DECLARATORY RULING REQUEST

10-5-22

Petitioner:

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On behalf of the OPLC Pharmacy Enforcement Inspectors

RELEVANT FACTS:

Enforcement Pharmacy Inspectors, Kaitlyn Simoneau, Elsa Croteau and I (James Queenan) inspect several practitioners & facilities that are administering and dispensing Controlled substances. Record keeping complies, for the most part, with a frequently noticed exception. That exception being the records do not contain the address of the individual recipient. Inspectors alert the practitioners or their agent that the address is missing, and the common response is *"we have their address in our Electronic Medical Record (EMR)."* (Privacy regulations, HIPAA, do not permit inspectors to view EMR data records)

Example 1:

A surgery center could have multiple operating theatres and 30 to 60 surgeries performed daily. A detail summary regarding the patient's name, date, drug, strength, dosage form, quantity, time given are printed on sticky label computer generated and fastened to the Controlled substance logbook. To comply with both Federal and State regulation the address needs to be handwritten.

Example 2:

Anesthesiologist will remove a "anesthesia kit" with several controlled substances. As patient requires, they removed the appropriate controlled substance administer and document administration in a manual proof of use sheet. The proof of use sheets do not contain the address of the patient.

FEDERAL LAW

21 CFR 1304.22 (Exhibit 1)

Records for dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this

paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with § 1304.26.

STATE LAW (Exhibit 2)

RSA 318-B:12 I

I. Practitioners, including physicians, podiatrists, dentists, veterinarians, optometrists, advanced practice registered nurses, manufacturers, wholesalers, pharmacists, clinics, hospitals, and laboratories, shall keep separate records, so as not to breach the confidentiality of patient records, to show the receipt and disposition of all controlled drugs. Such records shall meet the requirements of the department of health and human services and federal laws and regulations relative to the receipt, manufacture, inventory, distributions, sale, dispensing, loss, theft, and any other disposition of controlled drugs. The records shall indicate at least the name, dosage form, strength, and quantity of the controlled drug; the name and address of any person to whom the drug was administered, dispensed, sold or transferred and the date of any and all transactions involved with the controlled drug.

RULING REQUEST:

Is the patient address that is located in a EMR, not in a separate administration and dispensing controlled substance log book, sufficient to comply with 21 CFR 1304.22 (C) and RSA 318-B:12 I ?

EXPECTATION OF THE INSPECTORS QUESTION:

How does the New Hampshire Board of Pharmacy recommend Enforcement Pharmacy Inspectors handle a situation in which a Controlled Substance Administration & Dispensing Log does **NOT** contain the individual recipient's (patient's) address?

1. Issue a Notice of Violation
2. Issue a comment on the Inspection Form
3. Issue a verbal advisory
4. Practitioner complies if the address is in the EMR data base, no notation required

EXHIBIT 1.

Title 21 - Food and Drugs
Chapter II - Drug Enforcement Administration, Department of Justice
Part 1304 - Records and Reports of Registrants
Continuing Records

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors.

Each person registered or authorized (by §§ 1301.13(e), 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, dispense, import, export, reverse distribute, destroy, conduct research with controlled substances, or collect controlled substances from ultimate users, shall maintain records with the information listed in paragraphs (a) through (f) of this section.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(ix) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iii) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(v) of this section,

(iv) The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;

(v) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(vi) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The operation performed (e.g., repackaging or relabeling);

(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(D) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;

(viii) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(ix) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

(b) *Records for distributors.* Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with § 1304.26.

(d) *Records for importers and exporters.* Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to paragraphs (a)(1) (iv) and (v) of this section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to paragraphs (a)(1)(xiii) or (a)(2)(xiii) of this section.

(e) *Records for registrants that reverse distribute.* Each person registered or authorized to reverse distribute controlled substances shall maintain records with the following information for each controlled substance:

(1) For controlled substances acquired for the purpose of return or recall to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf pursuant to part 1317 of this chapter:

(i) The date of receipt; the name and quantity of each controlled substance received; the name, address, and registration number of the person from whom the substance was received; and the reason for return (e.g., recall or return); and

(ii) The date of return to the manufacturer or other registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; the name and quantity of each controlled substance returned; the name, address, and registration number of the person from whom the substance was received; the name, address, and registration number of the registrant to whom the substance was returned; and the method of return (e.g., common or contract carrier).

(2) For controlled substances acquired from registrant inventory for destruction pursuant to § 1317.05(a)(2), (b)(2), and (b)(4) of this chapter:

(i) The date of receipt; the name and quantity of each controlled substance received, and the name, address, and registration number of the person from whom the substance was received, and

(ii) The date, place, and method of destruction; the name and quantity of each controlled substance destroyed; the name, address, and registration number of the person from whom the substance was received, and the name and signatures of the two employees of the registrant that witnessed the destruction.

(3) The total quantity of each controlled substance shall be recorded in accordance with the following:

(i) For controlled substances in bulk form: To the nearest metric unit weight or volume consistent with unit size;

(ii) For controlled substances in finished form: Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and

(iii) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II make an exact count or measure of the contents, or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made.

(4) For each sealed inner liner acquired from collectors or law enforcement and each sealed mail-back package acquired from law enforcement pursuant to § 1317.55 of this chapter:

(i) The number of sealed inner liners acquired from other persons, including the date of acquisition, the number and, for sealed inner liners the size (e.g., five 10-gallon liners, etc.), of all sealed inner liners and mail-back packages acquired to inventory, the unique identification number of each sealed inner liner and mail-back package, and the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received, and

(ii) The date, place, and method of destruction; the number of sealed inner liners and mail-back packages destroyed; the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; the number and, for sealed inner liners the size (e.g., five 10-gallon liners, etc.), of all sealed inner liners and mail-back packages destroyed; the unique identification number of each sealed inner liner and sealed mail-back package destroyed; and the name and signatures of the two employees of the registrant that witnessed the destruction.

(5) For all records, the record of receipt shall be maintained together with the corresponding record of return or destruction (DEA Form 41).

(f) *Records for collectors.* Each person registered or authorized to collect controlled substances from ultimate users shall maintain the following records:

(1) Mail-Back Packages:

(i) For unused packages that the collector makes available to ultimate users and other authorized non-registrants at the collector's registered address: The date made available, the number of packages, and the unique identification number of each package;

(ii) For unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: The name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers;

(iii) For sealed mail-back packages received by the collector: Date of receipt and the unique identification number on the individual package; and

(iv) For sealed mail-back packages destroyed on-site by the collector: Number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witnessed the destruction.

(2) Collection receptacle inner liners:

(i) Date each unused inner liner acquired, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired;

(ii) Date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;

(iii) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal.

(iv) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage;

(v) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and signatures of the two employees that transferred each sealed inner liner to the reverse distributor or distributor; and

(vi) For sealed inner liners destroyed on-site by the collector. The same information required of reverse distributors in paragraph (e)(4)(ii) of this section.

[62 FR 13960, Mar. 24, 1997, as amended at 68 FR 41229, July 11, 2003, 70 FR 293, Jan. 4, 2005, 79 FR 53564, Sept. 9, 2014]

EXHIBIT 2

TITLE XXX
OCCUPATIONS AND PROFESSIONS

CHAPTER 318-B
CONTROLLED DRUG ACT

Section 318-B:12

318-B:12 Records to be Kept; Confidentiality. –

I. Practitioners, including physicians, podiatrists, dentists, veterinarians, optometrists, advanced practice registered nurses, manufacturers, wholesalers, pharmacists, clinics, hospitals, and laboratories, shall keep separate records, so as not to breach the confidentiality of patient records, to show the receipt and disposition of all controlled drugs. Such records shall meet the requirements of the department of health and human services and federal laws and regulations relative to the receipt, manufacture, inventory, distributions, sale, dispensing, loss, theft, and any other disposition of controlled drugs. The records shall indicate at least the name, dosage form, strength, and quantity of the controlled drug; the name and address of any person to whom the drug was administered, dispensed, sold or transferred and the date of any and all transactions involved with the controlled drug.

II. Prescription orders and records required by this chapter and stocks of controlled drugs shall be open for inspection only to federal, state, county and municipal law enforcement officers; all officers, agents, inspectors, and representatives of the board of pharmacy who are charged with the responsibility to enforce this chapter; all peace officers within the state; the attorney general; and all county attorneys whose duty it is to enforce the laws of this state or of the United States relating to controlled drugs. No officer having knowledge by virtue of his office of any such prescription, order, or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.

III. Practitioners including physicians, podiatrists, dentists, veterinarians, optometrists, advanced practice registered nurses, manufacturers, wholesalers, pharmacies, clinics, hospitals, laboratories, and any other person required by federal law to conduct biennial controlled substance inventories, shall do so in accordance with 21 U.S.C. section 1304.11(c) inventory requirements every odd-numbered year. The pharmacy board, established in RSA 318:2, may adopt rules, pursuant to RSA 541-A, relative to the board's responsibility for ensuring compliance with this paragraph.

IV. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise required by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act or practice within the meaning of

RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this paragraph.

Source. 1969, 421:1. 1977, 547:14. 1983, 292:10. 1985, 324:21. 1990, 129:4. 1993, 333:5, 6. 1994, 333:22, 23. 1995, 310:181. 2006, 328:2, eff. June 30, 2006. 2019, 8:1, eff. July 9, 2019.