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IN THE SUPREME COURT OF THE STATE OF WASHINGTON

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MARC YOUNGS, Petitioner,

vs.

PEACEHEALTH, a Washington corporation d/b/a PEACEHEALTH ST.  
JOSEPH MEDICAL CENTER and d/b/a PEACEHEALTH MEDICAL  
GROUP, and UNKNOWN JOHN DOES, Respondents,

and

AOLANI E. GLOVER, a single individual, Respondent,

vs.

THE STATE OF WASHINGTON d/b/a HARBORVIEW MEDICAL  
CENTER; AND LULU M. GIZAW, PA-C, Petitioners,

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BRIEF OF AMICUS CURIAE  
WASHINGTON STATE ASSOCIATION FOR JUSTICE FOUNDATION

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On Behalf of  
Washington State Association for Justice Foundation

ORIGINAL

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## I. IDENTITY AND INTEREST OF AMICUS CURIAE

Washington State Association for Justice Foundation (WSAJ Foundation, formerly Washington State Trial Lawyers Association Foundation) is a not-for-profit corporation under Washington law, and a supporting organization to Washington State Association for Justice (formerly Washington State Trial Lawyers Association). WSAJ Foundation has an interest in the rights of persons seeking redress in the civil justice system, including an interest in the rules governing the conduct of parties to litigation. WSAJ Foundation's predecessor appeared as amicus curiae in Loudon v. Mhyre, 110 Wn.2d 675, 756 P.2d 138 (1988), and the Foundation appeared as amicus curiae in Smith v. Orthopedics Int'l, Ltd., 170 Wn.2d 659, 244 P.3d 939 (2010), which, like these cases, involve ex parte contact between defense counsel and a plaintiff's nonparty treating physicians.

## II. INTRODUCTION AND STATEMENT OF THE CASE

Marc Youngs (Youngs) filed suit for medical negligence against PeaceHealth (PeaceHealth), a hospital, and several "John Doe" defendants. Aolani E. Glover (Glover) separately filed suit for medical negligence against the State of Washington and a certified physician assistant, Lulu M. Gizaw (collectively the State). These linked cases focus on whether the prohibition of ex parte contact expressed in Loudon and

Smith, supra, applies when the nonparty treating physician is an employee of a corporate defendant. The underlying facts are drawn from the briefing of the parties. See Youngs Br. at 4-6; PeaceHealth Br. at 6-16; State Br. at 3-10; Glover Br. at 1-6; State Reply Br. at 4-5.

*Youngs v. PeaceHealth*: Youngs was admitted to PeaceHealth for lung surgery, and during his hospitalization, he developed an infection that resulted in the amputation of both legs below the knee and both hands above the wrist. He subsequently filed suit against PeaceHealth and several “unknown John Does.” In the course of the lawsuit, Youngs contended that Loudon and Smith prohibited ex parte contact between defense counsel and all nonparty treating physicians at PeaceHealth except (1) those who would be considered managing or speaking agents of the hospital under Wright v. Group Health Hosp., 103 Wn.2d 192, 691 P.2d 564 (1984); and (2) tortfeasor-physicians employed by PeaceHealth for whom it would be vicariously liable. Youngs asked PeaceHealth to identify any managing-speaking agents, but the hospital declined to do so. Youngs identified two physicians who were not named as parties, Drs. Richard Leone and Donald Berry, whose conduct forms the basis for his claim of vicarious liability on the part of PeaceHealth.<sup>1</sup> For its part,

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<sup>1</sup> PeaceHealth questions whether Youngs’ vicarious liability claims are limited to these two physicians. See PeaceHealth Br. at 8-9, 14-15 & n.5.

PeaceHealth contended that ex parte contact was permitted with any physician in its employ, without limitation.

Youngs initially obtained a protective order from the superior court prohibiting ex parte contact with Youngs' treating health care providers, except Drs. Leone and Berry, as follows:

Defense counsel and the defendant's risk manager are prohibited from *ex parte* contact, directly or indirectly, with any of plaintiff Mark [sic] Youngs' treating physicians other than Dr. Richard Leone and Dr. Donald Berry.

Youngs Br. at 5 (quoting order). On reconsideration, the superior court reversed itself, vacated the protective order, and ruled that "counsel for PeaceHealth may have ex parte contact with PeaceHealth employees who provided health care to plaintiff Marc Youngs." *Id.* at 6 (quoting order). Youngs sought discretionary review, which this Court accepted, and the case has been linked with Glover.

*Glover v. State*: Glover went to the emergency room at Harborview Medical Center (Harborview), a State medical facility, suffering from chest pains. After waiting for a period of time, she was given a blood test, which revealed a serious heart problem. However, the attending certified physician assistant (PA-C) did not review Glover's test results. Instead, he allegedly reviewed another patient's test results, which were normal, and then discharged Glover. The PA-C discovered his error

approximately two hours later, found Glover at a pharmacy, and asked her to return to the emergency department. A repeat blood test administered upon her return confirmed the existence of the heart problem, but by this time Glover could not be successfully treated at Harborview. She was transferred to the University of Washington Medical Center (UWMC), also a State facility, where she ultimately received a heart transplant.

Glover filed suit against the State, alleging negligence only on the part of the Harborview health care providers who treated her before she returned to the emergency department, and objected to any *ex parte* contact with her treating health care providers at UWMC.<sup>2</sup> The State sought a protective order allowing such *ex parte* contact. The superior court denied the State's motion, and ordered:

Defense counsel and the defendant's risk manager are prohibited from *ex parte* contact, directly or indirectly, with any of Plaintiff Aolani Glover's treating physicians at University of Washington Medical Center.

State Br. at 10 (quoting order). The State sought discretionary review of the foregoing order, and the Court accepted direct review.

***Arguments Before The Court:*** In their briefing before the Court, Youngs and Glover each advocate for application of the Loudon rule to prohibit *ex parte* contact with all nonparty treating physicians, regardless

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<sup>2</sup> The State notes that Glover does not object to *ex parte* contact with Harborview health care providers involved in her care, so long as those individuals are not shown any records of her subsequent care. See State Br. at 9.

of whether they are employed by the same corporate defendant. However, they appear to concede that physicians who are managing or speaking agents of a corporate defendant are properly considered “parties” under Wright, although in Youngs no managing-speaking agents have been identified, and in Glover there appears to be a dispute whether certain UWMC physicians are managing-speaking agents. Youngs and Glover also appear to concede that ex parte contact is permitted with physicians whose conduct may subject the corporate defendant to vicarious liability.

In response to Youngs, PeaceHealth argues: (1) Loudon and Smith are distinguishable to the extent that they did not involve ex parte contact with treating physicians employed by the same corporate defendant; (2) the Loudon rule has been undermined, if not eclipsed, by the expanded waiver of the physician-patient privilege in the current version of RCW 5.60.060(4)(b); (3) defense counsel cannot adequately represent a corporate defendant without the ability to have ex parte contact with all employees, and that this is a matter of due process; and (4) the Uniform Health Care Information Act, Ch. 70.02 RCW (UHCIA),<sup>3</sup> and Washington’s quality improvement program statute, RCW 70.41.200, both

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<sup>3</sup> PeaceHealth seems to make a similar argument, based on regulations adopted under the Health Insurance Portability and Accountability Act (HIPAA), P.L. 104-191, 110 Stat. 1936 (1996). See PeaceHealth Br. at 4 n.2 & 40 n.20 (citing 45 C.F.R. § 164.506(a) & (c)). (The State also refers to the UHCIA and HIPAA. See State Br. at 11, 15-17 & nn.8-10; State Reply Br. at 10-11.)

allow for unfettered disclosure of health care information within and among the employees of a corporate health care entity.<sup>4</sup>

In response to Glover, the State claims that four of Glover's treating physicians at UWMC are managing-speaking agents under Wright.<sup>5</sup> In addition to these physicians, the State argues that application of the Loudon rule to employees of what it describes as an "integrated health system"<sup>6</sup> is not supported by the rationales for the rule, and that application of the rule in this context interferes with (1) the attorney-client relationship, (2) the attorney-client privilege and work product protection, and (3) the performance of its quality improvement functions.

### III. ISSUE PRESENTED FOR REVIEW

Whether the rule adopted in Loudon, and recently affirmed in Smith, prohibiting direct and indirect ex parte contact between defense counsel and a nonparty treating physician, applies when the nonparty physician is an employee of the corporate defendant?

### IV. SUMMARY OF ARGUMENT

Loudon creates a bright-line rule designed to conserve judicial resources. The primary purpose of the rule is to protect and foster the physician-patient relationship. Ex parte contact between defense counsel

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<sup>4</sup> PeaceHealth separately argues that Youngs waived the Loudon rule by submitting discovery requests that required ex parte contact with nonparty treating health care providers. This amicus curiae brief does not address this waiver issue.

<sup>5</sup> It appears that the State wants to rely on these health care providers as consulting or testifying experts. See State Br. at 7-9 & 28-29.

<sup>6</sup> The State notes that Harborview and UWMC share a single medical records system, personnel, management, expertise, and transfer patients between facilities. See State Br. at 6-7.

and a nonparty treating physician risks chilling this fiduciary relationship and hindering treatment, regardless of the form of business under which the physician chooses to practice medicine. As a result, the Loudon rule applies when the plaintiff's nonparty treating physicians are employees of a corporate defendant.

However, the Loudon rule is limited to *nonparty* treating physicians. Under Wright, *supra*, employees of a corporate defendant having authority to speak for and bind the corporation are considered "parties" in litigation involving the corporation. Thus, if the corporation establishes that the physician in question is its managing or speaking agent, then the Loudon rule would be inapplicable. Defense counsel seeking to avoid application of the rule on this basis should designate its managing or speaking agents, and notify plaintiff's counsel of the basis for the designations. In the absence of agreement, either party may seek appropriate relief by protective order under CR 26(c).

As harmonized with Wright, the Loudon rule does not unduly interfere with the attorney-client relationship between counsel and a corporate defendant, nor does it implicate due process, principally because there is no information that counsel can legitimately obtain from ex parte contact with plaintiff's nonparty treating physicians that cannot be obtained through formal discovery methods or informal discovery

conducted in the presence of plaintiff's counsel. This rule poses no more inconvenience to counsel for the corporation than when the plaintiff's treating health care providers are employed elsewhere, and any inconvenience is outweighed by the potential harm to the physician-patient relationship and the other public policies underlying Loudon.

The waiver of the physician-patient privilege under RCW 5.60.060(4) does not undermine the Loudon rule because: (1) application of the rule presupposes that the privilege has already been waived; (2) the plaintiff has a substantive privacy interest in his or her health care information under the UHCIA and HIPAA that is distinct from the privilege; and (3) the plaintiff has the right to limit the scope of discovery based on principles of relevance, CR 26(b)(1), and to tailor the manner of discovery to protect his or her privacy under CR 26(c).

The UHCIA and HIPAA do not override the Loudon rule to permit ex parte interviews with plaintiff's nonparty treating physicians. These laws are compatible with the rule and do not preempt it in this context.

Finally, application of the Loudon rule in this medical negligence context does not prevent hospitals or their risk managers from complying with their quality improvement obligations. However, an appropriate screening mechanism should be employed to separate litigation defense from quality improvement functions, in order to protect both the

physician-patient relationship and the hospital's quality improvement program.

## V. ARGUMENT

### A. Overview Of The *Loudon* Rule And Its Underpinnings.

Almost 23 years ago, in Loudon, this Court adopted a broad and bright-line rule prohibiting ex parte contact between defense counsel and a plaintiff's nonparty treating physicians,<sup>7</sup> even though under governing case law the plaintiff was deemed to have waived the statutory physician-patient privilege for conditions at issue in the suit. See 110 Wn.2d at 675-76. The Loudon rule is simple in application, and designed to conserve judicial resources in supervising the discovery process. See id. at 679.

More recently, in Smith, the Court reaffirmed both the rule and its bright-line nature, without regard for the more expansive statutory waiver of the physician-patient privilege that exists under current law.<sup>8</sup> In Smith, the Court confirms that the rule prohibits *all* contact with nonparty treating physicians, direct or indirect, and that it is not limited to communications

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<sup>7</sup> The briefing is unclear whether the parties consider the Loudon rule to prohibit ex parte contact with nonparty treating health care providers other than physicians. The protective orders in question are phrased in terms of physicians only.

<sup>8</sup> The privilege, codified at RCW 5.60.060(4), now imposes a qualified waiver of the privilege 90 days after commencement of a civil action. The full text of the current version of the statute is reproduced in the Appendix to this brief. The effect of waiver under the statute is discussed infra.

or interviews. See 170 Wn.2d at 665-69 (prohibiting transmission of public information via email to physician's lawyer).<sup>9</sup>

Several distinct rationales for the Loudon rule are evident from the Court's decisions. The first is to protect the plaintiff from the risk of disclosure of irrelevant personal information. See Loudon at 678. Even under circumstances where the physician-patient privilege has been waived by the plaintiff, discovery of health care information, like all discovery, is limited by principles of relevance. See id. at 678 (citing CR 26(b)(1)).<sup>10</sup> The Court explained the difficulty involved in relying solely on health care providers and defense counsel to limit the disclosure of irrelevant health care information:

We are concerned ... with the difficulty of determining whether a particular piece of information is relevant to the claim being litigated. Placing the burden of determining relevancy on an attorney, who does not know the nature of the confidential disclosure about to be elicited, is risky. Asking the physician, untrained in the law, to assume this burden is a greater gamble and is unfair to the physician. We believe this determination is better made in a setting in which counsel for each party is

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<sup>9</sup> The 3-Justice lead opinion in Smith finds a Loudon violation, but concludes that the plaintiff failed to demonstrate prejudice. See 170 Wn.2d at 665-73 (Alexander, J.). The 4-Justice concurrence/dissent agrees with the finding of a Loudon violation, but presumes prejudice. See id. at 678-79 (C. Johnson, J.). The 2-Justice concurrence is with the result only, finding no Loudon violation and not addressing the prejudice issue. See id. at 675 (Fairhurst, J.). Thus, the finding of a Loudon violation, joined by seven Justices, constitutes a holding, but there appears to be no holding regarding the issue of prejudice. Citations in this brief are to the lead opinion by Justice Alexander, unless otherwise indicated.

<sup>10</sup> Accord Smith, at 674 (Fairhurst, J., concurring, stating “[d]espite this waiver [of the physician-patient privilege under RCW 5.60.060(4)(b)] the *Loudon* rule reflects our concern of a nonparty treating physician inadvertently disclosing *irrelevant* confidential information to the defense”; emphasis added).

present and the court is available to settle disputes.

Loudon at 678 (ellipses added; quotation omitted); accord Smith at 668.

The second rationale for the Loudon rule is to protect the physician from the consequences of improper disclosure of health care information. See Loudon at 680; Smith at 667; see also RCW 70.02.170 (remedies for violation of UHCIA). Thus, the participation of plaintiff's counsel to prevent improper questioning or inadvertent disclosures protects the physicians as well as the plaintiff. See Loudon at 680; Smith at 667.

The third rationale for the rule is to prevent disputes regarding the content of ex parte communications with a physician, protecting defense counsel from becoming an impeachment witness if the physician's testimony at trial should differ from statements made during ex parte communications. See Loudon at 680.

The fourth rationale is to prevent the plaintiff's treating physicians from "improperly assum[ing] a role akin to that of an expert witness for the defense." Smith at 668 (brackets added). A treating physician may testify both as to facts and medical opinions in a medical negligence action, but "such testimony is limited to 'the medical judgments and opinions *which were derived from the treatment.*'" Id. (quoting Carson v. Fine, 123 Wn.2d 206, 216, 867 P.2d 610 (1994); emphasis in original); accord Carson, 123 Wn.2d at 216 & 226-27 (approving physician

testimony at trial regarding knowledge and opinions derived from treatment, where probative value outweighs prejudice *and* there is no Loudon violation).

The fifth rationale is specific to the medical negligence context. Although the Loudon rule applies to all personal injury actions, ex parte contact is particularly problematic and susceptible to abuse in medical negligence cases:

Courts have recognized that, in the past, permitting “ex parte contacts with an adversary’s treating physician may have been a valuable tool in the arsenal of savvy counsel. The element of surprise could lead to case altering, if not case dispositive results.” *Law v. Zuckerman*, 307 F.Supp.2d 705, 711 (D.Md.2004) (citing *Ngo v. Standard Tools & Equip., Co.*, 197 F.R.D. 263 (D.Md.2000)); *see also State ex rel. Woytus v. Ryan*, 776 S.W.2d 389, 395 (Mo.1989) (acknowledging that ex parte contact in medical malpractice cases between defense counsel and a nonparty treating physician creates risks that are not generally present in other types of personal injury litigation, including the risk of discussing “ ‘the impact of a jury’s award upon a physician’s professional reputation, the rising cost of malpractice insurance premiums, the notion that the treating physician might be the next person to be sued,’ ” among others (quoting *Manion v. N.P.W. Med. Ctr. of N.E. Pa., Inc.*, 676 F.Supp. 585, 594–95 (M.D.Pa.1987))), *abrogated on other grounds by Brandt v. Pelican*, 856 S.W.2d 658, 661 (Mo.1993).

Smith at 669 n.2. Ultimately, the Court has identified “an inherent risk that the nonparty treating physician’s testimony will to some extent be shaped and influenced by” information received in the course of ex parte contact. Id. at 668.

As important as the foregoing rationales are, the preeminent

rationale for the Loudon rule is *protection of the physician-patient relationship*. The relationship between physician and patient is ““a fiduciary one of the highest degree ... involv[ing] every element of trust, confidence and good faith.”” Loudon at 679 (quoting Lockett v. Goodill, 71 Wn.2d 654, 656, 430 P.2d 589 (1967); alterations in original); accord Smith at 667. The nature of the relationship is confirmed by and reflected in professional ethical guidelines applicable to physicians. See Loudon at 680 & n.3. This type of relationship is incompatible with *ex parte* contact between the physician and defense counsel:

[W]e find it difficult to believe that a physician can engage in an *ex parte* conference with the legal adversary of his patient without endangering the trust and faith invested in him by his patient.

Id. at 679 (quotation omitted; brackets in original); accord Smith at 669. The presence of the patient’s counsel “preserve[s] the fiduciary trust relationship between physician and patient.” Loudon at 679-80.

The centrality and importance of the physician-patient relationship as the basis for the Loudon rule is also supported by the other rationales for the rule. Disclosure of irrelevant health care information—the first rationale above—is problematic by itself, but it also risks undermining the physician-patient relationship:

The mere threat that a physician might engage in private interviews with defense counsel would, for some, have a chilling effect on the physician-patient relationship and hinder further treatment.

Loudon at 679; accord Smith at 666-67. Likewise, the risk that a nonparty treating physician might assume the role of a defense expert—the fourth rationale above—justifies the Loudon rule precisely because it undermines the physician-patient relationship:

If there is a risk that a nonparty treating physician testifying as a fact witness might assume the role of a nonretained expert for the defense, it may result in chilling communication between patients and their physicians about privileged medical information.

Smith at 668.

Finally, the importance of the physician-patient relationship is confirmed by the statutory physician-patient privilege. The privilege has instrumental value in protecting and fostering the physician-patient relationship, not as an end in itself:

The purpose of the physician-patient privilege, set forth in RCW 5.60.060(4), is twofold: (1) to “surround patient-physician communications with a ‘cloak of confidentiality’ to promote proper treatment by facilitating full disclosure of information” and (2) “to protect the patient from embarrassment or scandal which may result from revelation of intimate details of medical treatment.”

Smith at 667 (quoting Carson, 123 Wn.2d at 213).

PeaceHealth argues that the automatic waiver provision of the privilege statute, taking effect after Loudon and not specifically discussed in the lead opinion in Smith, has “superseded” or “displaced” the Loudon rule. See PeaceHealth Br. at 3, 5, 15 & 36-37. At the time Loudon was decided, the physician-patient privilege was deemed waived only as to

those conditions at issue in the particular lawsuit. See 110 Wn.2d at 677-78. As amended, RCW 5.60.060(4)(b) now imposes an automatic waiver of the privilege and expands it to all conditions, “subject to such limitations as a court may impose pursuant to court rules.”

PeaceHealth reasons that the more expansive, post-Loudon waiver has essentially eliminated the reason for the Loudon rule. It bases this argument on two passages in the 3-Justice lead opinion in Smith, seeming to suggest that the physician-patient privilege, rather than the relationship, is the primary rationale for the rule. The first passage states:

Underlying our decision [in Loudon] was a concern for protecting the physician-patient *privilege*. Consistent with that notion, we determined that a plaintiff’s waiver of the privilege does not authorize ex parte contact with a plaintiff’s nonparty treating physician.

Smith at 665 (brackets & emphasis added). From the context, it appears that the highlighted use of the word “privilege” actually speaks to the physician-patient *relationship*, because the very next sentence recognizes that the privilege had been at least partially waived in Loudon, and, of course, it was fully waived in Smith. Following waiver of the privilege, there is no privilege to protect. This explains why the Court in Loudon focused on the risk of disclosure of *irrelevant* information, rather than the risk of disclosure of *privileged* information. See Loudon at 678.

The second passage on which PeaceHealth relies states:

As we have indicated above, the fundamental purpose of the *Loudon* rule is to protect the physician-patient *privilege* and to that end, we emphasized the importance of protecting the sanctity of that *relationship*[.]

Smith at 667 (emphasis & brackets added). From the context, it appears that the use of the word “privilege” again speaks to the instrumental nature of the privilege in protecting and fostering the *relationship*, rather than vice-versa.

In any event, to the extent either of these passages can be read to suggest that the privilege, rather than the relationship, underlies Loudon, such a reading would be incorrect. While Loudon acknowledged the existence of the privilege and the fact that it was partially waived by filing suit, the privilege itself was not an explicit rationale for the Loudon rule. See Loudon at 678 n.1. The expanded waiver of the privilege under the current version of RCW 5.60.060(4) does nothing to undermine any of the six distinct rationales for the rule, discussed above.

The “subject to” clause of RCW 5.60.060(4)(b) confirms that, even today, the scope of the waiver is limited by principles of relevance under CR 26(b)(1), as it was when Loudon was decided. See Loudon at 678. It is therefore not surprising that the Court’s decision in Smith did not find it necessary to address whether the Loudon rule had been superseded or displaced by RCW 5.60.060(4)(b).

The fact that the waiver of the physician-patient privilege is more expansive now than when Loudon was decided is all the more reason why the Loudon rule is necessary. Independent of the privilege, a patient's privacy interest in his or her health care information is recognized under the UHCIA and HIPAA, along with the importance of limiting the disclosure of such private information to protect the physician-patient relationship. See RCW 70.02.005(1), (3); 45 C.F.R. pts. 160 & 164.<sup>11</sup> Health care providers have a duty to minimize unauthorized disclosure of health care information, regardless of whether it is privileged.<sup>12</sup> In the context of discovery, courts retain the ability to fashion an appropriate protective order under CR 26(c) that safeguards the plaintiff's privacy and the physician-patient relationship, again without regard for the privilege.<sup>13</sup> Both the UHCIA and HIPAA post-date Loudon, but their recognition of a freestanding privacy interest in health care information bolsters the rationales for the Loudon rule.

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<sup>11</sup> The full text of the current versions of UHCIA provisions cited herein (RCW 70.02.005, .010, .020, .030, .040, .050, .060, .170 & .900), and HIPAA regulations cited herein (45 C.F.R. §§ 160.103, 160.202, 160.203, 164.501, 164.502, 164.504, 164.506, 164.512 & 164.514), are reproduced in the Appendix to this brief.

<sup>12</sup> See RCW 70.02.050(1) (limiting disclosure "to the extent a recipient needs to know the information"); 45 C.F.R. § 164.502(b) (stating general rule limiting use and disclosure to "the minimum necessary"); id. § 164.514(d) (describing implementation of "minimum necessary" standard).

<sup>13</sup> See RCW 70.02.030(5) (providing authorization for disclosure of health care information "is not a waiver of any rights a patient has under other statutes, the rules of evidence, or common law"); RCW 70.02.060(3) (providing discovery of health care information "does not constitute a waiver of any privilege, objection, or defense existing under other law or rule of evidence or procedure"); 45 C.F.R. § 164.512(e) (describing standard for disclosures in judicial proceedings).

**B. The *Loudon* Rule Should Apply When A Plaintiff's Nonparty Treating Physicians Are Employees Of A Corporate Defendant, Unless The Corporation Establishes That The Physician In Question Is Its Managing Or Speaking Agent.**

The relationship between the patient and a treating physician is the same, regardless of the form of business entity under which the physician chooses to practice medicine, and the rationales supporting the Loudon rule are equally applicable when the physician practices medicine as an employee of a corporation. A nonparty treating physician is not necessarily the client nor is s/he deemed to be a party in most instances involving litigation against the corporation. When the corporate defendant establishes that a nonparty treating physician has sufficient managing or speaking authority on behalf of the corporation to be deemed a party, only in these limited circumstances should ex parte contact be allowed.

In the defense of a lawsuit against a corporation, the corporation itself is the client, even though it can only act through its constituents, i.e., directors, officers, shareholders and employees, among others. See Wright, 103 Wn.2d at 194-95; RPC 1.13(a) & cmts. 1-3.<sup>14</sup> Corporate counsel is required to act in the best interests of the corporation, even under circumstances when it is contrary to the wishes of the constituents. See RPC 1.13(b) & cmts. 4-5. Counsel is required to advise constituents

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<sup>14</sup> The full text of the current version of RPC 1.13 & cmts. is reproduced in the Appendix to this brief.

when the corporation's interests are adverse. See RPC 1.13(c) & cmts. 9-10. The attorney-client privilege and work product protection that may apply to corporate counsel's interactions with constituents of the corporate defendant do not necessarily turn those constituents into clients. See Wright at 194-95; see also RPC 1.13 cmt. 2 (indicating RPC 1.6 client confidences are held by the corporation). The privilege and work product protection belong to the corporate defendant, and may even be waived by the corporation to the detriment of its constituents. See e.g. United States v. Ruehle, 583 F.3d 600, 604-06 & n.3 (9<sup>th</sup> Cir. 2009).<sup>15</sup>

Only those constituents of the corporate defendant who have managing authority sufficient to give them the right to speak for and bind the corporation can be considered parties to the litigation. See Wright at 195-202. The “‘managing-speaking’ agent test” is well-established, flexible, and based on principles of agency and evidence law. See id. at 201. There is no sound reason why this test should not be employed to determine whether a plaintiff's treating physician is deemed a “party” in a lawsuit against the physician's corporate employer for purposes of applying the Loudon rule. See Loudon, at 681 (rejecting argument that

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<sup>15</sup> Counsel may not jointly represent the corporate defendant and its constituents if the obligations to one would be materially limited by obligations to the other. See RPC 1.13(d) (referencing RPC 1.7). Presumably, the Loudon rule would materially limit corporate counsel's ability to represent a nonparty treating physician. In Youngs and Glover, however, there is no suggestion in the briefing that corporate counsel also represents the plaintiffs' nonparty treating physicians.

Wright is inconsistent). The test strikes the proper balance between the policies underlying the Loudon rule and the corporation's interest in defending itself in a lawsuit.<sup>16</sup>

If there is a dispute among the parties regarding which employees of a corporate defendant satisfy the test, then it can be resolved by the trial court on a motion for protective order under CR 26(c). The corporate defendant should not be able to make the designation unilaterally. Cf. In re Firestorm 1991, 129 Wn.2d 130, 138-39, 916 P.2d 411 (1996) (stating counsel should not unilaterally determine whether ex parte contact is permissible with consulting expert); see also Lowy v. PeaceHealth, 174 Wn.2d 769, 789, 280 P.3d 1078 (2012) (requiring hospital to seek protective order if it believes disclosure of information would implicate quality improvement privilege).

PeaceHealth and the State argue that prohibiting ex parte contact with any nonparty treating physicians who are corporate employees interferes with their attorney-client privilege, work product, and, ultimately, the attorney-client relationship itself. However, the Court has already rejected similar arguments. See Loudon at 677 & 680 (rejecting

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<sup>16</sup> PeaceHealth and the State both point out that Wright involved a plaintiff's counsel's right to contact employees of a corporate defendant ex parte, not a corporate defendant's counsel's right to contact its own employees ex parte, and attempt to distinguish Wright on this basis. See PeaceHealth Br. at 12, 26-28; State Br. at 22-23. However, this distinction ignores the clear import of the Court's holdings regarding who can be considered a client or a party in litigation involving the corporation.

argument “that requiring defendants to depose treating physicians gives plaintiffs a tactical advantage by enabling them to monitor the defendants’ case preparation” because the argument “does not comport with a purpose behind the discovery rules – to prevent surprise at trial”); Smith at 665. PeaceHealth and the State cannot identify any information that they could legitimately obtain from ex parte contact with plaintiff’s nonparty treating physicians (who are not managing-speaking agents) that cannot be obtained through formal discovery methods or informal interviews conducted in the presence of plaintiff’s counsel. See Loudon at 680 (stating use of formal discovery methods not overly burdensome because defendants could still reach the relevant records); Smith at 667. In any event, any inconvenience involved in using formal discovery methods in this context is outweighed by the potential risks involved in ex parte contacts. See Loudon at 677; Smith at 665. Harmonizing Wright and Loudon to permit ex parte contact only with managing-speaking agents sufficiently protects the attorney-client relationship.<sup>17</sup>

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<sup>17</sup> Youngs and Glover also appear to concede for purposes of this review that ex parte contact is permissible with tortfeasor-physicians for whom PeaceHealth or the State would be vicariously liable, although the briefing is unclear whether Youngs is seeking to impose vicarious liability for only two physicians (Drs. Leone and Berry) or other health care providers. In this regard, it should be noted that Wright specifically considered, and rejected, a definition of “parties” in litigation against a corporate defendant that would include employees whose acts or omissions are imputed to the corporation for purposes of civil liability. See 103 Wn.2d at 199. The Court explained: “We find no reason to distinguish between employees who in fact witnessed an event and those whose act or

Next, PeaceHealth and the State argue that HIPAA permits ex parte contact in this corporate context, and imply that the Court cannot therefore prohibit it. See PeaceHealth Br. at 4 n.2 & 40 n.20 (citing 45 C.F.R. § 164.506(a) & (c)); State Br. at 11, 15-17 & nn.10-12 (citing 45 C.F.R. §§ 164.506(a) & 164.514(d)(3)(iii)(C)). Notably, however, they do not suggest that HIPAA preempts the Loudon rule. They overlook the HIPAA provision that expressly does *not* preempt state law that “relates to the privacy of individually identifiable health information and is more stringent than” HIPAA. 45 C.F.R. § 160.203(b). In this sense, HIPAA establishes the floor rather than the ceiling for protection of health care information. The phrase “more stringent than” is defined in part to mean “[w]ith respect to a use or disclosure, the [state] law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under [HIPAA].” 45 C.F.R. § 160.202, ¶ 1 (brackets added).<sup>18</sup> The phrase “state law” is defined to include state common law rules. See id. The Loudon rule satisfies these definitions, and is therefore entirely compatible with, and unaffected by, HIPAA.

Similar to the HIPAA argument, PeaceHealth and the State also argue that the UHCIA permits ex parte contact in the corporate context,

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omission caused the event leading to the action. It is not the purpose of the rule to protect a corporate party from the revelation of prejudicial facts.” Id. at 200.

<sup>18</sup> The Loudon rule also appears to be more stringent than HIPAA under ¶¶ 4 & 6 of the definition. See 45 C.F.R. § 160.202.

again implying that the Court may not prohibit it. See PeaceHealth Br. at 39-42 (citing RCW 70.02.050(1)(b)); State Br. at 11 (same). This argument ignores the provision of the UHCIA stating that “[t]his chapter does not restrict a health care provider ... from complying with obligations imposed by ... state law.” RCW 70.02.900(1). The plain meaning of “state law” includes common law rules like Loudon.<sup>19</sup>

Finally, PeaceHealth and the State argue that ex parte contact between defense counsel and a plaintiff’s nonparty treating physicians is necessary for them to maintain a quality improvement program as required by RCW 70.41.200.<sup>20</sup> See PeaceHealth Br. at 43-47; State Br. at 29-31. A quality improvement program includes gathering information to review services rendered in the hospital and the performance of staff, among other things, for the sake of improving the quality of care in the hospital. See RCW 70.41.200(1). PeaceHealth and the State appear to be arguing that litigation defense counsel must have ex parte contact with a plaintiff’s nonparty treating physicians in order to fulfill the requirements of a quality improvement program. This argument should be rejected, and the

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<sup>19</sup> See State ex rel. Ralston v. State Dep’t of Licenses, 60 Wn.2d 535, 539-42, 374 P.2d 571 (1962) (indicating “laws of this state” as used in former RCW 46.20.290(4) “connotes states law in the generic sense; i.e., encompassing all sources of law including decisions of the courts ...”); Matter of Cashaw, 123 Wn.2d 138, 149 n.6, 866 P.2d 8 (1994) (citing Ralston with approval); Black’s Law Dictionary, s.v. “state law” (9<sup>th</sup> ed. 2009) (defining state law as “[a] body of law in a particular state consisting of the state’s constitution, statutes, regulations, and common law”).

<sup>20</sup> The full text of the current version of RCW 70.41.200 is reproduced in the Appendix to this brief.

litigation defense and quality improvement functions should be separated. In an analogous context, the Court has approved a screening mechanism based on the duty of good faith and the quasi-fiduciary relationship between an underinsured motorist insurer and its insured. See Ellwein v. Hartford Acc. & Indem. Co., 142 Wn.2d 766, 782 & n.11, 15 P.3d 640 (2001); *overruled on other grounds*, Smith v. Safeco Ins. Co., 150 Wn.2d 478, 78 P.3d 1274 (2003). The grounds for imposing an appropriate screening mechanism are even stronger in this physician-patient context, because here the physician is a true fiduciary. See Lockett, 71 Wn.2d at 656; Loudon at 679; Smith at 667.

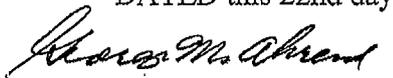
An appropriate screening mechanism would also protect the integrity of the quality improvement program. Under the quality improvement statute, information and documents “created specifically for, and collected and maintained by, a quality improvement committee are not subject to review or disclosure[.]” RCW 70.41.200(3). PeaceHealth and the State further argue that this privilege would be “meaningless,” see PeaceHealth Br. at 46, and “negated,” see State Br. at 31, unless litigation defense counsel can have ex parte contact with a plaintiff’s nonparty treating physicians. To the contrary, they would jeopardize the privilege by involving litigation defense counsel in the quality improvement process because, under those circumstances, the information would not be “created

specifically for” or “collected and maintained by” the quality improvement committee. At the very least, not screening litigation defense counsel from quality improvement function engenders uncertainty regarding the applicability of the quality improvement privilege.<sup>21</sup>

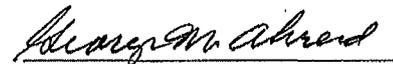
## VI. CONCLUSION

Consistent with the analysis in this brief, the Court should confirm that the Loudon rule prohibits direct or indirect contact with a plaintiff’s nonparty treating physicians, even when the physicians are employed by a corporate defendant.

DATED this 22nd day of January, 2013.

  
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GEORGE M. AHREND

  
\_\_\_\_\_  
FOR BRYAN P. HARNETIAUX, WITH  
AUTHORITY

  
\_\_\_\_\_  
FOR DAVID P. GARDNER, WITH  
AUTHORITY

On Behalf of WSAJ Foundation

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<sup>21</sup> The protective orders at issue in these cases apply to risk managers as well as counsel. To the extent that there is an appropriate screening mechanism between litigation defense and quality improvement functions, this may be unnecessary. Of course, this assumes risk managers will not make indirect ex parte contact with nonparty treating health care providers on behalf of defense counsel. Cf. Smith at 668-69 (prohibiting defense attorneys from accomplishing indirectly what they cannot accomplish directly). In Lowy, 174 Wn.2d at 780-81, the Court indicated that defense counsel may look at quality improvement records if necessary to answer discovery requests, but there is nothing in Lowy that would authorize ex parte contact with nonparty treating physicians.

# Appendix

**RCW 5.60.060. Who is disqualified--Privileged communications**

(1) A spouse or domestic partner shall not be examined for or against his or her spouse or domestic partner, without the consent of the spouse or domestic partner; nor can either during marriage or during the domestic partnership or afterward, be without the consent of the other, examined as to any communication made by one to the other during the marriage or the domestic partnership. But this exception shall not apply to a civil action or proceeding by one against the other, nor to a criminal action or proceeding for a crime committed by one against the other, nor to a criminal action or proceeding against a spouse or domestic partner if the marriage or the domestic partnership occurred subsequent to the filing of formal charges against the defendant, nor to a criminal action or proceeding for a crime committed by said spouse or domestic partner against any child of whom said spouse or domestic partner is the parent or guardian, nor to a proceeding under chapter 70.96A, 70.96B, 71.05, or 71.09 RCW: PROVIDED, That the spouse or the domestic partner of a person sought to be detained under chapter 70.96A, 70.96B, 71.05, or 71.09 RCW may not be compelled to testify and shall be so informed by the court prior to being called as a witness.

(2)(a) An attorney or counselor shall not, without the consent of his or her client, be examined as to any communication made by the client to him or her, or his or her advice given thereon in the course of professional employment.

(b) A parent or guardian of a minor child arrested on a criminal charge may not be examined as to a communication between the child and his or her attorney if the communication was made in the presence of the parent or guardian. This privilege does not extend to communications made prior to the arrest.

(3) A member of the clergy, a Christian Science practitioner listed in the Christian Science Journal, or a priest shall not, without the consent of a person making the confession or sacred confidence, be examined as to any confession or sacred confidence made to him or her in his or her professional character, in the course of discipline enjoined by the church to which he or she belongs.

(4) Subject to the limitations under RCW 70.96A.140 or 71.05.360 (8) and (9), a physician or surgeon or osteopathic physician or surgeon or podiatric physician or surgeon shall not, without the consent of his or her patient, be examined in a civil action as to any information acquired in attending such patient, which was necessary to enable him or her to prescribe or act for the patient, except as follows:

(a) In any judicial proceedings regarding a child's injury, neglect, or sexual abuse or the cause thereof; and

(b) Ninety days after filing an action for personal injuries or wrongful death, the claimant shall be deemed to waive the physician-patient privilege. Waiver of the physician-patient privilege for any one physician or condition constitutes a waiver of the privilege as to all physicians or conditions, subject to such limitations as a court may impose pursuant to court rules.

(5) A public officer shall not be examined as a witness as to communications made to him or her in official confidence, when the public interest would suffer by the disclosure.

(6)(a) A peer support group counselor shall not, without consent of the law enforcement officer or firefighter making the communication, be compelled to testify about any communication made to the counselor by the officer or firefighter while receiving counseling. The counselor must be designated as such by the sheriff, police chief, fire chief, or chief of the Washington state patrol, prior to the incident that results in counseling. The privilege only applies when the communication was made to the counselor while acting in his or her capacity as a peer support group counselor. The privilege does not apply if the counselor was an initial responding officer or firefighter, a witness, or a party to the incident which prompted the delivery of peer support group counseling services to the law enforcement officer or firefighter.

(b) For purposes of this section, "peer support group counselor" means a:

(i) Law enforcement officer, firefighter, civilian employee of a law enforcement agency, or civilian employee of a fire department, who has received training to provide emotional and moral support and counseling to an officer or firefighter who needs those services as a result of an incident in which the officer or firefighter was involved while acting in his or her official capacity; or

(ii) Nonemployee counselor who has been designated by the sheriff, police chief, fire chief, or chief of the Washington state patrol to provide emotional and moral support and counseling to an officer or firefighter who needs those services as a result of an incident in which the officer or firefighter was involved while acting in his or her official capacity.

(7) A sexual assault advocate may not, without the consent of the victim, be examined as to any communication made between the victim and the sexual assault advocate.

(a) For purposes of this section, "sexual assault advocate" means the employee or volunteer from a community sexual assault program or underserved populations provider, victim assistance unit, program, or association, that provides information, medical or legal advocacy, counseling, or support to victims of sexual assault, who is designated by the victim to accompany the victim to the hospital or other health care facility and to proceedings concerning the alleged assault, including police and prosecution interviews and court proceedings.

(b) A sexual assault advocate may disclose a confidential communication without the consent of the victim if failure to disclose is likely to result in a clear, imminent risk of serious physical injury or death of the victim or another person. Any sexual assault advocate participating in good faith in the disclosing of records and communications under this section shall have immunity from any liability, civil, criminal, or otherwise, that might result from the action. In any proceeding, civil or criminal, arising out of a disclosure under this section, the good faith of the sexual assault advocate who disclosed the confidential communication shall be presumed.

(8) A domestic violence advocate may not, without the consent of the victim, be examined as to any communication between the victim and the domestic violence advocate.

(a) For purposes of this section, "domestic violence advocate" means an employee or supervised volunteer from a community-based domestic violence program or human services program that provides information, advocacy, counseling, crisis intervention, emergency shelter, or support to victims of domestic violence and who is not employed by, or under the direct supervision of, a law enforcement agency, a prosecutor's office, or the child protective services section of the department of social and health services as defined in RCW 26.44.020.

(b) A domestic violence advocate may disclose a confidential communication without the consent of the victim if failure to disclose is likely to result in a clear, imminent risk of serious physical injury or death of the victim or another person. This section does not relieve a domestic violence advocate from the requirement to report or cause to be reported an incident under RCW 26.44.030(1) or to disclose relevant records relating to a child as required by \*RCW 26.44.030(12). Any domestic violence advocate participating in good faith in the disclosing of communications under this subsection is immune from liability, civil, criminal, or otherwise, that might result from the action. In any proceeding, civil or criminal, arising out of a disclosure under this subsection, the good faith of the domestic violence advocate who disclosed the confidential communication shall be presumed.

(9) A mental health counselor, independent clinical social worker, or marriage and family therapist licensed under chapter 18.225 RCW may not disclose, or be compelled to testify about, any information acquired from persons consulting the individual in a professional capacity when the information was necessary to enable the individual to render professional services to those persons except:

(a) With the written authorization of that person or, in the case of death or disability, the person's personal representative;

(b) If the person waives the privilege by bringing charges against the mental health counselor licensed under chapter 18.225 RCW;

(c) In response to a subpoena from the secretary of health. The secretary may subpoena only records related to a complaint or report under RCW 18.130.050;

(d) As required under chapter 26.44 or 74.34 RCW or RCW 71.05.360 (8) and (9); or

(e) To any individual if the mental health counselor, independent clinical social worker, or marriage and family therapist licensed under chapter 18.225 RCW reasonably believes that disclosure will avoid or minimize an imminent danger to the health or safety of the individual or any other individual; however, there is no obligation on the part of the provider to so disclose.

[2012 c 29 § 12, eff. June 7, 2012; 2009 c 424 § 1, eff. July 26, 2009; 2008 c 6 § 402, eff. June 12, 2008; 2007 c 472 § 1, eff. July 22, 2007. Prior: 2006 c 259 § 2, eff. June 7, 2006; 2006 c 202 § 1, eff. June 7, 2006; 2006 c 30 § 1, eff. June 7, 2006; 2005 c 504 § 705, eff. July 1, 2005; 2001 c 286 § 2; 1998 c 72 § 1; 1997 c 338 § 1; 1996 c 156 § 1; 1995 c 240 § 1; 1989 c 271 § 301; prior: 1989 c 10 § 1; 1987 c 439 § 11; 1987 c 212 § 1501; 1986 c 305 § 101; 1982 c 56 § 1; 1979 ex.s. c 215 § 2; 1965 c 13 § 7; Code 1881 § 392; 1879 p 118 § 1; 1877 p 86 § 394; 1873 p 107 § 385; 1869 p 104 § 387; 1854 p 187 § 294; RRS § 1214. Cf. 1886 p 73 § 1.]

### **RCW 70.02.005. Findings**

The legislature finds that:

- (1) Health care information is personal and sensitive information that if improperly used or released may do significant harm to a patient's interests in privacy, health care, or other interests.
- (2) Patients need access to their own health care information as a matter of fairness to enable them to make informed decisions about their health care and correct inaccurate or incomplete information about themselves.
- (3) In order to retain the full trust and confidence of patients, health care providers have an interest in assuring that health care information is not improperly disclosed and in having clear and certain rules for the disclosure of health care information.
- (4) Persons other than health care providers obtain, use, and disclose health record information in many different contexts and for many different purposes. It is the public policy of this state that a patient's interest in the proper use and disclosure of the patient's health care information survives even when the information is held by persons other than health care providers.
- (5) The movement of patients and their health care information across state lines, access to and exchange of health care information from automated data banks, and the emergence of multistate health care providers creates a compelling need for uniform law, rules, and procedures governing the use and disclosure of health care information.

[1991 c 335 § 101.]

## RCW 70.02.010. Definitions

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Audit" means an assessment, evaluation, determination, or investigation of a health care provider by a person not employed by or affiliated with the provider to determine compliance with:

- (a) Statutory, regulatory, fiscal, medical, or scientific standards;
- (b) A private or public program of payments to a health care provider; or
- (c) Requirements for licensing, accreditation, or certification.

(2) "Directory information" means information disclosing the presence, and for the purpose of identification, the name, location within a health care facility, and the general health condition of a particular patient who is a patient in a health care facility or who is currently receiving emergency health care in a health care facility.

(3) "Federal, state, or local law enforcement authorities" means an officer of any agency or authority in the United States, a state, a tribe, a territory, or a political subdivision of a state, a tribe, or a territory who is empowered by law to: (a) Investigate or conduct an official inquiry into a potential criminal violation of law; or (b) prosecute or otherwise conduct a criminal proceeding arising from an alleged violation of law.

(4) "General health condition" means the patient's health status described in terms of "critical," "poor," "fair," "good," "excellent," or terms denoting similar conditions.

(5) "Health care" means any care, service, or procedure provided by a health care provider:

- (a) To diagnose, treat, or maintain a patient's physical or mental condition; or
- (b) That affects the structure or any function of the human body.

(6) "Health care facility" means a hospital, clinic, nursing home, laboratory, office, or similar place where a health care provider provides health care to patients.

(7) "Health care information" means any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care, including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs. The term includes any required accounting of disclosures of health care information.

(8) "Health care operations" means any of the following activities of a health care provider, health care facility, or third-party payor to the extent that the activities are

related to functions that make an entity a health care provider, a health care facility, or a third-party payor:

- (a) Conducting: Quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, if the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;
- (b) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance and third-party payor performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of nonhealth care professionals, accreditation, certification, licensing, or credentialing activities;
- (c) Underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care, including stop-loss insurance and excess of loss insurance, if any applicable legal requirements are met;
- (d) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
- (e) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the health care facility or third-party payor, including formulary development and administration, development, or improvement of methods of payment or coverage policies; and
- (f) Business management and general administrative activities of the health care facility, health care provider, or third-party payor including, but not limited to:
  - (i) Management activities relating to implementation of and compliance with the requirements of this chapter;
  - (ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that health care information is not disclosed to such policy holder, plan sponsor, or customer;
  - (iii) Resolution of internal grievances;
  - (iv) The sale, transfer, merger, or consolidation of all or part of a health care provider, health care facility, or third-party payor with another health care provider, health care facility, or third-party payor or an entity that following such activity will become a health care provider, health care facility, or third-party payor, and due diligence related to such activity; and

(v) Consistent with applicable legal requirements, creating deidentified health care information or a limited dataset and fund-raising for the benefit of the health care provider, health care facility, or third-party payor.

(9) "Health care provider" means a person who is licensed, certified, registered, or otherwise authorized by the law of this state to provide health care in the ordinary course of business or practice of a profession.

(10) "Institutional review board" means any board, committee, or other group formally designated by an institution, or authorized under federal or state law, to review, approve the initiation of, or conduct periodic review of research programs to assure the protection of the rights and welfare of human research subjects.

(11) "Maintain," as related to health care information, means to hold, possess, preserve, retain, store, or control that information.

(12) "Patient" means an individual who receives or has received health care. The term includes a deceased individual who has received health care.

(13) "Payment" means:

(a) The activities undertaken by:

(i) A third-party payor to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits by the third-party payor; or

(ii) A health care provider, health care facility, or third-party payor, to obtain or provide reimbursement for the provision of health care; and

(b) The activities in (a) of this subsection that relate to the patient to whom health care is provided and that include, but are not limited to:

(i) Determinations of eligibility or coverage, including coordination of benefits or the determination of cost-sharing amounts, and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance, including stop-loss insurance and excess of loss insurance, and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, and concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following health care information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider, health care facility, and/or third-party payor.

(14) "Person" means an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government, governmental subdivision or agency, or any other legal or commercial entity.

(15) "Reasonable fee" means the charges for duplicating or searching the record, but shall not exceed sixty-five cents per page for the first thirty pages and fifty cents per page for all other pages. In addition, a clerical fee for searching and handling may be charged not to exceed fifteen dollars. These amounts shall be adjusted biennially in accordance with changes in the consumer price index, all consumers, for Seattle-Tacoma metropolitan statistical area as determined by the secretary of health. However, where editing of records by a health care provider is required by statute and is done by the provider personally, the fee may be the usual and customary charge for a basic office visit.

(16) "Third-party payor" means an insurer regulated under Title 48 RCW authorized to transact business in this state or other jurisdiction, including a health care service contractor, and health maintenance organization; or an employee welfare benefit plan; or a state or federal health benefit program.

(17) "Treatment" means the provision, coordination, or management of health care and related services by one or more health care providers or health care facilities, including the coordination or management of health care by a health care provider or health care facility with a third party; consultation between health care providers or health care facilities relating to a patient; or the referral of a patient for health care from one health care provider or health care facility to another.

[2006 c 235 § 2, eff. March 27, 2006; 2005 c 468 § 1, eff. July 24, 2005; 2002 c 318 § 1; 1993 c 448 § 1; 1991 c 335 § 102.]

**RCW 70.02.020. Disclosure by health care provider**

(1) Except as authorized in RCW 70.02.050, a health care provider, an individual who assists a health care provider in the delivery of health care, or an agent and employee of a health care provider may not disclose health care information about a patient to any other person without the patient's written authorization. A disclosure made under a patient's written authorization must conform to the authorization.

(2) A patient has a right to receive an accounting of disclosures of health care information made by a health care provider or a health care facility in the six years before the date on which the accounting is requested, except for disclosures:

- (a) To carry out treatment, payment, and health care operations;
- (b) To the patient of health care information about him or her;
- (c) Incident to a use or disclosure that is otherwise permitted or required;
- (d) Pursuant to an authorization where the patient authorized the disclosure of health care information about himself or herself;
- (e) Of directory information;
- (f) To persons involved in the patient's care;
- (g) For national security or intelligence purposes if an accounting of disclosures is not permitted by law;
- (h) To correctional institutions or law enforcement officials if an accounting of disclosures is not permitted by law; and
- (i) Of a limited data set that excludes direct identifiers of the patient or of relatives, employers, or household members of the patient.

[2005 c 468 § 2, eff. July 24, 2005; 1993 c 448 § 2; 1991 c 335 § 201.]

**RCW 70.02.030. Patient authorization of disclosure**

(1) A patient may authorize a health care provider or health care facility to disclose the patient's health care information. A health care provider or health care facility shall honor an authorization and, if requested, provide a copy of the recorded health care information unless the health care provider or health care facility denies the patient access to health care information under RCW 70.02.090.

(2) A health care provider or health care facility may charge a reasonable fee for providing the health care information and is not required to honor an authorization until the fee is paid.

(3) To be valid, a disclosure authorization to a health care provider or health care facility shall:

(a) Be in writing, dated, and signed by the patient;

(b) Identify the nature of the information to be disclosed;

(c) Identify the name and institutional affiliation of the person or class of persons to whom the information is to be disclosed;

(d) Identify the provider or class of providers who are to make the disclosure;

(e) Identify the patient; and

(f) Contain an expiration date or an expiration event that relates to the patient or the purpose of the use or disclosure.

(4) Unless disclosure without authorization is otherwise permitted under RCW 70.02.050 or the federal health insurance portability and accountability act of 1996 and its implementing regulations, an authorization may permit the disclosure of health care information to a class of persons that includes:

(a) Researchers if the health care provider or health care facility obtains the informed consent for the use of the patient's health care information for research purposes; or

(b) Third-party payors if the information is only disclosed for payment purposes.

(5) Except as provided by this chapter, the signing of an authorization by a patient is not a waiver of any rights a patient has under other statutes, the rules of evidence, or common law.

(6) When an authorization permits the disclosure of health care information to a financial institution or an employer of the patient for purposes other than payment, the authorization as it pertains to those disclosures shall expire ninety days after the signing of the authorization, unless the authorization is renewed by the patient.

(7) A health care provider or health care facility shall retain the original or a copy of each authorization or revocation in conjunction with any health care information from which disclosures are made.

(8) Where the patient is under the supervision of the department of corrections, an authorization signed pursuant to this section for health care information related to mental health or drug or alcohol treatment expires at the end of the term of supervision, unless the patient is part of a treatment program that requires the continued exchange of information until the end of the period of treatment.

[2005 c 468 § 3, eff. July 24, 2005; 2004 c 166 § 19, eff. July 1, 2004; 1994 sp.s. c 9 § 741; 1993 c 448 § 3; 1991 c 335 § 202.]

#### **RCW 70.02.040. Patient's revocation of authorization for disclosure**

A patient may revoke in writing a disclosure authorization to a health care provider at any time unless disclosure is required to effectuate payments for health care that has been provided or other substantial action has been taken in reliance on the authorization. A patient may not maintain an action against the health care provider for disclosures made in good-faith reliance on an authorization if the health care provider had no actual notice of the revocation of the authorization.

[1991 c 335 § 203.]

#### **RCW 70.02.050. Disclosure without patient's authorization**

(1) A health care provider or health care facility may disclose health care information about a patient without the patient's authorization to the extent a recipient needs to know the information, if the disclosure is:

(a) To a person who the provider or facility reasonably believes is providing health care to the patient;

(b) To any other person who requires health care information for health care education, or to provide planning, quality assurance, peer review, or administrative, legal, financial, actuarial services to, or other health care operations for or on behalf of the health care provider or health care facility; or for assisting the health care provider or health care facility in the delivery of health care and the health care provider or health care facility reasonably believes that the person:

(i) Will not use or disclose the health care information for any other purpose; and

(ii) Will take appropriate steps to protect the health care information;

(c) To any other health care provider or health care facility reasonably believed to have previously provided health care to the patient, to the extent necessary to provide health care to the patient, unless the patient has instructed the health care provider or health care facility in writing not to make the disclosure;

(d) To any person if the health care provider or health care facility reasonably believes that disclosure will avoid or minimize an imminent danger to the health or safety of the patient or any other individual, however there is no obligation under this chapter on the part of the provider or facility to so disclose;

(e) To immediate family members of the patient, including a patient's state registered domestic partner, or any other individual with whom the patient is known to have a close personal relationship, if made in accordance with good medical or other professional

practice, unless the patient has instructed the health care provider or health care facility in writing not to make the disclosure;

(f) To a health care provider or health care facility who is the successor in interest to the health care provider or health care facility maintaining the health care information;

(g) For use in a research project that an institutional review board has determined:

(i) Is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure;

(ii) Is impracticable without the use or disclosure of the health care information in individually identifiable form;

(iii) Contains reasonable safeguards to protect the information from redisclosure;

(iv) Contains reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research project; and

(v) Contains procedures to remove or destroy at the earliest opportunity, consistent with the purposes of the project, information that would enable the patient to be identified, unless an institutional review board authorizes retention of identifying information for purposes of another research project;

(h) To a person who obtains information for purposes of an audit, if that person agrees in writing to:

(i) Remove or destroy, at the earliest opportunity consistent with the purpose of the audit, information that would enable the patient to be identified; and

(ii) Not to disclose the information further, except to accomplish the audit or report unlawful or improper conduct involving fraud in payment for health care by a health care provider or patient, or other unlawful conduct by the health care provider;

(i) To an official of a penal or other custodial institution in which the patient is detained;

(j) To provide directory information, unless the patient has instructed the health care provider or health care facility not to make the disclosure;

(k) To fire, police, sheriff, or another public authority, that brought, or caused to be brought, the patient to the health care facility or health care provider if the disclosure is limited to the patient's name, residence, sex, age, occupation, condition, diagnosis, estimated or actual discharge date, or extent and location of injuries as determined by a physician, and whether the patient was conscious when admitted;

(l) To federal, state, or local law enforcement authorities and the health care provider, health care facility, or third-party payor believes in good faith that the health care

information disclosed constitutes evidence of criminal conduct that occurred on the premises of the health care provider, health care facility, or third-party payor;

(m) To another health care provider, health care facility, or third-party payor for the health care operations of the health care provider, health care facility, or third-party payor that receives the information, if each entity has or had a relationship with the patient who is the subject of the health care information being requested, the health care information pertains to such relationship, and the disclosure is for the purposes described in RCW 70.02.010(8)(a) and (b); or

(n) For payment.

(2) A health care provider shall disclose health care information about a patient without the patient's authorization if the disclosure is:

(a) To federal, state, or local public health authorities, to the extent the health care provider is required by law to report health care information; when needed to determine compliance with state or federal licensure, certification or registration rules or laws; or when needed to protect the public health;

(b) To federal, state, or local law enforcement authorities to the extent the health care provider is required by law;

(c) To federal, state, or local law enforcement authorities, upon receipt of a written or oral request made to a nursing supervisor, administrator, or designated privacy official, in a case in which the patient is being treated or has been treated for a bullet wound, gunshot wound, powder burn, or other injury arising from or caused by the discharge of a firearm, or an injury caused by a knife, an ice pick, or any other sharp or pointed instrument which federal, state, or local law enforcement authorities reasonably believe to have been intentionally inflicted upon a person, or a blunt force injury that federal, state, or local law enforcement authorities reasonably believe resulted from a criminal act, the following information, if known:

(i) The name of the patient;

(ii) The patient's residence;

(iii) The patient's sex;

(iv) The patient's age;

(v) The patient's condition;

(vi) The patient's diagnosis, or extent and location of injuries as determined by a health care provider;

(vii) Whether the patient was conscious when admitted;

(viii) The name of the health care provider making the determination in (c)(v), (vi), and (vii) of this subsection;

(ix) Whether the patient has been transferred to another facility; and

(x) The patient's discharge time and date;

(d) To county coroners and medical examiners for the investigations of deaths;

(e) Pursuant to compulsory process in accordance with RCW 70.02.060.

(3) All state or local agencies obtaining patient health care information pursuant to this section shall adopt rules establishing their record acquisition, retention, and security policies that are consistent with this chapter.

[2007 c 156 § 12, eff. July 22, 2007; 2006 c 235 § 3, eff. March 27, 2006; 2005 c 468 § 4, eff. July 24, 2005; 1998 c 158 § 1; 1993 c 448 § 4; 1991 c 335 § 204.]

#### **RCW 70.02.060. Discovery request or compulsory process**

(1) Before service of a discovery request or compulsory process on a health care provider for health care information, an attorney shall provide advance notice to the health care provider and the patient or the patient's attorney involved through service of process or first-class mail, indicating the health care provider from whom the information is sought, what health care information is sought, and the date by which a protective order must be obtained to prevent the health care provider from complying. Such date shall give the patient and the health care provider adequate time to seek a protective order, but in no event be less than fourteen days since the date of service or delivery to the patient and the health care provider of the foregoing. Thereafter the request for discovery or compulsory process shall be served on the health care provider.

(2) Without the written consent of the patient, the health care provider may not disclose the health care information sought under subsection (1) of this section if the requestor has not complied with the requirements of subsection (1) of this section. In the absence of a protective order issued by a court of competent jurisdiction forbidding compliance, the health care provider shall disclose the information in accordance with this chapter. In the case of compliance, the request for discovery or compulsory process shall be made a part of the patient record.

(3) Production of health care information under this section, in and of itself, does not constitute a waiver of any privilege, objection, or defense existing under other law or rule of evidence or procedure.

[1991 c 335 § 205.]

#### **RCW 70.02.170. Civil remedies**

(1) A person who has complied with this chapter may maintain an action for the relief provided in this section against a health care provider or facility who has not complied with this chapter.

(2) The court may order the health care provider or other person to comply with this chapter. Such relief may include actual damages, but shall not include consequential or incidental damages. The court shall award reasonable attorneys' fees and all other expenses reasonably incurred to the prevailing party.

(3) Any action under this chapter is barred unless the action is commenced within two years after the cause of action is discovered.

(4) A violation of this chapter shall not be deemed a violation of the consumer protection act, chapter 19.86 RCW.

[1991 c 335 § 801.]

#### **RCW 70.02.900. Conflicting laws**

(1) This chapter does not restrict a health care provider, a third-party payor, or an insurer regulated under Title 48 RCW from complying with obligations imposed by federal or state health care payment programs or federal or state law.

(2) This chapter does not modify the terms and conditions of disclosure under Title 51 RCW and chapters 13.50, 26.09, 70.24, 70.96A, 71.05, 71.34, and 74.09 RCW and rules adopted under these provisions.

[2011 c 305 § 10, eff. July 22, 2011; 2000 c 5 § 4; 1991 c 335 § 901.]

#### **RCW 70.41.200. Quality improvement and medical malpractice prevention program--Quality improvement committee--Sanction and grievance procedures--Information collection, reporting, and sharing**

(1) Every hospital shall maintain a coordinated quality improvement program for the improvement of the quality of health care services rendered to patients and the identification and prevention of medical malpractice. The program shall include at least the following:

(a) The establishment of a quality improvement committee with the responsibility to review the services rendered in the hospital, both retrospectively and prospectively, in order to improve the quality of medical care of patients and to prevent medical malpractice. The committee shall oversee and coordinate the quality improvement and

medical malpractice prevention program and shall ensure that information gathered pursuant to the program is used to review and to revise hospital policies and procedures;

(b) A medical staff privileges sanction procedure through which credentials, physical and mental capacity, and competence in delivering health care services are periodically reviewed as part of an evaluation of staff privileges;

(c) The periodic review of the credentials, physical and mental capacity, and competence in delivering health care services of all persons who are employed or associated with the hospital;

(d) A procedure for the prompt resolution of grievances by patients or their representatives related to accidents, injuries, treatment, and other events that may result in claims of medical malpractice;

(e) The maintenance and continuous collection of information concerning the hospital's experience with negative health care outcomes and incidents injurious to patients including health care-associated infections as defined in RCW 43.70.056, patient grievances, professional liability premiums, settlements, awards, costs incurred by the hospital for patient injury prevention, and safety improvement activities;

(f) The maintenance of relevant and appropriate information gathered pursuant to (a) through (e) of this subsection concerning individual physicians within the physician's personnel or credential file maintained by the hospital;

(g) Education programs dealing with quality improvement, patient safety, medication errors, injury prevention, infection control, staff responsibility to report professional misconduct, the legal aspects of patient care, improved communication with patients, and causes of malpractice claims for staff personnel engaged in patient care activities; and

(h) Policies to ensure compliance with the reporting requirements of this section.

(2) Any person who, in substantial good faith, provides information to further the purposes of the quality improvement and medical malpractice prevention program or who, in substantial good faith, participates on the quality improvement committee shall not be subject to an action for civil damages or other relief as a result of such activity. Any person or entity participating in a coordinated quality improvement program that, in substantial good faith, shares information or documents with one or more other programs, committees, or boards under subsection (8) of this section is not subject to an action for civil damages or other relief as a result of the activity. For the purposes of this section, sharing information is presumed to be in substantial good faith. However, the presumption may be rebutted upon a showing of clear, cogent, and convincing evidence that the information shared was knowingly false or deliberately misleading.

(3) Information and documents, including complaints and incident reports, created specifically for, and collected and maintained by, a quality improvement committee are not subject to review or disclosure, except as provided in this section, or discovery or introduction into evidence in any civil action, and no person who was in attendance at a

meeting of such committee or who participated in the creation, collection, or maintenance of information or documents specifically for the committee shall be permitted or required to testify in any civil action as to the content of such proceedings or the documents and information prepared specifically for the committee. This subsection does not preclude: (a) In any civil action, the discovery of the identity of persons involved in the medical care that is the basis of the civil action whose involvement was independent of any quality improvement activity; (b) in any civil action, the testimony of any person concerning the facts which form the basis for the institution of such proceedings of which the person had personal knowledge acquired independently of such proceedings; (c) in any civil action by a health care provider regarding the restriction or revocation of that individual's clinical or staff privileges, introduction into evidence information collected and maintained by quality improvement committees regarding such health care provider; (d) in any civil action, disclosure of the fact that staff privileges were terminated or restricted, including the specific restrictions imposed, if any and the reasons for the restrictions; or (e) in any civil action, discovery and introduction into evidence of the patient's medical records required by regulation of the department of health to be made regarding the care and treatment received.

(4) Each quality improvement committee shall, on at least a semiannual basis, report to the governing board of the hospital in which the committee is located. The report shall review the quality improvement activities conducted by the committee, and any actions taken as a result of those activities.

(5) The department of health shall adopt such rules as are deemed appropriate to effectuate the purposes of this section.

(6) The medical quality assurance commission or the board of osteopathic medicine and surgery, as appropriate, may review and audit the records of committee decisions in which a physician's privileges are terminated or restricted. Each hospital shall produce and make accessible to the commission or board the appropriate records and otherwise facilitate the review and audit. Information so gained shall not be subject to the discovery process and confidentiality shall be respected as required by subsection (3) of this section. Failure of a hospital to comply with this subsection is punishable by a civil penalty not to exceed two hundred fifty dollars.

(7) The department, the joint commission on accreditation of health care organizations, and any other accrediting organization may review and audit the records of a quality improvement committee or peer review committee in connection with their inspection and review of hospitals. Information so obtained shall not be subject to the discovery process, and confidentiality shall be respected as required by subsection (3) of this section. Each hospital shall produce and make accessible to the department the appropriate records and otherwise facilitate the review and audit.

(8) A coordinated quality improvement program may share information and documents, including complaints and incident reports, created specifically for, and collected and maintained by, a quality improvement committee or a peer review committee under RCW 4.24.250 with one or more other coordinated quality improvement programs maintained

in accordance with this section or RCW 43.70.510, a coordinated quality improvement committee maintained by an ambulatory surgical facility under RCW 70.230.070, a quality assurance committee maintained in accordance with RCW 18.20.390 or 74.42.640, or a peer review committee under RCW 4.24.250, for the improvement of the quality of health care services rendered to patients and the identification and prevention of medical malpractice. The privacy protections of chapter 70.02 RCW and the federal health insurance portability and accountability act of 1996 and its implementing regulations apply to the sharing of individually identifiable patient information held by a coordinated quality improvement program. Any rules necessary to implement this section shall meet the requirements of applicable federal and state privacy laws. Information and documents disclosed by one coordinated quality improvement program to another coordinated quality improvement program or a peer review committee under RCW 4.24.250 and any information and documents created or maintained as a result of the sharing of information and documents shall not be subject to the discovery process and confidentiality shall be respected as required by subsection (3) of this section, RCW 18.20.390 (6) and (8), 74.42.640 (7) and (9), and 4.24.250.

(9) A hospital that operates a nursing home as defined in RCW 18.51.010 may conduct quality improvement activities for both the hospital and the nursing home through a quality improvement committee under this section, and such activities shall be subject to the provisions of subsections (2) through (8) of this section.

(10) Violation of this section shall not be considered negligence per se.

[2007 c 273 § 22, eff. July 1, 2009; 2007 c 261 § 3, eff. July 22, 2007. Prior: 2005 c 291 § 3, eff. July 24, 2005; 2005 c 33 § 7, eff. July 24, 2005; 2004 c 145 § 3, eff. June 10, 2004; 2000 c 6 § 3; 1994 sp.s. c 9 § 742; 1993 c 492 § 415; 1991 c 3 § 336; 1987 c 269 § 5; 1986 c 300 § 4.]

### **RPC 1.13 ORGANIZATION AS CLIENT**

(a) A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents.

(b) If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then the lawyer shall proceed as is reasonably necessary in the best interest of the organization. Unless the lawyer reasonably believes that it is not necessary in the best interest of the organization to do so, the lawyer shall refer the matter to higher authority in the organization, including, if warranted by the circumstances, to the highest authority that can act on behalf of the organization as determined by applicable law.

(c) Except as provided in paragraph (d), if

(1) despite the lawyer's efforts in accordance with paragraph (b) the highest authority that can act on behalf of the organization insists upon or fails to address in a timely and appropriate manner an action, or a refusal to act, that is clearly a violation of law, and

(2) the lawyer reasonably believes that the violation is reasonably certain to result in substantial injury to the organization.

then the lawyer may reveal information relating to the representation whether or not Rule 1.6 permits such disclosure, but only if and to the extent the lawyer reasonably believes necessary to prevent substantial injury to the organization.

(d) Paragraph (c) shall not apply with respect to information relating to a lawyer's representation of an organization to investigate an alleged violation of law, or to defend the organization or an officer, employee or other constituent associated with the organization against a claim arising out of an alleged violation of law.

(e) A lawyer who reasonably believes that he or she has been discharged because of the lawyer's actions taken pursuant to paragraphs (b) and (c), or who withdraws under circumstances that require or permit the lawyer to take action under either of those paragraphs, shall proceed as the lawyer reasonably believes necessary to assure that the organization's highest authority is informed of the lawyer's discharge or withdrawal.

(f) In dealing with an organization's directors, officers, employees, members, shareholders or other constituents, a lawyer shall explain the identity of the client when the lawyer knows or reasonably should know that the organization's interests are adverse to those of the constituents with whom the lawyer is dealing.

(g) A lawyer representing an organization may also represent any of its directors, officers, employees, members, shareholders or other constituents, subject to the provisions of Rule 1.7. If the organization's consent to the dual representation is required by Rule 1.7, the consent shall be given by an appropriate official of the organization other than the individual who is to be represented, or by the shareholders.

(h) For purposes of this Rule, when a lawyer who is not a public officer or employee represents a discrete governmental agency or unit that is part of a broader governmental entity, the lawyer's client is the particular governmental agency or unit represented, and not the broader governmental entity of which the agency or unit is a part, unless:

(1) otherwise provided in a written agreement between the lawyer and the governmental agency or unit; or

(2) the broader governmental entity gives the lawyer timely written notice to the contrary, in which case the client shall be designated by such entity. Notice under this subsection shall be given by the person designated by law as the chief legal officer of the broader governmental entity, or in the absence of such designation, by the chief executive officer of the entity.

[Adopted effective September 1, 2006.]

## COMMENT

### *The Entity as the Client*

[1] An organizational client is a legal entity, but it cannot act except through its officers, directors, employees, shareholders and other constituents. Officers, directors, employees and shareholders are the constituents of the corporate organizational client. The duties defined in this Comment apply equally to unincorporated associations. "Other constituents" as used in this Comment means the positions equivalent to officers, directors, employees and shareholders held by persons acting for organizational clients that are not corporations.

[2] When one of the constituents of an organizational client communicates with the organization's lawyer in that person's organizational capacity, the communication is protected by Rule 1.6. Thus, by way of example, if an organizational client requests its lawyer to investigate allegations of wrongdoing, interviews made in the course of that investigation between the lawyer and the client's employees or other constituents are covered by Rule 1.6. This does not mean, however, that constituents of an organizational client are the clients of the lawyer. The lawyer may not disclose to such constituents information relating to the representation except for disclosures explicitly or impliedly authorized by the organizational client in order to carry out the representation or as otherwise permitted by Rule 1.6.

[3] When constituents of the organization make decisions for it, the decisions ordinarily must be accepted by the lawyer even if their utility or prudence is doubtful. Decisions concerning policy and operations, including ones entailing serious risk, are not as such in the lawyer's province. Paragraph (b) makes clear, however, that when the lawyer knows that the organization is likely to be substantially injured by action of an officer or other constituent that violates a legal obligation to the organization or is in violation of law that might be imputed to the organization, the lawyer must proceed as is reasonably necessary in the best interest of the organization. As defined in Rule 1.0(f), knowledge can be inferred from circumstances, and a lawyer cannot ignore the obvious.

[4] In determining how to proceed under paragraph (b), the lawyer should give due consideration to the seriousness of the violation and its consequences, the responsibility in the organization and the apparent motivation of the person involved, the policies of the organization concerning such matters, and any other relevant considerations. Ordinarily, referral to a higher authority would be necessary. In some circumstances, however, it may be appropriate for the lawyer to ask the constituent to reconsider the matter; for example, if the circumstances involve a constituent's innocent misunderstanding of law and subsequent acceptance of the lawyer's advice, the lawyer may reasonably conclude that the best interest of the organization does not require that the matter be referred to a higher authority. If a constituent persists in conduct contrary to the lawyer's advice, it will be necessary for the lawyer to take steps to have the matter reviewed by a higher authority in the organization. If the matter is of sufficient seriousness and importance or urgency to the organization, referral to higher authority in the organization may be necessary even if the lawyer has not communicated with the constituent. Any measures taken should, to the

extent practicable, minimize the risk of revealing information relating to the representation to persons outside the organization. Even in circumstances where a lawyer is not obligated by Rule 1.13 to proceed, a lawyer may bring to the attention of an organizational client, including its highest authority, matters that the lawyer reasonably believes to be of sufficient importance to warrant doing so in the best interest of the organization.

[5] Paragraph (b) also makes clear that when it is reasonably necessary to enable the organization to address the matter in a timely and appropriate manner, the lawyer must refer the matter to higher authority, including, if warranted by the circumstances, the highest authority that can act on behalf of the organization under applicable law. The organization's highest authority to whom a matter may be referred ordinarily will be the board of directors or similar governing body. However, applicable law may prescribe that under certain conditions the highest authority reposes elsewhere, for example, in the independent directors of a corporation.

#### *Relation to Other Rules*

[6] The authority and responsibility provided in this Rule are concurrent with the authority and responsibility provided in other Rules. In particular, this Rule does not limit or expand the lawyer's responsibility under Rules 1.8, 1.16, 3.3 or 4.1. Paragraph (c) of this Rule supplements Rule 1.6(b) by providing an additional basis upon which the lawyer may reveal information relating to the representation, but does not modify, restrict, or limit the provisions of Rule 1.6(b)(1)-(7). Under paragraph (c) the lawyer may reveal such information only when the organization's highest authority insists upon or fails to address threatened or ongoing action that is clearly a violation of law, and then only to the extent the lawyer reasonably believes necessary to prevent reasonably certain substantial injury to the organization. It is not necessary that the lawyer's services be used in furtherance of the violation, but it is required that the matter be related to the lawyer's representation of the organization. If the lawyer's services are being used by an organization to further a crime or fraud by the organization, Rules 1.6(b)(2) and 1.6(b)(3) may permit the lawyer to disclose confidential information. In such circumstances Rule 1.2(d) may also be applicable, in which event, withdrawal from the representation under Rule 1.16(a)(1) may be required.

[7] Paragraph (d) makes clear that the authority of a lawyer to disclose information relating to a representation in circumstances described in paragraph (c) does not apply with respect to information relating to a lawyer's engagement by an organization to investigate an alleged violation of law or to defend the organization or an officer, employee or other person associated with the organization against a claim arising out of an alleged violation of law. This is necessary in order to enable organizational clients to enjoy the full benefits of legal counsel in conducting an investigation or defending against a claim.

[8] A lawyer who reasonably believes that he or she has been discharged because of the lawyer's actions taken pursuant to paragraph (b) or (c), or who withdraws in circumstances that require or permit the lawyer to take action under either of these

paragraphs, must proceed as the lawyer reasonably believes necessary to assure that the organization's highest authority is informed of the lawyer's discharge or withdrawal.

#### *Government Agency*

[9] The duty defined in this Rule applies to governmental organizations. Defining precisely the identity of the client and prescribing the resulting obligations of such lawyers may be more difficult in the government context and is a matter beyond the scope of these Rules. See Scope [18]. Although in some circumstances the client may be a specific agency, it may also be a branch of government, such as the executive branch, or the government as a whole. For example, if the action or failure to act involves the head of a bureau either the department of which the bureau is a part or the relevant branch of government may be the client for purposes of this Rule. Moreover, in a matter involving the conduct of government officials, a government lawyer may have authority under applicable law to question such conduct more extensively than that of a lawyer for a private organization in similar circumstances. Thus, when the client is a governmental organization, a different balance may be appropriate between maintaining confidentiality and assuring that the wrongful act is prevented or rectified, for public business is involved. In addition, duties of lawyers employed by the government or lawyers in military service may be defined by statutes and regulation. This Rule does not limit that authority. See Scope.

#### *Clarifying the Lawyer's Role*

[10] There are times when the organization's interest may be or become adverse to those of one or more of its constituents. In such circumstances the lawyer should advise any constituent, whose interest the lawyer finds adverse to that of the organization of the conflict or potential conflict of interest, that the lawyer cannot represent such constituent, and that such person may wish to obtain independent representation. Care must be taken to assure that the individual understands that, when there is such adversity of interest, the lawyer for the organization cannot provide legal representation for that constituent individual, and that discussions between the lawyer for the organization and the individual may not be privileged.

[11] Whether such a warning should be given by the lawyer for the organization to any constituent individual may turn on the facts of each case.

#### *Dual Representation*

[12] Paragraph (g) recognizes that a lawyer for an organization may also represent a principal officer or major shareholder.

#### *Derivative Actions*

[13] Under generally prevailing law, the shareholders or members of a corporation may bring suit to compel the directors to perform their legal obligations in the supervision of the organization. Members of unincorporated associations have essentially the same right.

Such an action may be brought nominally by the organization, but usually is, in fact, a legal controversy over management of the organization.

[14] The question can arise whether counsel for the organization may defend such an action. The proposition that the organization is the lawyer's client does not alone resolve the issue. Most derivative actions are a normal incident of an organization's affairs, to be defended by the organization's lawyer like any other suit. However, if the claim involves serious charges of wrongdoing by those in control of the organization, a conflict may arise between the lawyer's duty to the organization and the lawyer's relationship with the board. In those circumstances, Rule 1.7 governs who should represent the directors and the organization.

**Additional Washington Comment (15)**

[15] Paragraph (h) was taken from former Washington RPC 1.7(c); it addresses the obligations of a lawyer who is not a public officer or employee but is representing a discrete governmental agency or unit.

[Comment adopted effective September 1, 2006.]

(b) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

#### § 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

*Act* means the Social Security Act.

*ANSI* stands for the American National Standards Institute.

*Business associate*: (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and pricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

*CMS* stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

*Compliance date* means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

*Covered entity* means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

*Disclosure* means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

*EIN* stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

*Electronic media* means:

(1) Electronic storage media including memory devices in computers (hard

drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

*Electronic protected health information* means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

*Employer* is defined as it is in 26 U.S.C. 3401(d).

*Group health plan* (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

*HHS* stands for the Department of Health and Human Services.

*Health care* means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or

palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

*Health care clearinghouse* means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

*Health care provider* means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

*Health information* means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

*Health insurance issuer* (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization

(including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

*Health maintenance organization (HMO)* (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

*Health plan* means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq.*

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq.*

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq.*

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq.*

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

*Implementation specification* means specific requirements or instructions for implementing a standard.

*Individual* means the person who is the subject of protected health information.

*Individually identifiable health information* is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the

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past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

*Modify* or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

*Organized health care arrangement* means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

*Person* means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

*Protected health information* means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media;

or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

*Secretary* means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

*Small health plan* means a health plan with annual receipts of \$5 million or less.

*Standard* means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

*Standard setting organization (SSO)* means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

*State* refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

*Trading partner agreement* means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

*Transaction* means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

- (1) Health care claims or equivalent encounter information.
- (2) Health care payment and remittance advice.
- (3) Coordination of benefits.
- (4) Health care claim status.
- (5) Enrollment and disenrollment in a health plan.
- (6) Eligibility for a health plan.
- (7) Health plan premium payments.
- (8) Referral certification and authorization.
- (9) First report of injury.
- (10) Health claims attachments.
- (11) Other transactions that the Secretary may prescribe by regulation.

*Use* means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

*Workforce* means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002; 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003; 71 FR 8424, Feb. 16, 2006]

#### § 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002]

#### Subpart B—Preemption of State Law

##### § 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104-191.

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§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

*Contrary*, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104-191, as applicable.

*More stringent* means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or dura-

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tion, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

*Relates to the privacy of individually identifiable health information* means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

*State law* means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

**§160.204 Process for requesting exception determinations.**

(a) A request to except a provision of State law from preemption under §160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the addi-

tional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at §160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the FEDERAL REGISTER. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at §160.203(a) has been met.

**§160.205 Duration of effectiveness of exception determinations.**

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

**Subpart C—Compliance and Investigations**

SOURCE: 71 FR 8424, Feb. 16, 2006, unless otherwise noted.

**§160.300 Applicability.**

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with, and the enforcement of, the applicable provisions of this part 160 and parts 162 and 164 of this subchapter.

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
		Encryption (A)

**Subpart D [Reserved]**

**Subpart E—Privacy of Individually Identifiable Health Information**

AUTHORITY: 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)).

**§ 164.500 Applicability.**

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

**§ 164.501 Definitions.**

As used in this subpart, the following terms have the following meanings:

*Correctional institution* means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

*Data aggregation* means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with

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the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

*Designated record set* means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

*Direct treatment relationship* means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

*Health care operations* means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care

learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

*Health oversight agency* means an agency or authority of the United States, a State, a territory, a political

subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

*Indirect treatment relationship* means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

*Inmate* means a person incarcerated in or otherwise confined to a correctional institution.

*Law enforcement official* means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

*Marketing* means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about the entities participating in a health care provider network or health plan

network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

*Payment* means:

(1) The activities undertaken by:

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and

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preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

- (A) Name and address;
- (B) Date of birth;
- (C) Social security number;
- (D) Payment history;
- (E) Account number; and
- (F) Name and address of the health care provider and/or health plan.

*Psychotherapy notes* means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

*Public health authority* means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

*Treatment* means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to

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a patient; or the referral of a patient for health care from one health care provider to another.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

- (i) To the individual;
- (ii) For treatment, payment, or health care operations, as permitted by and in compliance with §164.506;
- (iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §164.502(b), §164.514(d), and §164.530(c) with respect to such otherwise permitted or required use or disclosure;
- (iv) Pursuant to and in compliance with a valid authorization under §164.508;
- (v) Pursuant to an agreement under, or as otherwise permitted by, §164.510; and
- (vi) As permitted by and in compliance with this section, §164.512, or §164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

- (i) To an individual, when requested under, and required by §164.524 or §164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary—(1) Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must

make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.*

This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by § 164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.*, de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of § 164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under § 164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by § 164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by § 164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in § 164.520(b)(1)(iii)(A)–(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims—(1) Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002]

#### § 164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

*Plan administration functions* means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

*Summary health information* means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B)

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need only be aggregated to the level of a five digit zip code.

(b)-(d) [Reserved]

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement between the covered entity and the business associate required by §164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in §164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with §164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with §164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(ii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and

its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section.

(i) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of *business associate* in §160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(i) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(2) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under §164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of:

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a

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health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance

by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(ii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by § 164.520(b)(1)(iii)(C) is included in the appropriate notice; and (iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.* (1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

**§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.**

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.* (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.* (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

[67 FR 53268, Aug. 14, 2002]

**§ 164.508 Uses and disclosures for which an authorization is required.**

(a) *Standard: authorizations for uses and disclosures—(1) Authorization required: general rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use

or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (3), or (4) of this section, as applicable.

(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to

pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) *Use and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

**§164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.**

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: uses and disclosures for public health activities—(1) Permitted disclosures.* A covered entity may disclose protected health information for the

public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:

(1) To conduct an evaluation relating to medical surveillance of the workplace; or

(2) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(1) By giving a copy of the notice to the individual at the time the health care is provided; or

(2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence—(1) Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency,

authorized by law to receive reports of such abuse, neglect, or domestic violence:

(1) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(d) *Standard: Uses and disclosures for health oversight activities—(1) Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, ad-

ministrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Notwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) *Standard: Disclosures for judicial and administrative proceedings—(1) Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only

the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protecting health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(1) No objections were filed; or

(2) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written state-

ment and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.

(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(1) The information sought is relevant and material to a legitimate law enforcement inquiry;

(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(3) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(1) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct

that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.* (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

- (A) The commission and nature of a crime;
- (B) The location of such crime or of the victim(s) of such crime; and
- (C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) *Standard: Uses and disclosures about decedents—(1) Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or

other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes—(1) Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by § 164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(1) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(2) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(3) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (1)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (1)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (1)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (1)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is

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being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety—*

(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual;

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.

(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy

described in paragraph (j)(2)(1) of this section.

(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) *Standard: Uses and disclosures for specialized government functions—(1) Military and veterans activities—(i) Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the FEDERAL REGISTER the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Transportation may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the FEDERAL REGISTER pursuant to paragraph (k)(1)(i) of this section.

(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.*, Executive Order 12333).

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or to for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:

(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12698;

(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or

(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) *Correctional institutions and other law enforcement custodial situations.* (1) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; and

(F) The administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

(6) *Covered entities that are government programs providing public benefits.* (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government

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agencies is required or expressly authorized by statute or regulation.

(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.

(1) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

**§ 164.514 Other requirements relating to uses and disclosures of protected health information.**

(a) *Standard: de-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) *Implementation specifications: requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to

identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(1) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except

as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) *Implementation specifications: re-identification.* A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) *Security.* The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) *Standard: minimum necessary requirements.* In order to comply with §164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) *Implementation specifications: minimum necessary uses of protected health information.* (i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine

and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of §164.512(i) have been provided by a person requesting the information for research purposes.

(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the

amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- (i) Names;
- (ii) Postal address information, other than town or city, State, and zip code;
- (iii) Telephone numbers;
- (iv) Fax numbers;
- (v) Electronic mail addresses;
- (vi) Social security numbers;
- (vii) Medical record numbers;
- (viii) Health plan beneficiary numbers;
- (ix) Account numbers;
- (x) Certificate/license numbers;
- (xi) Vehicle identifiers and serial numbers, including license plate numbers;
- (xii) Device identifiers and serial numbers;
- (xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.*

(i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement.*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(1) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(2) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(3) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(4) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(5) Not identify the information or contact the individuals.

(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

(f)(1) *Standard: Uses and disclosures for fundraising.* A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual; and

(ii) Dates of health care provided to an individual.

(2) *Implementation specifications: Fundraising requirements.* (i) The covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(ii)(B) is included in the covered entity's notice;

(ii) The covered entity must include in any fundraising materials it sends to

an individual under this paragraph a description of how the individual may opt out of receiving any further fundraising communications.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.

(g) *Standard: Uses and disclosures for underwriting and related purposes.* If a health plan receives protected health information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such protected health information for any other purpose, except as may be required by law.

(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) *Implementation specifications: Verification.* (i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar

§ 164.520

process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(1)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(1) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(ii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional

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judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

[65 FR 82802, Dec. 23, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.520 Notice of privacy practices for protected health information.

(a) *Standard: notice of privacy practices—(1) Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an

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**To:** George Ahrend  
**Cc:** Bryan P Harnetiaux; Stewart A. Estes; Andy Hoyal; Spillane, Mary; dferm@williamskastner.com; Tom Golden; Mike Madden; csjanes@bblaw.com; David P. Gardner; amagnano@bblaw.com  
**Subject:** RE: Youngs v. PeaceHealth/Glover v. State (SC #87811-1)

Rec'd 1-22-13

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**Sent:** Tuesday, January 22, 2013 4:46 PM  
**To:** OFFICE RECEPTIONIST, CLERK  
**Cc:** Bryan P Harnetiaux; Stewart A. Estes; Andy Hoyal; Spillane, Mary; dferm@williamskastner.com; Tom Golden; Mike Madden; csjanes@bblaw.com; David P. Gardner; amagnano@bblaw.com  
**Subject:** Youngs v. PeaceHealth/Glover v. State (SC #87811-1)

Dear Mr. Carpenter,

On behalf of the Washington State Association for Justice Foundation, a motion to file an overlength amicus curiae brief along with a proposed amicus curiae brief is attached to this email. Counsel for the parties and the Washington Defense Trial Lawyers are being served simultaneously by copy of this email, by prior agreement among counsel.

Respectfully submitted,

--

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