No. 14-35402

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

OREGON PRESCRIPTION DRUG MONITORING PROGRAM
Plaintiff-Appellee,

ACLU FOUNDATION OF OREGON, INC., et al.,
Plaintiffs-Intervenors-Appellees

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,
Defendant-Appellant

On Appeal from the United States District Court for the District of Oregon
No. 12-02023

BRIEF OF *AMICI CURIAE* OREGON MEDICAL ASSOCIATION AMERICAN MEDICAL ASSOCIATION ALASKA STATE MEDICAL ASSOCIATION ARIZONA MEDICAL ASSOCIATION CALIFORNIA MEDICAL ASSOCIATION HAWAII MEDICAL ASSOCIATION IDAHO MEDICAL ASSOCIATION MONTANA MEDICAL ASSOCIATION NEVADA STATE MEDICAL ASSOCIATION WASHINGTON STATE MEDICAL ASSOCIATION

In support of affirming the judgment of the District Court and supporting Plaintiffs.

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CORPORATE DISCLOSURE STATEMENTS

OREGON MEDICAL ASSOCIATION

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, amicus Oregon Medical Association by and through its undersigned attorney hereby certifies that: There is no parent corporation to the Oregon Medical Association and there is no publicly held corporation that owns Oregon Medical Association stock.

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Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, amicus Washington State Medical Association by and through the undersigned attorney hereby certifies that: There is no parent corporation to the Washington State Medical Association and there is no publicly held corporation that owns Washington State Medical Association stock.

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OTHER AUTHORITIES

Amici curiae respectfully submit this brief pursuant to Fed. R. App. P. 29, in support of affirming the judgment of the District Court and supporting Plaintiffs.

I. STATEMENT OF IDENTITY AND AUTHORITY

Amici curiae are the Oregon Medical Association, the American Medical Association, and the state medical association of every state (including Oregon) in the jurisdiction of the United States Court of Appeals for the Ninth Circuit: Alaska State Medical Association, Arizona Medical Association, California Medical Association, Hawaii Medical Association, Idaho Medical Association, Montana Medical Association, Nevada State Medical Association, and the Washington State Medical Association. (*Amici curiae* are referred to collectively as the "Medical Associations.") The Oregon Medical Association represents the interests of physicians licensed to practice medicine in Oregon; the other state medical associations represent the interests of physicians licensed to practice medicine throughout the other states within the Ninth Circuit; and the American Medical Association ("AMA") represents the interests of physicians nationally. Each entity appears with the authority of its respective Board of Directors or other executive authority empowered to authorize this appearance on their own behalves and as representatives of the AMA's Litigation Center.

II. STATEMENT OF AUTHORSHIP AND FUNDING

The brief of *amici curiae* was not authored in whole or in part by counsel for any party to the action or appeal. The preparation and submission of the brief of *amici curiae* was funded entirely by *amici curiae*; money was not contributed by a party or a party's counsel or any other person for the preparation or submission of the brief of *amici curiae*.

III. STATEMENT OF INTERESTS

The Medical Associations' interests are stated more fully in their Motion to Appear *Amici Curiae*. The core interests of the Medical Associations include protecting patient privacy; preventing the disclosure of patient health information without a patient's informed consent, which is essential for a patient-physician relationship built on trust; and ensuring the integrity and confidentiality of the patient-physician relationship so that patients will seek care and so that doctors may provide the most efficacious health care for the patient's benefit. The Medical Associations' interests also and accordingly include advocating for the strongest possible protections for patient prescription data collected by state prescription drug monitoring programs ("PDMPs") so that the data is used by doctors and pharmacists for responsible treatment and prescription practices, public health and safety, and not as a law enforcement tool without the most stringent legal requirements for disclosure to law enforcement. The Medical Associations also have an interest in

supporting their role in working with and providing policy and practice expertise to state legislatures to enact and enforce laws that are consistent with the above-stated core values, as is the case with the statutory requirements of individualized probable cause and a court order for disclosure of prescription information contained in Oregon's PDMP.

IV. SUMMARY OF ARGUMENT

A. THE FOURTH AMENDMENT

The Medical Associations appear as *amici curiae* to urge the Court to sustain the viability of the Oregon PDMP's requirements of individualized probable cause and a court order or warrant for release of prescription information to federal law enforcement. The District Court's judgment that both of those requirements exist here -- by virtue of the Fourth Amendment's protections for the significant privacy interests at stake -- should be affirmed.

The establishment of Oregon's PDMP must be understood in three important contexts that inform all of the issues in this case:

First, Oregon's PDMP must be examined in the context of other Oregon laws that preceded its adoption, which go to great lengths to protect confidential patient health information, including prescriptions, from disclosure without the patient's informed consent. Examined together, Oregon's health care privacy laws, including the PDMP, establish the high premium on and expectation of privacy that the state

places on protection of patient health information from disclosure without consent or the most stringent legal safeguards (here, individualized probable cause and a court order).

Second, Oregon's PDMP should be placed in context of state PDMPs more generally and the primary purposes they are set up to serve. PDMPs were enacted by states nationwide principally to focus on the efficacious provision of health care and public health, not enhancement of federal law enforcement. To the extent that the Drug Enforcement Administration asserts an unfettered right to access data from the PDMP without probable cause or judicial oversight and approval, that not only takes improper advantage of the health care data system -- which by its terms in Oregon prohibits such access -- but undermines the health care purposes that the state PDMPs were set up to serve.

Third, Oregon's PDMP must be understood in the broader framework of the policies and principles that inform and protect patient privacy and the integrity and confidentiality of the physician-patient relationship. As patient health information increasingly is digitized and centralized, it becomes especially critical to recognize and respect legislative choices and constitutional protections that work to maintain the private health care nature of such records, free from effectively unrestrained and unsupervised law enforcement access. As a society, it is well-established as a matter

of history, science, and medical ethics that patients must be able to trust the confidentiality of their records to facilitate their proper diagnosis and treatment, and prescribers must be able to rely on confidentiality with their patients to diagnose medical conditions and prescribe the most effective medication for those treatments without the chill of unsupervised law enforcement oversight.

B. THE REQUIREMENTS OF AN INDIVIDUALIZED COURT ORDER

If the Court reaches the issue, then the Court should conclude that the Oregon statute's independent requirements of an individualized court order or warrant prior to disclosure must be enforced in the context of a federal administrative subpoena, so that federal law enforcement may not unilaterally force disclosure of highly confidential personal medical information without judicial oversight and approval. Indeed, Plaintiff-Appellee Oregon Prescription Drug Monitoring Program correctly asserts that the requirements of a court order or warrant focused on an individualized investigation are enforceable under both state and federal law, independent of and separate from the statutory requirement (or any Fourth Amendment requirement) of probable cause. (Appellee's Br. at 21.) The profound privacy interests at stake underscore the importance of judicial oversight.

C. PREEMPTION

Plaintiff-Appellee the Oregon PDMP concedes that the Oregon statutory requirement of probable cause is preempted by the federal law authorizing an

administrative subpoena to issue based on the lesser requirement of reasonable suspicion and not probable cause. (*Id*. at 13.) However, the District Court did not reach this preemption issue and the concession on this point of law by the Oregon PDMP is far from clear and correct as a matter of actual law. Accordingly, if this Court were to reach the preemption issue, it should proceed with caution with respect to accepting the concession, while limiting any treatment of the State's concession to the context of this case only, recognizing that the concession is not free from legal doubt.

V. ARGUMENT

A. STATUTORY CONTEXT

1. Introduction

The Oregon Legislative Assembly in 2009 did not enact Oregon's Prescription Drug Monitoring Program in a statutory vacuum, including the enactment of the PDMP's requirements of individualized probable cause and a court order for disclosure to law enforcement. Indeed, Oregon's PDMP was adopted in the context of and as part of a pervasive statutory framework for the protection of the privacy of patients' health information.

This is not a case in which this Court is being asked by the Drug Enforcement Administration to affirm administrative searches *permitted* by state law. If it were such a case, the state's decision to permit the search might inform the privacy

calculus and bear on the question of the subjective and objectively reasonable expectation of privacy. Here, however, the Oregon legislature has adopted a PDMP in the context of an overall state statutory framework that is highly protective of patient and prescription privacy and, moreover, has built into the PDMP itself stringent statutory safeguards for that privacy that would *prohibit* DEA access based on an administrative subpoena without individualized probable cause and without a court order. Those state legislative choices matter and necessarily inform the court's privacy inquiry.

Those provisions of law, in addition to Oregon's PDMP, are discussed further below and include: 1) Or. Rev. Stat. §§ 192.553 *et seq*. (stating policy of the State of Oregon to protect the privacy of patient information and protecting that information generally from disclosure without patient consent); 2) Or. Rev. Stat. §§ 192.502(2) and 192.496(1) (privacy protection from disclosure of medical records held by the government, under the Oregon Public Records Law); and 3) the privacy rules of the federal Health Information Portability and Accountability Act Privacy Rule ("HIPAA"), 45 C.F.R. parts 160 and 164, which are expressly referenced by Oregon statutes including Or. Rev. Stat. § 192.553(2) and the PDMP itself, Or. Rev. Stat. § 431.962(2)(d).

2. The Relevance of State Law

An objectively reasonable expectation of privacy that gives rise to Fourth Amendment protection is one that "has a source outside of the Fourth Amendment, either by reference to concepts of real or personal property law or to understandings that are recognized and permitted by society." *Minnesota v. Carter*, 525 U.S. 83, 88 (1988) (citing *Rakas v. Illinois*, 439 U.S. 128, 143 n.12 (1978)). There is no single source that determines whether a given expectation of privacy is objectively reasonable for purposes of the Fourth Amendment. *See Oliver v. United States*, 466 U.S. 170, 177 (1984). In appropriate cases, the Supreme Court has "looked to prevailing rules in individual jurisdictions" to inform a Fourth Amendment analysis. *Tennessee v. Garner*, 471 U.S. 1, 15–16 (1985) (citing *United States v. Watson*, 423 U.S. 411, 421–22 (1976)). Accordingly, while state law does not determine the scope of the Fourth Amendment, *see Virginia v. Moore*, 553 U.S. 164 (2008), its provisions with respect to privacy nonetheless can be applicable to a Fourth Amendment analysis.

Thus, the Tenth Circuit Court of Appeals specifically found that patients have a right to privacy in their prescription records and then looked to state law to assess the contours or extent of that right for purposes of a federal constitutional analysis. *Douglas v. Dobbs*, 419 F.3d 1097 (10th Cir. 2005). In so doing, the court stated that the right to privacy may be diminished by state law, "which [right] in this case may

be tempered by the fact that New Mexico apparently requires pharmacies to make these records available to law enforcement." *Id.* at 1102 (citations omitted).

If state law that is *permissive with respect to law enforcement access* to prescription drug records (as in *Douglas v. Dobbs, supra*) can inform a court's privacy inquiry, it must also be true that state law such as Oregon's that includes *material privacy safeguards from law enforcement access* -- requiring individualized probable cause and a court order – likewise should inform this Court's privacy inquiry. Indeed, unless a court is prepared to conclude that state law is *irrelevant* to the privacy determination, and that all cases thus would come out the same way under the Fourth Amendment when examining the constitutionality of a federal administrative subpoena regardless of what state law may provide, then it must be the case that the terms and conditions that state law imposes on disclosure to law enforcement inform the privacy analysis. Accordingly, consideration turns to Oregon law as it pertains to the privacy of individual medical information, including prescription records under the Oregon PDMP.

3. Or. Rev. Stat. §§ 192.553 *et seq*.

Or. Rev. Stat. §§ 192.553 *et seq.* underscore the State of Oregon's commitment to protect the privacy of personal health information including patient prescription information. Or. Rev. Stat. § 192.553(1)(a) provides:

> (1) It is the policy of the State of Oregon that an individual has:
>
> (a) The right to have protected health information of the individual safeguarded from unlawful use or disclosure[.]

"Protected health information" and "individually identifiable health information" are defined terms, each of which includes patient prescription information. Or. Rev. Stat. § 192.556(11)(a) defines "Protected health information" to mean:

> [I]ndividually identifiable health information that is maintained or transmitted in any form of electronic or other medium by a covered entity.

Or. Rev. Stat. § 192.556(8) pertinently defines "Individually identifiable health information":

> (8) "Individually identifiable health information" means any oral or written health information in any form or medium that is:
>
> (a) created or received by a covered entity***; and
>
> (b) identifiable to an individual, including demographic information that identifies the individual, or for which there is a reasonable basis to believe the information can be used to identify an individual and that relates to:
>
> (A) The past, present or future physical or mental health or condition of an individual;
>
> (B) The provision of health care to an individual[.]

Or. Rev. Stat. § 192.525(1) (2001) specifically committed the state to protecting a patient's right to confidentiality, with limits on that policy permitted only if they benefit the patient:

> The Legislative Assembly declares that *it is the policy of the State of Oregon to protect both the right of an individual to have the medical history of the individual protected from disclosure to persons other than the health care provider and insurer of the individual* who needs such information, and the right of an individual to review the medical records of that individual. It is recognized that *both rights may be limited but only to benefit the patient.* These rights of confidentiality and full access *must be protected by private and public institutions providing health care services* and by private practitioners of the healing arts. *The State of Oregon commits itself to fulfilling the objectives of this public policy for public providers of health care.* Private practitioners of the healing arts and private institutions providing health care services are encouraged to adopt voluntary guidelines that will grant health care recipients access to their own medical records while preserving those records from unnecessary disclosure.

(Emphases added.)

Or. Rev. Stat. §§ 192.553 *et seq.* were enacted in 2003 to make sure, to the extent possible that Oregon law and HIPAA, which was slated to go into effect in April 2003, would work together. That revision included the legislative intent to preserve the preexisting statutory policy (quoted above) and protections for patients' information. *See Classen v. Arete,* 254 Or. App. 216, 233 (2012) (so holding). Accordingly, Or. Rev. Stat. § 192.553(2) expressly provides: "In addition to the rights and obligations expressed in ORS 192.553 to ORS 192.581,

[HIPAA] establish[es] additional rights and obligations regarding the use and disclosure of protected health information and the rights of individuals regarding the protected health information of the individual."

It would make little sense for the Oregon legislature to have established an elaborate structure for patients and health care providers -- defined by Or. Rev. Stat. § 192.556(5) to include individual physician providers as well as entities that provide health care services -- to safeguard protected health information from disclosure, and then to create a new state database a few years later and thereby open up those records wholesale to federal law enforcement without judicial oversight or approval. And, in fact, as discussed further below, when the Oregon Legislative Assembly created the PDMP in 2009, the legislature made sure, in no uncertain terms, that law enforcement access was prohibited absent individualized probable cause and a court order.

4. Or. Rev. Stat. §§ 192.502(2) and 192.496(1)

The Oregon Public Records Law ("OPRL"), Or. Rev. Stat. §§ 192.501 *et seq*., and the medical privacy exemptions pertinent to that law, Or. Rev. Stat. §§ 192.502(2) and 192.496(1), reveal that the Oregon legislature recognized that *government possession* of an individual's personal health information -- such as occurs when the Oregon Health Authority maintains a database of personal prescription information within Oregon's PDMP -- should not thereby remove that

person's right to maintain the privacy of that information, without a compelling reason and the attendant safeguards.

The current public records exemption for personal information traces verbatim to the original adoption of the OPRL in 1973. 1973 Or. Laws Ch. 794, § 11(2)(b). Or. Rev. Stat. § 192.502(2) provides that "[i]nformation of a personal nature such as but not limited to that kept in a personal, medical or similar file" shall not be disclosed "unless the public interest by clear and convincing evidence requires disclosure in the particular instance." *See also* Or. Rev. Stat. § 192.496(1) (providing specific privacy protection for medical records, on the same terms). In addition, the PDMP expressly exempts the prescription information it contains from the OPRL. Or. Rev. Stat. § 431.966(1)(a).

Like the other provisions of Oregon law discussed above, the privacy protections *for medical records held by the government* make unmistakably clear that the state generally ascribes the highest possible importance to protecting patient privacy, specifically including *health records maintained by the government such as the records at issue here*.

5. HIPAA and Oregon Law; Preemption

Or. Rev. Stat. §§ 192.553 *et seq.* harmonize Oregon law with the terminology of the federal Health Information Portability and Accountability Act

("HIPAA"). It is thus not surprising that the provisions of HIPAA itself also protect the patient information here from disclosure as "protected health information" ("PHI") and "Individually Identifiable Health Information." 45 C.F.R. § § 160.103, 164.502. Like Or. Rev. Stat. § 192.556(8), PHI under HIPAA expressly includes information received by a provider relating to a patient's health, condition or provision of health care to the individual that either identifies the individual or provides a reasonable basis to believe the information can be used to identify the individual. *Id.*

HIPAA contains a provision that authorizes permissive disclosures pursuant to an administrative subpoena by federal law enforcement based on reasonable suspicion, 45 C.F.R. § 164.512(a)(1), 45 C.F.R. § 164.103. Oregon's PDMP specifically requires compliance with the HIPAA minimum protections, Or. Rev. Stat. § 431.962(2)(d), thereby tying the PDMP to HIPAA in that respect, and then expressly places a *higher standard* than HIPAA on disclosure of information to law enforcement collected by the state's PDMP, requiring individualized probable cause and a court order before disclosure, Or. Rev. Stat. § 431.966(2)(a)(D).

HIPAA provides that its protections for patient privacy set a national floor and that states are free to provide additional or more protective provisions. That

is, HIPAA generally preempts state health care privacy laws that are contrary to HIPAA, unless the state law is "more stringent" than the applicable HIPAA provision. 45 C.F.R. § 160.203(b). In the context of a disclosure to a third party under HIPAA, "more stringent" means "the 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. State law thus is rarely preempted because "it is extremely unlikely that a state law will be both contrary to HIPAA and less stringent than HIPAA." Beverly Cohen, *Reconciling the HIPAA Privacy Rule with State Laws Regulating Ex Parte Interviews of Plaintiffs' Treating Physicians: A Guide to Performing HIPAA Preemption Analysis*, 43 Hous. L. Rev. 1091, 1139-41 (2006).

That preemption analysis, and its assumption that HIPAA's preemption provisions apply to all other provisions under HIPAA, is endorsed by the U.S. Department of Health & Human Services ("DHHS"). In an online "FAQ",[1] DHHS opined that HIPAA's privacy rule establishes the floor, but states are free to provide more protection:

[1] U.S. Dept. of Health & Human Services, Health Information Privacy, FAQ 405, *My State law provides greater privacy protections on patients' HIV information than the HIPAA Privacy Rule. Is this more protective State law preempted by the Privacy Rule?* (2006), http://www.hhs.gov/ocr/privacy/hipaa/faq/preemption_of_state_law/ 405.html.

> If a provision of State law provides greater privacy protection than a provision of the Privacy Rule, and it is possible to comply with both the State law and the Privacy Rule (e.g., where a State law prohibits the disclosure of HIV status while the Privacy Rule permits such disclosure), there is no conflict between the State law and the Privacy Rule, and no preemption.
>
> Further, even in the unusual case where a "more stringent" provision of a State law is "contrary" to a provision of the Privacy Rule – that is, it is impossible to comply with both the Privacy Rule and the State law, or the State law is an obstacle to accomplishing the full purposes and objectives of HIPAA's Administrative Simplification provisions – the Administrative Simplification Rules specifically provide an exception to preemption of State law. Thus, if a more stringent provision of State law protects HIV patient information and is contrary to the Privacy Rule, the "more stringent" State law would prevail. Because HIPAA's Administrative Simplification Rules themselves except more stringent, contrary State law from preemption, it is neither necessary nor appropriate to request a preemption exception determination from the Department of Health and Human Services.

The premises that more restrictive state law may obtain and that HIPAA can make it *more difficult* for law enforcement to access personal health information than simply by issuing an administrative subpoena also are reflected in two additional "FAQ" guidances provided by DHHS.[2]

[2] FAQ 349, *Will this HIPAA Privacy Rule make it easier for police and law enforcement agencies to get my medical information?* (2006), (http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/349.html, and FAQ 505, *When does the Privacy Rule allow covered entities to disclose protected health information to law enforcement officials?* (2005), http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/505.html). (APPX-4-6.)

That guidance from DHHS appears to be in tension with other qualified guidance that it has provided with respect to DHHS' understanding of legislative intent on a related point:

> We *** considered whether section 264(c)(2) [preemption] could be read to apply [more stringent] State laws to procedures and activities of federal agencies, such as administrative subpoenas and summons, that are prescribed under the authority of federal law. In general, we do not think that section 264(c)(2) would work to apply State law provisions to federal programs or activities with respect to which the state law provisions do not presently apply. Rather, the effect of section 264(c)(2) is to give preemptive effect to State laws that would otherwise be in effect, to the extent they conflict with and are more stringent than the requirements promulgated under the Administrative Simplification authority of HIPAA. Thus, we do not believe that it is the intent of section 264(c)(2) to give an effect to State law that it would not otherwise have in the absence of section 264(c)(2).

Standards for Privacy of Individually Identifiable Health Info., 64 Fed. Reg. 59918-01, 60000 (Nov. 3, 1999).

Thus, although the State has conceded in this case that the State's more stringent statutory probable cause requirement is preempted by the lesser standard of reasonable suspicion for a DEA-issued administrative subpoena, the Court nonetheless should be circumspect not only about accepting the concession but turning it into a holding that would apply beyond the confines of this case. Although the State has ascribed primacy here to the federal administrative subpoena statute, that legal conclusion is far from clear and correct. The District Court did not reach the issue and also was not presented with an argument that

HIPAA expressly recognizes the right of the states to enact patient privacy protections for protected health information that are more stringent than those in HIPAA, including patient privacy protections greater than those that accompany a federal administrative subpoena.

6. Oregon's PDMP

Oregon adopted its Prescription Drug Monitoring Program in the context and wake of its broad statutory commitment, detailed above, to protecting the privacy of patient health information. That commitment expressly extended to patient health information held by the government, such as the patient prescription information gathered and held by the State of Oregon Health Authority under the Oregon PDMP.

Thus it comes as no surprise that the Oregon legislature was careful when formulating the PDMP in 2009 not to create a program to improve health care that would indirectly then become a vehicle for wholesale law enforcement access to patients' private health information without patient consent. Accordingly, Oregon's PDMP requires compliance with "[HIPAA] and regulations adopted under it *** and state health and mental health confidentiality laws, including ORS *** 192.553 to 192.581." Or. Rev. Stat. § 431.962(2)(d). The law also provides that information provided to the program is "protected health information

under ORS 192.553 to ORS 192.581" and is not subject to disclosure under the Oregon Public Records Law. Or. Rev. Stat. § 431.966(1)(a).

Furthermore, Oregon's PDMP expressly protects patient privacy by providing that law enforcement only may access the information "[p]ursuant to a valid court order based on probable cause[.]" Or. Rev. Stat. § 431.966(2)(a)(D). The law also forbids broad-based fishing expeditions by law enforcement by requiring that a court order be based on a request by law enforcement "engaged in an authorized drug-related investigation involving a person to whom the requested information pertains." *Id*.

Not surprisingly given the background and context, the Oregon legislature made a self-conscious determination to add those restrictions on law enforcement access to the legislation. Colloquies with the Chair of the Senate Committee on Human Services and Rural Health Policy, Senator Morissette, set forth at APPX-1-3, make that clear.

7. Conclusion

The statutory context detailed above all leads to the same unmistakable conclusion. Personal health information and the patient's right to privacy with respect to that information are entitled to the utmost protection under state law, as a matter of public policy and statutory enforcement. The patient's high expectation of

privacy is not diminished when a patient fills a prescription provided by her physician for her treatment, merely because the state then collects and centralizes that data.

B. THE PRIMARY PURPOSE OF PDMPs IS HEALTH CARE, NOT LAW ENFORCEMENT

Examination of the entirety of Oregon's PDMP reveals that the only reference anywhere to law enforcement access to the database is pursuant to Or. Rev. Stat. § 431.966(2)(a)(D). That is the provision that requires a "valid court order based on probable cause and issued at the request of a federal, state or local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains."

There is nothing in the Oregon law itself that refers to or even suggests a *law enforcement purpose* for the PDMP. Rather, as noted above, the only relevant provision in that regard is the one that stringently regulates the circumstances under which law enforcement may gain access to information in the database, which was manifestly created for other purposes. Those other purposes are made clear from the statute itself, and include monitoring and reporting prescription drugs and establishing a system that "must operate and be accessible by practitioners and pharmacies 24 hours a day, seven days a week." Or. Rev. Stat. § 431.962(1)(b)(A), (B). Permissible disclosures include for education, research and public health, and to practitioners, the State Medical Examiner and professional oversight boards and

other state PDMPs "if the confidentiality, security and privacy standards *** are equivalent to [Oregon's]." Or. Rev. Stat. § 431.966(2).

With the exception of Missouri, every state and the District of Columbia all have enacted PDMPs. The National Alliance for Model State Drug Laws has promulgated a Model Prescription Monitoring Program Act (2013), http://www.namsdl.org/library/84938F44-65BE-F4BB-AE62F3BE542A3C23/. Section 3 of the Model Act sets forth its "Purpose," which expressly focuses on patient care and treatment, prescription behavior that points toward abuse, and on maintaining confidentiality of prescription records. To the extent the Model Act's "Purpose" recognizes a law enforcement component, it provides for referrals *to* law enforcement by the program, not establishing the program as a tool or repository for law enforcement *to initiate* access to gather information, as is the case here with the DEA's administrative subpoena.[3]

[3] Section 3 of the Model Act provides:

> The purpose of this [Act] is to reduce prescription drug abuse and fraud by providing a tool that will ensure that doctors making prescription decisions have complete and reliable information about what, if any, other prescription drugs have recently been prescribed to their patients. It is the purpose of this [Act] to provide reporting mechanisms – with full confidentiality protections – in which prescribers, dispensers and other health care practitioners report prescription information to a central repository, in order to identify patient and doctor behavior that gives rise to a reasonable suspicion that prescription drugs are being inappropriately obtained or prescribed, so that appropriate ameliorative

Consistent with the foregoing, the American Medical Association has adopted policies whereby physicians nationally expressly and resoundingly have called for PDMPs to be utilized in a confidential manner for the health care purposes they are designed for, and not as a law enforcement tool without informed patient consent or a court order predicated on clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for information outweighs the privacy interest of the individual to whom the information pertains. American Medical Association, Policy, *Patient Privacy and Confidentiality*, H-315.983(9) (APPX-9). Those AMA policies also include policies directed specifically to PDMPs that advocate treating "PDMP data as health information that is protected from release outside of the health care system" and "limiting database access by non-health care individuals to only those instances in which probable

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> and corrective action – treatment for individuals suffering from drug and alcohol addiction – may be taken. This Act is further intended to help detect, refer to law enforcement and regulatory agencies, and deter prescription drug fraud and diversion.

See also Sections 8(d)(ii) (providing for access by law enforcement when the program refers information to law enforcement), and 8(f)(iii) (requiring training and procedures for law enforcement individuals who may be given access).

cause exists that an unlawful act or breach of the standard of care may have occurred." American Medical Association, Policy, *Prescription Drug Monitoring Program Confidentiality*, H-95.946 (APPX-8); American Medical Association, Policy, *Prescription Drug Diversion, Misuse and Addiction*, H-95.945 (APPX-7).

In sum, neither Oregon's PDMP, nor the national Model Act, nor the policies of the American Medical Association with respect to PDMPs, point to a material law enforcement purpose or role in these programs. At the same time they all expressly recognize the significant personal privacy interests at stake in maintaining the confidentiality of the records that the state collects. Moreover, the kind of unsupervised and self-regulating law enforcement access at issue here appears to undermine the core purposes that Oregon's PDMP is designed to serve.

C. PATIENT AND PHYSICIAN PRIVACY AND THE INTEGRITY OF THE PATIENT-PHYSICIAN RELATIONSHIP

The District Court correctly found that the patients and physician intervenors had both a subjective and objectively reasonable expectation of privacy in prescription and prescribing information, basically because prescription records can reveal a patient's medical condition, treatment or diagnosis, and law enforcement access may affect the manner in which a doctor prescribes controlled substances for patients' health care. (ER7.) The District Court concluded that "It is difficult to

conceive of information that is more private or more deserving of Fourth Amendment protections." (ER9.)

The Medical Associations, representing physicians in Oregon, the Ninth Circuit and nationally, urge the Court to recognize the profound interests that this case places at issue in the areas of patient privacy, physician privacy, and the integrity of the patient-physician relationship. Unsupervised law enforcement access to the database could undermine the core purposes of the law. Patients have a basic right to privacy of their medical information. That privacy should be honored unless there is meaningful waiver by the patient or a strong countervailing public health or safety interest, and then only with stringent safeguards. With unsupervised law enforcement access to their prescription care records, patients may fear to fill prescriptions and thereby compromise their care. Physicians who treat individuals or populations with pronounced need for pain medications, for example, may feel compromised in their ability to prescribe for fear of unsupervised law enforcement access to those patient prescription records.

The privacy interests of patients in their prescription information are particularly acute in the context of the mass accumulation of personal medical information by the state. As a 2014 Report of the Congressional Research Service ("CRS"), *Prescription Drug Monitoring Programs*, has recognized, patients may

fear law enforcement prosecution if they come forward to a physician in good faith with legitimate medical concerns: "Limiting access to medication for patients with legitimate medical need is a potential unintended consequence of PDMP implementation." Cong. Research Serv. Rep. No. R42593, at 21 (2014) *available at* (http://www.fas.org/sgp/crs/misc/R42593.pdf.) The Supreme Court likewise has recognized that violating patient privacy "may have adverse consequences because it may deter patients from receiving needed medical care." *Ferguson v. City of Charleston*, 532 U.S. 67, 78 n.14 (2001) (citing *Whalen v. Roe*, 429 U.S. 589, 599-600 (1977)); *see also Whalen*, 429 U.S. at 602 ("Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention.").

Indeed, the CRS Report highlights that: "The prescription drug abuse prevention strategy of the Center for Lawful Access and Abuse Deterrence (CLAAD), which is endorsed by more than 20 organizations, emphasizes that 'efforts to prevent abuse must not impede proper medical practice and patient care.'" *Id*. at 22 (quoting Center for Lawful Access and Abuse Deterrence, National Prescription Drug Abuse Prevention Strategy: *2011-2012 Update*, http://www.claad.org/downloads/CLAAD_Strategy2011_v3.pdf). The CRS further reports:

> Patients may worry about changes in prescribing behavior, which may limit their access to needed medications. Patients may worry about the additional cost of more frequent office visits if prescribers become more cautious about writing prescriptions with refills. Patients may also have concerns about privacy and security of their prescription information if it is submitted to a PDMP.

Id. at 11-12.

The patients' fundamental right to privacy in their individual health information, including prescriptions, is further reflected in the policies of the American Medical Association regarding patient privacy and confidentiality, consistent with the ethical strictures of the medical profession. *See* American Medical Association, Policy, *Patient Privacy and Confidentiality*, H-315.983(1), (5) (APPX-9); American Medical Association, Code of Medical Ethics, Opinion 10.01, *Fundamental Elements of the Patient-Physician Relationship* (APPX-11-12). Indeed, the brief of Intervenors-Appellees (at 36-40) points to a broad and consistent array of historical, scientific and ethical sources in support of the proposition restated in the Rothstein Declaration (¶3, I-ER 214), that the confidentiality of patient medical information is the "cornerstone of medical practice."

Although perhaps less obvious than concerns for patient privacy, there are also important privacy concerns at stake for the physicians who prescribe. Indeed, both the Supreme Court and the 2014 Report of the Congressional Research Service have pointedly recognized the legitimacy of those privacy interests of physicians.

In *Sorrell v. IMS Health Inc.*, ___ U.S. ___, 131 S. Ct. 2653, 2668 (2011), the majority observed: "It may be assumed that, for many reasons, physicians have an interest in keeping their prescription decisions confidential." Likewise, the dissent recognized a legitimate and substantial state interest in adopting a statute for the express purpose of "protecting the privacy of prescribers and prescribing information," (*Id.* at 2681 (Breyer, J., dissenting) (quoting Vt. Stat. Ann., Tit. 18, § 4631(a)), as well as "a meaningful interest in increasing the protection given to prescriber privacy" (*id*. at 2683). Those statements echo the Court's opinion in *Whalen v. Roe*, 429 U.S. at 600, which stated that the risk of privacy violations can make "some doctors reluctant to prescribe *** drugs even when their use is medically indicated[.]"

The 2014 CRS Report likewise recognizes that physicians may fear prosecution if they prescribe in good faith, and that *studies have shown* that physicians may use less efficacious drugs to treat patients out of fear that law enforcement will focus on prescriptions for more potent medications. Cong. Research Serv. Rep. No. R42593, at 11. The CRS Report further expressly recognizes the concerns of the AMA and the American Society of Addiction Medicine over physician privacy in the context of protecting PDMP prescription information from law enforcement access on terms less restrictive than law enforcement access to medical records more generally. *Id*. at 21-22.

The integrity and confidentiality of the patient-physician relationship is recognized in addition nationally not only by professional ethics and national policies but also by the evidentiary privilege that protects the privacy of a patient's medical information from disclosure in civil actions. The evidentiary privilege is recognized in 43 states (including Oregon) and the District of Columbia. (*See* Intervenors-Appellees' Brief at 45 & n. 26, citing jurisdictions.) Patients must be able to expect that their communications and treatment will remain private, an expectation that is manifestly essential to a doctor's ability to get the whole picture from the patient to enable accurate diagnosis and effective treatment.

The Oregon legislature enacted a PDMP that took cognizance of the critical interests at stake and set an appropriately high statutory standard of protection for patient health information. The state is entitled to establish a PDMP for health care purposes and safeguard against its being repurposed by law enforcement for its own use, at the expense of legitimate patient and physician privacy interests.

Respectfully submitted this 12th day of December, 2014.

HOLLAND & KNIGHT LLP

s/ Roy Pulvers
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APPENDIX

2009 Oregon Legislative Assembly:
Senate Bill ("SB") 355 Legislative History

Excerpted Testimony Regarding SB 355 Before the Senate Committee on Human Services and Rural Health Policy, February 9, 2009:

Gail Meyer: When it comes to law-enforcement seeking access affirmatively on its initiative to the database, I would suggest that, as currently framed, the statute is not very clear as to the actual process, or procedure, or standards by which law enforcement can gain access. In section 5 subsection (2)(a)(c) it says that law enforcement can have access pursuant to a valid court order. That term is vague and lacks specificity in the law. We don't know what that means. Is it a based on probable cause? Is it based on reasonable suspension? Do they merely need to establish good cause shown, or that it would be relevant to an ongoing investigation? Those are huge variances and standards, and I think they should be spelled out. And secondly, it's unclear what kind of a proceeding it would be. If law enforcement were to go to a court to get a court order, the question is would it be an ex parte proceeding, where law-enforcement simply goes, similar to securing a search warrant, where they would simply go to a court and say we have an ongoing investigation we would like to get into the database, or must there be notice provided at least to the prescriber that this information is being sought? And in our opinion, we would also like to see notice being provided to the patient, so that they're also on notice that the information is being received.

Chair Morrisette: Um, wouldn't probable cause be sufficient?

Gail Meyer: Probable cause would be an ideal standard, yes, but it's not spelled out in the statute, and I would encourage the committee to do that.

Chair Morrisette: Ok. The court order, would be, you would need probable cause, wouldn't you?

Gail Meyer: Court orders can be, can be issued on lesser standards, and so it would be, I think as currently phrased just simply saying valid court order, it would leave the court in a quagmire to know what

the legislature intended, so I do believe probable cause would be the ideal standard.

Chair Morrisette: Ok, thank you.

Audio Recording, Senate Committee on Human Services and Rural Health Policy, SB 355, Feb. 9, 2009, http://arcweb.sos.state.or.us/pages/records/legislative/legislativeminutes/2009/senate/human_serv/index.html (statements of Gail Meyer and Senator Morrissette).

Excerpted Testimony Regarding SB 355 Before the Senate Committee on Human Services and Rural Health Policy, February 11, 2009:

Chair Morrisette: There was one other question that came up the other day concerning law enforcement access to the program and what criteria we would use to allow law enforcement to access the program.

Danna Droz: From what I've read your current law or current proposal is requiring a court order. There are several states that operate in that manner others don't. Here in Ohio we use a 2-step request process where 2 separate law enforcement officers have to sign off on any request. They also have to have an investigation already going on a specific individual they cannot use the program for fishing expeditions. But if you are requiring a court order that is a pretty high standard and it is not unreasonable to go that route.

Chair Morrisette: And we could use probable cause insert that into the language is that…

Danna Droz: You could but generally that's inferred from a court order.

Chair Morrisette: Yeah, you're right.

[Morrissette and Droz talking over each other, 1:08:57 – 1:09:03]

Danna Droz: It certainly wouldn't hurt to enumerate that in your bill.

> Chair Morrisette: Well the question came up last time about that and I said I just don't understand why it isn't probable cause because if we are dealing with a court order there has to be probable cause.
>
> Danna Droz: Right.
>
> Chair Morrisette: But we could insert the language just to be sure.

Audio Recording, Senate Committee on Human Services and Rural Health Policy, SB 355, Feb. 11, 2009, http://arcweb.sos.state.or.us/pages/records/legislative/legislativeminutes/2009/senate/human_serv/index.html (statements of Danna Droz and Senator Morrissette).[1]

[1] The preceding transcript is amici's best attempt to transcribe the excerpted testimony of the SB 355 public hearings on February 9, 2009 and February 11, 2009. The audio recording of the public hearings is available at http://arcweb.sos.state.or.us/pages/records/legislative/legislativeminutes/2009/senate/human_serv/index.html, 2/9/09 at 2:11:50-2:15:25; 2/11/09 at 1:08:01-1:09:30.

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Health Information Privacy

Will this HIPAA Privacy Rule make it easier for police and law enforcement agencies to get my medical information?

Answer:

No. The Rule does not expand current law enforcement access to individually identifiable health information. In fact, it limits access to a greater degree than currently exists, since the Rule establishes new procedures and safeguards that restrict the circumstances under which a covered entity may give such information to law enforcement officers.

For example, the Rule limits the type of information that covered entities may disclose to law enforcement, absent a warrant or other prior process, when law enforcement is seeking to identify or locate a suspect. It specifically prohibits disclosure of DNA information for this purpose, absent some other legal requirements such as a warrant. Similarly, under most circumstances, the Privacy Rule requires covered entities to obtain permission from persons who have been the victim of domestic violence or abuse before disclosing information about them to law enforcement.

In most States, such permission is not required today. Where State law imposes additional restrictions on disclosure of health information to law enforcement, those State laws continue to apply. This Rule sets a national floor of legal protections; it is not a set of "best practices." Even in those circumstances when disclosure to law enforcement is permitted by the Rule, the Privacy Rule does not require covered entities to disclose any information. Some other Federal or State law may require a disclosure, and the Privacy Rule does not interfere with the operation of these other laws. However, unless the disclosure is required by some other law, covered entities should use their professional judgment to decide whether to disclose information, reflecting their own policies and ethical principles. In other words, doctors, hospitals, and health plans could continue to follow their own policies to protect privacy in such instances.

Learn More:

When does the Privacy Rule allow covered entities to disclose protected health information to law enforcement officials?

Date Created: 12/20/2002
Last Updated: 11/06/2006

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U.S. Department of Health & Human Services

Improving the health, safety, and well-being of America

Health Information Privacy

When does the Privacy Rule allow covered entities to disclose protected health information to law enforcement officials?

Answer:

The Privacy Rule is balanced to protect an individual's privacy while allowing important law enforcement functions to continue. The Rule permits covered entities to disclose protected health information (PHI) to law enforcement officials, without the individual's written authorization, under specific circumstances summarized below. For a complete understanding of the conditions and requirements for these disclosures, please review the exact regulatory text at the citations provided. Disclosures for law enforcement purposes are permitted as follows:

- **To comply with a court order or court-ordered warrant, a subpoena or summons issued by a judicial officer, or a grand jury subpoena.** The Rule recognizes that the legal process in obtaining a court order and the secrecy of the grand jury process provides protections for the individual's private information (45 CFR 164.512(f)(1)(ii)(A)-(B)).
- **To respond to an administrative request,** such as an administrative subpoena or investigative demand or other written request from a law enforcement official. Because an administrative request may be made without judicial involvement, the Rule requires all administrative requests to include or be accompanied by a written statement that the information requested is relevant and material, specific and limited in scope, and de-identified information cannot be used (45 CFR 164.512(f)(1)(ii)(C)).
- **To respond to a request for PHI for purposes of identifying or locating a suspect, fugitive, material witness or missing person; but the covered entity must limit disclosures** of PHI to name and address, date and place of birth, social security number, ABO blood type and rh factor, type of injury, date and time of treatment, date and time of death, and a description of distinguishing physical characteristics. Other information related to the individual's DNA, dental records, body fluid or tissue typing, samples, or analysis cannot be disclosed under this provision, but may be disclosed in response to a court order, warrant, or written administrative request (45 CFR 164.512(f)(2)).

  This same limited information may be reported to law enforcement:

  - **About a suspected perpetrator of a crime when the report is made by the victim who is a member of the covered entity's workforce** (45 CFR 164.502(j)(2));
  - **To identify or apprehend an individual who has admitted participation in a violent crime** that the covered entity reasonably believes may have caused serious physical harm to a victim, provided that the admission was not made in the course of or based on the individual's request for therapy, counseling, or treatment related to the propensity to commit this type of violent act (45 CFR 164.512(j)(1)(ii)(A), (j)(2)-(3)).
- **To respond to a request for PHI about a victim of a crime, and the victim agrees.** If, because of an emergency or the person's incapacity, the individual cannot agree, the covered entity may disclose the PHI if law enforcement officials represent that the PHI is not intended to be used against the victim, is needed to determine whether another person broke the law, the investigation would be materially and adversely affected by waiting until the victim could agree, and the covered entity believes in its professional judgment that doing so is in the best interests of the individual whose information is requested (45 CFR 164.512(f)(3)).

  Where child abuse victims or adult victims of abuse, neglect or domestic violence are concerned, other provisions of the Rule apply:

  - **Child abuse or neglect may be reported** to any law enforcement official authorized by law to receive such reports and the agreement of the individual is not required (45 CFR 164.512(b)(1)(ii)).
  - **Adult abuse, neglect, or domestic violence may be reported** to a law enforcement official authorized by law to receive such reports (45 CFR 164.512(c)):
    - If the individual agrees;
    - If the report is required by law; or
    - If expressly authorized by law, and based on the exercise of professional judgment, the report is necessary to prevent serious harm to the individual or others, or in certain other emergency situations (see 45 CFR 164.512(c)(1)(iii)(B)).
    - Notice to the individual of the report may be required (see 45 CFR 164.512(c)(2)).
- **To report PHI to law enforcement when required by law** to do so (45 CFR 164.512(f)(1)(i)). For example, state laws commonly require health care providers to report incidents of gunshot or stab wounds, or other violent injuries; and the Rule permits disclosures of PHI as necessary to comply with these laws.
- **To alert law enforcement to the death of the individual,** when there is a suspicion that death resulted from criminal conduct (45 CFR 164.512(f)(4)).
  - Information about a decedent may also be shared with **medical examiners or coroners to assist them in identifying the decedent, determining the cause of death, or to carry out their other authorized duties***(45 CFR 164.512(g)(1))*.
- **To report PHI that the covered entity in good faith believes to be evidence of a crime that occurred on the covered entity's premises** (45 CFR 164.512(f)(5)).
- **When responding to an off-site medical emergency, as necessary to alert law enforcement about criminal activity,** specifically,

the commission and nature of the crime, the location of the crime or any victims, and the identity, description, and location of the perpetrator of the crime (45 CFR 164.512(f)(6)). This provision does not apply if the covered health care provider believes that the individual in need of the emergency medical care is the victim of abuse, neglect or domestic violence; see above Adult abuse, neglect, or domestic violence for when reports to law enforcement are allowed under 45 CFR 164.512(c).

- When consistent with applicable law and ethical standards:
  - To a law enforcement official reasonably able to **prevent or lessen a serious and imminent threat to the health or safety of an individual or the public** (45 CFR 164.512(j)(1)(i)); or
  - **To identify or apprehend an individual who appears to have escaped from lawful custody** (45 CFR 164.512(j)(1)(ii)(B)).
- **For certain other specialized governmental law enforcement purposes**, such as:
  - **To federal officials authorized to conduct** intelligence, counter-intelligence, and other national security activities under the National Security Act (45 CFR 164.512(k)(2)) or to provide protective services to the President and others and conduct related investigations (45 CFR 164.512(k)(3));
  - **To respond to a request for PHI by a correctional institution or a law enforcement official having lawful custody** of an inmate or others if they represent such PHI is needed to provide health care to the individual; for the health and safety of the individual, other inmates, officers or employees of or others at a correctional institution or responsible for the transporting or transferring inmates; or for the administration and maintenance of the safety, security, and good order of the correctional facility, including law enforcement on the premises of the facility (45 CFR 164.512(k)(5)).

Except when required by law, the disclosures to law enforcement summarized above are subject to a minimum necessary determination by the covered entity (45 CFR 164.502(b), 164.514(d)). When reasonable to do so, the covered entity may rely upon the representations of the law enforcement official (as a public officer) as to what information is the minimum necessary for their lawful purpose (45 CFR 164.514(d)(3)(iii)(A)). Moreover, if the law enforcement official making the request for information is not known to the covered entity, the covered entity must verify the identity and authority of such person prior to disclosing the information (45 CFR 164.514(h)).

Date Created: 07/23/2004

Last Updated: 08/08/2005

H-95.945 Prescription Drug Diversion, Misuse and Addiction

H-95.945 Prescription Drug Diversion, Misuse and Addiction

Our AMA: (1) supports permanent authorization of and adequate funding for the National All Schedules Prescription Electronic Reporting (NASPER) program so that every state, district and territory of the US can have an operational Prescription Drug Monitoring Program (PDMP) for use of clinicians in all jurisdictions; (2) considers PDMP data to be protected health information, and thus protected from release outside the healthcare system unless there is a HIPAA exception or specific authorization from the individual patient to release personal health information, and recommends that others recognize that PDMP data is health information; (3) recommends that PDMP's be designed such that data is immediately available when clinicians query the database and are considering a decision to prescribe a controlled substance; (4) recommends that individual PDMP databases be designed with connectivity among each other so that clinicians can have access to PDMP controlled substances dispensing data across state boundaries; and (5) will promote medical school and postgraduate training that incorporates curriculum topics focusing on pain medicine, addiction medicine, safe prescribing practices, safe medication storage and disposal practices, functional assessment of patients with chronic conditions, and the role of the prescriber in patient education regarding safe medication storage and disposal practices, in order to have future generations of physicians better prepared to contribute to positive solutions to the problems of prescription drug diversion, misuse, addiction and overdose deaths. (Res. 223, A-12)

H-95.946 Prescription Drug Monitoring Program Confidentiality

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H-95.946 Prescription Drug Monitoring Program Confidentiality

Our AMA will: (1) advocate for the placement and management of state-based prescription drug monitoring programs with a state agency whose primary purpose and mission is health care quality and safety rather than a state agency whose primary purpose is law enforcement or prosecutorial; (2) encourage all state agencies responsible for maintaining and managing a prescription drug monitoring program (PDMP) to do so in a manner that treats PDMP data as health information that is protected from release outside of the health care system; and (3) advocate for strong confidentiality safeguards and protections of state databases by limiting database access by non-health care individuals to only those instances in which probable cause exists that an unlawful act or breach of the standard of care may have occurred. (Res. 221, A-12)

H-315.983 Patient Privacy and Confidentiality

Next Policy | Previous Policy

H-315.983 Patient Privacy and Confidentiality

(1) Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) That patients' privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly controlled; and (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure.

(2) Our AMA affirms: (a) that physicians who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be regarded as fraudulent or inappropriate concealment, and (c) that physicians should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law.

(3) Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals. (a) Release forms that authorize access should be explicit about to whom access is being granted and for what purpose, and should be as narrowly tailored as possible. (b) Patients and physicians should be educated about the consequences of signing overly-broad consent forms. (c) Employers and insurers should adopt explicit and public policies to assure the security and confidentiality of patients' medical information. (d) A patient's ability to join or a physician's participation in an insurance plan should not be contingent on signing a broad and indefinite consent for release and disclosure.

(4) Whenever possible, medical records should be de-identified for purposes of use in connection with utilization review, panel credentialing, quality assurance, and peer review.

(5) The fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use.

(6) Our AMA recommends that the confidentiality of data collected by race and ethnicity as part of the medical record, be maintained.

(7) Genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual.

(8) When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end.

(9) Law enforcement agencies requesting private medical information should be given access to such information only through a court order. This court order for disclosure should be granted only if the law enforcement entity has shown, by clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains. These records should be subject to stringent security measures.

(10) Our AMA must guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB.

(11) Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures

(12) Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the health plans of which they are a part, and securing appropriate physicians' control over the disposition of information from their patients' medical records. (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights.

(13) Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned.

(14) Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to comply with laws regarding public health reporting for the purpose of disease surveillance.

(15) In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. Only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands.

(16) The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine.

(17) Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing.

(18) Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes.

(19) Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls.

(20) Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes. (BOT Rep. 9, A-98; Reaffirmation I-98; Appended: Res. 4, and Reaffirmed: BOT Rep. 36, A-99; Appended: BOT Rep. 16 and Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: Res. 246 and 504 and Appended Res. 504 and 509, A-01; Reaffirmed: BOT Rep. 19, I-01; Appended: Res. 524, A-02; Reaffirmed: Sub. Res. 206, A-04; Reaffirmed: BOT Rep. 24, I-04; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07; Reaffirmed: BOT Rep. 19, A-07; Reaffirmed: CEJA Rep. 6, A-11; Reaffirmed in lieu of Res. 705, A-12; Reaffirmed: BOT Rep. 17, A-13)

Resources

- About the Ethics Group
- AMA Code of Medical Ethics
- Opinion 10.01
- History of AMA Ethics
- Frequently Asked Questions
- Purchase the Code of Medical Ethics
- The Ethical Force Program®
- Virtual Mentor: A Forum for Medical Ethics
- Declaration of Professional Responsibility
- Ethics Group Internship Program

Opinion 10.01 - Fundamental Elements of the Patient-Physician Relationship

From ancient times, physicians have recognized that the health and well-being of patients depends upon a collaborative effort between physician and patient. Patients share with physicians the responsibility for their own health care. The patient-physician relationship is of greatest benefit to patients when they bring medical problems to the attention of their physicians in a timely fashion, provide information about their medical condition to the best of their ability, and work with their physicians in a mutually respectful alliance. Physicians can best contribute to this alliance by serving as their patients' advocate and by fostering these rights:

(1) The patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives. Patients should receive guidance from their physicians as to the optimal course of action. Patients are also entitled to obtain copies or summaries of their medical records, to have their questions answered, to be advised of potential conflicts of interest that their physicians might have, and to receive independent professional opinions.

(2) The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.

(3) The patient has the right to courtesy, respect, dignity, responsiveness, and timely attention to his or her needs.

(4) The patient has the right to confidentiality. The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest.

(5) The patient has the right to continuity of health care. The physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient. The physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.

(6) The patient has a basic right to have available adequate health care. Physicians, along with the rest of society, should continue to work toward this goal. Fulfillment of this right is dependent on society providing resources so that no patient is deprived of necessary care because of an inability to pay for the care. Physicians should continue their traditional assumption of a part of the responsibility for the medical care of those who cannot afford essential health care. Physicians should advocate

Related Links

Purchase the Code of Medical Ethics
Council on Ethical and Judicial Affairs
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for patients in dealing with third parties when appropriate. (I, IV, V, VIII, IX)

Issued June 1992 based on the report "Fundamental Elements of the Patient-Physician Relationship," adopted June 1990 (JAMA. 1990; 262: 3/33); Updated 1993.

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

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Respectfully submitted this 12th day of December, 2014.

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of December, 2014, I electronically filed the foregoing BRIEF OF *AMICI CURIAE* OF OREGON MEDICAL ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, ALASKA STATE MEDICAL ASSOCIATION, ARIZONA MEDICAL ASSOCIATION, CALIFORNIA MEDICAL ASSOCIATION, HAWAII MEDICAL ASSOCIATION, IDAHO MEDICAL ASSOCIATION, MONTANA MEDICAL ASSOCIATION, NEVADA STATE MEDICAL ASSOCIATION AND WASHINGTON STATE MEDICAL ASSOCIATION, with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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