# New Hampshire Board of Pharmacy Order on Petition for Declaratory Ruling

Petitioner: Sharps Compliance, Inc.

Sharps Compliance, Inc., a United States Drug Enforcement Administration ("DEA") Reverse Distributor and Collector ("Sharps" or "Petitioner") filed a Petition for Declaratory Ruling requesting the Board of Pharmacy ("Board") find that Sharps DEA-compliant Drug Collection Receptacles may be utilized in long-term care facilities ("LTCF") in New Hampshire as an allowable drug take-back program under the current state statutes and regulations. The Board considered this matter at its December 21, 2022, meeting.

## I. Background

Sharps is a DEA Reverse Distributor and Collector, and it has a DEA-compliant drug collection receptacle, MedSafe ("receptacles"), which is utilized nationally in LTCF for allowable drug take-back programs and is in compliance with federal DEA regulations contained in 21 CFR part 1300 *et. Seq.* In its petition, Sharps reports that when it attempted to place MedSafe receptacles in New Hampshire customers' LTCF, the consultant pharmacists 'pushed back' asserting that the receptacles were not allowed because they did not comply with the current state statutes and rules. Sharps disagrees and filed this petition with the Board.

In support, Sharps asserts that since the MedSafe receptacle complies with the DEA regulations in 21 C.F.R. part 1300 *et seq.*, it meets the requirements to establish a controlled and noncontrolled pharmaceutical drug take-back program under RSA 318-E:1, I-a. Sharps also asserts that the statutory requirements in RSA 318-B:17-a, pertaining in relevant part to the disposal of controlled drugs in possession of a nursing home, do not apply to LTCF because it "applies ONLY to medications *in possession of a practitioner*, i.e., inventory medications" and LTCF do not own or possess any medication except those in the

<sup>&</sup>lt;sup>1</sup> See Documentation to support Sharps Compliance, Inc. 's Request for Declaratory Ruling Confirming Allowance of DEA-Complaint Drug Take-Back Programs, p. 1.

emergency drug kit. Sharps contends that in LTCF, all medications are dispensed to and owned by the resident—the ultimate users—and are not owned and controlled by the facility or pharmacy. Sharps then points to specific provisions of 21 C.F.R. 1300 *et seq.* that it contends are federal regulations that allow for drug take-back programs and support that 'ultimate user controlled substances' cannot be transferred to a pharmacist for destruction.<sup>2</sup>

## II. Standard of Review

A declaratory ruling is "an agency ruling as to the specific applicability of any statutory provision or of any rule or order of the agency." RSA 541-A:1, V; *See* N.H. Admin. R. Pt. Ph ("Ph") 201.02(c). A declaratory ruling is a statement by the Board regarding whether a particular statute or rule applies to the specific situation presented in the petition. <u>Id</u>. Therefore, they do not have precedential value; nor do they apply to anyone other than the petitioner.

#### III. Legal Analysis

RSA 318-B:17-a, entitled "Disposal of Controlled Drugs in Possession of Practitioner" provides in pertinent part:

No person other than the pharmacy board, its officers, agents, and inspectors is authorized to destroy any out-dated, deteriorated, excessive or otherwise unwanted or confiscated controlled drugs which are in the possession of a practitioner, veterinarian, pharmacy, peace officer, nursing home, manufacturer, wholesaler, clinic, or laboratory of hospital. No payment shall be made to any person or institution for any drug surrendered for destruction. A record shall be maintained which indicates the name, strength, and quantity of all drugs destroyed; the place and manner of destruction; the date and time destroyed; the name of the practitioner or institution surrendering the drugs; and the signature and title of the person witnessing destruction. Such records shall conform to any federal requirements and shall be open to inspection by all federal or state officers charged with the enforcement of federal or state controlled drug laws. (Emphasis added)

The Board has adopted rules governing the "Board Authorized Controlled Drug Destruction" which provide in pertinent part:

-

<sup>&</sup>lt;sup>2</sup> <u>Id</u>. at p.1-2.

(a) A **consultant pharmacist** to a nursing home, group home, or assisted living facility shall be designated agent of the pharmacy board for the sole purpose of destroying controlled drugs at the licensed home or homes for which he or she serves as consultant by filing a written request at the board office, identified in Ph 103.03. Ph 705.03(a) (Emphasis added).

The remainder of Ph 705.03 details the process to be followed by the consultant pharmacist and/or LTCF when destroying controlled drugs.

Under the aforementioned statute and rules, neither Sharps nor the MedSafe receptacle qualifies as a designated agent of the Board with the authority to destroy outdated, unwanted or unused controlled medications in possession of a LTCF in New Hampshire. Only the consultant pharmacist, as the designated agent of the Board, has the authority to do so. Sharps assertion that RSA 318-B:17-a does not apply to a LTCF resident's medications is contrary to the plain language of the statue, which expressly applies to the disposal of outdated, deteriorated, excessive or otherwise unwanted or confiscated controlled drugs in the possession of a LTCF. Furthermore, Sharps reliance on provisions in the federal statute to support its assertion that the disposal requirements contained in RSA 318-B:17-a, don't apply to LTCF is misplaced. The disposal requirements stipulated in RSA 318-B:17-a in conjunction with Ph 705.03(a) expressly apply to the disposal of medications in LTCF in New Hampshire.

RSA 318-E:1, is the state statute that authorizes the establishment of controlled and non-controlled pharmaceutical drug take-back programs, and provides in pertinent part:

- I. A local, county, regional, state, or other governmental entity or private entity in conjunction with the chief law enforcement officer of a law enforcement agency may establish a controlled and non-controlled pharmaceutical drug take-back program. For the purposes of this chapter, "pharmaceutical drug' means a prescription or over-the-counter drug, including, but not limited to, controlled drugs as defined in this chapter. (Emphasis added)
- I-a. **A registered pharmacy** may establish a controlled and noncontrolled pharmaceutical drug take-back program provided it complies with the United States Drug

Enforcement Administration regulations, 21 C.F.R. part 1300 et seq. (Emphasis added)

"The disposal requirements for controlled drugs that are stipulated in RSA 318-B:17 shall not apply to controlled and non-controlled drugs **collected in accordance with this section.**" RSA 318-E:1, IV. (Emphasis added).

Thus, under state law, the only entities authorized to establish a pharmaceutical drug take-back program in New Hampshire are governmental entities or private entities in conjunction with the chief law enforcement officer of a law enforcement agency or a registered pharmacy. See RSA 318\_E:1, I and I-a. Sharps is a private entity that is seeking to establish a drug take-back program in its own right. It is not working in conjunction with a chief law enforcement officer of a law enforcement agency and therefore, it does not meet the requirements of RSA 318-E:1, I. Furthermore, Sharps is a DEA Reverse Distributor and Collector, not a registered pharmacy. Given that a registered pharmacy is the only entity authorized to establish a pharmaceutical drug take-back program in its own right—and not in conjunction with a law enforcement agency—Sharps is not authorized to establish a drug take-back program in New Hampshire. While the Sharps MedSafe receptacle may meet the federal requirements for a drug take-back program, it does not meet the state requirements set forth in RSA 318-E:1.

Since the Sharps MedSafe receptacle does not qualify as an authorized drug take-back program in New Hampshire, the disposal requirements for controlled drugs stipulated in RSA 318-B:17 apply and LTCF in New Hampshire must comply with those requirements.

#### IV. Conclusion

For the foregoing reasons, the Board concludes that the Sharps DEA-compliant Drug Collection Receptacles—MedSafe—do not qualify as an allowable drug take-back program under RSA 318-E:1 and therefore, may not be utilized in long-term care facilities ("LTCF") in New Hampshire.

Date: 04-06-2023

Board Chair or Board Administrator on behalf of the Board of Pharmacy