addressed by the Board. Considering the additional allegations and the evidence presented, the Board will have a different response than it would without considering the new allegations. Moreover, to go forward with the hearing without the amendments would be doubling the efforts, resources and time for everyone involved, the parties and the Board. Thus, by continuing the hearing, this matter would be addressed judiciously and economically.

2.2 Next, the Respondent has had an opportunity for the Board to reconsider the summary suspension by responding to the Respondent's Motion to Modify the Summary Action. After considering it, the Board still has determined that the Respondent's actions presently pose a risk to the public. The Respondent's license has been restricted before and the Respondent is aware of the Board's concerns. Further, an expedited hearing should not be considered to be another opportunity for a

prompt hearing. By setting the hearing time at the next scheduled meeting of the Board, this matter is being handled expeditiously and is being made a priority matter. The Presiding Officer concludes that good cause exist to continue the hearing and to place it on the docket when the Board meets at it next regularly scheduled meeting on December 2, 1999. The Presiding Officer also coordinated with the parties a new prehearing conference date.

III. ORDER

Based upon the above, the Presiding Officer hereby ORDERS the following:

3.1 The Department's Motion for a Continuance in this matter is GRANTED.

3.2 There shall be a **telephonic** prehearing conference at **11:00 a.m., November 8, 1999.** The Presiding Officer shall initiate the telephone conference call.

3.3 The hearing date, now set for October 21, 1999, is CONTINUED to **December 2, 1999**. The Adjudicative Clerk Office will issue a notice of hearing, stating the date, time and location of the hearing.

DATED THIS 26 DAY OF OCTOBER, 1999

ARTHUR E. DeBUSSCHERE, Health Law Judge
Presiding Officer

DECLARATION OF SERVICE BY MAIL
I declare that today I served a copy of this document upon the following parties of record:
DAVID HANKINS, AAG AND W. BERNARD BAUMAN by mailing a copy properly addressed with postage prepaid.
DATED AT OLYMPIA, WASHINGTON THIS 26 DAY OF OCTOBER, 1999.

Adjudicative Clerk Office

cc: GEORGIA ROBINSON-SAGE

FOR INTERNAL USE ONLY: (Internal tracking numbers)
Program No. 99-02-0003, 99-04-0007, 99-04-0004, 99-05-0003, 99-02-0071

State of Washington
Department of Health
Board of Pharmacy

In the Matter of the License to Practice Pharmacy of: MICHAEL S. JONES, R.Ph., License No. 10993 In the Matter of the Pharmacy Location License of: The Medicine Shoppe Pharmacy, License No. 55751, Respondents.	Docket No. 99-08-A-1016PH Docket No. 99-08-A-1017CF STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER

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The State of Washington Board of Pharmacy, by and through David M. Hankins, Assistant Attorney General Prosecutor and Michael S. Jones, R.Ph., represented by W. Bernard Bauman stipulate and agree to the following:

Section 1: Procedural Stipulations

1.1 Michael S. Jones, Respondent, was issued a license to practice pharmacy in the state of Washington in June 1980. Respondent's license to practice pharmacy in the state of Washington expires on October 24, 1999.

1.2 On October 25, 1999 the Board of Pharmacy issued an Amended Statement of Charges against Respondent.

1.3 The Statement of Charges alleges that Respondent violated RCW 18.64.160(5), .165(2), .245, .246, 270, 18.130.180(1),(4), (6), (7), (12), (13), 69.04.450, .490, .510, 69.41.030,

ORIGINAL

EXHIBIT 17

.042, .050, 69.50.306, .308(d)(e), .401(1)(d); WAC 246-863-095(f), -110, 246-869-100(1)(2)(a)-(c), -130, -150, -160(4)(5), -190, -210, -230, 246-875-001, -020, -040, 246-901-080(2), -090, -100(3).

1.4 Respondent understands that the State is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.5 Respondent understands that he has the right to defend himself against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.6 Respondent understands that, should the State prove at a hearing the allegations in the Statement of Charges, the Board of Pharmacy has the power and authority to impose sanctions pursuant to RCW 18.130.160.

1.7 Respondent and the Board of Pharmacy agree to expedite the resolution of this matter by means of this Stipulated Findings of Fact, Conclusions of Law, and Agreed Order (Agreed Order).

1.8 Respondent waives the opportunity for a hearing on the Statement of Charges contingent upon signature and acceptance of this Agreed Order by the Board of Pharmacy.

1.9 This Agreed Order is not binding unless and until it is signed and accepted by the Board of Pharmacy.

1.10 Should this Agreed Order be signed and accepted it will be subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any applicable interstate/national reporting requirements.

1.11 Should this Agreed Order be rejected, Respondent waives any objection to the participation at hearing of all or some of the Board members who heard the Agreed Order presentation.

Section 2: Stipulated Facts

While Respondent does not admit to the following conduct, Respondent acknowledges that the evidence is sufficient to justify the following findings:

2.1 Respondent Medicine Shoppe Pharmacy located at 9430 State Avenue, Marysville, Washington was issued a location license to operate as a pharmacy in the state of Washington in October 1996. The current location license expires on June 1, 2000.

2.2 Respondent Michael Jones is the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

2.3 On March 1, 1994, a Statement of Charges was issued against Respondent Michael Jones related to a prescription filling error while Respondent was working as a pharmacist at Safeway Pharmacy # 497 in Seattle, Washington

2.4 On July 6, 1994, the Board entered a Findings of Fact, Conclusions of Law and Order placing Respondent's license to practice pharmacy in the state of Washington on probation for a period of one year and imposing certain terms and conditions. One of the conditions imposed on Respondent was a requirement that he create and submit a plan to avoid violations of pharmacy law related to the filling of prescriptions.

2.5 On December 7, 1995, Respondent's license to practice pharmacy in the state of Washington was fully reinstated.

2.6 In approximately October 1996, Respondent Jones purchased and operated The Medicine Shoppe in Marysville, Washington.

2.7 On December 17, 1998, Respondent Medicine Shoppe received a failing inspection grade of 79 from Board of Pharmacy Investigator Wene while conducting a routine inspection of the pharmacy. An inspection score of 90-100 is classified as a passing pharmacy

inspection score. An inspection score of 80-89 is classified as a conditional pharmacy inspection score. An inspection score of 0-79 is classified as an unsatisfactory pharmacy inspection score. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The violations included but were not limited to:

2.7.1 Failing to obtain chronic conditions on patients of the pharmacy;

2.7.2 Dispensing the majority of prescriptions in non child-resistant containers without a written request from either the patient or the prescriber;

2.7.3 Various required records required by state and federal law were either inaccurate, incomplete or not available;

2.7.4 There was a box of filled prescription containers, many unlabeled, on the floor of the pharmacy.

2.7.5 Investigator Wene discovered a prescription filling error in the will call area. A prescription for Prozac was incorrectly filled with Prilosec;

2.7.6 Many of the prescriptions in the will call area had labeled expiration dates exceeding the manufacturer's expiration date;

2.7.7 Most of the prescriptions in the will call area contained the incorrect NDC number for the product in the prescription container;

2.8 On February 3, 1999, Board of Pharmacy Investigator Wene conducted a re-inspection in relation to the December 1998 failing score. During the February 3, 1999 inspection, the pharmacy, received a passing score of 94. The deducted points were related to

inaccurate. incomplete or missing records required by state or federal law. At that time. Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington.

2.9 On July 12, 1999, Board of Pharmacy Investigators Wene and Jeppesen conducted a routine inspection of the Medicine Shoppe Pharmacy in Marysville. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. The pharmacy received an extremely low failing grade of 48. At that time the violations included but were not limited to:

2.9.1 Failing to obtain chronic conditions and allergies on patients of the pharmacy. Disease state management is coded in ICD-9 codes and provides the information in coded form, not readily readable by the Pharmacist.

2.9.2 Numerous (greater than 10) prescriptions were labeled with a different generic product than indicated on the label or NDC Code. Several of these prescriptions were dispensed in the presence of the Board of Pharmacy Investigators.

2.9.3 Dispensing the majority (in excess of 90%) of prescriptions in non-child- resistant containers without a written request from either the patient or the prescriber for non child-resistant packaging.;

2.9.4 Thirty-eight (38) drug products were outdated. Of those, 18 drugs were legend or controlled substances and 20 were OTC products.

2.9.5 Various records required by federal law (DEA) were either inaccurate, incomplete or not available. DEA order forms and invoices could not be reconciled. Respondent was unable to locate several required DEA forms. There was poor organization of DEA inventory records,

including non-sequential filing. Several DEA records did not include date and amount received on DEA 222 forms.

2.9.6 DEA Inventory incomplete, DEA inventory for Schedules III-V was missing. Respondent was unable to generate reports for Schedule II drugs. The daily refill reports were not signed, stored in various locations, out of sequence, with several months not located.

2.9.7 Facts and Comparisons, the only reference source in the pharmacy, had not been updated for at least nine (9) months.

2.9.8 Pharmacy Assistant did not have a name badge and none had been ordered. No Pharmacy Assistant certificate had been generated or signed. Modifications to the Pharmacy Assistant Utilization Plan were in place without Board approval.

2.9.9 The prescription records were inaccurate, missing and poorly organized. Examples include prescription files with non-sequential order. Several prescriptions, both C-II and other drugs were unaccounted for. Prescription files were kept with no organization. Respondent Jones was unable to locate files in a timely manner.

2.9.10 Minimum procedures for utilization of the patient medication system were inadequate.

2.9.11 During the inspection, a patient returned a prescription so that Respondent Jones could correct the instructions for use. The correction was made but no audit trail of the change was entered in the pharmacy computer

2.9.12 The pharmacy was generally disorganized and dirty. The pharmacy sink and immediate area were dirty and with numerous dirty food dishes.

2.10 On July 13, 1999, Investigator Jeppesen returned to the pharmacy to retrieve documents promised by Respondent Jones. At that time Respondent Jones stated he could not locate the documents. Respondent stated that his computer could generate the required reports but that he, (Respondent) did not know how to generate them.

2.11 On August 10, 1999, Investigators Wene and Jeppesen returned to the Medicine Shop Pharmacy in Marysville, Washington, to conduct the re-inspection in relation to the July 12, 1999 failing score. This inspection again resulted in an extremely low failing score of 56. At that time, Respondent Michael Jones was the owner, responsible manager, and only pharmacist listed as working at the Medicine Shoppe in Marysville, Washington. At that time the violations included but were not limited to:

2.11.1 Six prescriptions selected randomly in the will call area did not have allergy or chronic conditions noted in the patient profile. The disease state - drug interaction fields had been turned off. Respondent Jones was unable to explain the purpose or the clinical significance of the clinical interaction levels that appeared for drug interaction messages.

2.11.2 Three prescriptions selected randomly from the will call area were labeled with a different generic product than indicated on the label and/or NDC Code.

2.11.3 Forty-one (41) prescriptions were located in the will call area. Of those, forty (40) were packaged in non child-resistant containers and the one that was in a child resistant container was in a container supplied by the manufacturer.

2.11.4 Eleven legend or controlled substances on the shelf were beyond the manufacturer's expiration date.

2.11.5 As in the July 12, 1999 inspection, various records required by federal law (DEA) were either inaccurate, incomplete or not available. The invoices for the C II drugs were not filed separately. Several DEA records did not include date and amount received on DEA 222 forms.

2.11.6 DEA Inventory records incomplete. There was no signature on the C-II, C-III - C-V inventories. Requested records could not be located.

2.11.7 Five prescriptions which had been filled and returned to the stock area were checked for accuracy of product on the label and against correct NDC numbers. All five prescriptions failed to comply with state and/or federal law.

2.11.8 Minimum procedures for utilization of the patient medication system were inadequate. The pharmacy QS-1 system was not able to create an accurate and complete audit trail for changes made to the prescriptions after filling including directions for use and drug dispensed.

2.11.9 During the period August 4, 1999 through August 5, 1999, forty-eight prescriptions were processed in the pharmacy. Of those forty-eight prescriptions, twenty-one did not have a hard copy in the prescriptions.

2.12 Respondent Michael S. Jones operated the Medicine Shoppe Pharmacy in a manner below the standard of care for the operation of a pharmacy and therefore placed the patients of his pharmacy at serious risk of significant harm.

2.13 That on or about 4-1-99, respondent refilled a prescription for patient A for Vicoprofen, a controlled substance. Respondent misfilled the prescription by filling it with Adalat 60 mg. Patient A consumed 8 Adalat tablets over an 8-12 hour period. Respondent had to be taken to the emergency room at Providence Hospital Colby Campus, Everett, Washington for treatment for a medication reaction.

2.14 That on or about 2-8-99, patient C was prescribed 30 capsules of Cardizem 180 SR by his physician and phoned in to respondent's pharmacy. The original prescription permitted substitution, but did not permit refills. Respondent failed to note in his phone prescription if substitution was permitted.

2.15 On or about 2-8-99, respondent filled the prescription for patient C with Diltia XT 180 mg. Respondent without authorization from the physician refilled Diltia 180 mg. prescription, and misfilled and mislabeled the medication with an increase in dosage strength on 3-1-99 and on 3-7-99 with 90 capsules Diltia XT 240 mg.

2.16 Respondent failed to maintain the prescription hardcopy, failed to maintain accurate records and/or altered or manipulated the computer records by:

2.16.1 On 5-7-99, the pharmacy investigator obtained records from respondent's pharmacy. Patient C's medication profile record indicate respondent filled the prescription for Cardizem 180 SR with a generic substitute Diltia XT 240 mg. on 2-8-99, 3-1-99 and 3-7-99. The patient's son indicated that they never received the medication on 3-7-99. Respondent's daily audit log for 2-8-99 indicates he filled the prescription with Diltia XT 240 mg. The investigator also received a previous copy of respondent's daily audit log for 2-8-99 which indicates that on 2-8-99, respondent filled the medication with Diltia XT 180 mg.

2.17 That on or about 9-14-98, patient D obtained a prescription of Wellbutrin SR 150 mg 60 tablets and had the prescription filled by respondent. The patient indicated he did not obtain a refill of the medication. The prescription authorized only one refill. Respondent's records indicate that he refilled the Wellbutrin on 1-8-99, 2-16-99, and 3-27-99 without authorization from the prescriber and/or billed the state for prescriptions never obtained by the patient.

2.18 That on or about 10-23-98 patient D had respondent fill a prescription for #30 Toprol XL 100 mg. The patient's physician only prescribed Toprol XL 100 mg. Respondent's records indicate that he filled a prescription for #30 Toprol XL 100 mg and #15 Toprol XL 200 mg. He refilled the Toprol XL 100 mg on 11-19-98, 11-30-98, and 3-27-98. Respondent's records indicate he also refilled the Toprol XL 200 mg on 11-19-98, 11-30-98, 12-5-98, 1-8-99, 2-16-99 and 3-27-99. The patient indicated that he never received any Toprol XL 200 mg. Respondent failed to maintain a hardcopy of the prescription and filled a prescription without authorization from the physician and/or billed the state for medication that a patient did not receive.

2.19 That on or about 2-15-99, respondent filled a prescription for patient D for Phenergan with codeine cough syrup, a controlled substance. Respondent's medication profile records for patient D show that respondent filled the prescription as Promethazine with codeine cough syrup and also filled a prescription for hydrocodone bitartrate syrup. Respondent filled and refilled the hydrocodone bitartrate prescription without the physician's authorization on 2-15-99, 2-25-99 and 3-22-99. Respondent also refilled on 3-22-99, the patient's prescription for Promethazine with codeine. The investigator was unable to locate a hard copy of the prescription for hydrocodone bitartrate syrup. The patient indicated to the pharmacy investigator that he received the hydrocodone bitartrate syrup, but not the Promethazine cough syrup.

2.20 That on or about December 1998, patient D observed respondent provide an unlabeled prescription vial containing large white caplet shaped tablets, which appear to be hydrocodone/APAP tablets, a controlled substance, to a person in exchange for respondent's car repair.

2.21 That respondent without the physician's authorization or approval refilled a prescription for Cipro 500 mg tablets for patient E on 4-3-99 and 4-29-99.

2.22 That respondent misfilled patient F's prescription for Coumadin with 1mg. instead of 5mg, as prescribed by the physician.

Section 3: Conclusions of Law

The State and Respondent agree to the entry of the following Conclusions of Law:

3.1 The Board of Pharmacy has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 The above facts constitute unprofessional conduct in violation of RCW 18.64.160(5), .165(2), .245, .246, 270, 18.130.180(1), (4), (6), (7), (12), (13), 69.04.450, .490, .510, 69.41.030, .042, .050, 69.50.306, .308(d)(e), .401(1)(d); WAC 246-863-095(f), -110, 246-869-100(1)(2)(a)-(c), -130, -150, -160(4)(5), -190, -210, -230, 246-875-001, -020, -040, 246-901-080(2), -090, -100(3).

3.3 For purposes of settlement, the state **withdraws** allegation 1.15 in the amended statement of charges and the violations outlined in paragraph 2.30.

3.4 The above violations are grounds for the imposition of sanctions under RCW 18.130.160.

Section 4: Agreed Order

Based on the preceding Stipulated Facts and Conclusions of Law, Respondent agrees to entry of the following Order:

4.1 The Pharmacy location license of Medicine Shoppe Pharmacy, license No. 55751 shall be **REVOKED.** Respondent shall have no right to re-apply for a pharmacy location license for at least five (5) years from the date of this order. Respondent shall promptly deliver to the Board the original license and current registration.

4.2 The license to practice pharmacy issued to Michael S. Jones, shall be **SUSPENDED WITHOUT STAY** effective from the date of August 17, 1999.

4.3 The respondent is prohibited from functioning in a pharmacy or any other drug-related employment during the respondent's suspension. The respondent will not make public appearances representing himself as a pharmacist.

4.4 Respondent's license to practice pharmacy shall be **Suspended With Stay** for at least 5 years from the date of January 13, 2000.

4.5 Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.6 Respondent shall assume all costs of complying with this Order.

4.7 If Respondent violates any provision of this Order in any respect, the Board of Pharmacy may take further action against Respondent's license.

4.8 Respondent shall inform the Board of Pharmacy, in writing, of changes in his residential address.

4.9 In the event respondent should leave Washington to reside or to practice outside the state, respondent must notify in writing the Board of Pharmacy of the date of departure and return. Periods of residency or practice outside Washington will not apply to the reduction of this probationary or suspension period.

4.10 The respondent shall submit written notification to the Board of Pharmacy, addressed to the Program Manager, of any employment or residence address changes. The notification shall include the complete new address and telephone number. The notification must be made within twenty (20) days of the change in employment or residence address.

4.11 The respondent shall submit periodic declarations under penalty of perjury stating whether there has been compliance with all conditions of this Order. Failure to submit information and/or to make true statements may subject the respondent to referral for prosecution under RCW 9A.76.020 and/or RCW 9A.72.030.

4.12 The respondent shall advise any employer who hires him or her, to function in the capacity of a health care practitioner, of the terms of this Order imposed by the Board of Pharmacy. The Respondent's employer must submit written notification to the Board indicating he or she has seen the Board's Order.

4.13 The respondent shall submit a quarterly declaration under penalty of perjury stating whether there has been compliance with all conditions of this Order. The first report is due 30 days, and on the first day of Apr. 1, Jul 1, Oct and Jan and thereafter until ——, —— unless otherwise ordered by the Board of Pharmacy.

4.14 Respondent shall notify Board of Pharmacy of any employment in the health care field, including any change in employment or practice status. Respondent shall, within twenty (20) days of the effective date of this Order, or as soon thereafter as deemed by the Board of Pharmacy, submit to the Board of Pharmacy for the Board of Pharmacy's approval, a job description or description of practice and clinical privilege of respondent's present practice or position. Thereafter respondent shall submit a job description or description of practice and clinical privilege of respondent's practice or position to the Board of Pharmacy for their approval prior to making the contemplated change.

4.15 Respondent shall cause the respondent's employer to submit quarterly performance reports directly to the Board of Pharmacy on forms provided by the Board of Pharmacy. The first report is due 30 days and on the first day of Apr. 1, Jul 1, Oct and Jan.

/ and thereafter. The respondent shall ensure that the respondent's employer has been given a copy of this Order and the employer understands the decision of the Board of Pharmacy in this case. The respondent shall ensure that the employer makes reference to Board of Pharmacy decision in the reports to the Board of Pharmacy.

4.16 The respondent is hereby placed on notice that it is the responsibility of the respondent to ensure that all required reports are submitted to the Board of Pharmacy in a timely manner.

4.17 Within thirty (30) days of the effective date of this Order, or as soon thereafter as deemed by the Board of Pharmacy, respondent shall make an appointment to undergo a psychological evaluation by a psychologist designated by the Board of Pharmacy who shall furnish a report to the Board of Pharmacy according to the following protocol adopted by the Board of Pharmacy:

Please perform a psychological examination to assess:

1. Psychological diagnosis, if any.
2. Treatment recommendations, if any.

The evaluation should consist of the following components:

1. A complete social, past medical, developmental and psychological history.
2. A review of this Agreed Order.
3. Any other physical examinations, psychological or laboratory studies deemed necessary by the evaluator.

The report of examination should discuss fully and with specificity the basis for the diagnosis, if any, conclusions and recommendations made pursuant to items 1-3 in the first paragraph above. The report of examination should be sent to:

Board of Pharmacy
PO Box 47863
Olympia WA 98504-7863

A copy shall be provided to the Respondent.

4.18 Within sixty (60) days of the effective date of this decision, or as soon thereafter as deemed by the Board of Pharmacy, respondent shall submit to the Board of Pharmacy for its prior approval, a program of remedial education, related to the violations found in the decision. The exact number of hours and the specific content of the program shall be determined by the Board of Pharmacy and shall not total less than twenty-five (25). This program shall be in addition to the Continuing Education requirement for re-licensure. The Board of Pharmacy may also require respondent to pass an examination related to the content of the program.

4.19 Respondent shall submit to the Board of Pharmacy for its prior approval, a clinical education program related to the violations found in the decision. The exact number of hours and the specific content of the program shall be determined by the Board of Pharmacy and shall total not less than four (4) nor more than twenty (20) hours per week. Respondent shall complete the clinical training program prior to seeking modification. The Board of Pharmacy may require the respondent to pass an examination related to the content of the program.

4.20 Respondent shall take and pass the MPJE examination within 60 days from the date of this order. Failure to pass the examination may result in the suspension of the license until such time as a passing score is achieved. Respondent shall not engage in the practice of the profession until respondent has passed the examination and has been so notified by the Board in writing.

4.21 Respondent is prohibited from serving as the responsible manager of a pharmacy or supervising pharmacy interns.

4.22 **SUPERVISING PHARMACIST AGREEMENT**

The supervising pharmacists signs an agreement that they:

1. Have reviewed, are aware of, and understands the terms of the Order.

2. Agree to be a supervising pharmacist and provide quarterly reports concerning:
   a. obey the laws and rules of practice of pharmacy;
   b. obey rules of employment and job performance;
   c. relationship with other employees and customers;
   d. any other relevant matters.

LEVELS OF SUPERVISION

X Specific Percentage Supervision requires that a supervising pharmacist have contact with and/or personally be present for supervision at least forty (40) percent of the time or 2 ½ hours – 3 ½ hours per day;

This percentage may be decreased by the reviewing board member upon submission of an employment description to 40 percent the first year, 30 percent the second year, and 20 the third year or less as the discretion of the reviewing board member.

4.23 The respondent shall submit to the Board of Pharmacy, within thirty (30) days of the effective date of the Order, policy and procedures relating to:

the process of receiving written and telephone prescriptions, filling the prescriptions, and checking the label and the product to prevent errors;

disposition of prescription filling errors which shall include, but not be limited to: documentation of filling errors, description of filling errors, explanation of how filling errors occurred, notification of patient and physician, and steps to be taken to prevent future errors;

error reports shall be kept for two (2) years;

A Pharmacy Board Investigator will contact the respondent to determine if the respondent is in compliance with the policy and procedures.

4.24 The respondent must implement a quality assurance program with thirty (30) days of receipt of the Order.

___ The quality assurance program is directed at prescription filling and misfilling and the number of errors in filling or labeling prescriptions. The respondent shall maintain a log of all errors in prescription filling. The log shall be maintained at the pharmacy and made available to Pharmacy Board Investigators and Staff at their request.

___ Develop an effective quality assurance set of criteria or guidelines by which to monitor patient profiles for inappropriate, excessive or non-therapeutic quantities of medications. An outline of the process and screening questions must be submitted to the Disciplinary Authority for approval.

A Pharmacy Board Investigator will contact the Respondent to determine if the respondent is in compliance with the quality assurance program.

4.25 The Respondent shall comply with the Board's probation surveillance program including appearing in person for interviews upon request at various intervals and with reasonable notice.

4.26 Respondent may submit a written request for modification of the Board's Order for his pharmacist license only, no sooner than three years from the date of this order. Respondent, at the Board's discretion shall personally appear before the Board of Pharmacy

4.27 At the conclusion of the stayed suspension, Respondent, if requested by the Board, shall appear before the Board of Pharmacy prior to seeking reinstatement of his license to practice pharmacy.

4.28 Respondent shall assume all costs associated with the compliance of this Order.

4.29 If the respondent violates any provision of this Order in any respect, the Board of Pharmacy, after giving the respondent notice and the opportunity to be heard, may **SET ASIDE THE STAY ORDER AND IMPOSE THE SUSPENSION OF THE RESPONDENT'S LICENSURE OR MAY** impose any sanction as appropriate under RCW 18.130.160 to protect the public, or may take emergency action ordering summary suspension or restriction or limitation of the respondent's practice as authorized by RCW 18.130.050.

4.30 Within 10 days of the effective date of this order, Respondent shall thoroughly complete the attached Healthcare Integrity and Protection Data Bank Reporting Form (Section 1128E of the Social Security Act) and return it to the disciplining authority.

IT IS FURTHER ORDERED that all parties shall be bound by the terms and conditions of this Order. Any failure to comply with the terms and conditions of this Order will subject the respondent's license to practice as a pharmacist to further disciplinary action.

I, Michael S. Jones, Respondent, certify that I have read this Stipulated Findings of Fact, Conclusions of Law and Agreed Order in its entirety; that my counsel of record, if any, has fully explained the legal significance and consequence of it; that I fully understand and agree to all of it; and that it may be presented to the Board of Pharmacy without my appearance. If the Board accepts the Stipulated Findings of Fact, Conclusions of Law and Agreed Order, I understand that I will receive a signed copy.

Michael S. Jones, R.Ph.
Respondent

January 11, 2000
Date

W. Bernard Bauman
WSBA #8849
Attorney for Respondent

January 11, 2000
Date

Section 5: Order

The Board of Pharmacy accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED this 4 day of February, 2005.

State of Washington
Department of Health
Board of Pharmacy

C. ALZOLA, R.PH
Panel Chair

Presented by:

DAVID M. HANKINS
WSBA #19194
Assistant Attorney General Prosecutor

Notice of Presentation Waived and Approved
As to Form:

W. Bernard Bauman
WSBA #8849
Attorney for Respondent

Section 5: Order

The Board of Pharmacy accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED this 4 day of February, 2020.

State of Washington
Department of Health
Board of Pharmacy

C. A. Alzola RPh

Presented by:

C. A. LEON ALZOLA, R.Ph
Panel Chair

DAVID M. HANKINS
WSBA #19194
Assistant Attorney General Prosecutor

Notice of Presentation Waived and Approved
As to Form:

W. Bernard Bauman
W. Bernard Bauman
WSBA #8849
Attorney for Respondent

Section 5: Order

The Board of Pharmacy accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED this _____ day of _____, _____.

State of Washington
Department of Health
Board of Pharmacy

~~Michael Kleinberg~~, CHAIR
CALcon 4/20/10

Presented by:

DAVID M. HANKINS
WSBA #19194
Assistant Attorney General Prosecutor

Notice of Presentation Waived and Approved
As to Form:

W. Bernard Bauman
WSBA #8849
Attorney for Respondent

APPENDIX I

RECEIVED
MAR 0 8 2004
BROWNLIE & EVANS, LLP

FILED
MAR 0 5 2004
PAM L. DANIELS
COUNTY CLERK
SNOHOMISH CO. WASH.

IN THE SUPERIOR COURT OF WASHINGTON FOR SNOHOMISH COUNTY

MICHAEL S. JONES, R. Ph.,

Plaintiff,

vs.

STATE OF WASHINGTON AND ITS DEPARTMENT OF HEALTH; WASHINGTON STATE BOARD OF PHARMACY; PHYLLIS WENE and STAN JEPPESEN, individually and as investigators for the Washington State Board of Pharmacy, and DONALD WILLIAMS, individually and as executive director of the Board of Pharmacy,

Defendants

Case No.: 02-2-10037-4

FIRST AMENDED COMPLAINT

I. PARTIES

1.1 **Plaintiff Michael S. Jones** is a single man who resides in the state of Washington ("Jones").

1.2 **Defendant State of Washington** is the state of Washington. Defendant Washington State Department of Health is a department of the state of Washington ("Health

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Bellingham, WA 98225
(360) 676-0306

Department"). Defendant Washington State Board of Pharmacy is a division of the Health Department ("Board of Pharmacy").

1.3 **Defendant Phyllis Wene** is an investigator for the Board of Pharmacy. She is believed to be a resident of the state of Washington ("Wene").

1.4 **Defendant Stan Jeppesen** is an investigator for the Board of Pharmacy. He is believed to be a resident of the state of Washington ("Jeppesen").

1.5 **Defendant Donald Williams** is the executive director of the Board of Pharmacy. He is believed to be a resident of the state of Washington ("Williams").

II. JURISDICTION and VENUE

2.1 The tortious and wrongful conduct complained of herein took place in Snohomish County, Washington. The court has jurisdiction and venue is proper.

III. RELEVANT FACTS

3.1 Michael Jones is a pharmacist licensed by the Board of Pharmacy. At all times material hereto, Jones was the president and sole shareholder of The Medicine Shoppe Pharmacy Inc., a Washington corporation, which owned and operated a pharmacy in Marysville, Snohomish County, Washington (the "Medicine Shoppe"). The Medicine Shoppe had a location license issued by the Board of Pharmacy.

3.2 On or about December 17, 1998, a routine inspection of Jones's pharmacy by inspectors for the Board of Pharmacy resulted in the pharmacy receiving a failing grade of 79. Under state law, Jones had 21 days to remedy the defects noted in the inspection report. On or about February 3, 1999, a re-inspection of Jones' pharmacy resulted in a passing grade of 96.

3.3 On or about March 1, 1999, Jones fired an employee, Mary Berlin ("Berlin"), for attempting to transfer a prescription for a controlled substance to another pharmacy in violation of the law. Based on information and belief, Berlin contacted the Board of Pharmacy after her termination and made false allegations of wrongdoing at Jones's pharmacy.

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3.4 Based on information and belief, Defendant Wene, an inspector with the Board of Pharmacy, responded to these false allegations by contacting Jones at Jones's pharmacy during the month of April, 1999. During that contact, Wene asked Jones about the whereabouts of Berlin. Jones told Wene that he had fired Berlin for attempting to transfer prescriptions for controlled substances in violation of the law. Wene did not inform Jones that Berlin had made allegations of wrongdoing against Jones and his pharmacy. Wene did not inform Jones that anyone else had made allegations of wrongdoing against Jones.

3.5 On or about July 11, 1999, Wene and Jeppesen returned to Jones' pharmacy. They told Jones that they had come to the pharmacy to conduct a training exercise. Based on information and belief, this was not true. Based on information and belief, Wene and Jeppeson had returned to Jones's pharmacy with the intent of closing down the pharmacy and putting Jones out of business. Based on information and belief, Williams knew of and directed Wene's and Jeppesen's actions. Wene and Jeppesen proceeded to harass Jones and his employees and to disrupt the operation of the pharmacy.

3.6 On or about July 12, 1999, Jeppesen returned to Jones's pharmacy. Jeppesen told Jones that he had returned as part of a training exercise. Jones told Jeppesen that he was not welcome to repeat his harassing behavior. Jeppesen responded by giving Jones an inspection report with a failing grade of 48. The failing grade was based on false and inaccurate information contained in the inspection report. The failing grade was also based on subjective and arbitrarily imposed standards. Based on information and belief, the false and inaccurate information and score was compiled by Jeppesen and by Wene. Based on information and belief, Jeppesen and Wene knew or should have known that the failing grade was erroneous. Based on information and belief, Williams knew of and directed Jeppesen's and Wene's actions. In the alternative, the failing grade was the result of Wene's and Jeppesen's reckless and/or negligent inspection.

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3.7 On or about August 10, 1999, Wene and Jeppesen returned to Jones's pharmacy and conducted a reinspection. The reinspection resulted in a failing grade of 56. Again, the failing grade was based on false and inaccurate information contained in the reinspection report. Again, the failing grade was based on subjective and arbitrarily imposed standards. Based on information and belief, the false and inaccurate information was compiled by Jeppesen and by Wene. Based on information and belief, Jeppesen and Wene knew or should have known that the failing grade was erroneous. Based on information and belief, Williams knew of and directed Jeppesen's and Wene's actions. In the alternative, the failing grade was the result of Wene's and Jeppesen's reckless and/or negligent inspection.

3.8 On or about August 16, 1999, Williams issued a Statement of Charges against Jones and the Medicine Shoppe based on allegations of wrongdoing contained in the inspection reports compiled by Wene and Jeppesen. Based on information and belief, Williams made the decision to pursue a summary suspension of Jones's professional license and of his pharmacy license. Based on information and belief, Williams made the decision not to notify Jones and give him an opportunity to be heard on the state's motion for an order of summary action.

3.9 On or about August 17, 1999, the Board of Pharmacy held a hearing on an Ex Parte Motion for Order of Summary Action brought by the Health Department. The hearing was based on Wene's and Jeppesen's inspection reports. The hearing was held without notice to Jones and without an opportunity for Jones to be heard. At the conclusion of the hearing, the Board of Pharmacy issued an Ex Parte Order of Summary Action which immediately and summarily suspended Jones's professional license and immediately and summarily suspended The Medicine Shoppe's location license. On August 20, 1999, Wene went to Jones's pharmacy, informed him of the order, and closed down Jones's practice and his pharmacy.

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3.10 Jones tried to save his business by making motions for a stay of the summary suspensions of his licenses pending a hearing. The Health Department opposed any modification of the summary order. The Board of Pharmacy denied Jones's motion for a stay.

3.11 Jones then tried to save his business by requesting an expedited hearing on the Statement of Charges as soon as practicable. The Health Department opposed an expedited hearing on the Statement of Charges. The Board of Pharmacy granted the motion for an expedited hearing and scheduled the hearing for October 21, 1999.

3.12 On October 18, 1999, the Health Department requested a continuance of the expedited hearing based on a proposed amendment to the Statement of Charges with new allegations. Jones opposed any continuance. The Board of Pharmacy granted the state's motion for a continuance and rescheduled the hearing for December 2, 1999.

3.13 Because of these and other delays, Jones lost the opportunity to save his business. On of about January 11, 2000, Jones signed the Stipulated Findings of Fact, Conclusions of Law and Agreed Order because he had already suffered financial ruin and had neither the financial wherewithal nor the incentive to continue opposing the state's charges.

IV. FIRST CAUSE OF ACTION AGAINST WENE, JEPPESEN AND WILLIAMS IN THEIR INDIVIDUAL CAPACITIES
Civil Rights Violation (42 U.S.C. §1983)

4.1 Jones realleges the allegations contained in paragraphs 1.1 through 3.12.

4.2. While acting under the color of state law, Wene, Jeppesen and Williams violated Jones's civil rights by initiating disciplinary proceedings that they knew or should have known were unreasonable and violated Jones's procedural due process rights under the United States Constitution. As a result, Jones suffered damages in an amount to be determined at trial.

V. SECOND CAUSE OF ACTION AGAINST ALL DEFENDANTS
Recklessness

5.1. Jones realleges the allegations contained in paragraphs 1.1 through 4.2 above.

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5.2 Wene's, Jeppesen's and Williams's investigation of Jones and of his pharmacy was conducted recklessly or with actual malice. The recklessness or malice resulted in false reports that caused the summary suspensions of Jones's professional license and of his pharmacy's location license. The summary suspensions in turn caused Jones to lose his business and to suffer damages in an amount to be determined at trial.

5.3 At all times material hereto, Wene, Jeppesen, and Williams were employees of the state of Washington and their actions were within the scope of their employment and were chargeable to their employer. As a result, the state of Washington is responsible under the theory of *respondeat superior*.

VI. THIRD CAUSE OF ACTION AGAINST ALL DEFENDANTS
Negligence

6.1 Jones realleges the allegations contained in paragraphs 1.1 through 5.3 above.

6.2 Wene's, Jeppesen's and Williams's investigation of Jones and of Jones's pharmacy was negligent. The negligence resulted in false reports that led to the summary suspensions of Jones' professional license and of his pharmacy's location license. The summary suspensions in turn caused Jones to lose his business and to suffer damages in an amount to be proven at trial.

6.3 At all times material hereto, Wene, Jeppesen and Williams were employees of the state of Washington and their actions were within the scope of their employment and were chargeable to their employer. As a result, the state of Washington is responsible under the theory of *respondeat superior*.

6.4 In the alternative, the state was negligent in the supervision of Wene, Jeppesen and Williams, and its negligent supervision led to the false reports that gave rise to the disciplinary proceedings which resulted in the loss of Jones's licenses.

VII. FOURTH CAUSE OF ACTION AGAINST ALL DEFENDANTS
Tortious Interference with a Business Expectancy

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Bellingham, WA 98225
(360) 676-0306

7.1 Jones realleges the allegations contained in paragraphs 1.1 through 6.4 above.

7.2 Jones had a valid business expectancy with the customers of his pharmacy and the continued operation of his pharmacy franchise. Wene, Jeppesen and Williams knew of this expectancy. Either through negligence, recklessness or actual malice, Wene, Jeppesen and Williams caused false inspection reports to be issued against Jones and secured an order which summarily suspended Jones's professional and pharmacy licenses in violation of Jones's due process rights. These summary suspensions interfered with Jones's business expectancy and caused him to lose his business. As a result, Jones suffered damages in an amount to be proven at trial.

7.3 At all times material hereto, Wene, Jeppesen and Williams were employees of the state of Washington and their actions were within the scope of their employment and were chargeable to their employer. As a result, the state of Washington is responsible under the theory of *respondeat superior*.

VIII. FIFTH CAUSE OF ACTION AGAINST STATE OF WASHINGTON, DEPARTMENT OF HEALTH AND BOARD OF PHARMACY
Injunctive Relief

8.1 Jones realleges the allegations contained in paragraphs 1.1 through 7.3 above.

8.2 Jones seeks an order expunging all records relating to the disciplinary action taken against him by the State of Washington, Department of Health, and/or Board of Pharmacy following the investigations of his pharmacy in July and August, 1999, and reinstating his full rights to practice pharmacy and to obtain a pharmacy location license.

IX. PRAYER FOR RELIEF

WHEREFORE, Jones prays for judgment as follows:

A. For money judgment against Wene, Jeppesen, and the State of Washington, jointly and severally, for Jones's economic damages, including but not limited to backpay, frontpay, lost earning potential, and out of pocket expenses in an amount to be proven at trial;

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B. For money judgment against Wene, Jeppesen, and the State of Washington, jointly and severally, for Jones's emotional distress and pain and suffering in an amount to be proven at trial;

C. For money judgment against Wene, Jeppesen, and the State of Washington, jointly and severally, for damages to Jones's reputation in an amount to be proven at trial;

D. For money judgment against Wene and Jeppesen, jointly and severally, for punitive damages as authorized by 42 U.S.C. §1983 *et seq.* and other applicable law;

E. For money judgment against Wene and Jeppesen, jointly and severally, for Jones's costs and reasonable attorney's fees as authorized by 42 U.S. C. §1983 *et seq.*;

F. For a declaratory judgment that Jones's constitutional right to due process was violated as a result of the actions of Wene, Jeppesen, Williams and/or the Board of Pharmacy as authorized by 42 U.S. C. §1983 *et seq.*;

G. For an order expunging any record of the disciplinary action taken against Jones following the investigations of his pharmacy in July and August, 1999, and reinstating his full rights to practice pharmacy and to obtain a pharmacy location license.

H. For such other equitable and legal relief as the court deems just and equitable.

DATED this 4th day of March, 2004.

BROWNLIE & EVANS, LLP

By: _____
Murphy Evans, WSBA #26293
Attorney for Michael Jones

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COURT OF APPEALS DIV. #1
STATE OF WASHINGTON
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COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION ONE

MICHAEL S. JONES R.Ph., Respondent/Plaintiff, v. STATE OF WASHINGTON AND ITS DEPARTMENT OF HEALTH, WASHINGTON STATE BOARD OF PHARMACY, ET AL. Petitioners/Defendants.	Court of Appeals No.: 57850-2 Superior Court No.: 02-2-08819-6 PROOF OF SERVICE

I, Suzanne M. Collins, certify under penalty of perjury under the laws of the state of Washington that I am over the age of 18, and on April 27, 2006, I caused to be delivered, via first class United States mail, postage prepaid, a true and correct copy of Jones's Opposition to State's Motion for Discretionary Review in the above-captioned action to:

John R. Nicholson
Assistant Attorney General
900 4th Avenue, Suite 2200
Seattle, WA 98164

ORIGINAL

DATED this 27th day of April, 2006, at Bellingham, Washington.

Suzanne M. Collins

Suzanne M. Collins, Paralegal
Brownlie Evans Wolf & Lee, LLP