United States Court of Appeals for the First Circuit

No. 19-1243

UNITED STATES DEPARTMENT OF JUSTICE

Petitioner - Appellee

v.

MICHELLE RICCO JONAS

Respondent - Appellant

Appeal from a Judgment Entered by the United States District Court for the District of New Hampshire

BRIEF FOR RESPONDENT-APPELLANT MICHELLE RICCO JONAS

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REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Pursuant to Local Rule 34.0, Respondent/Appellant Michelle Ricco Jonas states that oral argument will assist the Court. This appeal presents novel questions of statutory and constitutional law, and the outcome will have a substantial impact on the ability of states to operate and maintain prescription drug monitoring programs (PDMPs) in the interest of public health, while protecting the rights of patients to be free of unreasonable government intrusion into their private, intimate prescription drug therapies, contrary to their reasonable expectations of privacy under the Fourth Amendment.

JURISDICTIONAL STATEMENT

A. The Basis for the District Court's Jurisdiction

The Attorney General of the United States, by its designee, the Drug Enforcement Administration ("DEA"), served an administrative subpoena upon Michelle R. Ricco Jonas, Program Manager of the New Hampshire Board of Pharmacy's Prescription Drug Monitoring Program, commanding that she appear before a Diversion Investigator of the DEA, that she give testimony and that she bring with her and produce for examination certain patient-specific prescription drug records. Appendix to Appellant's Brief ("Appx") at 24. According to the text of the subpoena, the DEA was authorized to issue the instrument by 21 U.S.C. § 876 [Controlled Substances Act – Subpena]. Id. Following receipt of a duly presented objection to the subpoena, *id.* at 18, the United States Department of Justice filed a "Petition to Compel Compliance with Administrative Subpoena" in the United States District Court for the District of New Hampshire, stating that it invoked the Court's jurisdiction pursuant to 21 U.S.C. § 876(c) [Controlled Substances Act – Subpena – Enforcement], id. at 3, which provides, in relevant part, that "in the case of contumacy or refusal to obey a subpena issued to any person, the [U.S.] 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."

B. The Basis for the Court of Appeals' Jurisdiction

On November 1, 2018, U.S. Magistrate Judge Andrea K. Johnstone issued a Report and Recommendation, which concluded with a "recommend[ation] that the district judge grant the government's petition to compel[,] doc. No. 1." Appellant's Brief – Addendum ("Addendum") at 1, 19. By Order dated January 17, 2019, the District Court (McCafferty, J.) issued an Order, over Ms. Ricco Jonas' objection, approving the November 1, 2018 Report and Recommendation. Id. at 21. On January 29, 2019, the District Court entered Judgment in accordance with the January 17, 2019 Order. Id. at 22. On February 28, 2019, Ms. Ricco Jonas filed a Notice of Appeal, invoking the jurisdiction of the United States Court of Appeals for the First Circuit. This Court has jurisdiction over the instant appeal pursuant to 28 U.S.C. § 1291 [Jurisdiction and Venue – Final Decisions of District Courts], which recites, in relevant part, that [t]he courts of appeals ... shall have jurisdiction of appeals from all final decisions of the district courts of the United States...."

C. The Filing Dates Establishing the Timeliness of the Appeal

As noted *supra*, on January 29, 2019, the District Court entered Judgment in accordance with the January 17, 2019 Order. *Id.* Thirty (30) days thereafter, on February 28, 2019, Ms. Ricco Jonas filed a Notice of Appeal. *See* Fed. R. App. P. 4(a)(1)(B) ("The notice of appeal may be filed by any party within 60 days after entry

of the judgment or order appealed from if one of the parties is ... a United States agency.")

D. An Assertion that the Appeal is from a Final Order or Judgment that Disposes of All Parties' Claims

The January 17, 2019 Order of the Court (McCafferty, J.) is a reviewable "final order" under 28 U.S.C. § 1291 [Jurisdiction and Venue – Final Decisions of District Courts], as it "end[ed] the litigation on the merits and le[ft] nothing for the court to do but execute the judgment." *Whitfield v. Municipality of Fajardo*, 564 F.3d 40, 45 (1st Cir. 2009), *quoting Catlin v. United States*, 324 U.S. 229, 233 (1945).

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Whether 21 U.S.C. § 876 [Controlled Substances Act – Subpena] authorizes the United States Attorney General, by his designee, the Drug Enforcement Administration, to enforce an administrative investigatory subpoena against a state official, commanding that she violate state law and turn over state-collected, patient-specific, privacy-protected prescription drug information that is kept in a state established database managed by the Board of Pharmacy's Prescription Drug Monitoring Program ("PDMP), where 21 U.S.C. § 876(c) permits the enforcement of subpoenas only against a "person," and the text, structure, purpose, legislative history, and executive interpretation of the Controlled Substances Act do not reveal an affirmative intent to include the States, their agencies, and their officials in their official capacities within the meaning of the word "person".

2. Whether the District Court erred in concluding that patients do not have a reasonable expectation of privacy in their involuntarily collected, PDMP-kept prescription drug information, so that the Drug Enforcement Administration may freely mine such information, via administrative investigatory subpoena, without a probable cause-based court order, without violating the Fourth Amendment.

STATEMENT OF THE CASE

The New Hampshire Prescription Drug Monitoring Program ("PDMP") is a state-created, -maintained and -controlled database - a health care measure to "facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances...." RSA 318-B:32. The statute establishing the PDMP does not permit law enforcement to access the database except with "a court order based on probable cause." RSA 318-B:35, I(b)(3). Releasing information to law enforcement without such a court order is a state-law class B felony. RSA 318-B:36, VII. Individuals do not voluntarily provide their prescription drug information to the PDMP or otherwise consent to its inclusion in the database. Instead, New Hampshire law requires all of its licensed dispensers to input schedule II-IV prescription drug information into the PDMP database when a prescription is filled. RSA 318-B:33, III-V. The only way for patients to avoid having their prescribed drug therapies entered into the PDMP database is to forgo schedule II-IV prescription drugs. This case concerns an effort by the United States Drug Enforcement Administration

("DEA") to mine PDMP data, including patient-specific prescription drug therapies, via extra-judicial administrative investigatory subpoena.

A. The Board of Pharmacy, Which Presides Over the PDMP, is a Sovereign Agency of the State of New Hampshire.

The PDMP is an arm of the New Hampshire Board of Pharmacy (the "Pharmacy" Board"), RSA 318-B:31-41, which was established by the New Hampshire Legislature pursuant to RSA 318:2 [Pharmacy Board]. Its members are appointed by the governor, with the advice and consent of the executive council. RSA 318:2. It has authority to make and adopt rules, RSA 318:5-a [Rulemaking Authority], and to adjudicate contested cases. RSA 318-31 [Hearings, Decisions and Appeals]. As a state "agency" is defined to include any "board . . . authorized by law to make rules or to determine contested cases," RSA 541-A-1, II [Administrative Procedure Act – Definitions], the Pharmacy Board is a sovereign agency of the State of New Hampshire. Further, all "boards," as "agencies" of the State, enjoy sovereign immunity, except as otherwise authorized by statute, see RSA 99-D:1, and are subject only to certain claims, RSA 541-B:1, I [Claims Against the State – Definitions]. Such claims may result in judgments that are, by statute, limited in amount, see RSA 541-B:14 [Limitation on Actions and Claims], and ultimately paid from the State treasury or otherwise satisfied out of budgeted appropriations by the Legislature. See RSA 541-B:13 [Claims Against the State – Payment of Claims].

B. The Prescription Drug Monitoring Program (PDMP)

On June 12, 2012, New Hampshire Governor Lynch signed Senate Bill 286, codified at RSA 318-B:31-41 [Controlled Drug Prescription Health and Safety Program], which directed the Pharmacy Board to "design, establish, and contract with a third party for the implementation and operation of an electronic system [the PDMP] to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances, by prescribers and dispensers within the state." RSA 318-B:32. The database, populated by the mandatory reporting of dispensers, includes fulsome patient and prescription drug identifiers. RSA 318-B:33, IV. For each prescription dispensed of a schedule II-IV controlled substance, a pharmacy must electronically submit certain information to the PDMP database that includes, but is not limited to:

- patient's name
- patient's address
- patient's date of birth
- patient's telephone number
- National Drug Code (NDC) of the drug dispensed
- quantity dispensed
- number of days of supply of drug
- number of refills granted

- whether the prescription is new or a refill
- prescriber's identifying DEA registration number
- Id.

The PDMP is not a law enforcement measure. Rather, it is an information sharing regime aimed squarely at "improv[ing] medical treatment *** [and] reduc[ing] patient morbidity and mortality by providing a secure program through which the prescriber and dispenser may access information on a patient's controlled drug prescription history." RSA 318-B:31-41 [Controlled Drug Prescription Health and Safety Program—Statement of Intent].

Since one who might freely mine the PDMP database would obtain significant patient-identifiable *and* diagnosis-suggestive health and treatment information, the New Hampshire Legislature declared that "[i]nformation contained in the [PDMP database] ... is confidential" and directed the Pharmacy Board to "establish and maintain procedures to ensure the privacy and confidentiality of patients and [of the] patient information" that dispensers were now commanded to input. RSA 318-B:34, II. Thus, the legislation authorized the Board to release information contained within the PDMP database for, among other things, "statistical analysis, public research, public policy, and educational purposes, *provided* that the data are *aggregated* or otherwise *de-identified*." RSA 318-B:34, III (emphasis added); *see also*, RSA 318-B:34, I [Confidentiality] (PDMP data "is confidential, is not a public record, and is not

subject to discovery, subpoena, or other means of legal compulsion for release, except

as provided ..."). The legislation also authorized the Board to disclose PDMP data to:

Authorized law enforcement officials on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause. No law enforcement agency or official shall have direct access to the program.

RSA 318-B:35, I(b)(3) (emphasis added).

Only upon receipt of "a court order based on probable cause"¹ is the PDMP's "Program Manager" (the office presently occupied by Ms. Ricco Jonas)² authorized and directed "to provide the information identified in the court order in the format requested by the court order." N.H. Admin. R. Ph 1505.03(c). These access limitations are punctuated by RSA 318-B:36, VII, which provides that *anyone*, including Ms. Ricco Jonas, "who knowingly accesses … or discloses program information except as authorized in [the foregoing RSA 318-B:35] … shall be guilty of a class B felony."

¹ The order must "include[] sufficient information to correctly identify the patient, prescriber or dispenser whose prescription monitoring information is the subject of the court order." N.H. Admin. R. Ph 1505.03(b).

² The "Program Manager" is "the person designated by the [B]oard to oversee the implementation and operation of the program by the [third party] program vendor." N.H. Admin. R. Ph. 1502.01(m), (n) [Definitions].

C. United States Department of Justice v. Michelle R. Ricco Jonas – The Procedural Background

The DEA issued an administrative investigatory subpoena to Michelle Ricco Jonas, the Program Manager for the PDMP, under 21 U.S.C. § 876, commanding that she use her official position with the State of New Hampshire, including her stateissued credentials, to access the PDMP database, remove information on schedule II-IV controlled drug therapies prescribed to a specified individual, and provide that information to the DEA, Appx. at 24, without a probable cause-based court order, in violation of state law. See RSA 318-B:35, I(b)(3); RSA 318-B:36, VII. Ms. Ricco Jonas, through the New Hampshire Attorney General's Office, resisted the subpoena on the ground that New Hampshire was the real party in interest and that Ms. Ricco Jonas, in her official capacity as Program Manager of the PDMP, was not a "person," under 21 U.S.C. § 876 and 1 U.S.C. § 1, against whom such an administrative investigatory subpoena could lawfully be issued, served, and enforced, as a matter of statutory construction. Appx. at 18-23.

The United States Department of Justice ("USDOJ") filed an action to enforce the subpoena under 21 U.S.C. § 876(c). Appx. at 3, *et seq*. Ms. Ricco Jonas, through the New Hampshire Attorney General's Office, defended the action, asserting that: (1) New Hampshire was the real party in interest and Ms. Ricco Jonas, in her official capacity as Program Manager of the PDMP, was not a "person," under 21 U.S.C. § 876 and 1 U.S.C. § 1, against whom an administrative investigatory subpoena could lawfully be issued, served, and enforced, as a matter of statutory construction; and (2) patients have a reasonable expectation of privacy in their PDMP-kept prescription drug data that, under the Fourth Amendment, the DEA cannot obtain absent a court order based on probable cause. Appx. at 29, *et seq*.

On November 1, 2018, the Magistrate issued a Report and Recommendation, which concluded with a "recommend[ation] that the district judge grant the government's petition to compel[,] doc. No. 1." Addendum at 19. Ms. Ricco Jonas timely objected, raising the legal errors at issue in this appeal. Appx. at 18. By Order dated January 17, 2019, the District Court (McCafferty, J.) summarily approved the Report and Recommendation. *Id.* at 21. On January 29, 2019, the District Court entered Judgment in accordance with the January 17, 2019 Order. *Id.* at 22. On February 28, 2019, Ms. Ricco Jonas filed a Notice of Appeal, invoking the jurisdiction of this Court.

SUMMARY OF THE ARGUMENT

The District Court-approved Report and Recommendation rejected Ms. Ricco Jonas' arguments that: (1) New Hampshire was the real party in interest and Ms. Ricco Jonas, in her official capacity as Program Manager of the PDMP, was not a "person," under 21 U.S.C. § 876 and 1 U.S.C. § 1, against whom an administrative investigatory subpoena could lawfully be issued, served, and enforced, as a matter of statutory construction; and (2) patients have a reasonable expectation of privacy in their PDMP- kept prescription drug data that, under the Fourth Amendment, the DEA cannot obtain absent a court order based on probable cause. Appx. at 29. In doing so, the Court's decision made two fundamental errors:

First, in addressing Ms. Ricco Jonas' statutory construction argument, the District Court improperly treated an administrative investigatory subpoena, issued under 21 U.S.C. § 876, as a discovery subpoena aimed at an *individual*, in order to circumvent Ms. Ricco Jonas' argument (a) that the State of New Hampshire was the real party in interest and (b) that Ms. Ricco Jonas, in her *official* capacity as Program Manager of the PDMP – *i.e.*, as a *State* actor and therefore as the *State* itself – was not a **"person,"** under 21 U.S.C. § 876 and 1 U.S.C. § 1, against whom an administrative investigatory subpoena could lawfully be issued, served, and enforced. Indeed, as discussed *infra*, there exists a "longstanding interpretive presumption that 'person' does not include the sovereign" – here, the State of New Hampshire. *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 780 (2000).

Administrative investigatory subpoenas differ from discovery subpoenas and their "enforcement is dependent upon the interpretation of statutory authority." *E.E.O.C. v. Deer Valley Unified Sch. Dist.*, 968 F.2d 904, 906 (9th Cir. 1992). Thus, "the commencement of an action to enforce an investigatory, administrative subpoena ... is not a 'discovery motion' It is a separate, statutorily authorized proceeding." *Id.* at 907. And an original statutory proceeding to enforce an administrative

investigatory subpoena is a "suit," as that term is commonly understood. Black's Law Dictionary at 1572 (9th ed. 2009) (defining "suit" to mean "any proceeding by a party or parties against another in a court of law").

The State of New Hampshire is also the real party in interest in this suit. It is well settled that a suit aimed at a State official is considered a suit against a State itself "if the judgment sought would . . . <u>interfere with the public administration</u>, or if the effect of the judgment would be to restrain the Government from acting, or <u>to compel</u> <u>it to act</u>." *Muirhead v. Mecham*, 427 F.3d 14, 19 (1st Cir. 2005), *quoting Dugan v. Rank*, 372 U.S. 609, 620 (1963) (emphases added). "When a plaintiff seeks specific performance, the answer to the inquiry about relief hinges on whether the redress obtained against the officer will, in practical effect, be <u>obtained through the sovereign</u>." *Id.* (emphasis added).

In this case, the DEA seeks state-collected information contained in a stateowned, -maintained, and -controlled, privacy-protected database. The effect of the administrative investigatory subpoena, and of the District Court's decision, is to command that Ms. Ricco Jonas, as PDMP Program Manager, access that state database, remove state-collected information therefrom, and provide it to the DEA – a class B felony under state law. *See* RSA 318-B:36, VI. Such a result can only be obtained "through the sovereign," here, the State of New Hampshire. *Muirhead*, 427 F.3d at 19. Such a result also "interferes with the public administration" of the PDMP and New Hampshire's criminal law. *Id.* And such a result "compel[s] [a state official in her official capacity] to act." *Id.* Simply put, the State of New Hampshire is the real party in interest and the true target of the DEA's administrative investigatory subpoena.

But, the State of New Hampshire, including its officials and agencies, is not a "person," under 21 U.S.C. § 876 and 1 U.S.C. § 1, against whom an administrative investigatory subpoena may lawfully be issued, served, and enforced, as a matter of statutory construction. See, e.g., Vt. Agency of Nat. Res., 529 U.S. at 780 (holding that, in interpreting the word "person" in a federal statute, the United States Supreme Court applies the "long-standing interpretive presumption that 'person' does not include the sovereign"). Instead, the text, structure, purpose, legislative history, and executive interpretation of 21 U.S.C. § 801, et seq. [the Controlled Substances Act] point to the States, their agencies, and their officials as cooperative, collaborative partners in the war on drugs, not as "persons" who may be targeted and commanded to comply with administrative investigatory subpoenas. As a result, the administrative investigatory subpoena in this case is not "for a proper purpose authorized by Congress" and thus cannot lawfully be enforced. United States v. Comley, 890 F.2d 539, 541 (1st Cir. 1989).

Second, the District Court failed to recognize that patients have a Fourth Amendment-based reasonable expectation of privacy in their PDMP-kept prescription drug information, so that that the DEA may not seize it absent a court order based on probable cause (e.g., a warrant). The United States Supreme Court's opinion in Carpenter v. United States, ____ U.S. ___, 138 S. Ct. 2206 (2018), discussed infra, supplies the framework for analyzing this issue and requires reversal of the District Court's decision. Specifically, courts have recognized that patients have a reasonable expectation of privacy in their medical and prescription drug records. *Ferguson v. City* of Charleston, 532 U.S. 67 (2001); Douglas v. Dobbs, 419 F.3d 1097 (10th Cir. 2005) (prescription drug records); Doe v. Se. Pa. Transp. Auth., 72 F.3d 1133, 1138 (3d Cir. 1995) (prescription drug records); see also, Eil v. U.S. Drug Enforcement Administration, 878 F.3d 392 (1st Cir. 2017) (medical records). Individuals do not voluntarily provide their prescription drug information to the PDMP; nor do they consent to its mandatory submission by dispensers to the PDMP database. See RSA 318-B:33, III-V. The only way to prevent information on one's private, schedule II-IV prescription drug therapies from entering the PDMP database is to actually forgo treatment. This constellation of circumstances-the pervasive need in modern life to receive medical treatment in the form of prescription drug therapies, the involuntary disclosure of that prescription drug information to the State for the advancement of public health, and the recognition in modern society of the private, sensitive, intimate nature of the content of one's prescription drug records—requires the DEA to obtain a warrant based on probable cause in order to obtain such PDMP-kept patient information. See Carpenter, __ U.S. at __, 138 S. Ct. at 2220. The extra-judicial,

indisputably low threshold of an administrative subpoena cannot suffice to allow this sort of intrusion on the right to privacy. *See United States v. Sturm, Ruger & Co., Inc.,* 84 F.3d 1, 3 (1st Cir. 1996) ("The requirements for enforcement of an administrative subpoena are not onerous.").

THE STANDARD OF REVIEW

"For purposes of standard of review, decisions by judges are traditionally divided into three categories, denominated questions of law (reviewable *de novo*), questions of fact (reviewable for clear error), and matters of discretion (reviewable for 'abuse of discretion")." *Pierce v. Underwood*, 487 U.S. 552, 558 (1988). In this case, the Court is asked to interpret a federal statute and to delimit the contours of the constitutional right to privacy – questions of law that are reviewable *de novo*.

ARGUMENT

"An administrative subpoena is not self-executing and is therefore technically not a 'search." *United States v. Sturm, Ruger & Co., Inc.*, 84 F.3d 1, 3 (1st Cir. 1996). "It is at most a constructive search, amounting to no more than a simple direction to produce documents, subject to judicial review and enforcement." *Id.* "Thus, unlike the subject of an actual search, the subject of an administrative subpoena has an opportunity to challenge the subpoena before yielding the information." *Id.*

In order to enforce an administrative subpoena, "the [proponent] agency must prove that (1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena." *Id.* at 5. "[T]he Fourth Amendment is [also] available to the challenger as a defense against enforcement of the subpoena." *Id.* at 4; *see Carpenter*, _____U.S. ___, 138 S. Ct. at 2221-22 ("[T]his Court has never held that the Government may subpoena third parties for records in which the suspect has a reasonable expectation of privacy.... If the choice to proceed by subpoena provided a categorical limitation on Fourth Amendment protection, no type of record would ever be protected by the warrant requirement.").

In this case, the DEA's administrative investigatory subpoena fails on two fronts. First, it has not been validly issued for a congressionally authorized purpose, as its true target, the State of New Hampshire, is not a "person" against whom the United States Attorney General may enforce an administrative subpoena under 21 U.S.C. § 876 [Controlled Substances Act – Subpoenas]. Second, it violates the Fourth Amendmentbased reasonable expectation of the privacy that the subpoena-specified patient has in his PDMP-kept prescription drug data. The District Court erred in adopting the Magistrate's decision to the contrary. Accordingly, the District Court's judgment must be reversed and the enforcement proceeding dismissed. I. The District Court Erred In Failing To Consider and Conclude that, Under 21 U.S.C. § 876, the States, their Sovereign Agencies and their Officials are *Not* "Persons" To and Against Whom Administrative Investigatory Subpoenas May Lawfully be Issued, Served, and Enforced.

The administrative investigatory subpoena at issue could only be enforced against PDMP Program Manager Ricco Jonas *if*, by enacting 21 U.S.C. § 876 [Controlled Substances Act – Subpoena], Congress *authorized* the U.S. Attorney General and, in turn, its designee, the DEA, to issue, serve and enforce such subpoenas against the States, their sovereign agencies, and their officials acting in their official capacities. *See United States v. Comley*, 890 F.2d 539, 541 (1st Cir. 1989).

The District Court-adopted Report and Recommendation ("R&R") deemed this threshold statutory issue to be "irrelevant." Addendum at 9. The R&R sought to justify this result on the basis that, in a federal court action, an effort to enforce a discovery subpoena against a non-party State custodian of records does not amount to a "suit" against the State for Eleventh Amendment immunity purposes.³ *Id.* That was error. The instant case has nothing to do with a discovery subpoena, under the Federal Rules

³ The Eleventh Amendment to the U.S. Constitution states that "[t]he Judicial power of the United States shall not be construed to extend to any <u>suit</u> in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. CONST. amend. 11 (emphasis added).

of Civil Procedure, against a State custodian of records or with the Eleventh Amendment.

Administrative investigatory subpoenas differ from discovery subpoenas and their "enforcement is dependent upon the interpretation of statutory authority." E.E.O.C. v. Deer Valley Unified Sch. Dist., 968 F.2d 904, 906 (9th Cir. 1992); see, e.g., Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp., 5 F.3d 1508, 1513 (D.C. Cir. 1993) ("Unlike a discovery procedure, an administrative investigation is a proceeding distinct from any litigation that may eventually flow from it."); Fed. R. Civ. P. 45, advisory committee notes ("This rule applies to subpoenas ad testificandum and duces tecum issued by the district courts for attendance at a hearing or a trial, or to take depositions. It does not apply to the enforcement of subpoenas issued by administrative officers and commissions pursuant to statutory authority. The enforcement of such subpoenas by the district courts is regulated by appropriate Thus, "the commencement of an action to enforce an investigatory, statutes."). administrative subpoena ... is not a 'discovery motion' It is a separate, statutorily authorized proceeding." Deer Valley Unified Sch. Dist., 968 F.2d at 907; see, e.g., N.L.R.B. v. Durham School Services, L.P., 2015 WL 150898, at *2 (N.D. Fla. Jan. 12, 2015) (unpublished) (explaining that "an administrative enforcement action" is "an original action, the resolution of which disposes of the entire action"). And an original statutory proceeding to enforce an administrative investigatory subpoena is a "suit" as

that term is commonly understood. Black's Law Dictionary at 1572 (9th ed. 2009) (defining "suit" to mean "any proceeding by a party or parties against another in a court of law").

Additionally, the issue raised in this case is one of statutory interpretation, not Eleventh Amendment immunity. The question is whether Congress intended the word "person" – *i.e.*, one subject to the Attorney General's subpoena power under 21 U.S.C. § 876(c) – to include the States, their agencies, and their officials in their official capacities, a question distinct from an Eleventh Amendment inquiry. *See, e.g., Vt. Agency of Natural Resources*, 529 U.S. at 779-80 ["We . . . have routinely addressed *before* the question whether the Eleventh Amendment forbids a particular statutory cause of action to be asserted against States, the question whether the statute itself *permits* the cause of action it creates to be asserted against States (which it can do only by clearly expressing such an intent.")].

The District Court also erred in accepting the USDOJ-constructed pretense that Ms. Ricco Jonas, in her *personal* capacity, was the actual target of the subpoena.⁴ Addendum at 5-9. It is well-settled that a suit aimed at a state official is considered a suit against a State "if the judgment sought would . . . <u>interfere with the public</u>

⁴ The administrative subpoena is addressed "**TO**: Michelle Ricco Jonas, Program Manager for the NH PDMP." Appx. at 24. But the USDOJ asserted, in furtherance of its Petition to Compel Compliance, that "the DEA subpoena was served on [Ms.] Ricco Jonas individually and does not seek any remedy from the State of New Hampshire." Appx. at 6.

<u>administration</u>, or if the effect of the judgment would be to restrain the Government from acting, or <u>to compel it to act</u>." *Muirhead*, 427 F.3d at 19, *quoting Dugan*, 372 U.S. at 620 (emphases added). "When a plaintiff seeks specific performance, the answer to the inquiry about relief hinges on whether the redress obtained against the officer will, in practical effect, be <u>obtained through the sovereign</u>." *Id*. (emphasis added)

In this case, the DEA seeks state-collected data contained in a state-owned, -maintained, and -controlled, privacy-protected database. The effect of the administrative investigatory subpoena, and of the District Court's enforcement decision, is to command Ms. Ricco Jonas, as PDMP Program Manager, to access that state database via her state-issued credentials, to remove the state-collected data from it, and to provide such data to the DEA without a probable cause-based court order, a RSA 318-B:36, VII.⁵ Compliance with the class B felony under state law. administrative subpoena can only be "obtained through the sovereign" - here, the State Likewise, compliance "interfere[s] with the public of New Hampshire. Id. administration" of the PDMP and the state's criminal law and "compel[s] [a state official in her official capacity] to act." Id. Indeed, Ms. Ricco Jonas cannot produce "from [her] own pocket" the PDMP information the DEA seeks, thus belying the notion

⁵ "Any person who knowingly accesses ... or discloses program information except as authorized in this subdivision ... shall be guilty of a class B felony."

that this enforcement suit is in any sense a personal capacity action. *See Asociacion de Subscripcion Conjunta del Seguro De Responsabilidad Obligatorio v. Flores Galarza*, 484 F.3d 1, 26 (1st Cir. 2007) (explaining that personal capacity suits seek relief "from the officer's own pocket," not from the State itself). Accordingly, the State of New Hampshire is the real party in interest and the true target of the subpoena in this case.

Because this statutory enforcement action is, in actuality, a suit against the State of the New Hampshire, the District Court was required to reach the threshold issue of whether a "person" against whom the U.S. Attorney General may lawfully enforce an administrative subpoena, *see* 21 U.S.C. § 876(c), includes the States, their agencies, and their officials acting in their official capacities. If it does not, then the administrative investigatory subpoena in this case has been issued for a purpose that Congress never authorized and may not be enforced against Program Manager Ricco Jonas.

A. The Text, Structure, Purpose, Legislative History, and Executive Interpretation of 21 U.S.C. § 876 and, More Broadly, the Entirety of the Controlled Substances Act, Reveal that the Word "Person," as Used in 21 U.S.C. § 876(c), Does Not Extend to the States, Their Agencies, Or Their Officials in Their Official Capacities.

Section 876(a) is that provision of the Controlled Substances Act ("CSA") which permits the U.S. Attorney General (or here, his designee, the DEA) to issue administrative subpoenas "[i]n any investigation relating to his functions under this subchapter," including subpoenaing witnesses, compelling the attendance of witnesses, and securing the production of records that "the Attorney General finds relevant or material to the investigation."

Section 876(b) authorizes service of these subpoenas upon "natural persons" or upon "domestic or foreign corporation[s] or upon a partnership or other unincorporated association." The State, its sovereign agencies and its officials are not mentioned in Section 876(b) and no mode of service is specified as to them.

Section 876(c) authorizes enforcement of administrative subpoenas only against

"any person." It provides in full as follows:

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. § 876(c) (emphases added).

While the CSA does not define the term "person," 1 U.S.C. § 1 does supply a definition. It provides that "[i]n determining the meaning of any Act of Congress, unless the context indicates otherwise: ... the words 'person' and 'whoever' include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." This definition does not extend to sovereign

governments and has therefore been construed to exclude them. *See United States v. United Mine Workers of America*, 330 U.S. 258, 275 (1947) ("Congress made express provision, R.S. s 1, 1 U.S.C. s 1, 1 U.S.C.A. s 1, for the term to extend to partnerships and corporations, and in s 13 of the Act itself for it to extend to associations. The absence of any comparable provision extending the term to sovereign governments implies that Congress did not desire the term to extend to them.").

Thus, there is established in the jurisprudence of the United States Supreme Court a "longstanding interpretive presumption" that the word "person," as used in a federal statute, "does not include the sovereign." Vt. Agency of Nat. Res., 529 U.S. at 780-81. "Particularly is this true where [as here] the statute imposes a burden or limitation, as distinguished from conferring a benefit or advantage." Wilson v. Omaha Tribe, 442 U.S. 653, 667 (1979) (emphasis added). The United States Supreme Court "has been especially reluctant to read [the term] 'person' to mean the sovereign where ... such a reading is 'decidedly awkward."" Int'l Primate Protection League v. Administrators of Tulane Ed. Fund, 500 U.S. 72, 83 (1991), quoting Will v. Michigan Dept. of State Police, 491 U.S. 58, 64 (1989). The presumption "may be disregarded only upon some affirmative showing of statutory intent to the contrary." Vt. Agency of Nat. Res., 529 U.S. at 781. That is because, ordinarily, "when Congress decides to include states within the term 'person,' Congress does so explicitly and clearly." Cashman v. Dolce International/Hartford, Inc., 225 F.R.D. 73, 81 (D. Conn. 2004).

Additionally, while the CSA does not define the term "person," it expressly defines the term "State." 21 U.S.C. § 802(26). The CSA then uses the terms "person" and "State" throughout its statutory text differently, including within statutory sections, and without any indication that the definitions overlap. *See, e.g.*, 21 U.S.C. § 873 (requiring the U.S. Attorney General to "cooperate" with "State ... agencies concerning traffic in controlled substances" and delineating the ways in which he may so cooperate); 21 U.S.C. § 878 (authorizing "[a]ny officer or employee of ... any State designated by the Attorney General" to perform certain official functions like serving search warrants, subpoenas, and making seizures of property); 21 U.S.C. § 882(c) (authorizing a "State" to bring certain actions against "a person, entity, or Internet site" that violates specific statutory provisions).

Thus, the text of 21 U.S.C. § 876, and the statutory definitions that apply to that provision, reveal that the word "person" contained in 21 U.S.C. § 876(c) does not include the State, its agencies, or its officials in their official capacities. Rather, construing the term "person" under 21 U.S.C. § 876(c) to *include* the State of New Hampshire, its sovereign agencies, and its officials acting in their official capacities makes little sense in the context of the statute and is "decidedly awkward." *Int'l Primate Protection League*, 500 U.S. at 83.

Specifically, Section 876(b) specifies how service of process of subpoenas under the statute may occur. For natural persons, service "may be made by personal delivery of the subpoena to him." For artificial, corporate persons, service may be made "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." Section 876(b) makes no allowance for the service of subpoenas on sovereign entities, such as the States or the United States and their respective agencies or officials. To read into the statute a separate authorization for service of process on those sovereign entities would re-write the statute to enable the DEA to do something Congress did not authorize it do in the first place.

Moreover, Section 876(c) states that, in enforcing the subpoena, 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." States are not inhabitants, they do not "carry on business" as that phrase is traditionally used, and they are not "found" within a jurisdiction. Moreover, the use of the pronoun "he" to refer to the term "person" casts doubt on including the States and their sovereign agencies and officials in the definition." *Id.* at 80 (explaining that it "ma[de] little sense" to read a statute as referencing an agency rather than an individual as the antecedent to the pronoun "him"). Thus, it is "decidedly awkward," if not contrary to the plain text of 21 U.S.C. § 876, to read the term "person" in 21

U.S.C. § 876(c) to include sovereign entities like the States, their agencies, or their officials acting in their official capacities.

1. The Structure and Purpose of the CSA Support This Conclusion.

A review of other provisions of the CSA reflects a statutory structure and purpose to exclude the States, their agencies, and their officials acting in their official capacities from the meaning of the word "person," as used in 21 U.S.C. § 876 and throughout the Act. *See Andrews v. United States*, 441 F.3d 220 (4th Cir. 2006) ("Under the *in pari materia* canon, neighboring statutory subsections that refer to the same subject matter 'must be read ... as if they were a single statute."") (citation omitted).

Specifically, the CSA identifies "persons" who are required to register with the U.S. Attorney General. 21 U.S.C. § 822. They include persons who manufacture, distribute, or dispense controlled substances. 21 U.S.C. § 822(a). The statutory section specifically exempts certain "persons" from registration, such as an agent or employee of a registered manufacturer, distributor, or dispenser, a common or contract carrier or warehouse man, and an ultimate user who possess the controlled substance under certain circumstances. 21 U.S.C. § 822(c). The States, their agencies and their officials are not mentioned in this section, either as regulated "persons" or as "persons" exempt from regulation. This statutory text and structure provides substantial context as to the

types of "persons" who are the proper subjects of administrative investigatory subpoenas under 21 U.S.C. § 876.

21 U.S.C. § 873, which appears in the same subchapter as 21 U.S.C. § 876, contemplates "cooperative arrangements" with the States, their sovereign agencies and their officials, not relationships where records will be seized via administrative investigatory subpoena. In fact, the statute expressly commands the U.S. Attorney General to "cooperate with ... State ... agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances." 21 U.S.C. § 873(a). In furtherance of this cooperation, the statute authorizes the U.S. Attorney General to do certain things, like: "arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances," 21 U.S.C. § 873(a)(1); "cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing board and courts of the several States," 21 U.S.C. § 873(a)(2); "assist State ... governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by ... establishing cooperative investigative efforts to control diversion," 21 U.S.C. § 873(a)(6)(C); and "enter into contractual agreements with State ... and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this chapter." 21 U.S.C. § 873(a)(7).

These provisions would, in significant part, be rendered meaningless if the U.S. Attorney General, through the DEA, could coerce the State, its sovereign agencies and its officials into action via administrative investigatory subpoena. Consequently, 21 U.S.C. § 873(a)(6)'s cooperative provisions properly govern how the DEA should interact with the State and its agencies with respect to investigations (*i.e.*, through "cooperative" arrangements and investigative efforts) and belie the notion that the DEA can use an administrative investigatory subpoena under 21 U.S.C. § 876 to seize the records of one of its sovereign partners. These statutory provisions also reveal the CSA to be a statute based on cooperative federalism principles, not a statute under which the federal government may commandeer state officials, force them to remove state records, and deliver them to the federal government, in violation of state law.

The CSA also recognizes "State boards of pharmacy," like the New Hampshire Pharmacy Board, which operates, maintains and controls the New Hampshire PDMP, as entities that should receive certain notifications that the U.S. Attorney General receives under 21 U.S.C. § 831(d), and makes no mention of the term being synonymous with the term "person" as used in the CSA generally.

Moreover, in addition to 21 U.S.C. § 873, other CSA provisions acknowledge cooperative federalism principles that seek to preserve State sovereignty and autonomy to the greatest extent possible. For example, 21 U.S.C. § 882(c)(3) makes clear that the United States will not intrude on the sovereign rights of the States to conduct their own investigations and prosecute drug offenses. In the same vein, 21 U.S.C. § 903 specifies a very narrow standard for when the CSA will preempt State law: "No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together." This limited preemption standard is purposefully respectful of State sovereignty and autonomy, disclaims field preemption, and recognizes the States, their agencies and their officials as partners in an ongoing national effort to combat abuse and diversion of controlled substances.⁶

2. The Legislative History and Executive Interpretation of the CSA Support this Conclusion.

The legislative history and executive interpretation also confirm that the CSA has always envisioned the States as <u>partners</u> in the national effort to combat abuse and diversion of controlled substances, not as adversaries whose sovereign interests can be infringed by administrative investigatory subpoena. Specifically, when passing the Comprehensive Drug Abuse Prevention and Control Act of 1970, Title II of which is

⁶ Indeed, New Hampshire, like other States, has enacted an extensive array of statutes in the area of controlled drugs in reliance on this special relationship. *See* RSA 318-B:1, *et seq.* [Controlled Drug Act].

the CSA, the House Report described Title II of the Act's Administration provisions as

follows:

THE BILL SPECIFIES A NUMBER OF ADMINISTRATIVE AUTHORITIES FOR THE ATTORNEY GENERAL, AUTHORIZING RESEARCH AND EDUCATION PROGRAMS RELATING TO LAW ENFORCEMENT ASPECTS OF DRUG ABUSE, COOPERATION WITH STATE AND LOCAL LAW ENFORCEMENT AUTHORITIES, INSPECTIONS, ADMINISTRATIVE FORFEITURES, AND EXECUTION OF SEARCH WARRANTS, INCLUDING AUTHORITY PREMISES TO ENTER WITHOUT GIVING NOTICE OF AUTHORITY AND PURPOSE IF A JUDGE OR U.S. MAGISTRATE HAS AUTHORIZED SUCH ENTRY IN THE WARRANT AFTER DETERMINING THAT THERE IS PROBABLE CAUSE TO BELIEVE THAT—

(1) PROPERTY SOUGHT MAY AND, IF NOTICE IS GIVEN, WILL BE EASILY AND QUICKLY DESTROYED OR DISPOSED OF, OR

(2) THE GIVING OF SUCH NOTICE WILL IMMEDIATELY ENDANGER THE LIFE OR SAFETY OF THE EXECUTING OFFICER OR ANOTHER PERSON.

H.R. Rep. 91-1444 (upper case in original; emphasis added).

"In 1973, President Richard Nixon declared 'an all-out global war on the drug

menace' and sent Reorganization Plan No. 2 to Congress."⁷ Reorganization Plan No.

2 of 1973 established the DEA.⁸ The Message of the President associated with the

⁷ Drug Enforcement Administration, History, The DEA Years, 1970-1975, <u>https://www.dea.gov/sites/default/files/2018-07/1970-1975%20p%2030-39.pdf</u> (last visited Aug. 22, 2018).

⁸ U.S.C.A. REORG. PLAN 2 1973 <u>https://www.gpo.gov/fdsys/pkg/USCODE-2010-title5/pdf/USCODE-2010-title5-app-reorganiz-other-dup96.pdf</u> (last visited Aug. 22, 2018).

Reorganization Plan No. 2 of 1973 explains that one of the "major responsibilities" of the DEA will include "full coordination and cooperation with State and local law enforcement officials on joint drug enforcement efforts."⁹

Thus, the text, structure, context, subject matter, legislative history, and executive interpretation of the CSA all confirm that the federal government and the States are intended to be cooperative partners in the struggle against the abuse and diversion of controlled substances. The collaboration envisioned by Congress bears no resemblance to the instant USDOJ effort to seize the records of its sovereign State agency partners via administrative investigatory subpoena. That is to say, the "longstanding" and well-settled presumption that "any person" under § 876(c) excludes States, their sovereign agencies, and their officials acting in their official capacities is consistent with the text, the plain meaning, and the clearly manifested intent of the CSA. Accordingly, the "longstanding interpretive presumption" is not overcome, Ms. Ricco Jonas, in her official capacity as PDMP Program Manager, is not a "person" within the meaning of 21 U.S.C. § 876, the DEA's administrative investigatory subpoena is invalid, and the USDOJ's Petition to Compel Compliance should properly have been dismissed. The District Court erred in failing to reach this conclusion.

3. Case Law in Other Jurisdictions Supports This Conclusion.

The following case law, albeit arising under other statutes, illustrates the analysis the District Court should not have avoided, but rather adopted. In *Al Fayed v. Central Intelligence Agency*, 229 F. 3d 272, 273 (D.C. Cir. 2000), Mohamed Al Fayed presented a request to a federal district court, under 28 U.S.C. § 1782 [Assistance to Foreign and International Tribunals], that it issue and enforce a subpoena to the Central Intelligence Agency for documents related to the automobile accident involving his son and Princess Diana. "Section 1782 provides for discovery [targeting **"persons"**] in federal courts at the behest of foreign and international tribunals." *Id.* at 273. The district court issued the subpoena, Al Fayed moved to compel compliance with it, and the CIA moved to quash it, stating that the federal agency was not a "person" from whom discovery could be sought under Section 1782. *Id.*

Applying the "longstanding interpretive presumption" that the term "person" does not include the sovereign, the district court agreed and declined to enforce the subpoena. *Id.* The United States Court of Appeals for the District of Columbia Circuit affirmed the district court's judgment on the same grounds. *Id.* at 274-77. In holding that the term "person" in Section 1782 did not apply to the CIA, neither the district court suggested that if only the subpoena had named the CIA's

director, or another credentialed employee with access to documents, then the subpoena

could have been enforced under Section 1782.

To the contrary, in applying Al Fayed, the United States Court of Appeals for

the District of Columbia Circuit has found that process directed at a United States

government official to compel him to take action is no different than process against

the sovereign itself:

ORDERED that the motion for summary affirmance be granted. The merits of the parties' positions are so clear as to warrant summary action. *See Taxpayers Watchdog, Inc. v. Stanley,* 819 F.2d 294, 297 (D.C.Cir.1987) (per curiam); *Walker v. Washington,* 627 F.2d 541, 545 (D.C. Cir. 1980) (per curiam), *cert. denied,* 449 U.S. 994 (1980). A complaint seeking to compel action by a federal official in his or her official capacity is actually a complaint against the United States. *Dugan v. Rank,* 372 U.S. 609, 620 (1963)); *Larson v. Domestic and Foreign Commerce Corp.,* 337 U.S. 682, 688 (1949). Therefore, the district court properly quashed the subpoenas in dispute here because the United States is not a "person" under 5 U.S.C. § 1782. *See Al Fayed v. Central Intelligence Agency,* 229 F.3d 272, 276-77 (D.C.Cir.2000).

De Gortari v. U.S. Dept. of Treasury, 2001 WL 476187, at *1 (D.C. Cir. April 30,

2001) (unpublished); see, e.g., In re Gushlak, 2011 WL 3651268, at *7-9 (E.D.N.Y.

Aug. 17, 2011) (unpublished) (applying the "longstanding interpretive presumption" and denying a Section 1782 application for subpoena directed to a federal prison warden, as it was "effectively an application directed at the United States government"); *McKevitt v. Mueller*, 689 F. Supp. 2d 661, 668 n. 1 (S.D.N.Y. 2010) (explaining in action naming FBI Director Robert Mueller, III, "[t]he Government is

not a 'person' under § 1782 and therefore cannot be compelled to provide documents for use in foreign litigation" and citing *Al Fayed* favorably).

The District Court-adopted R&R's effort to distinguish *Al Fayed, see* Addendum at 9-10 n. 4, is not persuasive and points only to the unmistakable irony of the USDOJ asserting the "longstanding interpretive presumption" when *resisting* a subpoena on behalf of a *federal* agency, yet downplaying that same presumption when *advancing* a subpoena against a *state* agency.¹⁰ That the shoe is now on the other foot does not amount to a meaningful distinction.

In a more recent case, *Robinson v. United States Dept. of Ed.*, 917 F.3d 799, 802-05 (4th Cir. 2019), the plaintiff alleged that the federal agency defendant violated the Fair Credit Reporting Act. The Fourth Circuit had to decide whether the term "person" in §§ 1681n and 16810 of the Act included the federal government. Applying the "longstanding interpretive presumption" that the term "person" excludes sovereigns, the Fourth Circuit held that the federal government did not constitute a "person" under

¹⁰ The District Court-adopted R&R recites that "*Al Fayed* ... involved a federal discovery subpoena served on a federal agency in private litigation, not, as here, an administrative subpoena served by a federal agency on a state-agency record custodian." Addendum at 9-10 n. 4. This "distinction" ignores established United States Supreme Court precedent extending the "longstanding interpretive presumption" to the States and is not material to whether Congress intended the word "person" in 21 U.S.C. § 876(c) to include the States, their sovereign agencies, and their officials acting in their official capacities.

these sections of the Act. The Fourth Circuit reviewed the text and structure of the Act in making its determination.

In the instant case, as in *Al Fayed* and *Robinson*, there is nothing in the text, structure, context, legislative history, or executive interpretation of the authorizing legislation – here, the CSA – that would counsel <u>against</u> application of the definition contained in 1 U.S.C. § 1 and the general presumption that the term "person" does not include sovereigns. Rather, there are numerous indications in the text, structure, purpose, legislative history, and executive interpretation of the CSA *confirming* that Congress did not intend the term "any person" in 21 U.S.C. § 876(c) to include the States, their sovereign agencies, and their officers in their official capacities.

Accordingly, the U.S. Attorney General and, in turn, his designee, the DEA, had no authority to issue and enforce an administrative investigatory subpoena under the CSA.

 II. Even If 21 U.S.C. § 876(c) Authorized Enforcement of Administrative Subpoenas Against the State, its Sovereign Agencies, and Its Officials, the USDOJ Cannot Overcome the Prohibition Against Their Use to Seize Information – Including Patient-Specific and Frequently Diagnosis- Suggestive Prescription Drug Data – in Which There is a Reasonable Expectation of Privacy.

If the CSA's collaborative scheme were found to contemplate administrative subpoenas visited upon the DEA's State sovereign agency partners, then this Court's analysis must turn to the Fourth Amendment to determine whether patients have a reasonable expectation of privacy in the content of their drug prescriptions, so that they must not be disclosed without court review and a finding of probable cause. The government may use an administrative subpoena to seize records *only if* its target lacks a reasonable expectation of privacy in their content. *In re Gimbel*, 77 F.3d 593, 599 (2d Cir. 1996) (the Fourth Amendment does not permit the use of an administrative subpoena where the "respondent maintains a reasonable expectation of privacy in the materials sought by the subpoena."); *Shea v. Office of Thrift Supervision*, 934 F.2d 41, 45 (3d Cir. 1990).

In *Ferguson v. City of Charleston*, 532 U.S. 67 (2001), the Supreme Court held that patients have a reasonable expectation of privacy in their medical records. The Court held that "[t]he reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with nonmedical personnel without their consent." *Id.* at 78. The Court went on to note that "an intrusion on that expectation may have adverse consequences because it may deter patients from receiving medical care." *Id.* at 78 n. 13, *citing Whalen v. Roe*, 429 U.S. 589, 599-60 (1977).

Courts across the country have recognized a reasonable expectation of privacy in all manner of medical records. The Fourth Circuit has stated that "medical treatment records contain intimate and private details that people do not wish to have disclosed, expect will remain private, and, as a result, believe are entitled to some measure of protection from unfettered access by government officials." *Doe v. Broderick*, 225 F.3d 440, 451 (4th Cir. 2000). The Ninth Circuit has stated that "all provision of medical services in private physicians' offices carries with it a high expectation of privacy for both physician and patient." *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 550 (9th Cir. 2004); *see also*, *Herring v. Keenan*, 218 F.3d 1171, 1173 (10th Cir. 2000) ("We conclude that there is a constitutional right to privacy that protects an individual from the disclosure of information concerning a person's health."). Notably, the First Circuit has stated that "patients have significant privacy interests in their medical records, which we have described as 'highly personal' and 'intimate in nature." *Eil v. U.S. Drug Enforcement Administration*, 878 F.3d 392 (1st Cir. 2017), *quoting Kurzon v. Dept. of Health & Human Servs.*, 649 F.2d 65, 68 (1st Cir. 1981).

As medical records include information on patients' prescribed drug therapies, courts have specifically recognized a reasonable expectation of privacy in prescription drug records. In *Douglas v. Dobbs*, 419 F.3d 1097 (10th Cir. 2005), the Tenth Circuit stated that patients "ha[ve] a constitutional right to privacy in [their] prescription drug records," explaining:

[P]rotection of a right to privacy in a person's prescription records, which contain intimate facts of a personal nature, is sufficiently similar to other areas protected within the ambit of privacy. Information contained in prescription records ... may reveal other facts about what illnesses a person has....

Id. at 1102 (emphasis added); *see also*, *State of Louisiana v. Skinner*, 10 So.3d 1212 (La. 2009) ("... we find that the right to privacy in one's medical and prescription

records is an expectation of privacy that society is prepared to recognize as reasonable[,] [so that] *** a warrant is required to conduct an investigatory search of medical and/or prescription records.").

The highlighted point raised in *Douglas* – that prescription drug records are frequently suggestive of patients' underlying medical diagnoses – is particularly noteworthy. As the Third Circuit explained:

It is now possible from looking at an individual's prescription records to determine that person's illnesses.... This is precisely the sort intended to be protected by penumbras of privacy. An individual using prescription drugs has a right to expect that such information will customarily remain private.

Doe v. Se. Pa. Transp. Auth., 72 F.3d 1133, 1138 (3rd Cir. 1995). This is certainly so with the schedule II-IV controlled substance data kept by the PDMP, including, by way of example, Xanax (alprazolam) (anxiety, panic disorders), Valium (diazepam) (anxiety disorders), Ritalin (ADHD), Testosterone (delayed puberty, impotence or other hormonal imbalances), and Marinol (dronabinol) (AIDS weight loss or chemotherapy induced nausea). Appx. at 77; *see also*, <u>www.pdr.net</u>; <u>www.drugs.com</u>.

In Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Agency, 998 F. Supp.2d 957, 966 (D. Or. 2014), reversed on other grounds, 860 F.3d 1228 (9th Cir. 2016) ("Oregon PDMP"), the only published decision addressing an effort by the DEA, via administrative subpoena, to obtain PDMP-kept, patient-identifiable and diagnosis-suggestive prescription drug data, the District of Oregon pointed to the abundance of Supreme and Circuit Court case law recognizing a reasonable expectation of privacy in medical records, including prescription drug records, and so "conclude[d] that the DEA's use of administrative subpoenas to obtain prescription drug records from [Oregon's] PDMP violate[d] the Fourth Amendment." *Id.* at 967.¹¹

It is worthy of note that the DEA contended in *Oregon PDMP*, just as the District Court-adopted R&R declares, that any such reasonable expectation of privacy was undermined by the "third party doctrine," which suggests that one cannot have an expectation of privacy in information, intimate or not, that is shared with a third party. *See id.*; Addendum at 17. The District of Oregon rejected that contention because, as in the instant case, "[t]he submission of prescription information to the PDMP is required by law ... and [t]he only way to avoid [it] is to forgo medical treatment or to leave the state." *Oregon PDMP*, 998 F. Supp. 2d at 967. Since this was not a "meaningful choice," *Oregon PDMP* declared that PDMP-kept prescription drug data was *not* actually "shared" (an intrinsically *voluntary* act) within the meaning of the "third party doctrine." *Id*.

While duly briefed by Program Manager Ricco Jonas, the District Court-adopted R&R did not meaningfully discuss the holding in *Oregon PDMP* and, instead,

¹¹ The District Court reached this issue because the question of whether the Attorney General's subpoena power under 21 U.S.C. § 876 extended to the DEA's sovereign State agency partners was not raised.

suggested that "the only case to address the issue" concluded that there exists no reasonable expectation of privacy in patients' PDMP-kept prescription drug data. Addendum at 16-18 (emphasis added). That case was United States Dept. of Justice v. Utah Dept. of Commerce, 2017 WL 3189868 (D. Utah July 27, 2017) ("Utah PDMP"), an unpublished opinion that put aside the Supreme and Circuit Court authorities that recognize patients' reasonable expectation of privacy in their intimate medical and prescription drug records and *adopted* the DEA's argument, rejected in Oregon PDMP, that the so-called "third party doctrine" extinguished any reasonable expectation of privacy in PDMP-kept prescription drug records. According to Utah PDMP, "a patient takes the risk – in this circumstance, a certainty – that his or her information will be conveyed to the government as required by [the Utah PDMP legislation]. Utah PDMP, 2017 WL 3189868, at *8. That very same reasoning, deemed by the R&R to be "persuasive," Addendum at 16, was squarely rejected by the United States Supreme Court in *Carpenter v. United States*, ____ U.S. ___, 138 S. Ct. 2206 (2018).

Carpenter concerned the time-stamped Cell Site Location Information ("CSLI") that is transmitted by customers to third party wireless carriers – that is, by moving about with their cell phones – and whether individuals, including crime suspects like Mr. Carpenter, have a reasonable expectation of privacy therein. Pointing to the "third party doctrine," the Sixth Circuit held that Mr. Carpenter had no reasonable expectation

of privacy in the time-stamped location data obtained by the FBI because he shared

that information with his wireless carrier. The Supreme Court reversed, stating that

Cell phone location [read: PDMP-kept prescription drug] information is not truly 'shared' as one normally understands the term. *** [C]ell phones [read: health care] and the services they provide are 'such a pervasive and insistent part of daily life' that carrying one [read: obtaining health care and drug treatment therapies] is indispensable to participation in modern society. *** Apart from disconnecting the phone from the network [read: forgoing health care and drug treatment therapies], there is no way to avoid leaving behind a trail of location [read: prescription drug] data. As a result, in no meaningful sense does the user [or patient] voluntarily assume[] the risk of turning over a comprehensive dossier of his physical movements [read: prescription drug data].

Id. at 2220. Carpenter therefore rejects Utah PDMP and endorses Oregon PDMP.

This Court recognized as much in its recently-issued decision in United States v. Hood,

920 F.3d 87 (1st Cir. 2019), which distinguished Carpenter because the defendant's IP

address was provided voluntarily to Kik, a mobile messaging application; unlike

PDMP-kept data and CSLI, defendant Hood's IP address was not involuntarily shared.

In the instant case, the District Court put aside patients' Fourth Amendment reasonable

expectation of privacy in their intimate medical information and approved the DEA's

use of an extra-judicial administrative investigatory subpoena – on the strength of Utah PDMP – which is contrary to the law of the land, as laid out in *Carpenter*.¹²

III. Standing

The District Court-adopted R&R noted the USDOJ's fleeting assertion, set forth in a Reply Memorandum, Appx. at 87-88, that PDMP Program Manager Ricco Jonas does not have standing to raise and assert Fourth Amendment privacy interests, while pointing out that "[t]he standing issue is not dispositive," Addendum at 14, and concluding that it would reach the substantive issue without determining Ricco Jonas' standing. To the extent the USDOJ raises that challenge in this appeal, Ms. Ricco Jonas has standing to make the foregoing arguments.

As Program Manager for the New Hampshire PDMP, Ms. Ricco Jonas has standing to assert such privacy rights as this State's residents may have in their PDMPkept prescription drug information. The *parens patriae* doctrine establishes an exception to the customary rules of standing – that is, "in recognition of the special role

¹² The R&R also repeated that portion of *Utah PDMP* which suggested that pharmaceuticals, like "mining, firearms and liquor," are so "pervasively regulated" that everybody expects "the prescription and use of controlled substances [to] happen under the watchful eye of the federal government." *Utah Dept of Commerce*, 2017 WL 3189868, at *8; Addendum at 16-17. But the delivery of health care services is in no way akin to "mining, firearms and liquor," and the reasonable privacy expectations of patients in their intimate medical or prescription drug records are in no way diminished by government oversight of the health care industry. *See Tucson Woman's Clinic*, 379 F.3d at 550-51; *Margaret S. v. Edwards*, 488 F. Supp. 181, 215-17 (E.D. La. 1980).

that a State plays in pursuing its quasi-sovereign interests," *Estados Unidos Mexicanos v. Austin J. DeCoster Co.*, 229 F.3d 332, 335 (1st Cir. 2000), which include "the health and well-being – both physical and economic – of [a substantial segment of] its residents." *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 600 (1982). That the New Hampshire PDMP is a measure aimed at safeguarding and advancing the "health and well-being" of a "substantial segment" of this State's residents is beyond dispute.¹³ Appx. at 77.

But according to the USDOJ,

[t]he Supreme Court has long rejected the argument that the State can assert the constitutional rights of its citizens against the United States. *Massachusetts v. Mellon*, 262 U.S. 447, 485-86 (1923).

Appx. at 87. The USDOJ misconstrues Mellon. Indeed, "it is a mischaracterization of

Mellon ... to speak of a 'prohibition' without further qualification." Aziz v. Trump,

The general court believes that a controlled drug prescription health and safety program that fully complies with all state and federal Health Insurance Portability and Accountability Act (HIPAA) privacy and security laws and regulations should be established as a tool to improve medical treatment. *** [It] will reduce patient morbidity and mortality associated with controlled drugs by providing a secure program through which the prescriber and dispenser may access information on a patient's controlled drug prescription history.

NH RSA 318-B:31-41.

¹³ The legislation establishing the New Hampshire PDMP includes a "Statement of Intent," which states, in part:

231 F. Supp.3d 23, 30 (D.C. Cir. 2017). As the Supreme Court noted some eighty years later in *Massachusetts v. EPA*, 549 U.S. 497, 520 n. 17 (2007), "*Mellon* itself disavowed any such broad reading[.]"

As discussed in *Aziz*, and as observed in *Mellon*, the "rationale for barring *parens patriae* challenges to federal statutes has less force when 'ministerial,' or executive, action [– in the instant case, the exercise of DEA administrative subpoena power in a manner that offends the Fourth Amendment –] is challenged." *Aziz*, 231 F. Supp.3d at 31, *citing Mellon*, 262 U.S. at 488. "In such situations, a court is on more familiar terrain, determining whether the executive branch has lawfully discharged the authority allocated to it, rather than opining on more delicate questions of federal supremacy." *Id.* Thus, where, as here, the State "raises a constitutional challenge to an executive act, ... argu[ing] that the executive's action is contrary to other, superior federal law[,]" like the Fourth Amendment, *Mellon* does not stand in the way. *Id.*

Moreover, the State of New Hampshire, which is the real party in interest in this case, has *independent* standing because the administrative investigatory subpoena invades a sovereign interest and purports to preempt a valid state-law imposed restriction on law enforcement's ability to access PDMP data, including a statute making the disclosure the DEA seeks a state crime. *See Wyoming, ex rel. Crank v. United States*, 539 F.3d 1236, 1242 (10th Cir. 2008) (explaining that "[f]ederal regulatory action that preempts state law creates a sufficient injury-in-fact" to give a

State standing), *citing Alaska v. U.S. Dep't of Transp.*, 868 F.2d 441, 443 (D.C. Cir. 1989) and *Ohio ex rel. Celebrezze v. U.S. Dep't of Transp.*, 766 F.2d 228, 232-33 (6th Cir. 1985).

CONCLUSION

The District Court-adopted R&R would, if affirmed, grant the DEA carte blanche to mine patients' PDMP-kept prescription drug and diagnosis-suggestive data. It would do so (a) by ignoring, as "irrelevant," the U.S. Attorney General's lack of authority, under 21 U.S.C. § 876, to seize the records of its State partners via administrative investigatory subpoena, and (b) by likewise paying no heed to the reasonable expectation of privacy that persons have in the documentation of their health diagnoses and drug therapies – that is, on the strength of a "third party doctrine" that, under *Carpenter*, cannot apply to the involuntary "sharing" of patient-specific prescription drug information. The District Court-adopted R&R would do so, despite the known and judicially recognized risk that patients will thereby forgo health care and that a database aimed at "improv[ing] medical treatment *** [and] reduc[ing] patient morbidity and mortality" will be undermined. RSA 318-B:31-41 [Controlled Drug Prescription Health and Safety Program—Statement of Intent].

This Court should reverse the District Court-adopted R&R and dismiss the DEA enforcement petition.

Respectfully submitted,

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Date: May 22, 2019

<u>Certificate of Compliance with Type-Volume</u> <u>Limitation and Typeface Requirement</u>

I hereby certify that the foregoing Brief complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B)(i) [no more than 13,000 words] and the typeface requirement of Fed. R. App. P. 32(a)(5)(A) [proportionally spaced face 14-point or larger]. The Brief, containing 10,955 words, exclusive of those items that, under Fed. R. App. P. 32(f) and Local Rule 34.0, are excluded from the word count, was prepared in proportionally spaced Times New Roman 14-point type.

Date: May 22, 2019

/s/ Anthony J. Galdieri Anthony J. Galdieri

Entry ID: 6255836

Certificate of Service

I hereby certify that copies of the foregoing Brief, with Addendum, and the accompanying Appendix were served on all counsel of record, this 22nd day of May, 2016, via the CM/ECF system:

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ADDENDUM

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

<u>United States</u> Department of Justice

v.

Case No. 18-mc-56-LM

Michelle Ricco Jonas

REPORT AND RECOMMENDATION

Before the court is the United States Department of Justice's (DOJ) petition to compel compliance with an administrative subpoena the United States Drug Enforcement Agency (DEA) issued to Michelle Ricco Jonas, manager of the New Hampshire Prescription Drug Monitoring Program (PDMP). Doc. no. 1. The district judge ordered Jonas to show cause why she should not be compelled to obey the subpoena and produce certain PDMP records. The judge referred the matter to the undersigned magistrate judge for a recommended disposition. Doc. no. 3. <u>See</u> 28 U.S.C. § 636(b)(1)(B); LR 72.1. After reviewing the parties' submissions and hearing their arguments, the court recommends that the district judge grant the petition.

I. Legal Standard

"The requirements for enforcement of an administrative subpoena are not onerous." <u>United States v. Sturm Ruger & Co</u>, 84 F.3d 1, 4 (1st Cir. 1996). The court will enforce the subpoena if the agency proves that: (1) the subpoena is issued for a congressionally authorized purpose, the information sought

is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena. <u>Id.</u> "As long as the agency satisfies these modest requirements, the subpoena is per se reasonable and Fourth Amendment concerns are deemed satisfied." <u>Id.</u> (citing <u>Oklahoma Press Pub. Co. v. Walling</u>, 327 U.S. 186, 208 (1946)). "The role of a court in a subpoena enforcement proceeding is strictly limited to inquiring whether the above requirements have been met. 'Such proceedings are designed to be summary in nature.'" <u>United States v. Comley</u>, 890 F.2d 539, 541 (1st Cir. 1989) (quoting <u>EEOC v. Tempel Steel Co.</u>, 814 F.2d 482, 485 (7th Cir. 1987)). "[A]ffidavits of government officials have been accepted as sufficient to make out a prima facie showing that these requirements are satisfied." Id.

II. Background¹

Pursuant to the Controlled Substances Act (CSA), the Attorney General is authorized to issue administrative subpoenas to investigate suspected criminal drug activity. 21 U.S.C. § 876(a). The Attorney General has delegated that authority to the DEA. 28 C.F.R. § 0.100. The subpoena power extends to "requir[ing] the production of any records (including books, papers, documents, and other tangible things which constitute or

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¹ The facts are drawn from the parties' filings. They are undisputed unless indicated otherwise.

contain evidence) which the Attorney General finds relevant or material to" any investigation being conducted pursuant to the CSA. 21 U.S.C. § 876(a). The CSA permits subpoenas to be served on natural persons by personal delivery. <u>Id.</u> § 876(b). The CSA further provides that "[i]n the case of contumacy by or refusal to obey a subp[o]ena issued to any person," the federal court has jurisdiction to compel compliance. Id. § 876(c).

The New Hampshire Board of Pharmacy operates the PDMP. N.H. Rev. Stat. Ann. § 318-B:33, I. All "prescribers and dispensers" of certain controlled substances are required to submit information to the PDMP database, including the patient's name and address and the type, quantity and refill regimen of the prescribed substance. <u>Id.</u> § 318-B:33, IV (a)-(o). Information the PDMP gathers is confidential and can be released for research and educational purposes if the data is "deidentified." <u>Id.</u> § 318-B:34. As particularly relevant here, the PDMP can release information to "authorized law enforcement officials . . . for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause." Id. § 318-B:35, I(a)(3).

On June 13, 2018, the DEA served a subpoena on Ricco Jonas which requested all PDMP records pertaining to a particular individual dating back to February 2016.² Subpoena, doc. no. 1-

² The DEA first served the subpoena naming PDMP. The New Hampshire Attorney General objected on the ground that the PDMP

3. Ricco Jonas, represented by the New Hampshire Attorney General, objected to providing the requested information. Galdieri Ltr., doc. no. 1-2. The instant petition followed.

III. Analysis

Ricco Jonas claims that the petition "is nothing more than an attempt to circumvent federal law," Def. Obj., doc. no. 7, at 3, and asserts several grounds for denial. The court addresses them in turn.

A. Threshold burden

Ricco Jonas first argues that the DOJ has failed to meet its burden of showing that its investigation has a legitimate authorized purpose. <u>Id.</u> DEA Investigator Stern's declaration doc. no. 8-1, persuades the court that DOJ has met these "modest requirements."³ <u>Sturm Ruger & Co</u>, 84 F.3d at 4. She states that the New Hampshire Board of Pharmacy provided her with information "regarding the potential diversion of large amounts of opiates through pharmacies" in New Hampshire. <u>Id.</u> ¶ 2.

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was not a "person" within the meaning of the CSA. Without conceding the point, the DEA nevertheless subsequently served the subpoena naming Ricco Jonas.

³ The DOJ asserts that it appended Stern's declaration to its reply memorandum, rather than its original petition, because Ricco Jonas raised this threshold argument for the first time in her objection to the Petition, rather than in the letter announcing her refusal to comply with the subpoena. Reply. Mem., doc no. 8, at 2 n.1. The court takes no issue with the timing of the submission.

Investigator Stern stated further that "an individual [was] reported to be filling fraudulent prescriptions for . . . control[led] substances which he receives from out-of-state practitioners in New Hampshire." Id.

"The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." <u>Gonzalez v. Raich</u>, 545 U.S. 1, 12-13 (2005) (footnotes omitted). Given this mandate and the Attorney General's authority under 21 U.S.C. § 876(a) to "require production of any records . . . which the Attorney General finds relevant or material to the investigation," the court has little trouble finding that the DOJ has proven that the subpoena is relevant to a congressionally authorized purpose, the information sought is adequately described and DEA followed proper procedures. <u>Sturm Ruger & Co.</u>, 84 F.3d at 4. Ricco Jonas does not contest the adequacy of the DOJ's evidence on this issue.

B. Suit against the State of New Hampshire

Ricco Jonas next asserts that the subpoena cannot be enforced because it was issued to her in her official capacity as PDMP Program Manager, rather than in her personal capacity. This distinction, she argues, has significant ramifications. Ricco Jonas contends that such an "official capacity" subpoena

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is the equivalent of an action against the State of New Hampshire. And, she argues, because the State is not a "person" under 21 U.S.C. § 876(c), the subpoena is unenforceable. Def. Mem., doc no. 7, at 13. Ricco Jonas's argument founders on the initial premise - that DOJ has sued the State by serving her with a subpoena. As will be explained in more detail below, the court finds that this action is not a suit against the State.

Ricco Jonas has cited no authority for her proposition that her being served because of her position as PDMP manager converts this subpoena enforcement action into a suit against the State of New Hampshire. Indeed, the weight of persuasive authority is against her.

Generally speaking, "[f]ederal subpoenas routinely issue to state and federal employees to produce official records or appear and testify in court and are fully enforceable despite any claim of immunity." <u>United States v. Juvenile Male 1</u>, 431 F. Supp. 2d 1012, 1016 (D. Ariz. 2006). Although the First Circuit Court of Appeals has not addressed the precise issue Ricco Jonas raises, another district court in this Circuit has recently observed that a motion to compel non-party discovery from a state agency is not a suit against the state because it "will not result in a judgment of any kind requiring financial payment from the state." <u>United States v. Univ. of. Mass.</u>, 167 F. Supp. 2d 221, 225 (D. Mass. 2016). In reaching this conclusion, the court relied on Allen v. Woodford, 544 F. Supp.

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2d 1074 (E.D. Cal. 2008), <u>adopting rep. and rec.</u>, 543 F. Supp. 2d 1138). In <u>Allen</u>, a prison inmate sought document production from several state agencies under the Federal Rules of Civil Procedure. <u>Id.</u> at 1075. The agencies claimed Eleventh Amendment immunity. <u>Id.</u> The court defined the "threshold issue [as] whether issuance and required compliance with a third-party subpoena by State custodians of records in an action in which the State is not a party constitutes" a suit against the state. <u>Id.</u> at 1078. The court concluded that the subpoena was not a suit. Id.

Several aspects of the <u>Allen</u> court's reasoning are instructive here. First, the court observed that discovery from a state agency can only be obtained through the custodians of records or "other employees having custody and control of the information or documents sought." <u>Id.</u> at 1079. In this case, the DEA served the subpoena on Ricco Jonas because, as her counsel conceded at oral argument, she has custody and control over PDMP information. Next, the <u>Allen</u> court remarked that:

Neither the State, nor any of its employees to whom subpoenas have been directed to obtain the information sought, that have been found essential to the prosecution of the Plaintiff's case, are parties, nor has any relief in law or equity been sought against them or the State. No judgment will be issued in this action against the State that could have any conceivable effect on the State treasury; the State custodians are only subpoenaed to produce documents for use in the prosecution of this federal civil rights action. <u>The Non-Parties' assertion that they</u> <u>must comply with the subpoenas in their official</u> capacities as custodians of record is irrelevant; no

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judgment or other relief of any kind is sought against them in this litigation.

Id. (emphasis added).

The <u>Allen</u> court also cited two cases that further persuade the court that this action is not a suit against the State. First, in <u>Florida Dept. of State v. Treasure Salvors, Inc.</u>, 458 U.S. 670 (1982), the plurality approved service of process on state officials in possession of certain artifacts. Rejecting the state's immunity argument, the Court declared that "[i]t is clear that the process at issue was directed only at state officials and not at the State itself or any agency of the State." <u>Id.</u> at 691. The Court concluded: "Treasure Salvors is not asserting a claim for damages against either the State of Florida or its officials. . . The relief sought is not barred by the Eleventh Amendment." Id. at 699.

<u>Allen</u> also cited with approval <u>Laxalt v. C.K. McClatchy</u>, 109 F.R.D. 632 (D. Nev. 1986), a libel suit in which the district court rejected a Nevada gaming agency's claim that the Eleventh Amendment barred compliance with a federal subpoena. <u>Id.</u> at 633. The <u>Laxalt</u> court first noted that only assertions of liability and claims for relief against the state are considered to be "lawsuits against a state." <u>Id.</u> at 634. It then found the case's similarity to <u>Treasure Salvors, Inc.</u>, dispositive, because "inspection and copying of state records is all that is being sought" Id. at 634-35. Other cases

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have employed the same analysis and reached the same result. <u>See, e.g.</u>, <u>Jackson v. AFSCME Local 196</u>, No. 3:07CV0471(JCH), 2008 WL 1848900, at *2 (D. Conn. Apr. 25, 2008) (finding that subpoena on state agency official was not an action against the state); <u>Arista Records LLC v. Does 1-14</u>, No. 7:08cv00205, 2008 WL 5350246, at *5 (W.D. Va. Dec. 22, 2008) (same; citing Jackson).

Ultimately, Ricco Jonas's argument that the State of New Hampshire is not a "person," within the meaning of the CSA begs the question of whether DOJ has initiated a suit against the State merely by naming her and her title in the subpoena. Given the one-sided authority that Ricco Jonas has not contradicted, the court finds that her assertion that she "must comply with the subpoenas in [her] official capacity[y] as custodians of record is irrelevant." <u>Allen</u>, 544 F. Supp. 2d at 1079. "[I]nspection and copying of state records is all that is being sought" <u>Laxalt</u>, 109 F.R.D. at 634-35. This action is not a suit against the State of New Hampshire. The court therefore need not reach the question of whether the State is a "person" within the meaning of the CSA.⁴

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⁴ DOJ also relies on <u>Ott v. City of Milwaukee</u>, 682 F.3d 552, 556 (7th Cir. 2012) in which the court rejected an immunity defense in a discovery dispute. <u>Ott</u>, however, is inapposite, as it relied on federal discovery rules definitions to find that a city agency was a "person." By contrast, this case involves a federal statute. Also misplaced is Ricco Jonas's reliance on <u>Al</u> <u>Fayed v. CIA</u>, 229 F.3d 272 (D.C. Cir. 2000), in which the Court held that the CIA is not a "person" within the meaning 28 U.S.C.

C. Supremacy Clause

Ricco Jonas next argues that DOJ must demonstrate probable cause to seize the PDMP records as required by N.H. Rev. Stat. Ann. § 318-B:35(I)(b)(3). This argument fails because the Supremacy Clause of the Constitution preempts the provisions of New Hampshire law upon which Ricco Jonas relies. Under the Supremacy Clause, state laws that "interfere with, or are contrary to the laws of [C]ongress" are invalid. U.S. Const. art. VI, cl. 2. Unless Congress directs otherwise, the Supremacy Clause preempts state laws which are in conflict with federal law. Hillman v. Maretta, 569 U.S. 483, 490 (2013). Such conflicts exist when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597 (1991) (quoting Hines v. Davidowitz, 312 U.S. 52 (1941)). "If the purpose of the [federal] act ... must be frustrated and its provisions be refused their natural effect," then a conflict exists. Savage v. Jones, 225 U.S. 501, 533 (1912).

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^{§ 1782,} which gives district courts power to order a person to produce documents for use in foreign or international tribunals. <u>Id.</u> at 275-76. <u>Al Fayed</u>, however, involved a federal discovery subpoena served on a federal agency in private litigation, not, as here, an administrative subpoena served by a federal agency on a state-agency record custodian. Regardless, because the court finds that this action is not a "suit" against the State, it does not reach the issue of whether the State is a "person" under the CSA.

Several courts have invoked the Supremacy Clause in enforcing administrative subpoenas issued under the CSA. As especially relevant here, three of those cases involved prescription drug databases similar to the NH PDMP. For example, in Oregon Prescription Drug Monitoring Program v. U.S. Drug Enforcement Admin., 860 F.3d 1228 (9th Cir. 2017) the court held that the CSA preempted an Oregon statute requiring "a valid court order" before that state's PDMP could comply with a DEA subpoena. Id. at 1236. The Court observed that the "Oregon statute stands as an obstacle to the full implementation of the CSA because it interferes with the methods by which the federal statute was designed to reach [its] goal." Id. (citing Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 103 (1992)) (internal quotation marks omitted). Similarly, in United States Dep't of Justice v. Utah Dep't of Commerce, No. 2:16-cv-611, 2017 WL 3189868 (D. Utah July 27, 2017), the court, relying on the Supremacy Clause, found that the CSA preempted the state's requirement of a warrant to access a state prescription database. Id. at *6. Also, in United States Dep't of Justice v. Colo. Bd. Of Pharm, Civ. No. 10-cv-0116-WYD-MEH, 2010 WL 3547898 (D. Colo. Aug. 13, 2010), rep. and rec. aff'd and adopted, 2010 WL 3547896 (Sept. 3, 2010), the court addressed a DEA subpoena issued to the Colorado PDMP seeking information about three prescription prescribers. The PDMP did not comply, arguing that a Colorado statute only allowed the release

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information related to patients. After observing that the state statute would require the DEA to individually review the records of hundreds of pharmacies to find information on three prescribers, the court found that the state statute was an "obstacle to the DEA's efforts to conduct its investigation," <u>id.</u> at *4, and that the CSA therefore preempted the state restriction. <u>Id.; see also United States v. Mich. Dep't of</u> <u>Cmty. Health</u>, No. 1:10-mc-109, 2011 WL 2412602 (W.D. Mich. June 9, 2011) (enforcing DEA subpoena seeking information from state medical marijuana database despite state confidentiality provision).

Courts have also relied on the Supremacy Clause to uphold administrative subpoenas in other contexts. <u>See, e.g., Presly</u> <u>v. United States</u>, 895 F.3d 1284 (8th Cir. 2018) (rejecting argument that Florida Constitution's privacy provisions can affect Internal Revenue Service's ability to subpoena bank records); <u>United States ex rel. Office of Inspector Gen. v.</u> <u>Philadelphia Hous. Auth.</u>, Misc. No. 10-0205, 2011 WL 382765, at *5 (E.D. Pa. Feb. 4, 2011) (rejecting city housing authority's reliance on state privacy laws because they "obstruct fulfillment" of an administrative subpoena issued by the Officer of Inspector General of the Department of Housing and Urban Development); <u>Massanari v. Nw. Cmty. Mental Health Ctr.</u>, No. 01-MC-50E, 2001 WL 1518137, at *1 (W.D.N.Y. Nov. 7, 2001) (finding that defendant must comply with Social Security Commissioner's

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administrative subpoena despite privacy provisions of New York law); <u>St. Luke's Reg'l Med. Ctr., Inc. v. United States</u>, 717 F. Supp. 665, 666 (N.D. Iowa 1989) (rejecting doctor's reliance on state disclosure prohibitions to avoid complying with Department of Health and Human Services administrative subpoena in Medicaid investigation).

Given the consistent weight of authority, the court is persuaded that giving effect to New Hampshire's requirement of a court order based on probable cause would create "an obstacle to the full implementation of the CSA because it interferes with the methods by which the federal statute was designed to reach [its] goal." <u>Oregon Prescription Drug Monitoring Program</u>, 860 F.3d at 1236. The state statute is therefore preempted and must give way to the CSA's subpoena process.

D. Fourth Amendment

Even if New Hampshire's warrant requirement is pre-empted, Ricco Jonas argues that DOJ must nevertheless satisfy the Fourth Amendment's protection against unreasonable searches and seizures.⁵

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⁵ Ricco Jonas also contends that the DOJ, apparently fearful of her argument that the State of New Hampshire is not a "person" under the CSA, is now claiming that it served her in her individual capacity. In that capacity, she argues, she can only comply with the subpoena by violating state law because, in her personal capacity, she has no legal right to the information." Def. Obj., doc. no. 7, at 9. As the court has already concluded, however, the official capacity/personal capacity analysis is irrelevant here.

Ricco Jonas asserts both the State's and other individuals' Fourth Amendment privacy interests in the personal information PDMP possesses. DOJ argues that Rico Jonas does not have standing to raise this argument on others' behalf. The standing issue is not dispositive. Assuming without deciding that Ricco Jonas does have standing - either in her own right or on behalf of others -- the Court of Appeals has held that "Fourth Amendment concerns are deemed satisfied" if the agency proves that the subpoena seeks information relevant to an authorized purpose, is adequately described and was issued in accordance with proper procedures. Sturm Ruger, 84 F.3d at 4; see also United States v. Tivian Labs., Inc., 589 F.2d 49, 54 (1st Cir. 1978) ("A subpoena may be issued without first obtaining a court's permission . . . and may be judicially enforced without a showing that probable, or even reasonable, cause exists to believe that a violation of law has occurred.") (citation omitted). As previously noted, supra, p. 6, DOJ has already cleared this hurdle.

Moreover, the court does not interpret the DOJ's argument in the manner Ricco Jonas suggests. The CSA allows service on a "natural person," 21 U.S.C. § 876(b), and allows court enforcement of a subpoena issued to "any person." <u>Id.</u> § 876(c). "If a party is going to subpoena documents from the government, they need to subpoena the <u>person</u> who has possession, custody, or control over the documents . . . "<u>United States v. 2121</u> <u>Celeste Road SW, Albuquerque, N.M.</u>, 307 F.R.D. 572, 590-91 (D.N.M. 2015) (emphasis added). Ricco Jonas does not dispute that she is that person. Def. Obj., doc. no. 7, at 6 (citing N.H. Admin. R. Ph. 1505.03(c)).

But that is not the end of the inquiry. As the Supreme Court recently observed, "[t]he Government will be able to use subpoenas to acquire records in the overwhelming majority of investigations" but "a warrant is required in the rare case where the suspect has a legitimate privacy interest in records held by a third party." Carpenter v. United States, 138 S. Ct. 2206, 2222 (2018). In Carpenter, the Court found that the criminal defendant had a reasonable expectation of privacy in "cell-site location information" that ostensibly tracked his whereabouts based on information retrieved from cell phone towers. Accordingly, it found that the government could not use a court order authorized by the Stored Communications Act which required only "reasonable grounds," rather than probable cause, to retrieve the information. Id. at 2222-23; see 18 U.S.C. § 2703(d). Here, however, the patients whose interests Ricco Jonas advances do not have such a reasonable expectation of privacy.

Ricco Jonas relies on two cases for the proposition that patients have a Fourth Amendment-based expectation of privacy in their prescription drug records and that DOJ must therefore demonstrate probable cause. <u>See Douglas v. Dobbs</u>, 419 F.3d 1097, 1102 (10th Cir. 2005); <u>Doe v. Se. Pa. Transp. Auth.</u>, 72 F.3d 1133, 1138 (3d Cir. 1995). But neither case supports the weight that Ricco Jonas places upon them. While both noted the patient's privacy interest in prescription information, both

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also noted that the right is "not absolute." <u>Douglas</u>, 419 F.3d at 1102 n.3; <u>Doe</u>, 72 F.3d at 1138. <u>See also Whalen v. Roe</u>, 429 U.S. 589, 602 (1977) (holding that patients' expectation of privacy in their prescription drug use must be weighed against the state's interest in monitoring the use of controlled substances). Moreover, <u>Dobbs</u> explicitly declined to resolve the issue of whether a warrant is required to conduct an investigatory search of prescription records, finding only that, for purposes of a qualified immunity analysis, the issue was unsettled. 419 F.3d at 1103; <u>see also, Pyle v. Woods</u>, 874 F.3d 1257, 1264 (10th Cir. 2017) (observing that as of April 2013 "no court had conducted the necessary analysis and no judicial opinion held that a warrantless search of a prescription drug database by state law enforcement officials is unconstitutional.").

Ultimately, Rico Jonas cites no case holding that the Fourth Amendment requires DOJ to obtain a warrant to secure information from a state prescription database and the only case to directly address the issue has held that the DEA may access state prescription databases without a warrant. In <u>Utah Dep't</u> <u>of Commerce</u>, <u>supra</u>, the court enforced a DEA subpoena issued to the Utah equivalent of the PDMP. The court's reasoning is persuasive. It first noted that "the pharmaceutical industry, like the mining, firearms, and liquor industries, is a pervasively regulated industry and that consequently pharmacists

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and distributors subject to the [CSA] have a reduced expectation of privacy in the records kept in compliance with the [CSA]." <u>Id.</u> at *8 (quoting <u>United States v. Acklen</u>, 690 F.2d 70, 75 (6th Cir. 1982)); <u>see also New York v. Burger</u>, 482 U.S. 691, 702 (1987) ("Because the owner or operator of commercial premises in a 'closely regulated' industry has a reduced expectation of privacy, the warrant and probable-cause requirements, which fulfill the traditional Fourth Amendment standard of reasonableness for a government search . . . have lessened application in this context."). The CSA, the court concluded, created the expectation that "the prescription and use of controlled substances will happen under the watchful eye of the federal government." <u>Id.</u>

Next, the court observed that the Utah prescription database's mandatory reporting requirements further eroded patients' claimed right to privacy. In trusting a prescribing physician with health information, "a patient takes the risk in this circumstance, a certainty - that his or her information will be conveyed to the government as required by the Database Act." <u>Id.</u> (citing <u>United States v. Miller</u>, 425 U.S. 435, 443 (1976) (holding that the Fourth Amendment does not bar the government from obtaining 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

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third party will not be betrayed.")). As a result, the Court found, the mandatory reporting requirement "means the State already has decided that any individual right to privacy in one's prescription drug records is outweighed by a countervailing interest in the government monitoring the prescriptions for unlawful or improper use," <u>id.</u>, and that "physicians and patients have no reasonable expectation of privacy from the DEA in the Utah database." Id.

The <u>Utah Dep't of Commerce</u> court's reasoning is an appropriate fit for this case. While New Hampshire law treats PDMP information as confidential, <u>see</u> N.H. Rev. Stat. Ann. § 318-B:34, I, it also makes clear that program information about a patient can be disclosed "to others who are authorized by state or federal law" to receive such information. <u>Id.</u> In addition, the law allows the PDMP to provide information to a variety of entities, including state medical boards and other states' prescription safety programs. <u>See id.</u>, § 318-B:35, I-III.

Ricco Jonas argues that the holding in <u>Utah Dep't of</u> <u>Commerce</u> is contrary to the Tenth Circuit Court of Appeals's declaration in <u>Dobbs</u>, that patients have a right to privacy in their prescription drug records. But as previously noted, <u>Dobbs</u> cautioned that that right is not absolute. In addition, <u>Dobbs</u> presciently observed that "state law can operate to diminish the privacy expectation in prescription drug records." 419 F.3d at

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1102 n.3. New Hampshire law has done exactly that. To the extent that Ricco Jonas has standing to assert their claims, patients do not have a reasonable expectation of privacy in the records maintained by the PDMP.

IV. Conclusion

The court agrees with the government's view that "Ricco Jonas's objection . . . make[s] the simple complicated. Gov. Rep., doc no. 8, at 1. The CSA authorizes the court to enforce subpoenas issued to "any person." 21 U.S.C. § 876(c). The government has met its burden to satisfy the "modest requirements" for enforcement. "The State has, admirably, placed considerable controls and precautions on [PDMP] access. The determination that a[n] [order supported by probable cause] is required of . . . State and local law enforcement officers . . . is within the State's authority. But the State's attempt to regulate federal law enforcement fails." Utah Dep't of Commerce, 2017 WL 3189868 at *9 (internal quotation marks and footnote omitted). Accordingly, the court recommends that the district judge grant the government's petition to compel doc. no. 1.

Any objections to this report and recommendation must be filed within fourteen days of receipt of this notice. See Fed.R.Civ.P. 72(b)(2). Failure to file specific written objections to this Report and Recommendation within the

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specified time waives the right to appeal the district court's order. <u>See Santos-Santos v. Torres-Centeno</u>, 842 F.3d 163, 168 (1st Cir. 2016).

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Andrea K. Johnstone United States Magistrate Judge

November 1, 2018

cc: Seth R. Aframe, Esq. Anthony Galdieri, Esq. Lawrence Edelman, Esq. UNITED STATES DISTRICT COURT DISTRICT OF NEW HAMPSHIRE

<u>United States</u> <u>Department of Justice</u>

v.

Civil No. 19-cv-030-LM

Michelle Ricco Jonas

ORDER

After due consideration of the objection and response filed, the court finds that oral argument is unnecessary to resolve the parties' dispute. The court herewith approves the Report and Recommendation of Magistrate Judge Andrea K. Johnstone dated 11/1/2018.

SO ORDERED.

lafferty Landya United States District Judge

January 17, 2019

cc: Seth R. Aframe, AUSA Anthony Galdieri, Esq. Lawrence Edelman, Esq.

UNITED STATES DISTRICT COURT DISTRICT OF NEW HAMPSHIRE

US Department of Justice

v.

Case No. 19-cv-30-LM

Michelle Ricco Jonas

JUDGMENT

In accordance with the Order by Chief Judge Landya B. McCafferty dated January 17, 2019, approving the Report and Recommendation of Magistrate Judge Andrea K. Johnstone dated November 1, 2018, judgment is hereby entered.

By the Court:

/s/ Tracy A. Uhrin Tracy A. Uhrin Chief Deputy Clerk

Date: January 29, 2019

cc: Counsel of Record

U.S. CODE – TITLE 21 – FOOD AND DRUGS CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL SUBCHAPTER I – CONTROL AND ENFORCEMENT

21 U.S.C. § 876 [Subpoenas]

(a) Authorization of Use by Attorney General

In any investigation relating to his functions under this subchapter with respect to controlled substances ..., the Attorney General may subpoena witnesses, compel the attendance and testimony of witnesses, and require the production of any records ... which the Attorney General finds relevant or material to the investigation. ***

(b) Service

A subpoena under this section may be served by any person 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. ***

(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 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.

NEW HAMPSHIRE REVISED STATUTES ANNOTATED – TITLE XXX – OCCUPATIONS AND PROFESSIONS

CHAPTER 318-B – CONTROLLED DRUG ACT CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

318-B:31 Definitions. -

In this subdivision:

I. "Board" means the pharmacy board, established in RSA 318:2.

II. "Controlled substance" means controlled drugs as defined in RSA 318-B:1, VI. III. "Dispense" means to deliver a controlled substance by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

IV. "Dispenser" means a person who is lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:

(a) A licensed hospital pharmacy that dispenses less than a 48-hour supply of a schedule II-IV controlled substance from a hospital emergency department or that dispenses for administration in the hospital;

(b) A practitioner, or other authorized person who administers such a substance;

(c) A wholesale distributor of a schedule II-IV controlled substance or its analog;

(d) A prescriber who dispenses less than a 48-hour supply of a schedule II-IV controlled substance from a hospital emergency department to a patient; or (e) A veterinarian who dispenses less than a 48-hour supply of a schedule II-IV controlled substance to a patient.

V. "Patient" means the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance or other such drug is lawfully dispensed.

VI. "Practitioner" means a physician, dentist, podiatrist, veterinarian, pharmacist, APRN, physician assistant, naturopath, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice. "Practitioner" shall also include practitioners with a federal license to prescribe or administer a controlled substance.

VII. "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient to lawfully obtain controlled substances.

VIII. "Prescriber" means a practitioner or other authorized person who prescribes a schedule II, III, and/or IV controlled substance.

IX. "Program" means the controlled drug prescription health and safety program that electronically facilitates the confidential sharing of information relating to the prescribing and dispensing of controlled substances listed in schedules II-IV, established by the board pursuant to RSA 318-B:32.

Source. 2012, 196:2. 2015, 48:1, 2. 2016, 309:1, eff. Jan. 1, 2017.

318-B:32 Controlled Drug Prescription Health and Safety Program Established. –

I. The board shall design, establish, and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances, by prescribers and dispensers within the state.
II. Any costs incurred by the board for the implementation and operation of the program may be supported through grants, gifts, or user contributions. The board may charge a fee to individuals who request their own prescription information. The amount charged for an individual's request for his or her prescription information.
III. Prescription information relating to any individual, which information does not meet the level established to suggest possible drug abuse or diversion shall be deleted within 36 months after the initial prescription was dispensed. All other information shall be deleted after 3 years.

Source. 2012, 196:2. 2015, 48:8. 2016, 2:5, eff. Jan. 21, 2016.

318-B:33 Controlled Drug Prescription Health and Safety Program Operation. –

I. The board shall develop a system of registration for all prescribers and dispensers of schedule II-IV controlled substances within the state. The system of registration shall be established by rules adopted by the board, pursuant to RSA 541-A.

II. All prescribers and dispensers authorized to prescribe or dispense schedule II-IV controlled substances within the state shall be required to register with the program as follows:

(a) Practitioners who prescribe but do not dispense schedule II-IV controlled substances shall register with the program as a prescriber;

(b) Practitioners who dispense but do not prescribe schedule II-IV controlled substances shall register with the program as a dispenser unless exempted pursuant to RSA 318-B:31, IV; and

(c) Practitioners who prescribe and dispense schedule II-IV controlled substances shall register with the program as both a prescriber and a dispenser unless exempted pursuant to RSA 318-B:31, IV.

II-a. Only registered prescribers, dispensers, or their designees, and federal health prescribers and dispensers working in federal facilities located in New Hampshire, Massachusetts, Maine, and Vermont shall be eligible to access the program. II-b. The chief medical examiner and delegates may register and access the program.

III. Each dispenser shall submit to the program the information regarding each dispensing of a schedule II-IV controlled substance. Any dispenser located outside the boundaries of the state of New Hampshire and who is licensed and registered by the board shall submit information regarding each prescription dispensed to a patient who resides within New Hampshire.

IV. Each dispenser required to report under paragraph III of this section shall submit to the program by electronic means information for each dispensing that shall include, but not be limited to:

(a) Dispenser's Drug Enforcement Administration (DEA) registration number.

- (b) Prescriber's DEA registration number.
- (c) Date of dispensing.
- (d) Prescription number.
- (e) Number of refills granted.
- (f) National Drug Code (NDC) of drug dispensed.
- (g) Quantity dispensed.
- (h) Number of days supply of drug.
- (i) Patient's name.
- (j) Patient's address.

(k) Patient's date of birth.

(*l*) Patient's telephone number, if available.

(m) Date prescription was written by prescriber.

(n) Whether the prescription is new or a refill.

(o) Source of payment for prescription.

V. (a) Except as provided in subparagraphs (b) and (c), each dispenser shall submit the required information in accordance with transmission methods daily by the close of business on the next business day from the date the prescription was dispensed.

(b) Veterinarians shall submit the information required under subparagraph (a) no more than 7 days from the date the prescription was dispensed.

(c) Dispensers who have a federal Drug Enforcement Administration license, but who do not dispense controlled substances may request a waiver from the requirements of subparagraph (a) from the board.

VI. The program may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required by paragraph IV is submitted in this alternative format and within the established time limit.

VII. The program may grant a reasonable extension to a dispenser that is unable, for good cause, to submit all the information required by paragraph IV within the established time limits.

VIII. Any dispenser who in good faith reports to the program as required by paragraphs III and IV shall be immune from any civil or criminal liability as the result of such good faith reporting.

Source. 2012, 196:2. 2015, 48:3. 2016, 2:6, eff. Jan. 21, 2016; 2:7, eff. Sept. 1, 2016. 2018, 158:1, eff. July 29, 2018.

318-B:34 Confidentiality. -

I. Information contained in the program, information obtained from it, and information contained in the records of requests for information from the program, is confidential, is not a public record or otherwise subject to disclosure under RSA 91-A, and is not subject to discovery, subpoena, or other means of legal compulsion for release and shall not be shared with an agency or institution, except as provided in this subdivision. This paragraph shall not prevent a practitioner from using or disclosing program information about a patient to others who are authorized by state or federal law or regulations to receive program information. II. The board shall establish and maintain procedures to ensure the privacy and confidentiality of patients and patient information. III. The board may use and release information and reports from the program for program analysis and evaluation, statistical analysis, public research, public policy, and educational purposes, provided that the data are aggregated or otherwise de-identified.

Source. 2012, 196:2. 2015, 48:4, 5, eff. July 20, 2015.

318-B:35 Providing Controlled Drug Prescription Health and Safety Information. –

I. The program may provide information in the prescription health and safety program upon request only to the following persons:

(a) By electronic or written request to prescribers, dispensers, and the chief medical examiner and delegates within the state who are registered with the program:

(1) For the purpose of providing medical or pharmaceutical care to a specific patient;

(2) For reviewing information regarding prescriptions issued or dispensed by the requester; or

(3) For the purpose of investigating the death of an individual.

(b) By written request, to:

(1) A patient who requests his or her own prescription monitoring information.

(2) The board of dentistry, the board of medicine, the board of nursing, the board of registration in optometry, the board of podiatry, the board of veterinary medicine, and the pharmacy board; provided, however, that the request is pursuant to the boards' official duties and responsibilities and the disclosures to each board relate only to its licensees and only with respect to those licensees whose prescribing or dispensing activities indicate possible fraudulent conduct.

(3) Authorized law enforcement officials on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause. No law enforcement agency or official shall have direct access to the program.

(4) [Repealed.]

(c) By electronic or written request on a case-by-case basis to:

A controlled prescription drug health and safety program from another state; provided, that there is an agreement in place with the other state to ensure that the information is used or disseminated pursuant to the requirements of this state.
 An entity that operates a secure interstate prescription drug data exchange system for the purpose of interoperability and the mutual secure exchange of information among prescription drug monitoring programs, provided that there is

an agreement in place with the entity to ensure that the information is used or

disseminated pursuant to the requirements of this state.

(3) [Repealed.]

II. The program shall notify the appropriate regulatory board listed in subparagraph I(b)(2) and the prescriber or dispenser at such regular intervals as may be established by the board if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred. The program shall provide prescription information required or necessary for an investigation.

III. The program shall review the information to identify information that appears to indicate whether a person may be obtaining prescriptions in a manner that may represent misuse or abuse of schedule II-IV controlled substances. When such information is identified, the program shall notify the practitioner who prescribed the prescription.

Source. 2012, 196:2. 2015, 48:6, 11. 2016, 2:8, eff. Jan. 21, 2016. 2018, 158:2, 3, eff. July 29, 2018.

318-B:36 Unlawful Act and Penalties. -

I. Any person who fails to submit the information required in RSA 318-B:33 or knowingly submits incorrect information shall be subject to a warning letter and provided with an opportunity to correct the failure. Any person who subsequently fails to correct or fails to resubmit the information may be subject to discipline by the board.

II. Any person whose failure to report the dispensing of a schedule II-IV controlled substance that conceals a pattern of diversion of controlled substances into illegal use shall be guilty of a violation and subject to the penalties established under RSA 318-B:26 and the board's rules as applicable. In addition, such person may be subject to appropriate criminal charges if the failure to report is determined to have been done knowingly to conceal criminal activity.

III. Any person who engages in prescribing or dispensing of controlled substances in schedule II-IV without having registered with the program may be subject to discipline by the appropriate regulatory board.

IV. Any person authorized to receive program information who knowingly discloses such information in violation of this subdivision shall be subject to discipline by the appropriate regulatory board and to all other relevant penalties under state and federal law.

V. Any person authorized to receive program information who uses such information for a purpose in violation of this subdivision shall be subject to disciplinary action by the appropriate regulatory board and to all other relevant penalties under state and federal law.

VI. Unauthorized use or disclosure of program information shall be grounds for

disciplinary action by the relevant regulatory board.

VII. Any person who knowingly accesses, alters, destroys, or discloses program information except as authorized in this subdivision or attempts to obtain such information by fraud, deceit, misrepresentation, or subterfuge shall be guilty of a class B felony.

Source. 2012, 196:2, eff. June 12, 2012.

318-B:37 Rulemaking. -

By June 30, 2013, the board shall adopt rules, pursuant to RSA 541-A, necessary to implement the program including:

I. The criteria for registration by dispensers and prescribers.

II. The criteria for a waiver pursuant to RSA 318-B:33, VI for dispensers with limited electronic access to the program.

III. The criteria for reviewing the prescribing and dispensing information collected by the program.

IV. The criteria for reporting matters to the applicable health care regulatory board for further investigation.

V. The criteria for notifying practitioners of individuals that are engaged in obtaining controlled substances from multiple practitioners or dispensers. VI. Content and format of all forms required under this subdivision.

Source. 2012, 196:2. 2015, 48:7, eff. July 20, 2015.

318-B:38 Advisory Council Established. -

I. There is hereby established an advisory council to assist the board in carrying out its duties under this subdivision. The members of the council shall be as follows:

(a) A representative of the board of medicine, appointed by such board.

(b) A representative of the pharmacy board, appointed by such board.

(c) A representative of the board of dental examiners, appointed by such board.

(d) A representative of the New Hampshire board of nursing, appointed by such board.

(e) A representative of the board of veterinary medicine, appointed by such board.

(f) The attorney general, or designee.

(g) The commissioner of the department of health and human services, or designee.

(h) A representative of the New Hampshire Medical Society, appointed by the society.

(i) A representative of the New Hampshire Dental Society, appointed by the society.

(j) A representative of the New Hampshire Association of Chiefs of Police,

appointed by the association.

(k) A representative of a retail pharmacy, appointed jointly by the New Hampshire Pharmacists Association, the New Hampshire Independent Pharmacy Association, and the New Hampshire Association of Chain Drug Stores.

(*l*) Two public members appointed by the governor's commission on alcohol and drug abuse prevention, treatment, and recovery, one of whom may be a member of the commission.

(m) A representative of the New Hampshire Hospital Association, appointed by the association.

(n) A representative of the New Hampshire naturopathic board of examiners, appointed by such board.

II. The council shall:

(a) Develop criteria for reviewing the prescribing and dispensing information collected.

(b) Develop criteria for reporting matters to the applicable health care regulatory board for further investigation.

(c) Develop criteria for notifying practitioners who are engaged in obtaining controlled substances from multiple prescribers or dispensers.

(d) Collect information on the outcomes and impact of the program including: satisfaction of users of the program, impact on prescribing patterns, impact on referrals to regulatory boards, and other relevant measures.

(e) Assist the board in meeting its responsibilities in RSA 318-B:32, I to implement and operate the program.

(f) Assist the board in adopting and revising the rules under RSA 541-A to implement the program.

III. The council may meet as often as necessary to effectuate its goals. The first meeting shall be called by the representative of the pharmacy board within 45 days of the effective date of this subdivision. At the first meeting, a chairman shall be elected by the members.

Source. 2012, 196:2. 2013, 79:1. 2014, 18:4, eff. July 22, 2014. 2018, 80:12, eff. July 24, 2018.

318-B:40 Competency Requirements. – Except for veterinarians who shall complete continuing education requirements in accordance with RSA 332-B:7-a, XV, all prescribers required to register with the program who possess a United States Drug Enforcement Administration (DEA) license number shall complete 3 contact hours of free appropriate prescriber's regulatory board-approved online continuing education or pass an online examination, in the area of pain management and addiction disorder or a combination, as a condition for initial

licensure and license renewal. Verification of successful completion of the examination or of the required continuing education shall be submitted to the prescriber's regulatory board with the licensee's application for initial licensure or renewal. A list of the prescriber's regulatory boards' approved continuing education courses and online examinations in pain management and addiction disorder, shall be available on the office of professional licensure and certification's Internet website.

Source. 2016, 2:9, eff. Sept. 1, 2016. 2017, 128:3, eff. Aug. 15, 2017.

318-B:41 Rulemaking for Prescribing Controlled Drugs. -

I. (a) Before September 1, 2016, the following boards shall submit to the joint legislative committee on administrative rules final proposed rules for prescribing schedule II, III, and IV opioids, for the management or treatment of pain:

(1) The board of medicine, concerning physicians and physician assistants.

(2) The board of dental examiners, concerning dentists.

(3) The board of nursing, concerning advanced practice registered nurses.

(4) The board of registration in optometry, concerning optometrists.

(5) The board of registration in podiatry, concerning podiatrists.

(6) The naturopathic board of examiners, concerning naturopaths.

(b) The rules required under paragraph I shall, at a minimum, contain mandatory standards for the practice components established in paragraph II.

II. The rules shall, at a minimum, contain mandatory standards for the following practice components:

(a) Standards for the use of opioids for the management or treatment of all pain:

(1) Conducting and documenting a detailed history and a physical exam in response to a complaint of pain or anticipated pain.

(2) Completing a board-approved risk assessment tool to determine whether a patient is an appropriate candidate for a schedule II, III, or IV opioid.

(3) Establishing and documenting an appropriate pain treatment plan that includes consideration of nonpharmacological modalities and non-opioid therapy.

(4)(A) Querying the program database when writing an initial schedule II, III, or IV opioid prescription for the management or treatment of a patient's pain and then periodically, at least twice a year. Such rules shall include exceptions for:

(i) Controlled substances administered to a patient in a health care setting;

(ii) The program is inaccessible or not functioning properly, due to an internal or external electronic issue; or

(iii) An emergency department is experiencing a higher than normal patient volume, and to query the program database would materially delay care.

(B) When a situation falling under exception (A)(ii) or (iii) is applicable, such

exception shall be documented in the patient's medical record.

(5) Establishing procedures for informed consent outlining the risks and benefits of opioid use.

 $(\overline{6})$ Requiring the lowest effective dosage for the fewest number of days with specific dose limits be prescribed for a medical condition or specialty.

(7) Providing for the enforcement of the prescribing rules by specifying that noncompliance with the rules may constitute unprofessional conduct under the board's practice act.

(b) Standards for the use of opioids for the management or treatment of acute pain: (1) Limiting the amount of days for an opioid prescription issued in an emergency department, urgent care setting, or walk-in clinic. This specific duration limit shall be set by each board no later than August 1, 2016 taking into consideration the recommendation from a majority vote of a policy group consisting of the chief medical officer of the department of health and human services, a physician designated by the New Hampshire chapter of the American College of Emergency Physicians, a physician designated by the New Hampshire Hospital Association, an advanced practice registered nurse designated by the New Hampshire Nurse Practitioner Association, a physician or advanced practice registered nurse designated by the New Hampshire Medical Society, and an oral surgeon designated by the New Hampshire Dental Society. Five members of the policy group shall constitute a quorum. All policy group meetings shall be open to the public and noticed in the house and senate calendars.

(2) In settings where continuity of care is anticipated, each board shall establish finite limits considering dose and duration of opioid prescriptions for treatment of acute pain and appropriate timing of office follow up for persistent, unresolved acute pain.

(c) Standards for the use of opioids for the management or treatment of chronic pain:

(1) Mandatory use of written treatment agreements, such as the agreement developed by the American Academy of Pain Medicine. Treatment agreements shall include conduct that triggers the discontinuation or tapering of opioid prescriptions.

(2) Establishing a requirement for periodic review conducted at reasonable intervals to reevaluate treatment plans and use of opioids.

(3) Establishing a procedure for, and documenting consideration of, consultation with, or referral to a specialist for patients receiving a high morphine equivalent dose for longer than 90 days.

(4) Creating exemptions to the prescribing rules for situations in which an opioid is being prescribed for the management of chronic pain for:

- (A) Patients with cancer pain;
- (B) Patients with a terminal condition;
- (C) Long-term, nonrehabilitative, residents of a nursing home facility.
- III. [Repealed.]
- IV. [Repealed.]

V. At a minimum, each board's Internet website shall include online links to board approved:

- (a) Continuing education on the prescribing of opioids.
- (b) Screening tools.
- (c) Treatment agreements.
- (d) Risks and benefits of opioid use.
- (e) Proper storage of opioids.
- (f) Proper disposal of unused opioids.

Source. 2016, 213:1, eff. June 7, 2016 except for RSA 318-B:41, pars. II(a)(4) and IV(a)(4) eff. Jan. 1, 2017. 2017, 128:4, eff. Aug. 15, 2017.