

No. 48870-1-II

**COURT OF APPEALS
OF THE STATE OF WASHINGTON
DIVISION TWO**

MICHAEL MURRAY, Appellant,

v.

DEPARTMENT OF LABOR AND INDUSTRIES, Respondent.

ON APPEAL FROM THE SUPERIOR COURT OF THE
STATE OF WASHINGTON FOR KITSAP COUNTY

#15-2-00566-1

**REPLY BRIEF OF
APPELLANT MICHAEL MURRAY**

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INTRODUCTION

According to the Department of Labor and Industries, the Health Technology Clinical Committee (HTCC) has administrative power beyond that of any other State agency, the Department included. The HTCC may unilaterally withdraw compensation for medical treatment without further agency or judicial review. The Department argues this is valid and constitutional “because procedural safeguards exist to control arbitrary administrative action: an open and transparent decision-making process and judicial review through the writ process.” (Response Brief at 45). If this were true, the Legislature could repeal all agency and judicial review under the Administrative Procedure Act and not violate the delegation doctrine.

The Department’s defense of the HTCC fails for at least three reasons. First, the Court’s inherent powers of review do not make delegation of unreviewable agency power constitutional. Second, the HTCC decision improperly supplanted the Department’s rule-making requirements. And third, Mr. Murray deserves a hearing on the merits of his claim. The HTCC’s “evidence-based” medical decision excludes the most compelling evidence here: that FAI surgery worked for Mr. Murray. The HTCC does not promote more

rational or reasonable outcomes in workers' compensation cases; it unfairly deprives injured workers of meaningful agency and judicial consideration.

I. A CONSTITUTIONAL WRIT OF REVIEW DOES NOT SAVE THIS FLAWED DELEGATION OF LEGISLATIVE POWER

When it created the HTCC, the Legislature recognized the need for judicial review of the Committee's decisions. Laws of 2006, ch. 307 § 6. The Governor's veto of this provision foreclosed appellate review, and created an unconstitutional delegation of legislative power to an executive agency. This Court recognized the problem in Joy v. Dep't. of Labor & Indus., but concluded "the absence of remedies under RCW 70.14.120 for workers denied coverage by L & I due to HTCC determinations is, nonetheless, a legislative problem that must be addressed by the legislature, not the courts." Joy v. Dep't of Labor & Indus., 170 Wn. App. 614, 627 n.13, 285 P.3d 187 (2012). This was in error. The delegation doctrine exists for cases like this – where the Legislature delegates its authority to make public policy to an agency with no oversight or accountability.

The HTCC statute permits no agency or judicial review of the HTCC's general coverage decision in Mr. Murray's case. RCW

70.14.120 (“shall not be subject to a determination in the case of an individual patient”). As the Department acknowledges, the only possible scrutiny of HTCC decisions is through a constitutional writ of review. (Corrected Response at 20). But this last ditch effort at judicial intervention does not save the flawed statute.

A. The Constitutional Writ of Review Alone Is Insufficient

The Department’s argument relies on the narrowest form of judicial review, the constitutional writ of certiorari.

The fundamental purpose of the constitutional writ of certiorari is to enable a court of review to determine whether the proceedings below were within the lower tribunal's jurisdiction and authority. Like the statutory writ of review, the scope of review under a constitutional writ of certiorari is more limited than an appeal. Review under article IV, section 6 is limited to whether the hearing officer's actions were arbitrary, capricious, or illegal, thus violating a claimant's fundamental right to be free from such action. This constitutional, or common law, writ of certiorari is only available as an avenue for review when both direct appeal and statutory writ of review are unavailable.

Coballes v. Spokane Cty., 167 Wn. App. 857, 866–67, 274 P.3d 1102 (2012) (citations omitted). A reviewing court cannot reverse errors of law or clearly erroneous factual findings. “In the constitutional certiorari context, illegality refers to an agency's jurisdiction and authority to perform an act.” Fed. Way Sch. Dist. No. 210 v. Vinson,

172 Wn.2d 756, 770, 261 P.3d 145 (2011). Only jurisdiction and authority are at issue, not the merits of the agency's decision.

A constitutional writ of review, standing alone, does not save an otherwise unreviewable delegation of legislative power to an executive branch agency. If it did, there would be no need for, or meaning left in, the delegation doctrine.

Delegation of legislative power is constitutional "when it can be shown...that procedural safeguards exist to control arbitrary administrative action and any administrative abuse of discretionary power." Barry & Barry, Inc. v. State Dep't of Motor Vehicles, 81 Wn.2d 155, 159, 500 P.2d 540 (1972). No Washington opinion has upheld a delegation based solely on the constitutional writ of certiorari, and for good reason. The writ exists to test jurisdiction, not to provide control over arbitrary administrative action and abuse of discretionary power. That requires review of the merits of an agency decision.

The Washington Supreme Court's latest opinion on the delegation doctrine, Auto. United Trades Org. v. State, 183 Wn.2d 842, 357 P.3d 615 (2015), emphasized safeguards *in addition* to a writ of review. "We have found sufficient safeguards exist because of administrative review and the availability of writs of certiorari,

among other things.” Auto. United, 183 Wn.2d at 861. A writ alone was not enough.

After Barry & Barry, the Supreme Court has required more procedural safeguards than the courts' inherent right to review. At minimum, review under the Administrative Procedure Act or similar scrutiny is required. See, e.g., Chicago Title Ins. Co. v. Washington State Office of Ins. Com'r, 178 Wn.2d 120, 144–45, 309 P.3d 372 (2013) (“rule...properly adopted following the statutory notice and comment procedures set forth in RCW 48.30.010 and RCW 34.05.310–.395”); Brown v. Vail, 169 Wn.2d 318, 332, 237 P.3d 263 (2010) (“opportunity for judicial review and the presence of adequate safeguards during the proceedings resulting in each appellant's judgment and sentence”); Larson v. Seattle Popular Monorail Auth., 156 Wn.2d 752, 763, 131 P.3d 892 (2006), as amended (May 24, 2006) (“authority is subject to all standard requirements of a governmental entity pursuant to RCW 35.21.759”); State v. Simmons, 152 Wn.2d 450, 457, 98 P.3d 789 (2004) (“DOC's rule making process provided for public scrutiny and judicial review of disciplinary action”); McGee Guest Home, Inc. v. Dep't of Soc. & Health Servs. of State of Wash., 142 Wn.2d 316, 327, 12 P.3d 144 (2000) (“CCFs...had...right to seek judicial review of the

Department's actions to determine if they complied with the terms of RCW 74.08.045"); McDonald v. Hogness, 92 Wn.2d 431, 444–45, 598 P.2d 707 (1979) (“adequate procedural safeguards in Administrative Procedure Act provisions providing...judicial review to protect against arbitrary and capricious administrative action”); Polygon Corp. v. City of Seattle, 90 Wn.2d 59, 67, 578 P.2d 1309 (1978) (“additional, more significant safeguard is the availability of judicial review of the entire record under the clearly erroneous standard”).

Despite this clear precedent, the Department asserts that a constitutional writ of review alone is sufficient procedural protection. (Response Brief at 40-43). But the three cases the Department cites do not prove such an extreme dilution of the delegation doctrine. First, in Auto United, quoted above, the Supreme Court listed a number of routes of review, including on the merits of the petitioners’ claims. “They could, for example, as AUTO did below, challenge the agreements on the grounds the legislature is giving a privilege to the tribes that is not enjoyed by others similarly situated in violation of the privileges and immunities clause (article I, section 12 of the state constitution), which, frankly, seems to be AUTO's real complaint—the abiding suspicion that the tribes got a privilege that they should

not have.” Auto. United, 183 Wn.2d at 861–62. Because multiple avenues existed to challenge the agency’s decision, including a writ of review, the Supreme Court found sufficient safeguards against the agency making rulings immune from scrutiny.

In contrast, Michael Murray has never had and, if the Department is correct, never will have a hearing on the merits of his case. The HTCC and the Department foreclosed *all* judicial review of his claim.

Second, in City of Auburn v. King County, 114 Wn.2d 447, 788 P.2d 534 (1990), the Supreme Court upheld arbitration of King County’s claim that Auburn must reimburse it for providing health services. Arbitration reached the merits of the dispute, which a court could then review under RCW 7.16.040, the statutory writ of review. “The writ can be granted if the board of arbitration exceeds its jurisdiction, acts illegally, proceeds in violation of the common law, or conducts erroneous or void proceedings.” City of Auburn, 114 Wn.2d at 452. A statutory writ of review allows a court to reverse for obvious or probable errors of law. City of Seattle v. Holifield, 170 Wn.2d 230, 244, 240 P.3d 1162 (2010) (“purpose served by a writ of review is sufficiently similar to that served by interlocutory review”).

This is greater procedural protection than review under a constitutional writ.

Third, in McDonald v. Hogness, 92 Wn.2d 431, 598 P.2d 707 (1979), also quoted above, the Supreme Court upheld delegation subject to judicial review for an abuse of discretion, as well as arbitrary and capricious decisions.

[C]ommittee decisions are subject to review as they were in DeFunis and the present case on the ground the committee acted arbitrarily and capriciously. The decisions are also subject to review for abuse of discretion.

McDonald v. Hogness, 92 Wn.2d at 446. Once again this is more searching scrutiny than the narrow scope of a constitutional writ.

None of these cases suggest that a constitutional writ of review alone is a sufficient procedural safeguard. There must be more, whether agency review or judicial scrutiny, to ensure that an unelected body is exercising delegated power correctly.

After Barry & Barry, Washington Courts have twice found a violation of the delegation doctrine based on a lack of procedural safeguards. Matter of Powell, 92 Wn.2d 882, 602 P.2d 711 (1979); United Chiropractors of Washington, Inc. v. State, 90 Wn.2d 1, 578 P.2d 38 (1978). Both cases address the outer boundaries of

legislative delegation and provide compelling reasons to find a violation here.

In Powell, the Supreme Court reversed Jennifer Powell's conviction for possessing Dalmane, a controlled substance. The State Board of Pharmacy adopted an emergency regulation listing Dalmane after the Supreme Court had invalidated earlier attempts. Powell, 92 Wn.2d at 844. The Powell Court held that the Board's emergency regulation violated the delegation doctrine because the Legislature failed to provide adequate procedural safeguards.

[W]e find the procedural safeguards afforded in this case to be almost nonexistent. Because the rule classifying Dalmane as a controlled substance was promulgated as an emergency rule, the board dispensed with notice and public comment procedures which are normally afforded in the rulemaking process. Theoretically, a party could petition for the repeal of a rule after its promulgation pursuant to RCW 34.04.060, but as discussed above, there was insufficient notice of the promulgation of the rule. In practical terms, a person cannot contest the promulgation of a rule which she or he has not received notice. As this case sadly illustrates, the first opportunity a person would have to contest such a rule would occur after she or he is already involved in a serious criminal matter. We deem the procedural safeguards available in this case to be inadequate.

Powell, 92 Wn.2d at 893.

The same conclusion applies here. As detailed in Section II below, the HTCC withdrew approval for FAI surgery after meetings

that dispensed with the notice and public comment procedures normally required in the rulemaking process. Furthermore, the Committee deprived Mr. Murray of any opportunity to prove the surgery was necessary and proper medical care in his case, a vested right under Washington's worker compensation laws. Willoughby v. Dep't of Labor and Indus., 147 Wn.2d 725, 733, 57 P.3d 611 (2002) ("all workers who suffer an industrial injury covered by the Industrial Insurance Act, Title 51 RCW, have a vested interest in disability payments upon determination of an industrial injury"). Like the statute in Powell, the HTCC statute delegated authority to an agency with inadequate procedural safeguards. The HTCC's decision, like the Board of Pharmacy's, is therefore not binding.

Second, in United Chiropractors, the Legislature delegated to the Governor power to appoint the three-member State Board of Chiropractic Examiners and seven-member Washington State Disciplinary Board for Chiropractors. Names for the appointees, however, came from two private Chiropractic organizations.

RCW 18.25.015 gives to the WCA "and/or" the CSW the authority to submit five names to the governor from which the governor must appoint the three-member State Board of Chiropractic Examiners. RCW 18.26.040 provides that the seven-member Washington State Disciplinary Board for Chiropractors is to be composed of three members appointed by the

WCA, three by the CSW, and one member who shall be the Director of the Department of Motor Vehicles or his designee. No provision is made for any governmental officer's review or approval of the selections made by either organization.

United Chiropractors of Washington, Inc. v. State, 90 Wn.2d 1, 2–3, 578 P.2d 38 (1978).

The Supreme Court found the delegation unconstitutional for a lack of procedural safeguards.

The procedural safeguards which exist in this scheme are inadequate to control arbitrary administrative action and abuse of discretion in licensing and disciplining of chiropractors not belonging to the favored groups... We think such a power to determine who shall have the right to engage in an otherwise lawful enterprise may not validly be delegated by the Legislature to a private body which, unlike a public official, is not subject to public accountability, at least where the exercise of such power is not accompanied by adequate legislative standards or safeguards whereby an applicant may be protected against arbitrary or self-motivated action on the part of such private body.

United Chiropractors, 90 Wn.2d at 6–7 (citation omitted). The Department discounts this opinion as based on delegation to private organizations. (Response Brief at 44 n.16). But the Court focused on “public accountability” – the need for those exercising public power to answer to those affected by it. Here, the HTCC operates without public accountability, answerable to no one but themselves.

The delegation doctrine protects against transferring legislative power to agencies with no review or direct accountability for their actions. This case illustrates what happens when the Legislature violates the doctrine. A group of unelected, appointed professionals, with no apparent experience with workers compensation, have unilaterally withdrawn FAI surgery from consideration in any case. No agency or court may review, modify, or qualify this decision, and as a consequence, Mr. Murray had to choose between enduring the disintegration of his hip and paying for the surgery himself.

The HTCC made its decision with unconstitutional procedures and no meaningful accountability for its consequences. The decision to withdraw FAI surgery from consideration, regardless of individual circumstances or competent medical evidence, is therefore unenforceable.

B. Recent Amendments To Health Care Authority Regulations Acknowledge The Flaw

Washington's Health Care Authority recognized the fundamental problems with the HTCC statute and amended its regulations to compensate for them. On September 26, 2016, the Authority, which supervises the HTCC, added provisions for judicial

review of its implementation of the Committee's decisions. Wash. St. Reg. 16-18-23 (August 26, 2016) (Attached as Appendix A). The amendments were necessary to make up for the lack of judicial review. Unfortunately for Mr. Murray, they apply only to final coverage determinations made after August 1, 2016. WAC 182-44-040.

The Health Care Authority substantially revised its rules governing adoption of HTCC final coverage determinations. Under WAC 182-44-040(4), the Authority made its implementation of HTCC decisions reviewable under the APA.

The health care authority's implementation of a final coverage determination can be reviewed as other agency action under RCW 34.05.570(4). A petition for review must be filed in superior court and comply with all statutory requirements for judicial review of other agency action required in chapter 34.05 RCW [the Administrative Procedure Act].

WAC 182-44-040(4). It remains an open question whether this new regulation conflicts with the Legislature's decree that "neither the committee nor any advisory group is an agency for purposes of chapter 34.05 RCW." RCW 70.14.090(5).

The Authority also adopted a new regulation on judicial review.

Nothing in this chapter limits the superior court's inherent authority to review health technology clinical committee determinations to the extent of assuring the decisions are not arbitrary, capricious, or contrary to law.

WAC 182-55-041. As noted above, the constitutional writ of review does not allow Mr. Murray or any aggrieved party to challenge the merits of an HTCC decision. It is not the same as review for error under the APA.

Why did the Authority adopt these amended regulations? There are at least two reasons. First, in the Washington Register filing, the Authority notes as "other findings required by other provisions of law as precondition to adoption or effectiveness of rule: *a settlement agreement related to King County Superior Court No. 13-2-03122-1 SEA.*" Wash. St. Reg. 16-18-023 at 1 (emphasis added). This is Sund v. Regence Blue Shield, King County No. 13-2-03122-1 SEA, described in Mr. Murray's opening brief and attached there as Appendix B. (Opening Brief at 24). It is also a ruling the Department derides as "a flawed superior court decision." (Response Brief at 44 n.17). Yet the Health Care Authority amended its regulations as a result of this decision.

Second, the amendments tacitly acknowledge the need for adequate judicial review of HTCC decisions. The statute on its own

impermissibly delegated unreviewable authority to the Committee. Even the Authority could not accept that. Because the HTCC decision on FAI surgery contains this constitutional flaw, its decision is void.

II. THE HTCC IMPROPERLY SUPPLANTED THE DEPARTMENT'S RULE-MAKING AUTHORITY.

To exclude a medical procedure from coverage, the Department of Labor and Industries must comply with rigorous, rule-making procedures under the APA. RCW 51.04.020; RCW 34.05.310-.395. For example, in WAC 296-20-3002, the Department has identified specific medical treatments that it will not allow or pay for. The Department adopted and then amended this regulation after notice of its proposed rule in the Washington State Register, RCW 34.05.320, a public hearing, RCW 34.05.325, and the right to judicial review of the process, RCW 34.05.330. Rios v. Washington Dep't of Labor & Indus., 145 Wn.2d 483, 507, 39 P.3d 961 (2002) (“allusion to fiscal considerations and prioritizing cannot be regarded as an unbeatable trump in the agency's hand; on review, a plaintiff has the opportunity to show that the agency's failure to act was “[a]rbitrary or capricious”).

The HTCC statute improperly supplants the Department's more rigorous rule-making authority under RCW 51.04.020. "The department is an administrative agency and cannot dispense with the essential forms of procedure which condition its wholly statutory powers." Leschner v. Dep't of Labor & Indus., 27 Wn.2d 911, 920, 185 P.2d 113 (1947). Yet the HTCC statute does not require notice of a proposed decision, let alone judicial review before it takes effect. RCW 70.14.110. Although the statute requires an "open and transparent process", the HTCC need not comply with the APA's rule-making procedures.

Recognizing the flaws in the HTCC's notice provisions, the Health Care Authority revised its regulations to require, after August 1, 2016, more rigorous notice of its reports and final decisions. WAC 182-55-030. Furthermore, the Authority then reviews the HTCC's final decision for procedural compliance with the notice provisions. WAC 185-55-040. None of these measures were in effect when the HTCC unilaterally excluded FAI surgery from coverage. The decision that deprived Mr. Murray of proper and necessary medical care was fatally flawed.

Mr. Murray takes no position on whether these recent regulations cure the constitutional problems in the HTCC. But the

Authority's action reasonably implies that decisions made without these new, minimal protections, are defective and unenforceable. Mr. Murray therefore has the right, like any other claimant, to prove that FAI surgery is proper and necessary medical care *in his case*.

III. MR. MURRAY DESERVES A HEARING

After devoting 24 pages to describing why Mr. Murray has no right to individualized consideration, the Department notes that if this Court finds the HTCC decision unenforceable, Mr. Murray deserves a hearing. "At most, this Court could remand the matter to the Department and direct it to consider whether the treatment that Murray seeks is proper and necessary care because the Department did not first adjudicate whether the treatment is proper and necessary." (Response Brief at 47-48).

The Department recognizes that before it may make an individual or mass determination on a medical procedure, claimants deserve notice and an opportunity to be heard. Citing American Mfrs. Mut. Ins. Co. v. Sullivan, 526 U.S. 40, 119 S. Ct. 977, 143 L. Ed. 2d 130 (1999), it argues that Mr. Murray has no vested right to benefits for a medical procedure not proven reasonable and necessary. But in American Mfrs., the United States Supreme Court assumed that a claimant had the right to prove this.

[F]or an employee's property interest in the payment of medical benefits to attach under state law, the employee must clear two hurdles: First, he must prove that an employer is liable for a work-related injury, and second, he must establish that the particular medical treatment at issue is reasonable and necessary.

American Mfrs., 526 U.S. at 60–61, 119 S. Ct. at 990. As Justice Ginsberg noted in her concurrence, “I do not doubt, however, that due process requires fair procedures for the adjudication of respondents' claims for workers' compensation benefits, including medical care.” American Mfrs., 526 U.S. at 62, 119 S. Ct. 977 at 991 (Ginsberg, J., concurring).

Here, Mr. Murray had no means to prove his case. There were no procedures, let alone fair ones, to adjudicate the merits of his claim.

The same is true for mass determinations. The Department may exclude medical treatments from compensation only after completing extensive rule-making process and judicial review of the decision. Although the Legislature, as an elected body, may make changes to workers compensation benefits, it may not delegate this power to an insular Committee with no review. And as the United States Supreme Court in Atkins v. Parker, 472 U.S. 115, 105 S.Ct.

2520, 86 L.Ed.2d. 81 (1985) noted, even mass determinations require procedural safeguards.

As the testimony of the class representatives indicates, every class member who contacted the Department had his or her benefit level frozen, and received a fair hearing, before any loss of benefit occurred. Thus, the Department's procedures provided adequate protection against any deprivation based on an unintended mistake.

Atkins v. Parker, 472 U.S. at 128, 105 S. Ct. at 2528. The Department assumes the Legislature has unqualified authority to change the Industrial Insurance Program or eliminate benefits entirely. Yet no Washington court has said this. By giving up their right to sue, injured workers are entitled to something.

Finally, the Department seeks to limit the arguments and evidence Mr. Murray may submit on remand. (Response Brief at 46 n.18) ("Murray did not argue for the hindsight test in his petition for review, thus waiving the argument"). The Department's refusal to consider the merits of Mr. Murray's claim – given the HTCC determination – undermines this assertion. Mr. Murray deserves, and should receive, a full hearing on his claim.

IV. MR. MURRAY SHOULD RECEIVE HIS ATTORNEYS' FEES ON APPEAL.

Because he has proven that the Department erred by relying on the HTCC decision, Mr. Murray is entitled to an award of reasonable attorney's fees on appeal. RCW 51.52.130. The Department objects, arguing that this litigation has not yet affected accident or medical aid funds. (Response Brief at 48). The Department also asserts that Mr. Murray has not obtained "additional relief" on appeal.

When a claimant prevails on appeal by obtaining a remand, this Court awards fees on appeal contingent on succeeding on remand.

Under RCW 51.52.130, attorney fees are awarded to the worker or beneficiary where his or her appeal to the superior or appellate court results in a reversal or modification of the BIIA decision and additional relief is granted to the worker or beneficiary, as well as to the worker or beneficiary whose right to relief is sustained when the Department or employer appeals. The statute encompasses fees in both superior and appellate courts when both courts review the matter.

* * * *

Doan must comply with RAP 18. 1, and the award of attorney fees is contingent, as was that in trial court, upon the condition that the medical aid fund or accident fund is affected and proof of such is supplied to the trial court.

Doan v. State Dep't of Labor & Indus., 143 Wn. App. 596, 607–08, 178 P.3d 1074 (2008).

Mr. Murray respectfully requests the Court to award reasonable attorneys' fees on appeal, contingent on his obtaining reimbursement for successful FAI surgery.

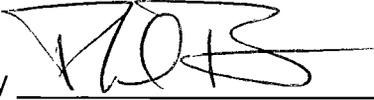
CONCLUSION

By exercising the police power, the Legislature becomes accountable to those it seeks to protect. The original bill creating the HTCC fulfilled this requirement by subjecting the Committee's decision to judicial review and oversight. The Governor vetoed this essential provision, creating the constitutional flaw presented in this case. Simply put, the HTCC cannot deprive Appellant Michael Murray of his right to necessary and proper medical treatment without notice and the opportunity to be heard. Because an "open and transparent" public meeting, followed by the opportunity to seek a constitutional writ of review, does not satisfy this minimal standard, Mr. Murray has a right to a fair hearing to present all his evidence.

Appellant Michael Murray respectfully requests this Court to reverse the Superior Court's decision and remand this case to the Department for a full and fair hearing on his claim.

DATED this 30th day of January, 2017.

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DECLARATION OF SERVICE

The undersigned declares under penalty of perjury under the laws of the State of Washington that on the date stated below, I mailed or caused delivery of Reply Brief of Appellant Michael Murray to:

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DATED this 30th day of January, 2017.


Philip Buri

APPENDIX A

WSR 16-18-023
PERMANENT RULES
HEALTH CARE AUTHORITY

[Filed August 26, 2016, 10:50 a.m., effective September 26, 2016]

Effective Date of Rule: Thirty-one days after filing.

Other Findings Required by Other Provisions of Law as Precondition to Adoption or Effectiveness of Rule: A settlement agreement related to King County Superior Court No. 13-2-03122-1-SEA.

Purpose: The health care authority (HCA) has not reviewed chapter 182-55 WAC since its adoption in 2006. HCA is conducting this rule-making action to provide clarification and modernization of the rules, as well as the adoption of a rule(s) addressing administrative review processes of health technology assessment (HTA) actions and decisions.

Citation of Existing Rules Affected by this Order: Amending WAC 182-55-005, 182-55-010, 182-55-015, 182-55-020, 182-55-025, 182-55-030, 182-55-035, 182-55-040, 182-55-045, 182-55-050, and 182-55-055.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Adopted under notice filed as WSR 16-11-067 on May 16, 2016.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

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Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 2, Amended 11, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 2, Amended 11, Repealed 0.

Date Adopted: August 26, 2016.

Wendy Barcus
Rules Coordinator

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-005 Authority and purpose.

Under RCW 70.14.080 through 70.14.140, the ~~((administrator))~~ director of the Washington state health care authority ~~((is required to establish and))~~ provides administrative support for, and ~~((is~~

~~authorized to~~) adopts rules to govern ~~((7))~~ the health technology clinical committee and a health technology assessment program ~~((that uses evidence to make coverage determinations for participating state agencies that purchased health care))~~ within the health care authority. The health technology assessment program will:

- ~~(1) ((Selects health technologies for assessment;~~
- ~~(2))~~ Contract ~~((s))~~ with an evidence-based technology assessment center to produce health technology assessments;
- ~~((3) Establishes an)~~ (2) Administratively support the independent health technology clinical committee; and
- ~~((4))~~ (3) Maintain ~~((s))~~ a centralized, internet-based communication tool.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-010 Definitions.

When used in this chapter:

(1) ~~(("~~Administrator" means the administrator of the Washington state health care authority under chapter 41.05 RCW, as set forth in RCW 70.14.080, as amended.

~~(2))~~ "Advisory group" as defined in RCW 70.14.080 means a group established under RCW 70.14.110 (2)(c).

(2) "Centralized, internet-based communication tool" means the health care authority's health technology assessment program internet web pages established under RCW 70.14.130(1).

(3) "Committee" as defined in RCW 70.14.080 means the health technology clinical committee established under RCW 70.14.090.

(4) "Coverage determination" as defined in RCW 70.14.080 means a determination of the circumstances, if any, under which a health technology will be included as a covered benefit in a state purchased health care program ~~((, as set forth in RCW 70.14.080, as amended))~~.

(5) "Decisions made under the federal medicare program" means national coverage determinations issued by the Centers for Medicare and Medicaid Services stating whether and to what extent medicare covers specific services, procedures, or technologies.

(6) "Director" means the director of the Washington state health care authority under chapter 41.05 RCW.

(7) "Health technology" as defined in RCW 70.14.080 means medical and surgical devices and procedures, medical equipment, and diagnostic tests. Health technologies do not include prescription drugs governed by RCW 70.14.050.

~~((6))~~ (8) "Health technology assessment" means a report produced by a contracted, evidence-based, technology assessment center or other appropriate entity, as provided for in RCW 70.14.100 (4), based on a systematic review of evidence of a technology's safety, efficacy, and cost-effectiveness.

(9) "Participating agency" as defined in RCW 70.14.080 means the department of social and health services, the state health care authority, and the department of labor and industries (~~(, as set forth in RCW 70.14.080, as amended.~~

~~(7) "Reimbursement determination" means a determination to provide or deny reimbursement for a health technology included as a covered benefit in a specific circumstance for an individual patient who is eligible to receive health care services from the state purchased health care program making the determination, as set forth in RCW 70.14.080, as amended.~~

~~(8) "Health technology assessment" means a report produced by a contracted evidence-based technology assessment center as provided for in RCW 70.14.100(4) that is based on a systematic review of evidence of a technology's safety, efficacy, and cost-effectiveness).~~

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-015 Committee purpose.

The purpose of the committee is to make coverage determinations for the participating agencies (~~(based on: A health technology assessment that reviews the scientific evidence of the relative safety, efficacy, and cost; information from any special advisory groups; and their professional knowledge and expertise)~~) as described under RCW 70.14.110.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-020 Committee selection.

(1) The (~~(administrator)~~) director, in consultation with the participating state agencies, (~~(shall make appointments to)~~) appoints vacant committee positions (~~(, including the appointment of a chair,)~~) from a pool of interested applicants. Interested persons (~~(will be)~~) are provided an opportunity to submit applications to the (~~(administrator)~~) director for consideration.

(2) When appointing committee members, the (~~(administrator will)~~) director considers, in addition to the membership requirements imposed by RCW 70.14.090 (~~(and any)~~), other relevant information, (~~(the following factors)~~) including:

(a) Practitioner specialty or type and use of health technologies, especially in relation to current committee member specialty or types;

(b) Practice location and community knowledge;

(c) Length of practice experience;

(d) Knowledge of and experience with evidence-based medicine, including formal additional training in fields relevant to evidence-based medicine;

(e) Medical quality assurance experience; and

(f) Health technology assessment review experience.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-025 Committee member requirements and committee member terms.

(1) As a continuing condition of appointment, committee members must:

(a) ~~((Shall))~~ Not have a substantial financial conflict of interest, such as an interest in a health technology company, including the holding of stock options, or the receipt of honoraria, or consultant moneys;

(b) ~~((Must))~~ Complete a conflict of interest disclosure form, update the form annually, and keep disclosure statements current;

(c) ~~((Must))~~ Abide by confidentiality requirements and keep all personal medical information and proprietary information confidential; and

(d) ~~((Shall not utilize))~~ Not use information gained ~~((as a result of))~~ from committee membership outside of committee responsibilities, unless ~~((such))~~ the information is publicly available.

(2) The ~~((administrator, in his/her))~~ director has the sole discretion~~((, may disqualify))~~ to terminate a committee ~~((members))~~ member's appointment if ~~((he/she))~~ the director determines that the committee member has violated a condition of appointment.

~~((2) Committee members shall be appointed to a term of three years and shall serve until a successor is appointed. A member may be reappointed for additional three-year terms for a total of nine years. One year after the end of a nine-year term, a person is eligible for appointment to one additional three-year term.))~~ (3) Committee members serve staggered three-year terms. ~~((Of the initial members, in order))~~ To provide for staggered terms, ((some)) committee members may be appointed initially for less than three years. ~~((If an initial appointment is for less than twenty-four months, that period of time shall not be counted toward the limitation of years of appointment. Vacancies on the committee will be filled for the balance of the unexpired term.))~~

~~((3) The appointed committee chair shall select a vice-chair from among the committee membership; ratify committee bylaws approved by the administrator; and operate the committee according to the bylaws and committee member agreements.))~~

(4) A committee member may be appointed for a total of nine years of committee service, but an initial appointment of less than twenty-four months is not included in the nine-year limitation.

(5) A committee member may serve until that member's successor is appointed, notwithstanding the limits on service in subsection (3) of this section.

(6) Mid-term vacancies on the committee are filled for the remainder of the unexpired three-year term.

NEW SECTION

WAC 182-55-026 Committee governance.

(1) The committee may establish bylaws, within applicable statutory and regulatory requirements, to govern the orderly resolution of the committee's purposes. Proposed bylaw amendments are published on the centralized, internet-based communication tool at least fourteen calendar days before adoption by the committee. Before adoption, the committee gives an opportunity at an open public meeting for public comment on proposed bylaw amendments. Committee bylaws shall be published on the centralized, internet-based communication tool.

(2) The director appoints a committee chair.

(3) The committee chair:

(a) Selects a vice-chair from among the committee membership;

(b) Presents bylaws, or amendments to the bylaws, to the committee for review and ratification; and

(c) Operates the committee according to the bylaws and committee member agreements.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-030 Committee coverage determination process.

(1) In making a coverage determination, committee members shall review and consider evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth in the health technology assessment. The committee (~~may~~) also considers other information it deems relevant, including other information provided by the (~~administrator~~) director, reports (~~and/or~~) or testimony from an advisory group, and submissions or comments from the public.

(2) The committee shall give the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee (~~may~~) also considers additional evidentiary valuation factors such as recency (~~(date of~~

information); ~~relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias (presence of conflict of interest or political considerations))~~, relevance, and bias.

(3) The committee also considers any unique impacts the health technology has on specific populations based on factors like sex, age, ethnicity, race, or disability, as identified in the health technology assessment.

(4) The committee provides an opportunity for public comment after the health technology assessment is published on the centralized, internet-based communication tool and before the committee's final coverage determination decision.

(5) After the committee makes a final coverage determination, the health technology assessment program publishes it on the centralized, internet-based communication tool and submits a notice in the *Washington State Register*.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-035 Committee coverage determination.

~~((Based on the evidence regarding safety, efficacy, and cost-effectiveness of the health technology,))~~ The committee shall:

(1) Determine the conditions, if any, under which the health technology will be included as a covered benefit in health care programs of participating agencies by deciding that:

(a) Coverage is allowed without special conditions because the evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions; or

(b) Coverage is allowed with special conditions because the evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective in only certain situations; or

(c) Coverage is not allowed because either the evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective or the evidence is sufficient to conclude that the health technology is unsafe, ~~((ineffectual))~~ inefficacious, or not cost-effective.

(2) Identify whether the coverage determination is consistent with ~~((the identified medicare))~~ decisions made under the federal medicare program and expert treatment guidelines.

(3) For decisions that are inconsistent with either ~~((the identified medicare))~~ decisions made under the federal medicare program or expert treatment guidelines, including those from specialty physician and patient advocacy organizations, specify the ~~((reason(s) for the decision and the evidentiary basis))~~ substantial evidence regarding the safety, efficacy, and cost-effectiveness of the technology that supports the contrary determination.

(4) For covered health technologies, specify criteria for participating agencies to use when deciding whether the health technology is medically necessary or proper and necessary treatment.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-040 ((Publication of committee)) Health care authority's implementation of final coverage determinations.

~~((1) The administrator shall publish final committee determinations by posting on a centralized, internet-based communication tool within ten days.~~

~~(2) Upon publication, participating agencies will implement the committee determination according to their statutory, regulatory, or contractual process unless:~~

~~(a) The determination conflicts with an applicable federal statute or regulation, or applicable state statute; or~~

~~(b) Reimbursement is provided under an agency policy regarding experimental or investigational treatment, services under a clinical investigation approved by an institutional review board, or health technologies that have a humanitarian device exemption from the federal food and drug administration.)~~ This section applies to all final coverage determinations made after August 1, 2016.

(1) The health care authority reviews the final coverage determination for conflicts identified in RCW 70.14.120 (1)(a) and (b).

(2) The health care authority reviews whether the health technology review process meets the requirements in this subsection before compliance by the health care authority's state-purchased health care programs. The review includes whether the:

(a) Notification of the health technology selected for review was made on the centralized, internet-based communication tool as required by RCW 70.14.130 (1)(a);

(b) Health technology assessment provided to the committee met the requirements in RCW 70.14.100(4) and WAC 182-55-055;

(c) Health technology assessment was published on the centralized, internet-based communication tool at least fourteen calendar days before the committee's consideration of the health technology assessment;

(d) Health technology assessment was considered by the committee in an open and transparent process, as required by RCW 70.14.110 (2)(a);

(e) Committee provided an opportunity for public comment prior to the committee's final coverage determination decision;

(f) Committee acknowledged public comment timely received after publication of the committee's draft coverage determination and before the committee's final coverage determination decision;

(g) Committee's final coverage determination specifies the reason or reasons for a decision that is inconsistent with the identified decisions made under the federal medicare program and expert treatment guidelines, including those from specialty physician and patient advocacy organizations, for the reviewed health technology; and

(h) Committee meetings complied with the requirements of the Open Public Meetings Act as required by RCW 70.14.090(3).

(3) After the health care authority completes its reviews under subsections (1) and (2) of this section, it establishes an implementation date for each of the health care authority's state-purchased health care programs and publishes the implementation dates on the health care authority's web site.

(4) The health care authority's implementation of a final coverage determination can be reviewed as other agency action under RCW 34.05.570(4). A petition for review must be filed in superior court and comply with all statutory requirements for judicial review of other agency action required in chapter 34.05 RCW.

NEW SECTION

WAC 182-55-041 Judicial review of final coverage determination.

Nothing in this chapter limits the superior court's inherent authority to review health technology clinical committee determinations to the extent of assuring the decisions are not arbitrary, capricious, or contrary to law.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-045 Advisory group.

~~(1) The committee chair, upon an affirmative vote of the committee members, may establish ad hoc temporary advisory ((group (s) if specialized expertise or input from enrollees or clients is needed to review a particular health technology or group of health technologies. The purpose or scope of the advisory group and time period shall be stated. The advisory group shall provide a report and/or testimony to the committee on the key questions identified by the committee as requiring the input of the advisory group.~~

~~(2) Advisory group membership+))~~ groups under RCW 70.14.110 (2) (c). At the time an ad hoc temporary advisory group is formed, the committee must state the ad hoc temporary advisory group's objective and questions to address. Notice of the formation of an ad hoc temporary advisory group, and information about how to participate, shall be posted on the centralized, internet-based communication tool.

(2) The committee chair, or designee, may appoint or remove an advisory group member. An ad hoc temporary advisory group (~~((shall))~~) must include at least three members. (~~((Membership should reflect the diverse perspectives and/or technical expertise that drive the need for the specialized advisory group.))~~) The advisory group will generally include at least one enrollee, client, or patient (~~((+ and))~~). The advisory group must have:

(a) Two or more experts or specialists within the field relevant to the health technology, preferably with demonstrated experience in the use, evaluation, or research of the health technology (~~((If substantial controversy over the health technology is present,))~~);

(b) At least one expert (~~((that))~~) who is a proponent or advocate of the health technology; and

(c) At least one expert (~~((that))~~) who is an opponent or critic of the health technology (~~((should be appointed. A majority of each advisory group shall have no substantial financial interest in the health technology under review))~~).

~~((3) ((As a continuing condition of appointment, advisory group members:~~

~~((a) Must))~~ Each advisory group member must:

(a) Not have a substantial financial conflict of interest, such as an interest in a health technology company, including the holding of stock options, or the receipt of honoraria, or consultant moneys;

(b) Complete an advisory group member agreement, including a conflict of interest disclosure form, and keep disclosure statements current;

~~((b) Must))~~ (c) Abide by confidentiality requirements and keep all personal medical information and proprietary information confidential; and

~~((c) Shall))~~ (d) Not utilize information gained as a result of advisory group membership outside of advisory group responsibilities, unless such information is publicly available.

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-050 Health technology selection.

~~((1) ((Prior to selection of a health technology for review or rereview, the administrator shall consider nominations from participating agencies and recommendations from the committee.))~~ The director, in consultation with participating agencies and the committee, selects health technologies to be reviewed or rereviewed by the committee.

(2) The (~~((administrator))~~) director or committee may also consider petitions requesting initial review of a health technology from interested parties. (~~((The administrator shall make available, including publication to the centralized internet-based~~

~~communication tool required at RCW 70.14.130, a petition for interested parties to request a health technology be selected for a review or rereview. Interested parties shall complete the petition and submit it to the administrator. The administrator, or designee, will provide copies of the petition to participating agencies and the committee for comment, and provide the completed petition, with any comments, to the administrator for consideration.~~

~~(2) Interested parties that have submitted a petition for the review or rereview of a health technology that was not selected by the administrator may submit the petition to the committee for review or rereview.~~

~~(3) The committee may consider petitions submitted by interested parties for review or rereview of a health technology. The committee shall apply the priority criteria set forth in RCW 70.14.100.~~

(4)) To suggest a topic for initial review, interested parties must use the petition form made available on the centralized, internet-based communication tool. The health technology assessment program will provide copies of the petition to the director, committee members, and participating agencies.

(a) Petitions are considered by the director, in consultation with participating agencies and the committee.

(b) Only after the director has declined to grant the petition can a petition be considered for selection by the committee, as described in RCW 70.14.100(3).

(c) If a health technology is selected by the committee ((shall be)), the health technology is referred to the ((administrator)) director for assignment to the next available contract for a health technology assessment review as described in RCW 70.14.100(4).

(3) Interested parties may submit a petition for the rereview of a health technology. Interested parties must use the petition form available on the centralized, internet-based communication tool and may submit to the health technology assessment program evidence that has since become available that could change the previous coverage determination. The health technology assessment program will provide copies of the petition to the director, committee members, and participating agencies.

(a) Petitions are considered by the director, in consultation with participating agencies and the committee.

(b) Only after the director has declined to grant the petition can a petition be reviewed by the committee, as described in RCW 70.14.100(3).

AMENDATORY SECTION (Amending WSR 06-23-083, filed 11/13/06, effective 12/14/06)

WAC 182-55-055 Health technology assessment.

(1) Upon providing notice (~~of the selection of the health technology for review, the administrator~~) on the centralized, internet-based communication tool required by RCW 70.14.100 (1)(b) that the health technology has been selected for review, the director shall post an invitation for interested parties to submit information relevant to the health technology for consideration by the evidence-based technology assessment center. (~~Such~~) The information (~~shall be required to~~) must be submitted to the (~~administrator,~~) director or designee (~~(, no earlier than)~~) within thirty calendar days from the date of the notice.

(2) Upon notice of the (~~selection of the~~) health technology selected for review, the (~~administrator~~) director or designee shall request participating agencies to provide information relevant to the health technology, including data on safety, health outcome, and cost. (~~Such~~) The relevant information (~~shall be required to~~) must be submitted to the (~~administrator,~~) director or designee (~~(, no earlier than)~~) within thirty calendar days from the date of the notice.

(3) Upon notice of the (~~selection of the~~) health technology selected for review, the (~~administrator~~) director or designee shall (~~require staff to~~) identify (~~and organize~~) relevant decisions made under the federal medicare (~~(national coverage determinations)~~) program and expert treatment guidelines, including those from specialty physician and patient advocacy organizations, and any referenced information used as the basis for such determinations (~~and/or~~) or guidelines.

(4) The (~~administrator~~) director shall provide all information (~~relevant to the selected health technology~~) gathered under subsections (1), (2), and (3) of this section to the evidence-based technology assessment center (~~(,)~~) and shall post such information, along with the key questions for review, on (~~(a)~~) the centralized, internet-based communication tool.

(5) Upon completion of the health technology assessment by the evidence-based technology assessment center, the (~~administrator~~) director shall publish a copy of the health technology assessment on the centralized, internet-based communication tool and provide the committee with:

(a) (~~Final~~) A copy of the health technology assessment;

(b) (~~Information as to whether the federal medicare program has made a national coverage determination;~~

~~(c)~~) A copy of (~~identified national coverage~~) decisions made under the federal medicare program related to the health technology being reviewed and accompanying information describing the basis for the decision;

~~(d)~~) (c) Information as to whether expert treatment guidelines exist, including those from specialty physician organizations and patient advocacy organizations (~~(, and~~

~~(e) A copy of identified guidelines and accompanying information~~), and describing the basis for the guidelines.

BURI FUNSTON PLLC

January 30, 2017 - 12:24 PM

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