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 FOR APPELLANT

JOYCE R. BRANDA
Acting Assistant Attorney General

BETH S. BRINKMANN
Deputy Assistant Attorney General

S. AMANDA MARSHALL
United States Attorney

MARK B. STERN
(202) 514-5089
SAMANTHA L. CHAIFETZ
(202) 514-4821
Attorneys, Appellate Staff
Civil Division, Room 7248
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

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STATEMENT OF JURISDICTION

Plaintiff and plaintiffs-intervenors invoked the district court's jurisdiction under 28 U.S.C. § 1331. The district court decided the parties' motions for summary judgment on February 11, 2014. Excerpts of Record ("ER") 3. On February 27, 2014, intervenors filed an unopposed motion asking the district court to set out the judgment in a separate order consistent with Rule 58(a). On March 12, 2014, the court issued a separate judgment, imposing a permanent injunction. ER 19. The defendant filed a timely notice of appeal on May 9, 2014. ER 1. *See* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

As part of an investigation into possible violations of the Controlled Substances Act, the Drug Enforcement Administration ("DEA") issued two administrative subpoenas to Oregon's Prescription Drug Monitoring Program ("PDMP") pursuant to 21 U.S.C. § 876. The subpoenas sought records pertaining to the prescriptions for controlled substances written by two physicians and filled by one patient. The PDMP filed suit, asserting that the subpoenas are contrary to state law. Intervenors are third parties who assert that the administrative subpoenas issued by DEA violate the Fourth Amendment and cannot constitutionally be enforced by a court. The questions presented are:

1. Whether the district court erred in concluding that it could lawfully adjudicate intervenors' Fourth Amendment claim.

2. Whether the district court erred in enjoining DEA from issuing administrative subpoenas requesting certain records from the PDMP.

STATEMENT OF THE CASE

I. Overview

The State of Oregon has established a mandatory Prescription Drug Monitoring Program. Under state law, if a pharmacy fills a prescription for a controlled substance in Oregon or to an address in the State, it must timely submit information to the PDMP about the prescription. The required information identifies both the patient and the prescribing physician.

In September 2012, DEA, acting pursuant to its authority under 21 U.S.C. § 876(a), issued two administrative subpoenas to the Oregon PDMP. The PDMP filed suit, arguing that the subpoenas were inconsistent with state law and asking the court to declare them invalid.

Intervenors are four individuals who fill their prescriptions for controlled substances in Oregon, one Oregon physician who prescribes controlled substances, and the American Civil Liberties Union Foundation of Oregon ("ACLU"). The court granted their motion to intervene over the government's objection. On cross-motions for summary judgment, the court held that the PDMP's compliance with the administrative subpoenas would violate the Fourth Amendment, and enjoined DEA from issuing subpoenas for the PDMP's records of controlled substance

prescriptions. ER 18, 19-20. The court held that, in light of its constitutional ruling, it need not reach the merits of Oregon's state law claim. ER 18.

II. Legal Framework

A. Authority of the Drug Enforcement Administration

Enacted in 1970, the Controlled Substances Act ("CSA" or "the Act") gives DEA broad authority to regulate the lawful production and use of controlled substances and to investigate civil and criminal violations of the Act. *See generally Gonzales v. Raich*, 545 U.S. 1, 13-14 (2005).[1]

1. The CSA requires that any person or entity wishing to lawfully manufacture, distribute, prescribe, dispense, or administer a controlled substance obtain and maintain registered status with DEA. *See* 21 U.S.C. §§ 822-823, 841; 21 C.F.R. §§ 1306.03, 1306.04; *see also* 21 U.S.C. §§ 823, 824 (authorizing DEA to revoke registrations that are found to be "inconsistent with the public interest").

[1] The CSA categorizes controlled substances into five schedules. "The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body." *Raich*, 545 U.S. at 13-14 (citing 21 U.S.C. §§ 811, 812). Schedule I drugs have no "currently accepted medical use." 21 U.S.C. § 812(b)(1). Schedule II drugs (such as oxycodone) have some "currently accepted medical use" but have "a high potential for abuse," resulting in "severe psychological or physical dependence." *Id.* § 812(b)(2). The drugs on Schedules III through V have potential for abuse leading to dependence, but the risks are considered progressively lower. *Id.* § 812(b)(3)-(5). Schedule II through V drugs may be prescribed and administered by registered physicians and dispensed by registered pharmacies.

DEA registrants are subject to numerous regulatory requirements and oversight provisions. For example, each registrant must maintain complete and accurate records of each controlled substance the registrant manufactures, receives, sells, delivers, or dispenses. 21 U.S.C. § 827; *see also* 21 U.S.C. § 880 (authorizing inspections of registrants' premises under certain circumstances). *See generally, e.g.*, *United States v. Goldfine*, 538 F.2d 815, 819 (9th Cir. 1976); *United States v. Jamieson-McKames Pharm., Inc.,* 651 F.2d 532, 540-41 (8th Cir. 1981) (quoting *Marshall v. Barlow's, Inc.*, 436 U.S. 307, 320 (1978) (requiring only that DEA satisfy "'reasonable legislative or administrative standards for conducting an … inspection'" (omission in original)).

2. DEA is charged with investigating CSA violations by registrants and nonregistrants alike. With regard to any investigation DEA is carrying out under the CSA, the agency is authorized to subpoena witnesses or records, provided only that the testimony or materials sought are found to be "relevant or material" to the investigation. 21 U.S.C. § 876(a).[2]

[2] The statute provides, in relevant part:

> In any investigation relating to his functions under [the CSA] with respect to controlled substances, . . ., the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation.

21 U.S.C. § 876(a). The Attorney General has delegated this authority to the DEA Administrator and supervisory personnel in the field. 28 C.F.R. Pt. 0, Subpt. R, §§ 0.100, 0.104; *id.* Pt. 0, Subpt. R, App. § 4.

An administrative subpoena issued pursuant to § 876(a) is valid when issued. Because subpoenas under § 876(a) are not self-enforcing, DEA is statutorily empowered to seek a court order to compel compliance, if necessary. 21 U.S.C. § 876(c). Parties may seek appellate review of the court's decision. *See Cobbledick v. United States*, 309 U.S. 323, 330 (1940) (enforcement order is immediately reviewable).

Information obtained through administrative subpoenas can be released only under limited circumstances—primarily to federal, state, and local prosecutors and state licensing boards engaged in the prosecution of cases involving controlled substances. 28 C.F.R. § 0.103.

B. Oregon's Drug Monitoring Authority

1. Oregon state law requires any person who wishes to manufacture, deliver, or dispense any controlled substance in the State to "obtain annually a registration issued by the State Board of Pharmacy." Or. Rev. Stat. Ann. § 475.125. Like DEA, Oregon's State Board of Pharmacy reserves the right to deny or revoke a registration upon a determination that it is "inconsistent with the public interest," *id.* § 475.135, and imposes recordkeeping requirements, *id.* § 475.165.

The State Board of Pharmacy is authorized to enter and conduct warrantless inspections of the "premises or records" of any drug outlet (*e.g.*, any pharmacy) at "all reasonable hours," Or. Rev. Stat. Ann. § 689.155(8), (10), and to assist law enforcement in enforcing drug laws, *see id.* § 689.155(5), (6), (9). This authority is not limited to controlled substance, but extends to all "medications, drugs, devices and

other materials used in [Oregon] in the diagnosis, mitigation and treatment or prevention of injury, illness and disease." *Id.* § 689.155.

2. Between 1999 and 2009, prescription drug overdose deaths in Oregon increased at an alarming rate; by 2009, pharmaceutical controlled substances were the leading cause of drug-related deaths in the State.[3]

The Oregon legislature responded in 2009 by enacting Senate Bill 355, which created the Oregon Prescription Drug Monitoring Program. *See* Or. Rev. Stat. Ann. § 431.960 *et seq.* The law requires the Oregon Health Authority, in consultation with the Prescription Monitoring Program Advisory Commission, to establish and maintain the State's PDMP, which consists principally of an electronic database "for monitoring and reporting prescription drugs dispensed by pharmacies in Oregon that are classified in schedules II through IV under the federal Controlled Substances Act." *Id.* § 431.962(1)(a).[4]

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[3] *See* Or. Prescription Drug Monitoring Program, *Annual Report* 2 (Jan. 2012), http://www.orpdmp.com/orpdmpfiles/PDF_Files/Reports/PDMP_AC_AnnualReport_2011.pdf; Or. Health Auth., *Unintentional Prescription Drug Overdose in Oregon* (Winter 2013), http://www.orpdmp.com/orpdmpfiles/PDF_Files/Reports/RxOverdose_FactSheet_Winter2013.pdf; *see also* Ctrs. for Disease Control & Prevention, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1998 to 2008*, Morbidity & Mortality Weekly Rep. (Nov. 4, 2011) (highest rate of nonmedical use nationwide in Oregon).

[4] By the time the Oregon PDMP became operational in 2011, Oregon was one of 42 states with a monitoring program. Today, 49 States and the District of Columbia have enacted legislation authorizing the creation and operation of prescription drug monitoring programs. *See, e.g.*, Bureau of Justice Assistance & Brandeis Univ., The Heller School, PDMP Training and Technical Assistance Ctr., *Frequently Asked*

Pharmacies that dispense Schedule II through IV prescription drugs in Oregon or to addresses in Oregon are required to timely report specified information to the Oregon Health Authority. For each controlled substance prescription filled, the required information includes the name, address, date of birth and sex of the patient for whom the prescription drug was prescribed; the identity of the pharmacy that dispensed the prescription drug and the date on which the prescription drug was dispensed; and the identity of the practitioner who prescribed the prescription drug and the date on which the prescription drug was prescribed. Or. Rev. Stat. Ann. § 431.964(1).[5] The information supplied by pharmacies is then compiled into the PDMP database.

3. State law specifies a variety of circumstances in which the Oregon Health Authority "shall disclose" information in the PDMP database and identifies other circumstances in which it "may disclose" certain information. Or. Rev. Stat. Ann. § 431.966(2). For example, the Oregon Health Authority is directed to disclose database information when presented with "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

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Questions, http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

[5] The Oregon law is described here as modified in 2013 by Senate Bill 470, which added the sex of the patient to the information collected and also added several disclosure-related provisions.

requested information pertains," so long as the disclosure is compliant with federal and state confidentiality laws. *Id.* § 431.966(2)(a)(D). The statute also mandates disclosures in a variety of other circumstances—e.g., disclosures to any "vendor or contractor" with whom Oregon has contracted to "establish or maintain" the PDMP; "[t]o a health professional regulatory board" requiring information for an "investigation related to licensure, renewal or disciplinary action"; "[t]o a prescription monitoring program of another state if the confidentiality, security and privacy standards of the requesting state are determined by the [Oregon Health Authority] to be equivalent to those of the authority"; "[t]o the State Medical Examiner … for the purpose of conducting a medicolegal investigation." *Id.* § 431.966(2)(a)(C), (E), (F), (G); *see id.* § 431.966(2)(a)(A)-(G)*; see also id.* § 431.966(2)(b) (permitting additional disclosures that do "not identify a patient, practitioner or drug outlet").

Information that identifies an individual patient must be removed from the PDMP database no later than three years from the date it was entered. Or. Rev. Stat. Ann. § 431.966(4).

III. Facts and Prior Proceedings

A. Plaintiff's Challenge

1. In September 2012, DEA issued two administrative subpoenas to the Oregon PDMP pursuant to 21 U.S.C. § 876(a). The subpoenas were issued as part of a "drug-related investigation into potential violations of federal law," Compl. ¶ 6 (ER 22), and requested the PDMP records associated with one patient and two prescribing

physicians. *See* Dist. Ct. Summ. J. Op. ("SJ Op.") 5 (ER 7). The State, citing Or. Rev. Stat. Ann. § 431.966, refused to comply with the subpoenas unless presented with a valid court order. Compl. ¶¶ 4, 9 (ER 22, 23).

This was not the first time that DEA had subpoenaed records from the Oregon PDMP and that the PDMP declined to comply on these grounds. Previously, when the State declined to comply, DEA sought and obtained a court order compelling compliance. *United States v. State of Oregon PDMP*, No. 12-298, Docket No. 6 (D. Or. Aug. 27, 2012). The order, issued by a Magistrate Judge, declared that to the extent Oregon Revised Statute ("ORS") § 431.966 requires a court order or showing of probable cause before permitting compliance with DEA's subpoena, the state law is preempted by the CSA. *Ibid.*

2. Upon receiving the two September 2012 subpoenas, the PDMP chose not to await the DEA's initiation of an enforcement proceeding. Before DEA commenced any action to compel compliance, the PDMP filed this suit, seeking a declaration that "it cannot be compelled to disclose an individual's protected health information to the DEA pursuant to an administrative subpoena unless so ordered by a federal court." Compl. 4 (ER 24); *see* Pl's Mem. in Support of Mot. for Summ. J. ("Pl's MSJ") 15-16 (asking the court to hold that the State "may not produce" the records absent a court order, or, in the alternative, that the State "*may* lawfully decline to produce protected records under ORS 431.966 in response to a DEA administrative subpoena until the

subpoena has been enforced by a court order finding that it meets all relevant federal requirements") (Docket No. 25).

Oregon PDMP rested its argument on ORS § 431.966(2)(a)(D), which purports to authorize disclosures to law enforcement only pursuant to a "valid court order based on probable cause." Oregon PDMP conceded that the provision's "probable cause" requirement is preempted by the CSA, but argued that the portion of the provision requiring a "valid court order" is *not* preempted by the CSA and thus must be satisfied before information is disclosed. *See* Pl's MSJ 10, 11-12, 16.[6]

The federal government responded that ORS § 431.966(2)(a)(D) is preempted by the CSA (as the Magistrate Judge had concluded in the previous enforcement proceeding). The federal government explained that the PDMP may decline to comply with an administrative subpoena provided that it has a good-faith basis for doing so. In that event, DEA could commence a judicial proceeding to enforce the subpoena (as it had when the PDMP previously declined to comply with an administrative subpoena). *See* DEA's Combined Mem. in Support of its Cross-Mot. 9-14 (Docket No. 41). *See generally See v. City of Seattle*, 387 U.S. 541, 545 (1967) (explaining that "judicial review of the reasonableness" of the subpoenaed demand is available before "penalties for refusing to comply" are incurred).

[6] When this suit commenced in 2012, the provision at issue appeared at subsection 431.966(2)(a)(C); following the 2013 amendments, the provision was transferred to subsection 431.966(2)(a)(D).

B. Intervenors' Challenge

1. In January 2013, the ACLU, four "John Doe" patients and a "Dr. James Roe" moved to intervene pursuant to Federal Rule of Civil Procedure 24(a). The patients are Oregon residents with prescriptions for controlled substances, and the doctor is registered to prescribe controlled substances. *See* Decl. of James Roe ¶ 5 (Docket No. 37).

There is no allegation or belief that the intervenors include either the individual patient or the two prescribing physicians named in the subpoenas issued to the Oregon PDMP. Intervenors' complaint nevertheless asserted that that DEA's requests for PDMP records containing personally identifiable prescription information violated their Fourth Amendment rights. Intervenors' Compl. 37 (ER 61). Intervenors requested a permanent injunction prohibiting DEA from obtaining prescription records from the PDMP without first securing a probable cause-based judicial warrant. *Ibid.*

2. On March 31, 2013, the district court granted the motion to intervene over DEA's opposition. *See* Order Granting Intervenors' Motion to Intervene ("Int. Order") 6 (ER 68). The district court found that intervenors "have colorable arguments that their interests are protected both by the Fourth Amendment and by ORS 431.966 and that those interests are related to the claims at issue in this litigation." *Ibid.* (stating that the PDMP's arguments "focus on preemption rather than on movants' related, though distinct, Fourth Amendment claim"). The district court

also found that "the disposition of this action without movants' participation 'may, as a practical matter, impair or impede … [their] ability to protect their interest.'" *Ibid.* (quoting *Citizens for Balanced Use v. Mont. Wilderness Ass'n,* 647 F.3d 893, 897 (9th Cir. 2012)). The court opined that it might "enter[] an order requiring PDPM [sic] to comply with § 876 subpoenas," and, in turn, "movants' ability to contest the lawfulness of such subpoenas will undoubtedly be impaired." *Ibid.*

C. Summary Judgment Ruling

1. The parties agreed that the case presented no disputed issues of fact and submitted cross-motions for summary judgment. On February 11, 2014, the district court issued a decision granting the intervenors' motion for summary judgment and denying DEA's cross-motions. SJ Op. 2 (ER 4). In light of its ruling on the intervenors' motion, the court denied Oregon PDMP's motion for summary judgment as moot. *Ibid.*

2. The court first addressed the question of whether "Article III erects any barriers to the justiciability of intervenors' arguments concerning the Fourth Amendment." SJ Op. 6-7 (ER 8-9). The court found that it was not required to analyze whether intervenors had standing to bring their Fourth Amendment claim because it had already allowed their intervention under Federal Rule of Civil Procedure 24(a), and "[i]n the Ninth Circuit, courts 'resolv[e] intervention questions without making reference to standing doctrine.'" *Ibid.* (citations omitted; alteration in original). The court stated that, "[w]ere intervenors pursuing claims wholly distinct

from those of the PDMP, this court might find cause to conduct a standing analysis," *ibid.* But the court found that "intervenors pursue claims related to PDMP's claims." *Ibid.*

The district court believed that, before addressing the PDMP's contention that § 876 subpoenas conflict with state law, the court "must first determine that the DEA's issuance of the administrative subpoenas is a constitutional exercise of its authority and that a conflict actually exists." *Ibid.* It was for this reason that the court concluded that intervenors' "arguments are merely an extension of those advanced by the PDMP requiring this court to begin at the beginning and consideration of those arguments in no way destroys the controversy already in existence." *Id.* at 8 (ER 10). The court therefore held "that intervenors do not need standing to raise arguments concerning the Fourth Amendment." *Ibid.*

3. The district court purported to consider whether the Fourth Amendment claim was ripe for adjudication. The court opined that "[r]egardless of whether intervenors themselves are currently subject to investigation by the DEA, it is clear that PDMP's rights and obligations must be determined at this time." SJ Op. 8 (ER 10). The court once more explained that, to determine whether "a positive conflict exists between § 876 and ORS 431.966"—that is, to resolve the challenge raised by the plaintiff Oregon PDMP—it would "first determine whether the issuance of the subpoenas is a constitutional exercise of the DEA's authority." *Id.* at 9 (ER 11) (concluding, on this basis, that the claim was ripe).

4. Having found no jurisdictional bars to adjudicating intervenors' Fourth Amendment claim, the district court went on to hold that DEA's § 876 subpoenas of records from the Oregon PDMP violate the Fourth Amendment's prohibition on unreasonable searches and seizures even though these subpoenas are enforceable only by a court order. *See* SJ Op. 9-16 (ER 11-18); *see also* 21 U.S.C. § 876(c).

The district court acknowledged this Court's Fourth Amendment test for the reasonableness of an administrative subpoena. SJ Op. 14 (ER 16). In particular, the court discussed *United States v. Golden Valley Electric Ass'n*, 689 F.3d 1108 (9th Cir. 2012) ("*Golden Valley*"), which upheld DEA subpoenas of business records issued under § 876 and explained that, "[i]n the context of an administrative [subpoena], the Fourth Amendment's restrictions are limited." 689 F.3d at 1115 (internal quotation marks and citation omitted) (second alteration in original). The court held that *Golden Valley* did not govern its decision, however, because "the prescription records here are protected by a heightened privacy interest rendering the use of administrative subpoenas unreasonable." SJ Op. 15 (ER 17).

The district court also acknowledged the line of cases holding that individuals have no protected Fourth Amendment interests in information or documents in the possession or control of another party. SJ Op. 15 (ER 17) (discussing *United States v. Miller*, 425 U.S. 435 (1976) (no expectation of privacy in account records held by bank); *Smith v. Maryland,* 442 U.S. 735 (1979) (no expectation of privacy in dialing records held by phone company)). The court concluded, however, that those cases

were "markedly different" because the subpoenaed records at issue here were "more inherently personal or private." *Ibid.* The court also believed it significant that Oregon required pharmacies to submit reports to the PDMP and that the information in the PDMP's database had not been volunteered directly by physicians and patients. SJ Op. 15-16 (ER 17-18).

The district court entered judgment for the intervenors on March 12, 2014, and permanently enjoined DEA from "obtaining prescription records from the Oregon [PDMP] without first securing a warrant based on probable cause." Judgment 2 (ER 20). The injunction purports to apply state-wide; it is not limited to the September 2012 subpoenas or to subpoenas implicating the records of the four John Doe patients and one Dr. James Roe. *See ibid.*

SUMMARY OF ARGUMENT

I. Pursuant to its authority under the Controlled Substances Act, 21 U.S.C. § 876, DEA issued two administrative subpoenas to the Oregon Prescription Drug Monitoring Program in September 2012. The subpoenas directed the state agency to produce certain records from its drug monitoring database, which compiles pharmacists' records of the controlled substances they have dispensed.

The PDMP brought this suit, asking the court to declare that—in light of state law ORS § 431.966(2)(a)(D), the PDMP must—or at least may—decline to comply with the subpoenas until a judicial enforcement order issues. DEA agreed that the PDMP may decline to comply with an administrative subpoena provided that it has a

good-faith basis for doing so. DEA explained, however, that ORS § 431.966(2)(a)(D) provides no basis for noncompliance because it is preempted by the federal Controlled Substances Act, 21 U.S.C. § 876.

The ACLU, an anonymous physician, and four anonymous patients intervened in the litigation to raise a Fourth Amendment claim. They have not suggested that they are directly affected by the September 2012 subpoenas. Rather, they assert that records of controlled substances they have prescribed to patients or have been prescribed by their physicians could potentially be turned over to DEA at some point in the future in response to an administrative subpoena. They allege that fear of this possibility may affect their conduct. On these grounds, they ask the court to rule that it is unconstitutional for DEA to subpoena prescription records from the PDMP under § 876, and that instead DEA must obtain "a probable cause warrant." Intervenors' Compl. 37.

The district court did not address whether intervenors established standing to introduce a Fourth Amendment claim in this litigation. The court claimed that it mattered only that the intervenors satisfied Federal Rule of Civil Procedure 24(a)(2)'s criteria for intervention. But even assuming intervenors met Rule 24(a)(2)'s requirements, the district court's approach disregarded the bedrock principle that jurisdiction must be established with regard to "each claim … press[ed]" and "each form of relief sought." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006).

No party has established standing to raise a ripe Fourth Amendment claim. The Oregon PDMP, of course, has presented no allegations or assertions related to the Fourth Amendment. And intervenors' speculative "[a]llegations of *possible* future injury" fall far short the standards imposed by Article III. *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013) (internal quotation marks omitted) (emphasis by the Court). As the Supreme Court made clear in *Clapper v. Amnesty Int'l USA*, intervenors do not advance their case by alleging that they are contemplating changing their prescription-filling practices in response to this perceived threat of investigation. An injury incurred in an effort to avoid a harm that is not "certainly impending," even "as a reasonable reaction to a risk of harm," does not establish standing. *Amnesty Int'l USA*, 133 S. Ct. at 1143, 1151. For similar reasons, intervenors' Fourth Amendment claim is not ripe; they have not shown that they face an imminent and genuine threat of government action. *Wolfson v. Brammer*, 616 F.3d 1045, 1058, 1064 (9th Cir. 2010).

II. Even assuming jurisdiction were proper, intervenors' Fourth Amendment claim does not bear scrutiny.

A. Intervenors cannot claim a reasonable expectation of privacy in Oregon PDMP's database, which aggregates information from pharmacies about controlled substance prescriptions that have been dispensed in the State.

Intervenors do not and cannot contend that that Oregon PDMP's collection of information intrudes on their privacy interests in the first instance. *See Whalen v. Roe*, 429 U.S. 589 (1977) (rejecting claims by patients and physicians that New York state's

collection of their controlled substance prescription information infringed their constitutionally-protected privacy interests). They offer no basis for asserting a privacy violation when the federal government obtains that information pursuant to an investigative subpoena.

The Fourth Amendment does not prevent the government from obtaining information about an individual from a third party, even if the third party obtained the information for a limited purpose and on the understanding that it would be not be disclosed to others. *See, e.g.*, *United States v. Miller*, 425 U.S. 435 (1976). And plainly it does not preclude the federal government from obtaining that information from a state.

B. Even if DEA's investigative subpoenas to the PDMP implicated a reasonable expectation of privacy, it is established that the Fourth Amendment requires only that administrative subpoenas be "sufficiently limited in scope, relevant in purpose, and specific in directive so that compliance [would] not be unreasonably burdensome." *See v. City of Seattle*, 387 U.S. 541, 544 (1967). Appellate courts have applied this standard in upholding administrative subpoenas of medical records, and there is no reason to depart from it here. *See, e.g.*, *In Re Subpoena Duces Tecum*, 228 F.3d 341 (4th Cir. 2000). Indeed, even under a more stringent test, DEA's subpoenas are constitutional. *See Tucson Women's Clinic v. Eden*, 379 F.3d 531, 551 (9th Cir. 2004) (setting out a five-part balancing test to weight governmental need against patients' privacy interests under the Fourteenth Amendment).

STANDARD OF REVIEW

A district court's grant of summary judgment is reviewed *de novo*. *See Grenning v. Miller-Stout*, 739 F.3d 1235, 1238 (9th Cir. 2014). "Summary judgment is appropriate when, with the evidence viewed in the light most favorable to the non-moving party, there are no genuine issues of material fact, so that the moving party is entitled to a judgment as a matter of law." *Ibid.* (internal quotation marks and citation omitted); *see* Fed. R. Civ. P. 56(c).

ARGUMENT

I. THE DISTRICT COURT LACKED JURISDICTION OVER INTERVENORS' FOURTH AMENDMENT CLAIM.

A. Courts Must Determine That Jurisdiction Is Established With Regard To Each Claim To Be Adjudicated.

The district court granted the motion to intervene filed by the ACLU, John Doe patients, and Dr. James Roe under Federal Rule of Civil Procedure 24(a)(2).[7]

This Court has held that a party seeking to intervene in ongoing litigation need only show that Federal Rule of Civil Procedure 24(a)(2)'s requirements are met; the intervenor "need not possess the standing necessary to initiate the lawsuit." *United States v. Imperial Irrigation Distr.*, 559 F.2d 509, 521 (9th Cir. 1977), *vacated on other grounds*

[7] Rule 24(a)(2) provides for intervention where a party "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2).

sub nom. Yellen v. Imperial Irrigation Dist., 447 U.S. 352 (1980). *See, e.g.*, *State of California Dep't of Soc. Servs. v. Thompson*, 321 F.3d 835, 846 n.9 (9th Cir. 2003) (stating, in conclusory fashion, that intervenor "did not need to meet Article III standing requirements to intervene" (citing Fed. R. Civ. P. 24(a) and *Sw. Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 817 (9th Cir. 2001)).

It is axiomatic, however, that a court must have jurisdiction over each claim it adjudicates, and that standing must be demonstrated "for *each claim* [a party] seeks to press." *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) (emphasis added). *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) (explaining that "a plaintiff must demonstrate standing for each claim he seeks to press" and "must demonstrate standing separately for each form of relief sought"); *Allen v. Wright*, 468 U.S. 737, 752 (1984) ("[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted.").

Thus, if a plaintiff-intervenor asserts claims that are different than those raised by the original plaintiff, the court must satisfy itself that the plaintiff-intervenor has standing to assert the new claims. That is the situation here. The Oregon PDMP brought suit to obtain a declaration that it need not comply with a DEA administrative subpoena until the subpoena is enforced by a court. This claim was based entirely on Oregon law, not on any constitutional provision. And the PDMP did *not* contend that either state law or the Fourth Amendment would preclude a

court from enforcing an administrative subpoena issued under the standards of 21 U.S.C. § 876. (In fact, the PDMP acknowledged that, under Supreme Court precedents, an agency may issue an administrative subpoena without probable cause. *See* Pl's MSJ 11-12, 16.)

It was thus incumbent on the district court to determine whether the intervenors had standing to claim that the Fourth Amendment precludes courts from enforcing subpoenas issued pursuant to § 876. Even assuming that the district court correctly determined that intervenors met the criteria for intervention under Rule 24(a)(2), the court could not rely on that ruling to ignore Article III prerequisites and to permit the court to resolve a new constitutional claim not raised by the plaintiff and to grant relief not sought by the plaintiff.[8]

B. Intervenors Lacked Standing To Introduce A Fourth Amendment Claim Into This Litigation.

1. To establish standing, a party must demonstrate that it has "suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v.*

[8] *See Mausolf v. Babbitt*, 85 F.3d 1295, 1299-1301 (8th Cir. 1996) (explaining that intervenors cannot raise new claims evading Article III requirements, such as standing); *City of Chicago v. FEMA*, 660 F.3d 980, 985 (7th Cir. 2011) ("The cases that dispense with the [Article III standing] requirement overlook the fact that even if a case is securely within federal jurisdiction by virtue of the stakes of the existing parties, an intervenor may be seeking relief different from that sought by any of the original parties. His presence may turn the case in a new direction—may make it really a new case."); *see also* Fed. R. Civ. P. 82 (recognizing that the federal rules cannot enlarge federal jurisdiction).

Defenders of Wildlife, 504 U.S. 555, 560 (1992) (citations and internal quotation marks omitted). The harm must be "real and immediate." *Scott v. Pasadena Unified Sch. Dist.*, 306 F.3d 646, 656 (9th Cir. 2002). "'[A]llegations of *possible* future injury' are not sufficient"; rather, as the Supreme Court has "repeatedly reiterated," "'threatened injury must be *certainly impending* to constitute injury in fact.'" *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)) (alteration and emphasis by the Court); *see Scott*, 306 F.3d at 656 (allegations of future injury are sufficient only where the party is "*immediately* in danger of sustaining some *direct* injury as the result of the challenged official conduct" (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983)) (emphasis in original)).[9]

Intervenors have not established any "actual or imminent" cognizable injury resulting from the challenged subpoenas or hypothetical future subpoenas. They do not claim that they are presently subject to any unreasonable search or seizure or that such an action is "*certainly* impending." *Amnesty Int'l USA*, 133 S. Ct. at 1147 (emphasis in original). Intervenors contend only that information about controlled substances they have prescribed (in the course of work as a DEA-registered physician) or been prescribed (as Oregon patients) is in the possession of state officials at the Oregon

[9] The Supreme Court observed in *Amnesty International USA* that in a few cases, the Court has "found standing based on a 'substantial risk' that the harm will occur." *Amnesty Int'l USA*, 133 S. Ct. at 1150 n.5. But "to the extent that the 'substantial risk' standard is relevant and is distinct from the 'clearly impending' requirement" in this context, intervenors "fall short of even that standard" for the reasons described below. *Ibid.*

PDMP, and that this information could be revealed to DEA officials in the future *if* responsive to an administrative subpoena. They urge that, if this were to occur, it would violate their Fourth Amendment rights.

Intervenors acknowledge that DEA has a variety of investigatory tools at its disposal.[10] They also recognize that the administrative subpoenas at issue in this litigation are not blanket requests for information about all Oregon doctors and patients but targeted requests for the records of two doctors and one patient. Nonetheless, intervenors speculate that, following a series of contingencies, information stored in the Oregon PDMP database that identifies them personally (and in which they maintain they have an objectively reasonable expectation of privacy) could be shared with DEA.[11]

The Supreme Court has stressed that this type of speculation is insufficient to establish standing. *Amnesty Int'l USA*, 133 S. Ct. at 1147, 1148 (citing cases). Moreover, a "'generalized threat of prosecution'"—let alone, as here, a generalized

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[10] Notably, intervenor Dr. James Roe is a DEA registrant. His prescriptions may be subject to DEA inspection, pursuant to 21 U.S.C. § 880(d), where justified by a "valid public interest." Information regarding both registered physicians and patients may also be obtained directly from registered pharmacies.

[11] Intervenors attempt to speak for themselves "and other Oregon patients and physicians," Intervenors' Compl. ¶ 181 (ER 60), but this is not a class action and parties may not rely on alleged injuries to others. *See, e.g.*, *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982). This is especially true here as Fourth Amendment rights are "'personal rights which … may not be vicariously asserted.'" *Rakas* v. *Illinois,* 439 U.S. 128, 133-34 (1978) (quoting *Alderman v. United States*, 394 U. S. 165, 174 (1969)).

perceived threat of investigation—does not satisfy Article III. *Wolfson v. Brammer*, 616 F.3d 1045, 1058 (9th Cir. 2010) (quoting *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc)). *See Sacks v. Office of Foreign Assets Control*, 466 F.3d 764, 773 (9th Cir. 2006) (requiring a genuine threat of imminent prosecution, not an "imaginary or speculative fear"); *Scott*, 306 F.3d at 656 (noting that a party does not have standing because of "[t]he mere existence of a statute, which may or may not ever be applied to [them]").

Intervenors do not suggest any ground on which to conclude that they face any specific or imminent threat.[12] They claim, instead, that they are contemplating changes to the ways in which they obtain their prescriptions to reduce the risk of their records being subpoenaed. *See, e.g.*, Decl. of John Doe 1 ¶ 27 (Docket No. 33) (stating, without further specificity: "At a minimum [if DEA is allowed to issue administrative subpoenas to the PDMP], my behavior would change each time I refilled my prescriptions, and I would seriously consider whether I had other treatment

[12] Even applying the test for a "well-founded fear of prosecution," it is clear that no such well-founded fear of investigation exists here. *See Wolfson*, 616 F.3d at 1057 (setting out the criteria which include "(1) whether the plaintiff has articulated a concrete plan to violate the law in question; (2) whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings; and (3) the history of past prosecution or enforcement under the challenged statute."). Intervenors' declarations do not suggest that they (or their physicians) are engaged in any improper conduct. To the contrary, they claim that their use of controlled substances—from sleep aids to pain medication and hormone treatments—is medically indicated. And DEA's past practices demonstrates the agency's targeted, rather than sweeping, approach to subpoenas issued to the PDMP.

options."); Decl. of John Doe 2 ¶ 21 (Docket No. 34) (suggesting that "[i]t would be distressing to [him] if the DEA was allowed to obtain prescription records from the PDMP without a warrant," and suggesting that he "might take steps to protect [his] privacy by, for example, requesting … smaller supplies of testosterone from the pharmacy in order to avoid potential suspicion and attention from law enforcement," thus requiring more frequent trips to the pharmacy for refills).

Vague assertions of possible changes in refill frequency due to fear of "potential suspicion and attention from law enforcement" do not constitute cognizable injuries to the plaintiffs. But even assuming they were, the Supreme Court made clear in *Clapper v. Amnesty International USA* that choosing to incur some costs or injury to avoid a harm that is not "certainly impending" does not advance a party's case. *Amnesty Int'l USA*, 133 S. Ct. at 1143, 1151 (explaining that incurring costs, even "as a reasonable reaction to a risk of harm," does not establish standing where that harm is "not certainly impending").

The facts of that case are instructive. The plaintiffs—a group of attorneys and human rights, labor, legal and media organizations—sought a declaration that a statute expanding the government's authority to conduct electronic surveillance of non-U.S. persons abroad violated, *inter alia*, the Fourth Amendment. *Amnesty Int'l USA*, 133 S. Ct. at 1144. The plaintiffs claimed that they were likely to be subject to surveillance because of their "sensitive and sometimes privileged telephone and e-mail communications" with colleagues and client abroad. *Id.* at 1145. They alleged that they

had incurred costs, such as travel for in-person meetings, to avoid surveillance. *Id.* at 1151. The Court concluded that they lacked standing—explaining that there was no indication that surveillance of the plaintiffs was "certainly impending" and that it would be improper to allow plaintiffs "to establish standing by asserting that they suffer present costs and burdens that are based on a fear" merely because that fear was not "'fanciful, paranoid, or otherwise unreasonable.'" *Ibid.* (citation omitted). The Supreme Court emphasized that allowing such a result would "water[] down the fundamental requirements of Article III." *Id.* at 1151-52. That reasoning applies with full force here.

2. Although the district court declined to address intervenors' standing, it did consider the issue of ripeness, SJ Op. 8 (ER 10), but failed to come to grips with this Court's decisions requiring that the threat of "imminent" government action be "genuine" to be ripe, and explaining that "[a] claim is not ripe for judicial resolution if it rests upon contingent future events that may not occur as anticipated[.]" *Wolfson*, 616 F.3d at 1058, 1064 (citations and internal quotation marks omitted).

The district court declared, instead, that, "[r]egardless of whether intervenors themselves are currently subject to investigation by the DEA," the court's analysis must begin by determining the constitutionality of DEA's administrative subpoena authority and, only upon holding that authority constitutional, consider Oregon PDMP's statutory argument. SJ Op. 8-9 (ER 10-11). That reasoning, which turns the

canon of constitutional avoidance on its head, wholly ignores established threshold requirements to bring suit.

II. SUBPOENAS ISSUED TO OREGON'S PRESCRIPTION DRUG MONITORING PROGRAM PURSUANT TO 21 U.S.C. § 876 DO NOT VIOLATE THE FOURTH AMENDMENT.

Intervenors have challenged the constitutionality of investigative subpoenas issued by DEA as authorized by Congress, 21 U.S.C § 876. Section 876 permits DEA to call for the testimony of witnesses or the production of records in connection with the agency's investigations of possible violations of the CSA. 21 U.S.C § 876(a). If the recipient of the subpoena does not comply, the agency may go to federal court to obtain a judicial order directing compliance under threat of contempt penalties. 21 U.S.C § 876(c). Section 876(a) does not require the agency or an enforcing court to have ascertained that probable cause exists to believe a violation of the CSA has occurred; recognizing the investigatory nature of § 876(a) subpoenas, Congress only required that the testimony or records sought be "relevant or material" to an agency investigation. *See generally United States v. Morton Salt Co.*, 338 U.S. 632, 642-43 (1950) (explaining that Congress has provide agencies with "powers of original inquiry," "analogous to the Grand Jury, which … can investigate merely on suspicion that the law is being violated").

Assuming this Court reaches the merits of intervenors' Fourth Amendment claim, the district court's judgment must be reversed. The Fourth Amendment establishes"[t]he right of the people to be secure in their persons, houses, papers, and

effects, against unreasonable searches and seizures ….” U.S Const. amend. IV. Its protections are implicated only when the government intrudes or seeks to intrude upon a person’s legitimate privacy interest. As discussed below, here, no party has a constitutionally-protected privacy interest in the records sought by DEA.

Even if a legitimate privacy interest could be identified, the Fourth Amendment would impose restrictions only so as to bar unreasonable intrusions. *See, e.g.*, *New York v. Burger*, 482 U.S. 691, 699-702 (1987) (discussing reasonableness factors weighed in determining the Fourth Amendment’s requirements for administrative inspections of premises of closely regulated industries); *United States v. Morton Salt Co.*, 338 U.S. 632, 652-54 (1950) (discussing factors relevant in evaluating Fourth Amendment parameters for administrative review of corporate documents). Here, the challenged subpoenas readily satisfy the Supreme Court’s well-established tests for reasonableness under the Fourth Amendment.

A. The Subpoenas At Issue Do Not Implicate The Fourth Amendment: There Is No Legitimate Privacy Interest In State Records That Aggregate Pharmacies’ Closely Regulated Records Of The Controlled Substances They Have Dispensed.

DEA subpoenaed certain records from the Oregon Prescription Drug Monitoring Program’s database, which collects information submitted by pharmacies regarding all controlled substances they have dispensed in the State or to Oregon addresses. This information includes the drug type and quantity, as well as the names of the patient and prescribing physician. Or. Rev. Stat. Ann. § 431.964(1).

The Oregon PDMP, a state agency, does not claim that it has or could have any Fourth Amendment interest in the information in its database. The only question is thus whether intervenors have an objectively reasonable expectation of privacy in the PDMP's records. As explained below, they do not.

1. Oregon is not the first state to establish a program for monitoring controlled substances. *See supra* note 4 (explaining that, by the time Oregon PDMP became operational, 42 states had monitoring programs). Indeed, prescription pharmaceuticals generally, and controlled substances in particular, have long been closely regulated by state and federal agencies: the first state monitoring program dates back to 1939.[13]

In 1977, the Supreme Court addressed the constitutionality of New York's program, which required that any prescription for a Schedule II controlled substance be reported to the State Health Department. *Whalen v. Roe*, 429 U.S. 589. The information collected under New York law was similar to that which is collected by Oregon's program (including the name and address of the patient and prescribing physician), and provided that it be retained for five years. *Id.* at 592-93. And, like

[13] California's triplicate prescription program for controlled substances such as opioids was established in 1939. Physicians were required to forward a copy of prescriptions for certain controlled substances to the Office of the Attorney General. *See generally* Karen Blumenschein et al. (KASPER Evaluation Team), *Review of Prescription Drug Monitoring in the United States,* Inst. for Pharm. Outcomes & Policy, Dep't of Pharmacy Practice & Sci., Univ. of Ky. 2, 6 (June 2010), http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf.

Oregon, New York sought to safeguard patients' information from public disclosure, but permitted disclosures in certain circumstances. *Id.* at 594-95 & n.12 (explaining that the New York permitted disclosure in various circumstances, including disclosures to DEA and other agencies or bodies "authorized to regulate, license or otherwise supervise" persons "authorized … to deal in controlled substances").

A group of physicians and patients challenged the law under the Fourth and Fourteenth Amendments. The Court observed that "[t]he constitutional question presented is whether the State of New York may record, in a centralized computer file, the names and addresses of all persons who have obtained, pursuant to a doctor's prescription, certain drugs for which there is both a lawful and an unlawful market." *Whalen*, 429 U.S. at 591.

While the lower court had found that the patient-identification provisions intruded on a constitutionally protected "zone of privacy," the Supreme Court did not. The Court found nothing novel about these types of disclosures to government officials—comparing them to a "host of other unpleasant invasions of privacy that are associated with many facets of health care. … [D]isclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice …." *Id.* at 602. The Court declined the plaintiffs' invitation to rule that, by requiring the disclosure of controlled substance prescription information to Health Department representatives, the New York law "amount[ed] to an impermissible invasion of privacy" or

"constitute[d] any invasion of any right or liberty protected by the Fourteenth Amendment." *Id.* at 602, 603-04.

Having rejected plaintiffs' Fourteenth Amendment invasion of privacy claims, the *Whalen* Court noted that plaintiffs had likewise raised a Fourth Amendment claim. *Id.* at 604 n.32. The Court observed: "We have never carried the Fourth Amendment's interest in privacy as far as the … appellees would have us. We decline to do so now." *Ibid.* The Court further stated that the patients had not established a "right to anonymity in medical treatment." *Ibid.*

2. In light of *Whalen*, the constitutionality of the Oregon PDMP is not in question. Nevertheless, intervenors maintain that they have a constitutionally protected privacy interest that is violated when the information collected by the PDMP is disclosed by the State to federal DEA officials pursuant to an administrative subpoena, as authorized by Congress.

Intervenors' position, however, disregards well-established Fourth Amendment doctrine. The Supreme Court "has held repeatedly that the Fourth Amendment does not prohibit the obtaining of information revealed to a third party and conveyed by him to Government authorities, even if the information is revealed on the assumption that it will be used only for a limited purpose and the confidence placed in the third party will not be betrayed." *United States v. Miller*, 425 U.S. 435, 443 (1976) (quoted in *United States v. Jacobsen*, 466 U.S. 109, 117 (1984) (citing cases)). The Supreme Court and this Court have explained that this is because, as a general matter, it is

unreasonable to assert an expectation of privacy in information or property that has been turned over to another party.

For example, in *Smith v. Maryland*, the police requested that a phone company install a "pen register" at its central office to record the phone numbers dialed from a specific home telephone. The company did so and provided the information to the government. The Supreme Court held that there had been no search within the meaning of the Fourth Amendment because the telephone user had no reasonable expectation of privacy in the information made available to the phone company. 442 U.S. at 737, 743-44.

In *United States v. Miller*, a bank—acting in satisfaction of federal recordkeeping requirements—kept records of a depositor's financing account. The depositor objected when the bank provided those records to the government in response to a grand jury subpoena, but the Supreme Court held that the depositor had no expectation of privacy in the bank's business records. 425 U.S. at 443. The Court noted that the records pertained to a transaction that involved both the bank and the depositor. *See id.* at 440-41, 442 (noting that the information was shared with "the banks and exposed to their employees in the ordinary course of business"). Likewise, the records provided by pharmacies to the PDMP reflect "transactions"—the filling

of prescriptions—typically involving at least three parties: patient, physician, and pharmacist.[14]

In 2012, this Court affirmed the continuing applicability of the third-party doctrine in a case brought by DEA to enforce an administrative subpoena issued to an electronic company. *United States v. Golden Valley Electric Ass'n*, 689 F.3d 1108 (9th Cir. 2012). The company attempted to invoke the Fourth Amendment rights of its customers. This Court ruled that, even if this were possible, the customers would have no legitimate expectation of privacy in usage data and payment records kept by the company. *Id.* at 1116.

3. Here, the district court recognized that the challenged subpoenas do not seek records from the intervenors, but seek records in the possession and control of a third party, the Oregon PDMP (and, in turn, that the PDMP's records reflect information supplied by pharmacies regarding prescriptions prepared by physicians).

[14] For other examples of Supreme Court decisions addressing the third-party doctrine, *see, e.g.*, *United States v. Payner*, 447 U.S. 727 (1980) (investigators stole a briefcase owned by a bank executive and copied its contents, which revealed information about an individual's bank account; the individual had no expectation of privacy in that information about his account, which had been in the bank's possession); *Couch v. United States*, 409 U.S. 322 (1973) (in response to IRS summons, accountant turned over tax document of a client; client had no expectation of privacy in the document); *United States v. White*, 401 U.S. 745 (1971) (defendant discussed crimes with undercover informant who was wearing a wire; the Court held that this did not constitute a search because no expectation of privacy in information conveyed to another person could be justified).

The court declined to apply the third-party doctrine, however, for two reasons: (i) the reporting of prescription information to the PDMP by pharmacies is mandatory, not voluntary, and (ii) the records at issue here are, in the court's view, "more inherently … private" than the financial statements, tax returns, and other information at issue in prior third-party cases. SJ Op. 15 (ER 17). But as explained below, the court offered no basis for these conclusory assessments, and did not identify any support for its departure from the Supreme Court's precedents.

From the moment a prescription for a controlled substance is prepared by a physician, it is subject to a variety of voluntary and mandatory disclosures by the patient and the physician, beginning with disclosures to pharmacists and third party payers, such as private insurers and government payers. *See Whalen*, 429 U.S. at 602. The district court did not explain why it deemed the decision to share a prescription with a pharmacist less "voluntary" than, for example, the decision to deposit money in a bank in *Miller*. The court noted that the pharmacists' reporting to the PDMP was mandatory under state law, but so too the bank was required to maintain account records under federal law. *Miller*, 425 U.S. at 440-41.

Furthermore, the district court's contention that individuals are entitled to regard their controlled substance prescriptions as "inherently … private" SJ Op. 15 (ER 17), cannot be reconciled with the longstanding state and federal frameworks for regulating prescriptions generally, and especially those for controlled substances.

Both state and federal law closely regulate the prescribing and dispensing of controlled substances by registered entities. *See, e.g.*, Or. Rev. Stat. Ann. § 689.155 (warrantless inspection); 21 U.S.C. § 880(d) (inspection warrants where there is a "valid public interest"). In addition to being subject to subpoena by DEA, prescription information may also be subpoenaed by the Attorney General or his designees in connection with investigations of health fraud. *See* 18 U.S.C. § 3486(a)(1)(A)(i)(I).

Moreover, both state and federal law anticipate that controlled substance prescription information held by the PDMP may be shared with others—from regulatory boards, to law enforcement officials, and health oversight authorities. *See, e.g.*, Or. Rev. Stat. Ann. § 431.966(2)(a)(E) (providing for disclosure in response to requests from "a health professional regulatory board" for information "necessary for an investigation related to licensure …. [of a] registrant").

The federal privacy rules for individually identifiable health information promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") confirm this expectation, and stand in sharp contrast with the district court's view that intervenors possess a "heightened expectation of privacy." SJ Op. 15 (ER 17). *See* 42 U.S.C. § 1320d(6) (defining "individually identifiable health information"); 65 Fed. Reg. 82462 (Dec. 28, 2000).

Under the HIPAA rules, a covered entity (such as a doctor, pharmacy, or insurer) may disclose individually identifiable health information without the prior written authorization of a patient or his representative in response to a an administrative subpoena from law enforcement, 45 C.F.R. § 164.512(f), or a request from a "health oversight agency" conducting "oversight activities authorized by law," such as prescription fraud investigations, 45 C.F.R. § 164.512(d). *See* 65 Fed. Reg. at 82492.

While the district court cited HIPAA as evidence "that privacy protections are … enshrined in certain aspects of federal law" and thus intervenors' expectation of privacy is justified, SJ Op.11 (ER 13), closer examination reveals the opposite. The subpoenas at issue in this suit fall squarely within HIPAA's law enforcement and health oversight exceptions, and the inclusion of those carefully crafted exceptions placed intervenors and other patients on notice that their prescription information could be disclosed in these types of circumstances. *See also* Or. Rev. Stat. Ann. § 192.558 (health care provider or state health plan may disclosed health information as "permitted or required by state or federal law or by order of the court").

In sum, the district court was quite incorrect when it concluded that "it is more than reasonable for patients to believe that law enforcement agencies will not have unfettered access to their records." SJ Op. 13 (ER 15). DEA has not sought or claimed "unfettered access," and, for all the reasons discussed above, it is wholly

unreasonable for patients to assert a constitutionally-protected privacy interest in the controlled substance prescription information in the Oregon PDMP database.

B. Even Assuming The Fourth Amendment's Protections Are Triggered, They Are Not Transgressed: DEA's Subpoenas Under 21 U.S.C. § 876 Easily Satisfy The Well-Established Reasonableness Standard.

Even assuming the administrative subpoenas issued to the PDMP implicated the Fourth Amendment, neither relief from the challenged subpoenas nor from future subpoenas would be appropriate.

1. In a typical case, a DEA subpoena under § 876 takes the form of a *subpoena duces tecum* issued to compel production of corporate records. *Cf.* 21 U.S.C. § 880(c).[15] The Supreme Court and this Court have long recognized that in such circumstances the Fourth Amendment is implicated insofar as the business entity may assert a privacy interest in its records, but its "'restrictions are limited.'" *United States v. Golden Valley Electric Ass'n*, 689 F.3d 1108, 1115 (9th Cir. 2012) (quoting *Reich v. Mont. Sulphur & Chem. Co.*, 32 F.3d 440, 448 (9th Cir. 1994)).

Nearly fifty years ago, the Supreme Court explained that it was already considered "settled" that "when an administrative agency subpoenas corporate books or records, the Fourth Amendment requires [only] that the subpoena be sufficiently

[15] A *subpoena duces tecum* calls for the production of documents, whereas a *subpoena ad testificandum* calls for oral testimony. To the extent § 876 subpoenas are used to secure the testimony of witnesses, they do not implicate the Fourth Amendment. *United States* v. *Dionisio*, 410 U.S. 1, 8-15 (1973) (explaining that, while the Fourth Amendment is inapplicable, Fifth Amendment protections apply).

limited in scope, relevant in purpose, and specific in directive so that compliance will not be unreasonably burdensome." *See v. City of Seattle*, 387 U.S. 541, 544-45 (1967) (describing these requirements as "rather minimal"); *see, e.g.*, *Donovan v. Lone Steer*, 464 U.S. 408, 415 (1984) (reaffirming this standard); *United States v. Powell*, 379 U.S. 48, 85 (1964) (restating the relevant factors).

This Court has summarized the test as follows: an administrative subpoena satisfies the Fourth Amendment is "if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant [to the inquiry]." *Golden Valley*, 689 F.3d at 1115 (instructing that "[a] subpoena should be enforced unless the party being investigated proves the inquiry is unreasonable because it is overbroad or unduly burdensome") (citations and internal quotation marks omitted); *see also United States v. Phibbs*, 999 F.2d 1053, 1077 (6th Cir. 1993) (applying with regard to § 876 administrative subpoenas).

The limited nature of the Fourth Amendment's restrictions reflects the nature and purpose of an agency's investigative *subpoena duces tecum*. *See, e.g.*, *In re Administrative Subpoena John Doe*, 253 F.3d 256, 264 (6th Cir. 2001) (explaining that even when such subpoenas implicate an entity's legitimate privacy interest in its own records, they do not present the "the immediacy and intrusiveness of a search and seizure conducted pursuant to a warrant" (quoting *In re Subpoena Duces Tecum*, 228 F.3d 341, 347-49 (4th Cir. 2000))). *See also* Pls' MSJ 11-12, 16 (recognizing that the "federal requirements" for administrative subpoenas are "rather minimal" and that Supreme Court "'cases

make it clear that [a federal agency] may issue an administrative subpoena without a warrant…'" (alteration in original)).

Neither the intervenors nor the district court has suggested that the subpoenas at issue here fall short of this standard. There is no question that the subpoenas are congressionally authorized, and there is no contention that they are indefinite, irrelevant, overbroad, or unduly burdensome. *See* SJ Op. 15. Nonetheless, intervenors urged, and the district court concluded, that the subpoenas must be subject to the same probable cause determination as search warrants.

2. The Supreme Court, however, has consistently rejected the need for a probable cause determination for administrative *subpoenas duces tecum*. *See, e.g.*, *Donovan*, 464 U.S. at 415; *Morton Salt Co.*, 338 U.S. at 652-54; *Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186 (1946). And appellate courts have applied the reasonableness standard from *See v. City of Seattle* and *United States v. Powell* to administrative subpoenas of medical records (*not* limited to prescription information) and concluded that subpoenas comported with the Fourth Amendment.

For example, in *Becker v. Kroll*, 494 F.3d 904 (10th Cir. 2007), an administrative subpoena was issued for a neurologist's medical records as part of a Medicaid billing fraud investigation. The Tenth Circuit observed that "an investigatory or administrative subpoena is not subject to the same probable cause requirements as a search warrant." *Id.* at 916 (citing cases); *see id.* at 916-17 (explaining that this is because a party has an opportunity to challenge a subpoena, while a warrant is

"immedia[te] and intrusive[]" (citations and internal quotation marks omitted) (alterations in original)). The court concluded that the subpoenas met the Fourth Amendment's "minimal requirements" for reasonableness. *Ibid.* (quoting factors from *See*).

Following the same reasoning, the Fourth and Sixth Circuits have applied this standard in upholding administrative subpoenas seeking "patient records." In both *In re Subpoena Duces Tecum*, 228 F.3d 341 (4th Cir. 2000), and *In re Administrative Subpoena John Doe*, 253 F.3d 256 (6th Cir. 2001), the Attorney General issued subpoenas to physicians under investigation for health care fraud pursuant to 18 U.S.C. § 3486. Paralleling DEA's investigative subpoena authority under 21 U.S.C. § 876, 18 U.S.C. § 3486 authorizes the Attorney General to issue a subpoena for "the production of any record or things relevant to the investigation" of a "Federal health care offense," such as health care fraud. 18 U.S.C. § 3486(a)(1)(A)(i)(I). The Fourth and Sixth Circuits agreed that the appropriate standard is the "long applied" "general reasonableness standard." *Doe*, 253 F.3d at 264-65; *In re Subpoena Duces Tecum*, 228 F.3d at 347-48.

Here, the district court insisted that because this case involves medical information the longstanding test for administrative subpoenas is inapplicable, but offered "no convincing basis upon which to distinguish" the appellate cases which have applied these standards. *Doe*, 253 F.3d at 265. In fact, the subpoenas at issue here present an easier case than most: they concern only prescription information for the

subset of drugs that are controlled substances, whereas the subpoena requests at issue in *Becker*, *Doe*, and *In re Subpoena Duces Tecum* encompassed patients' full medical records.

3. In any event, even under an expanded balancing test DEA's subpoenas are constitutional. In *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 551 (9th Cir. 2004), this Court considered the constitutionality of a state scheme that authorized warrantless inspections of abortion clinics and granted a state agency "unbounded access to unredacted patient records." *Id.* at 553. The Court observed that "abortion clinics are not a closely regulated industry," and therefore the provision allowing warrantless inspections could not be justified on that basis. *Id.* at 550 (contrasting the case with *New York v. Burger*, 482 U.S. 691, 701 (1987), and holding that the provision violated the Fourth Amendment).[16] The Court then turned to the plaintiffs' Fourteenth Amendment challenge to regulations giving the Department of Health Services full access to patients' unredacted medical files. The Court weighed five factors to determine whether the government's interest in obtaining the medical records of abortion clinic patients outweighed the patients' informational privacy interest in their medical files:

[16] *Compare Jamieson-McKames Pharm., Inc.,* 651 F.2d at 540-41 (regulators could enter and inspect drug manufacturing facility without meeting "traditional probable-cause standards" because the highly-regulated nature of drug industry reduced expectation of privacy).

> (1) the type of information requested, (2) the potential for harm in any subsequent non-consensual disclosure, (3) the adequacy of safeguards to prevent unauthorized disclosure, (4) the degree of need for access, and (5) whether there is an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access.

Id. at 551 (citing *Planned Parenthood v. Lawall*, 307 F.3d 783, 790 (9th Cir. 2002)).

In concluding that the regulation did not survive scrutiny, the Circuit stressed that the regulation permitted the agency to request "extremely broad" information, including patients' "full medical histories." *Id.* at 552. The court was concerned about the lack of internal agency safeguards, and, most significantly, found "little, if any, need for much of this information, such as the names and addresses of patients." *Ibid.* (The defendants asserted that they needed patients' identifying information to confirm that providers were complying with the State's requirement that this information be gathered. This Court noted that ensuring this compliance was only "tenuously related" to advancing health interests, the putative purposes of the regulations, and could still be accomplished with redacted files.)

DEA's administrative subpoenas, by contrast, would readily pass muster under *Tucson Woman's Clinic*'s five-part test. The information sought is limited to one patient and two physicians and the controlled substance prescription drugs they have received or prescribed, respectively. As we have noted, the subpoena does not seek comprehensive medical records, but information about controlled substance prescriptions that have been dispensed by Oregon pharmacies or to Oregon addresses. In addition, the Privacy Act and internal agency safeguards limit the

potential for additional non-consensual disclosure.[17] Moreover, the information pertains to a DEA investigation of possible CSA violations, and thus the government's "degree of need" is high.[18] Finally, Congress has specifically authorized the issuance of subpoenas for this purpose, and other federal laws (including HIPAA) confirm that this disclosure is consistent with public policy. This balancing demonstrates that the administrative subpoena process under 21 U.S.C. § 876(a)—which requires that the subpoenas seek specific, relevant information—satisfies the Fourth Amendment's reasonableness requirements.

4. The district court did not engage in the *Tucson Woman's Clinic* balancing test, suggesting that, because it arose in response to a Fourteenth Amendment claim, it is "inapplicable in the context of the Fourth Amendment." SJ Op. 13 n.3 (ER 15).

In *Seaton v. Mayberg*, 610 F.3d 530 (9th Cir. 2010), however, this Court applied the five-factor balancing test in adjudicating a prisoner's Fourth Amendment challenge. *Id.* at 539, 541 (assuming, without deciding, that the test from *Tucson*

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[17] Records received by DEA, in response to an administrative subpoena, are governed by significant restrictions, subjecting employees to discipline, termination, as well as civil and criminal sanctions for improper disclosure. *See* Decl. of Lori A. Cassity ¶ 2 (Docket No. 29-1).

[18] In addition to the importance of addressing CSA violations generally, DEA has a high "degree of need" for the prescription information collected by the PDMP. The PDMP database aggregates data for patients and physicians from pharmacies across the State—allowing the agency to determine whether a patient is "doctor shopping," a doctor is prescribing inappropriately, or a pharmacy is dispensing excess quantities. No other source offers as efficient a means of obtaining critical information regarding particular doctors, patients, or pharmacies.

Woman's Clinic was applicable). The Court observed that in *Whalen v. Roe* the Supreme Court did *not* recognize a general constitutional right to privacy in medical records. *Id.* at 536-37. Nonetheless, the Court weighed the prisoner's interest in his treatment records against the government's penological interest in reviewing his files. The Court concluded that the prisoner's privacy interest was not "constitutionally protected." *Id.* at 541.

The balancing test set out in *Tucson Woman's Clinic* is not required to determine the reasonableness of DEA's administrative subpoenas *duces tecum*; the legal standard articulated in *See v. City of Seattle* and *Golden Valley* is the appropriate mode of analysis. Nonetheless, it is instructive to note that DEA's challenged subpoenas readily survive even the *Tucson Woman's Clinic* multi-factor balancing test. The district court, by contrast, engaged in no balancing and improperly imposed an unprecedented probable cause requirement. SJ Op. 13 (ER 15).

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

JOYCE R. BRANDA
Acting Assistant Attorney General

BETH S. BRINKMANN
Deputy Assistant Attorney General

S. AMANDA MARSHALL
United States Attorney

MARK B. STERN
(202) 514-5089
SAMANTHA L. CHAIFETZ
(202) 514-4821
Attorneys, Appellate Staff
Civil Division, Room 7248
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

October 6, 2014

STATEMENT OF RELATED CASES

We are not aware of any related cases.

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(5), (6), (7)(B) and (C) and Ninth Circuit Rule 32, I certify that the attached Brief for Appellees contains 10990 words, and complies with type-volume limitations because it is prepared in Microsoft Word 2000, Garamond, font 14.

/s/ Samantha L. Chaifetz
SAMANTHA L. CHAIFETZ
Counsel for Appellant

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of October, 2014, I caused the foregoing brief to be electronically filed with the United States Court of Appeals for the Ninth Circuit, and served to counsel, via the ECF system.

/s/ Samantha L. Chaifetz
SAMANTHA L. CHAIFETZ
Counsel for Appellant

ADDENDUM

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18 U.S.C. § 3486
(a) Authorization.—
(1)
(A) In any investigation of—
(i)
(I) a Federal health care offense; or
(II) a Federal offense involving the sexual exploitation or abuse of children, the Attorney General;
(ii) an unregistered sex offender conducted by the United States Marshals Service, the Director of the United States Marshals Service; or
(iii) an offense under section 871 or 879, or a threat against a person protected by the United States Secret Service under paragraph (5) or (6) of section 3056,[1] if the Director of the Secret Service determines that the threat constituting the offense or the threat against the person protected is imminent, the Secretary of the Treasury, may issue in writing and cause to be served a subpoena requiring the production and testimony described in subparagraph (B).
(B) Except as provided in subparagraph (C), a subpoena issued under subparagraph (A) may require—
(i) the production of any records or other things relevant to the investigation; and
(ii) testimony by the custodian of the things required to be produced concerning the production and authenticity of those things.
(C) A subpoena issued under subparagraph (A) with respect to a provider of electronic communication service or remote computing service, in an investigation of a Federal offense involving the sexual exploitation or abuse of children shall not extend beyond—
(i) requiring that provider to disclose the information specified in section 2703 (c)(2), which may be relevant to an authorized law enforcement inquiry; or
(ii) requiring a custodian of the records of that provider to give testimony concerning the production and authentication of such records or information.
(D) As used in this paragraph—
(i) the term "Federal offense involving the sexual exploitation or abuse of children" means an offense under section 1201, 1591, 2241 (c), 2242, 2243, 2251, 2251A, 2252, 2252A, 2260, 2421, 2422, or 2423, in which the victim is an individual who has not attained the age of 18 years; and
(ii) the term "sex offender" means an individual required to register under the Sex Offender Registration and Notification Act (42 U.S.C. 16901 et seq.).
(2) A subpoena under this subsection shall describe the objects required to be produced and prescribe a return date within a reasonable period of time within which the objects can be assembled and made available.
(3) The production of records relating to a Federal health care offense shall not be required under this section at any place more than 500 miles distant from the place

where the subpoena for the production of such records is served. The production of things in any other case may be required from any place within the United States or subject to the laws or jurisdiction of the United States.
(4) Witnesses subpoenaed under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.
(5) At any time before the return date specified in the summons, the person or entity summoned may, in the United States district court for the district in which that person or entity does business or resides, petition for an order modifying or setting aside the summons, or a prohibition of disclosure ordered by a court under paragraph (6).
(6)
(A) A United States district court for the district in which the summons is or will be served, upon application of the United States, may issue an ex parte order that no person or entity disclose to any other person or entity (other than to an attorney in order to obtain legal advice) the existence of such summons for a period of up to 90 days.
(B) Such order may be issued on a showing that the things being sought may be relevant to the investigation and there is reason to believe that such disclosure may result in—
(i) endangerment to the life or physical safety of any person;
(ii) flight to avoid prosecution;
(iii) destruction of or tampering with evidence; or
(iv) intimidation of potential witnesses.
(C) An order under this paragraph may be renewed for additional periods of up to 90 days upon a showing that the circumstances described in subparagraph (B) continue to exist.
(7) A summons issued under this section shall not require the production of anything that would be protected from production under the standards applicable to a subpoena duces tecum issued by a court of the United States.
(8) If no case or proceeding arises from the production of records or other things pursuant to this section within a reasonable time after those records or things are produced, the agency to which those records or things were delivered shall, upon written demand made by the person producing those records or things, return them to that person, except where the production required was only of copies rather than originals.
(9) A subpoena issued under paragraph (1)(A)(i)(II) or (1)(A)(iii) may require production as soon as possible, but in no event less than 24 hours after service of the subpoena.
(10) As soon as practicable following the issuance of a subpoena under paragraph (1)(A)(iii), the Secretary of the Treasury shall notify the Attorney General of its issuance.

(b) Service.— A subpoena issued under this section may be served by any person who is at least 18 years of age and is designated in the subpoena to serve it. Service upon a natural person may be made by personal delivery of the subpoena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpoena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpoena entered on a true copy thereof by the person serving it shall be proof of service.

(c) Enforcement.— In the case of contumacy by or refusal to obey a subpoena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpoena. The court may issue an order requiring the subpoenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony concerning the production and authentication of such records. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

(d) Immunity From Civil Liability.— Notwithstanding any Federal, State, or local law, any person, including officers, agents, and employees, receiving a subpoena under this section, who complies in good faith with the subpoena and thus produces the materials sought, shall not be liable in any court of any State or the United States to any customer or other person for such production or for nondisclosure of that production to the customer.

(e) Limitation on Use.—

(1) Health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information unless the action or investigation arises out of and is directly related to receipt of health care or payment for health care or action involving a fraudulent claim related to health; or if authorized by an appropriate order of a court of competent jurisdiction, granted after application showing good cause therefor.

(2) In assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

(3) Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

[1] So in original. Probably should be section "3056(a)".

21 U.S.C. § 876

(a) Authorization of use by Attorney General

In any investigation relating to his functions under this subchapter with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) Service

A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

(c) Enforcement

In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

21 U.S.C. § 880

(a) "Controlled premises" defined

As used in this section, the term "controlled premises" means—

(1) places where original or other records or documents required under this subchapter are kept or required to be kept, and

(2) places, including factories, warehouses, and other establishments, and conveyances, where persons registered under section 823 of this title (or exempt from registration under section 822(d) of this title or by regulation of the Attorney General) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

(b) Grant of authority; scope of inspections

(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this subchapter and otherwise facilitating the carrying out of his functions under this subchapter, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as "inspectors") designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this subchapter;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs, listed chemicals, and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (4) of this subsection, all other things therein (including

records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this subchapter; and

(C) to inventory any stock of any controlled substance or listed chemical therein and obtain samples of any such substance or chemical.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) Situations not requiring warrants
A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 876 of this title, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(5) in any other situations where a warrant is not constitutionally required.

(d) Administrative inspection warrants; issuance; execution; probable cause
Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of the United States or of a State court of record, or any United States magistrate judge, may, within his territorial jurisdiction, and upon proper oath or

affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this subchapter or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" means a valid public interest in the effective enforcement of this subchapter or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate judge and establishing the grounds for issuing the warrant. If the judge or magistrate judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) of this section to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate judge to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate judge allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate judge, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and the applicant for the warrant.

(4) The judge or magistrate judge who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

Or. Rev. Stat. Ann. § 431.964

(1) Not later than one week after dispensing a prescription drug that is subject to the prescription monitoring program established under ORS 431.962 (Establishment of program), a pharmacy shall electronically report to the Oregon Health Authority:

(a) The name, address, date of birth and sex of the patient for whom the prescription drug was prescribed;

(b) The identity of the pharmacy that dispensed the prescription drug and the date on which the prescription drug was dispensed;

(c) The identity of the practitioner who prescribed the prescription drug and the date on which the prescription drug was prescribed;

(d) The national drug code number for the prescription drug;

(e) The prescription number assigned to the prescription drug;

(f) The quantity of the prescription drug dispensed;

(g) The number of days for which the prescription drug was dispensed; and

(h) The number of refills of the prescription authorized by the practitioner and the number of the refill that the pharmacy dispensed.

(2) Notwithstanding subsection (1) of this section, the authority may not:

(a) Require the reporting of prescription drugs administered directly to a patient or dispensed pursuant to ORS 127.800 (Definitions) to 127.897 (Form of the request);

(b) Collect or use Social Security numbers in the prescription monitoring program; or

(c) Disclose under ORS 431.966 (Disclosure of information) (2)(a) the sex of the patient for whom a drug was prescribed. The sex of the patient may be disclosed only

for the purpose of research or epidemiological study under ORS 431.966 (Disclosure of information) (2)(b).

(3) Upon receipt of the data reported pursuant to subsection (1) of this section, the authority shall record the data in the electronic system operated pursuant to the prescription monitoring program.

(4)(a) The authority may grant a pharmacy a waiver of the electronic submission requirement of subsection (1) of this section for good cause as determined by the authority. The waiver shall state the format, method and frequency of the alternate nonelectronic submissions from the pharmacy and the duration of the waiver.

(b) As used in this subsection, good cause includes financial hardship.

(5) This section does not apply to pharmacies in institutions as defined in ORS 179.010

Or. Rev. Stat. Ann. § 431.966

(1)(a) Except as provided under subsection (2) of this section, prescription monitoring information submitted under ORS 431.964 to the prescription monitoring program established in ORS 431.962:

(A) Is protected health information under ORS 192.553 to 192.581.

(B) Is not subject to disclosure pursuant to ORS 192.410 to 192.505.

(b) Except as provided under subsection (2)(a)(D) of this section, prescription monitoring information submitted under ORS 431.964 to the prescription monitoring program may not be used to evaluate a practitioner s professional practice.

(2)(a) If a disclosure of prescription monitoring information complies with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.553 to 192.581, the Oregon Health Authority shall disclose the information:

(A) To a practitioner or pharmacist who certifies that the requested information is for the purpose of evaluating the need for or providing medical or pharmaceutical

treatment for a patient to whom the practitioner or pharmacist anticipates providing, is providing or has provided care.

(B) To designated representatives of the authority or any vendor or contractor with whom the authority has contracted to establish or maintain the electronic system of the prescription monitoring program.

(C) Pursuant to 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.

(D) To a health professional regulatory board that certifies in writing that the requested information is necessary for an investigation related to licensure, renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains.

(E) To a prescription monitoring program of another state if the confidentiality, security and privacy standards of the requesting state are determined by the authority to be equivalent to those of the authority.

(b) The authority may disclose information from the prescription monitoring program that does not identify a patient, practitioner or drug outlet:

(A) For educational, research or public health purposes; and

(B) To officials of the authority who are conducting special epidemiologic morbidity and mortality studies in accordance with ORS 432.060 and rules adopted under ORS 431.110.

(c) The authority shall disclose information relating to a patient maintained in the electronic system operated pursuant to the prescription monitoring program established under ORS 431.962 to that patient at no cost to the patient within 10 business days after the authority receives a request from the patient for the information.

(d)(A) A patient may request the authority to correct any information about the patient that is erroneous. The authority shall grant or deny a request to correct information within 10 business days after the authority receives the request.

(B) If the authority denies a patient s request to correct information under this paragraph, or fails to grant a patient s request to correct information under this

paragraph within 10 business days after the authority receives the request, the patient may appeal the denial or failure to grant the request. Upon receipt of an appeal under this subparagraph, the authority shall conduct a contested case hearing as provided in ORS chapter 183. Notwithstanding ORS 183.450, in the contested case hearing, the authority has the burden of establishing that the information included in the prescription monitoring program is correct.

(e) The information in the prescription monitoring program may not be used for any commercial purpose.

(f) In accordance with ORS 192.553 to 192.581 and federal privacy regulations, any person authorized to prescribe or dispense a prescription drug and who is entitled to access a patient s prescription monitoring information may discuss or release the information to other health care providers involved with the patient s care, in order to provide safe and appropriate care coordination.

(3)(a) The authority shall maintain records of the information disclosed through the prescription monitoring program including, but not limited to:

(A) The identity of each person who requests or receives information from the program and the organization, if any, the person represents;

(B) The information released to each person or organization; and

(C) The date and time the information was requested and the date and time the information was provided.

(b) Records maintained as required by this subsection may be reviewed by the Prescription Monitoring Program Advisory Commission.

(4) Information in the prescription monitoring program that identifies an individual patient must be removed no later than three years from the date the information is entered into the program.

(5) The authority shall notify the Attorney General and each affected individual of an improper disclosure of information from the prescription monitoring program.

(6)(a) If the authority or a person or entity required to report or authorized to receive or release controlled substance prescription information under this section violates this section or ORS 431.964 or 431.968, a person injured by the violation may bring a

civil action against the authority, person or entity and may recover damages in the amount of $1,000 or actual damages, whichever is greater.

(b) Notwithstanding paragraph (a) of this subsection, the authority and a person or entity required to report or authorized to receive or release controlled substance prescription information under this section are immune from civil liability for violations of this section or ORS 431.964 or 431.968 unless the authority, person or entity acts with malice, criminal intent, gross negligence, recklessness or willful intent.

(7) Nothing in ORS 431.962 to 431.978 and 431.992 requires a practitioner or pharmacist who prescribes or dispenses a prescription drug to obtain information about a patient from the prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses a prescription drug may not be held liable for damages in any civil action on the basis that the practitioner or pharmacist did or did not request or obtain information from the prescription monitoring program.

Or. Rev. Stat. Ann. § 689.155

The State Board of Pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

(1) The regulation of the sale at retail, the administering by pharmacists to the extent provided in ORS 689.645 (Power to administer and prescribe vaccines) and 689.655 (Power to administer drugs and devices) and the dispensing of medications, drugs, devices and other materials including the right to seize any such drugs, devices and other materials found to be detrimental to the public health and welfare by the board after appropriate hearing as required under ORS chapter 183.

(2) The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding, administering and dispensing of such medications, drugs, devices and other materials within the practice of pharmacy and any drug outlet.

(3) The control of the purity and quality of such medications, drugs, devices and other materials within the practice of pharmacy and any drug outlet.

(4) The issuance and renewal of certificates of registration of drug outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs, receiving and collecting annual fees therefrom and suspending, revoking or refusing to renew such registration in the manner provided in this chapter.

(5) In conjunction with the regularly constituted law enforcement agencies of this state, enforce all laws of the state which pertain to the practice of pharmacy, the manufacture, production, sale or distribution of drugs, chemicals and poisons, and to their standard of strength and purity.

(6) Investigate all complaints of alleged violations of this chapter and take necessary action as the board may require or direct.

(7) Pursuant to ORS chapter 183, make such rules as are necessary and feasible for carrying out ORS 453.175 (Necessity for poison label), 453.185 (False representation by purchaser prohibited), 475.005 (Definitions for ORS 475.005 to 475.285 and 475.752 to 475.980), 475.135 (Grounds to grant or deny registration) and 475.185 (When prescriptions required) and this chapter and make rules relating to controlled substances, designated as such pursuant to ORS 475.025 and 475.035 (Authority to control schedule).

(8) At all reasonable hours, in performance of the duties imposed by this section, enter, or cause its authorized representatives to enter upon, and examine the premises or records required by law of any drug outlet under the jurisdiction of the board.

(9) Assist the regularly constituted law enforcement agencies of this state in enforcing ORS 453.005 (Definitions for ORS 453.005 to 453.135) to 453.135 (Notice required prior to institution of criminal proceedings), 475.005 (Definitions for ORS 475.005 to 475.285 and 475.752 to 475.980) and 475.135 (Grounds to grant or deny registration) and this chapter by prosecution in the courts of this state or otherwise.

(10) Cause to have made a regular inspection of all pharmacies.

(11) Pursuant to ORS chapter 183, make such rules as are necessary for pharmacies, drug manufacturers and wholesalers to sell or otherwise lawfully distribute designated pharmaceutical agents to licensed optometrists consistent with the provisions of ORS 683.010 (Definitions for ORS 683.010 to 683.310) to 683.340 (Duty to report prohibited conduct).

45 C.F.R. § 164.512, in relevant part

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:

(i) 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, administrative, 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. Nothwithstanding 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 statement 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) Nothwithstanding 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)(i) 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.