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MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee
FROM: Senior Legislative Research Analyst - Ryan Bush
DATE: September 20, 2013
SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - HB 017 (CPE) (Docket No. 27-0101-1207)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Compounding standards (Docket No. 27-0101-1301)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions (Docket No. 27-0101-1302)

(1) 27.01.01 - Rules of the Idaho State Board of Pharmacy - HB 017 (CPE) (Docket No. 27-0101-1207)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 Rules of the Idaho State Board of Pharmacy - HB 017 (CPE). The Board states that this rulemaking brings 27.01.01 into conformity with House Bill 17 (2013). Specifically, this rulemaking accomplishes the following:

- (1) Reduces the amount of Board-approved continuing pharmacy education (CPE) and provides more structure for such CPE;
- (2) Requires more CPE that is accredited by the Accreditation Counsel for Pharmacy Education or Continuing Medical Education;
- (3) Mandates one hour of CPE for all pharmacists engaged in the practice of sterile compounding;
- (4) Clarifies that four ounces is the maximum allowable quantity of a CV scheduled controlled substance that can be dispensed by a pharmacist without prescription;
- (5) Provides for information that must be included in an application to the Board for approval of a CPE program;
- (5) Allows drugs to be stored and removed from a secured area adjacent to a pharmacy pursuant to security restrictions; and
- (6) Clarifies that pharmacy structural security rules pertain to all pharmacies.

The Board states that negotiated rulemaking was conducted and Notices of Intent to Promulgate Rules were published in the December 2012, January, February, March, May, July and August issues of the Idaho Administrative Bulletin. The Board states that there will be a minimal positive fiscal impact in the form of saved personnel time.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(2) 27.01.01 - Rules of the Idaho State Board of Pharmacy - Compounding standards (Docket No. 27-0101-1301)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 Rules of the Idaho State Board of Pharmacy - Compounding standards. The Board states that this rulemaking establishes standards for the compounding of drugs in the following ways:

(1) Provides general compounding standards that regulate ingredients, prohibited acts, equipment, compromised drugs and hazardous drugs;

(2) Provides a scope of practice that regulates compounding of commercially available drugs, anticipatory compounding, compounding and distributing for office use, compounding for research and reconstitution exceptions; and

(3) Establishes drug compounding controls that regulate policies and procedures, compounding accuracy, certain records and labeling.

The Board further states that this rulemaking expands sterile product preparation rules by defining products that require sterilization, compounding responsibilities, environmental controls, equipment, sterile hazardous drugs, documentation requirements and policy and procedures. The FDA's Compliance Policy Guideline relating to compounding is incorporated by reference into these rules.

The Board states that negotiated rulemaking was conducted and Notices of Intent to Promulgate Rules were published in the December 2012, January, February, March, May, July and August issues of the Idaho Administrative Bulletin. The Board states that there will be a fiscal impact of approximately ten thousand dollars (\$10,000) from its request for funding to send Board inspectors to sterile compounding training.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(3) 27.01.01 - Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions (Docket No. 27-0101-1302)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions. The Board states that this rulemaking updates the list of acceptable forms of identification required to receive controlled substances prescriptions. These new forms of identification include a U.S. passport card (PASS Card) and Western Hemisphere Travel Initiative (WHTI) documents, including an Enhanced Driver's License or Nexus Air Card.

The Board states that negotiated rulemaking was not conducted because the rule is simple in nature. There is no fiscal impact associated with this rulemaking.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

cc: Board of Pharmacy
Mark Johnston, R.Ph.