



Eric Milstead  
Director

# Legislative Services Office

## Idaho State Legislature

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### MEMORANDUM

**TO:** Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

**FROM:** Legislative Research Analyst - Elizabeth Bowen

**DATE:** September 30, 2014

**SUBJECT:** Board of Pharmacy

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1403)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1404)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1405)

**(1) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401)**

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule would allow biosimilar products to be substituted for a prescribed biological product, in order to be consistent with federal law. There is no negative fiscal impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

**(2) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402)**

The Board of Pharmacy submits notice of temporary and proposed rulemaking at IDAPA 27.01.01. The temporary and proposed rule defines outsourcing facilities, creates a new registration category for outsourcing facilities, establishes a registration fee, and establishes practice standards for outsourcing facilities. The purpose of the temporary and proposed rule is to make Idaho's regulatory scheme consistent with the federal Drug Quality and Security Act. There is no apparent negative fiscal impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

**(3) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1403)**

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule relates to compounded drug product and is intended to protect public safety. The rule creates labeling requirements for compounded drug product, establishes general compounding standards, limits pharmacy distribution of non-sterile compounded drug product, and expands a sterile compounding rule and a hazardous drug sub-rule. The Board received \$14,000 in appropriations for FY2015 in order to train inspectors; otherwise, there is no apparent negative impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

**(4) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1404)**

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule provides clarification of several matters in order to be consistent with statutory changes made in 2014. The clarifications include the number of student pharmacist hours required for foreign graduates, the number of renewals for which a technician-in-training may qualify, the period of time when a controlled substance inventory must be conducted, and the security requirements for pharmacies. Additionally, the rule updates standard drug labeling requirements, creates a new limited pharmacy repackaging rule, allows pharmacist immunizers to use all forms of injectable epinephrine, combines various pharmacy authorized entry rules, and updates remote dispensing site security and training requirements. There is no negative impact on the state general fund, and negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

**(5) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1405)**

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule, which relates to wholesale distribution of drugs, is being updated to be consistent with the federal Drug Quality and Security Act. There is no apparent negative impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

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

## **PROPOSED RULE COST/BENEFIT ANALYSIS**

Section 67-5223(3), Idaho Code, requires the preparation of an economic impact statement for all proposed rules imposing or increasing fees or charges. This cost/benefit analysis, which must be filed with the proposed rule, must include the reasonably estimated costs to the agency to implement the rule and the reasonably estimated costs to be borne by citizens, or the private sector, or both.

**Department or Agency: Board of Pharmacy**

**Agency Contact: Mark Johnston, Executive Director      Phone: (208) 334-2356**

**Date: 9/2/14**

**IDAPA, Chapter and Title Number and Chapter Name: IDAPA 27.01.01 – Rules of the Idaho Board of Pharmacy**

**Fee Rule Status:        X   Proposed                        X   Temporary**

**Rulemaking Docket Number: 27-0101-1402**

### **STATEMENT OF ECONOMIC IMPACT:**

These rules will generate a small increase in the number of Board of Pharmacy registrants at either five hundred dollars (\$500) or two hundred fifty dollars (\$250) per initial registration and two hundred fifty dollars (\$250) per renewal. Currently the number of federally registered outsourcing facilities that are not already registered in another category appears to be three (3) — and the federal law has been in place since November of 2013.