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RULE ADOPTIONS

Reporter
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Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > **STATE BOARD OF PHARMACY**

Administrative Code Citation

Adopted Amendments: N.J.A.C. 13:39-11B.1, 11B.3, and 11B.4

Text

Compounding Antineoplastic Agents and Other Hazardous Substances: Sterile and Non-Sterile Preparations

Proposed: July 2, 2018, at 50 N.J.R. 1468(a).

Adopted: October 24, 2018, by the State Board of Pharmacy, Richard Palombo R.Ph., President.

Filed: December 10, 2018, as R.2019 d.007, **without change**.

Authority: N.J.S.A. 45:1-15.1 and 45:14-47.

Effective Date: January 7, 2019.

Expiration Date: November 3, 2024.

Summary of Public Comments and Agency Reponses:

The official comment period ended August 31, 2018. The Board of Pharmacy (Board) received comments from:

1. Anne Nolan Fellows, Director, State Government Affairs, National Association of Chain Drug Stores (NACDS); and

2. Elise M. Barry, MS, CFRE, Chief Executive Officer, New Jersey Pharmacists Association (NJPhA).

1. COMMENT: One commenter requested that the Board reconsider the December 2019 effective date for requiring compliance with Chapter 800 of the United States Pharmacopoeia/National Formulary (USP 800) and to delay the compliance date until 2021. The commenter noted that community pharmacies applaud the Board for recognizing the challenges that pharmacies face with the adoption of USP 800 and appreciate the initial delay to December 2019. The commenter, however, stated that, after continuous review of the requirements for compliance, the December 2019 effective date still does not allow enough time for pharmacies to properly and fully comply with these requirements. The commenter also stated that the December 2019 effective date would still impose significant implementation problems for pharmacies and could lead to patient access concerns for medications subject to the special handling requirements outlined in the USP chapter. The commenter noted that, while USP 800 provides flexibility for pharmacies that do not "manipulate" hazardous drugs to perform a risk assessment and then implement appropriate strategies to mitigate risk exposure, this undertaking will be a lengthy process that would be extremely difficult to comply with in the near future. The commenter contended that, for pharmacies that opt to perform a risk assessment, clinical teams still need time to complete risk assessments and then document both the process and the strategy to contain that risk for every drug product on the National Institute for Occupational Safety and Health (NIOSH) list of drugs that are considered hazardous substances that is in their stock. The commenter stated that pharmacies that are not eligible to comply with USP 800 by doing an assessment of risk face bigger compliance challenges and that, in order for pharmacies to fully comply, those pharmacies are likely to need extensive and costly renovations, special equipment, and will need to implement stringent operating procedures. The commenter also stated that all pharmacies, regardless of their containment strategy approach, need time to work through distribution logistics both in their own distribution centers and with vendor wholesalers. The commenter believes that, given the broad impact and extensive scope of USP 800, the pharmacy community needs additional time beyond the proposed December 2019 effective date to fully evaluate their individual operations, determine their compliance pathway, and implement any necessary facilities, operations, and practice changes, or relocate, as well as time to work any associated costs into their budget. The commenter also stated that, in some cases, this will be a multi-step, multi-year process that is subject to review by numerous organization stakeholders.

RESPONSE: The Board declines to further extend the implementation date to comply with USP 800 for pharmacies that engage in the compounding of

antineoplastic agents and other hazardous substances. The Board is adopting by reference the standards set forth at USP 800 as of the official (effective) date of General Chapter 800, which originally was July 1, 2018, and is currently December 1, 2019. The Board notes that, since at least February 1, 2016, when USP 800 was approved and finalized, New Jersey pharmacies were aware of the deadline to comply with the chapter's requirements. As that deadline has already been extended, the Board does not believe that a further extension is in the interest of public health.

2. COMMENT: One commenter commended the Board for its decision to conform the New Jersey timeline to the current USP effective date of December 1, 2019. The commenter noted that, while the Board and NJPhA have provided pharmacists with information about this matter, there remains uncertainty about some of the new requirements. The commenter, therefore, requested that the Board provide information from its recent survey about pharmacy readiness to comply with USP 800. The commenter noted that there is concern that the standards of USP 800 will also have an effect on basic compounding, currently conducted within the existing regulatory structure. The commenter also noted that the level of investment in facilities and equipment needed to meet the new standards may reduce access to basic compounds once the full standards are in place on November 30, 2019, which could negatively affect patients.

RESPONSE: The Board will continue to work with the regulated community to assist with implementing USP 800. As set forth at N.J.A.C. 13:39-11B, the Board is adopting rules such that the standards established in USP 800 will apply to the compounding, both sterile and non-sterile preparations, of antineoplastic agents and other hazardous substances. As defined at N.J.A.C. 13:39-11.2, "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription or medication order or initiative, based on the relationship of the practitioner or the patient with the pharmacist in the course of professional practice, or for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescriptions or medication orders based on routine, regularly-observed prescribing patterns. Compounding includes mixing, reconstituting, or assembling a drug according to the product's labeling or to the manufacturer's directions.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments are governed by N.J.S.A. 45:14-40 et seq., and do not

exceed, but rather reference the standard and requirements set forth in the USP, which may be viewed as establishing and setting forth Federally enforceable standards and requirements for compounding antineoplastic agents and other hazardous substances.

Regulations

Full text of the adoption follows:

SUBCHAPTER 11B. COMPOUNDING ANTINEOPLASTIC AGENTS AND OTHER HAZARDOUS SUBSTANCES: STERILE AND NON-STERILE PREPARATIONS

13:39-11B.1 Purpose and scope

(a) (No change.)

(b) Effective on the effective date of USP 800 (currently, December 1, 2019), the compounding of antineoplastic agents and other hazardous substances shall be consistent with the standards established in USP 800, which is incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org.

13:39-11B.3 Compounding antineoplastic agents and other hazardous products: sterile preparations

(a) (No change.)

[page=92] (b) A pressure indicator or air velocity meter shall be installed that can be readily monitored for correct room pressurization or air velocity, respectively, consistent with the following:

1. Effective up until the day before the effective date of USP 800 (currently, November 30, 2019), for compounding of antineoplastic agents and other hazardous substances in a cleanroom pursuant to N.J.A.C. 13:39-11.9, the primary engineering control shall be placed in an ISO class 7 buffer room that is physically separated from other preparation areas and has not less than 0.01 inch water column negative pressure to adjacent positive pressure ISO class 7 or better ante room, thus providing inward airflow to contain any airborne drug. Effective on the effective date of USP 800 (currently, December 1, 2019), for compounding of antineoplastic agents and other hazardous substances in a cleanroom pursuant to N.J.A.C. 13:39-11.9, the primary engineering control shall be placed consistent with the standards set forth in USP 800.

2. Effective up until the day before the effective date of USP 800 (currently, November 30, 2019), for compounding of antineoplastic agents and other hazardous substances outside of a cleanroom pursuant to N.J.A.C. 13:39-11.8, if a compounding aseptic containment isolator is used outside of a buffer area, the compounding area shall be physically separated from other areas and shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of 12 air exchanges per hour. Effective on the effective date of USP 800 (currently, December 1, 2019), for compounding of antineoplastic agents and other hazardous substances outside of a cleanroom pursuant to N.J.A.C. 13:39-11.8, if a compounding aseptic containment isolator is used outside of a buffer area, the compounding area shall meet the standards set forth in USP 800.

(c)-(d) (No change.)

(e) Effective up until the day before the effective date of USP 800 (currently, November 30, 2019), pharmacies shall compound antineoplastic agents and other hazardous substances only in:

1.-2. (No change.)

(f) Effective on the effective date of USP 800 (currently, December 1, 2019), pharmacies shall compound antineoplastic agents and other hazardous substances consistent with the standards set forth in USP 800.

(g) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to standards established by the Occupational Health and Safety Administration (OSHA) set forth in Section VI, Chapter 2 of OSHA's Technical Manual on Controlling Occupational Exposure to Hazardous Drugs (effective date January 20, 1999). OSHA's Technical Manual is incorporated herein by reference, as amended and supplemented, and can be found at the OSHA website, www.osha.gov, specifically, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. Personnel shall also comply with the standards established by NIOSH in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. The NIOSH Publication No. 2004-165 (2012 Edition) is incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/. Effective on the effective date of USP 800 (currently, December 1, 2019), personnel shall also comply with the standards set forth in USP 800.

(h) (No change.)

(i) Effective on the effective date of USP 800 (currently, December 1, 2019), antineoplastic agents and other hazardous substances used to compound sterile preparations shall be stored and handled consistent with the standards set forth in USP 800.

13:39-11B.4 Compounding antineoplastic agents and other hazardous products: non-sterile preparations

When antineoplastic agents and hazardous substances are utilized in the compounding of non-sterile preparations, a pharmacy shall adhere to standards established by the Occupational Health and Safety Administration (OSHA) set forth in Section VI, Chapter 2 of OSHA's Technical Manual on Controlling Occupational Exposure to Hazardous Drugs (effective date January 20, 1999). OSHA's Technical Manual is incorporated herein by reference, as amended and supplemented, and can be found at the OSHA website, www.osha.gov, specifically, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. Personnel shall also comply with the standards established by National Institute for Occupational Safety and Health (NIOSH) in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. The NIOSH standard is incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/. Effective on the effective date of USP 800 (currently, December 1, 2019), personnel shall also comply with the standards set forth in USP 800.