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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: October 5, 2015

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Fee Rule, Proposed Rule (Docket No. 27-0101-1501)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1502)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1503)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1504)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1505)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01.

The **first proposed rule** sets a flat registration or renewal fee of \$35 for the sale of over-the-counter products. This simplifies the present system, under which there are two different registrations and two different fees depending on the number of over-the-counter products in stock. The fee change is expected to be budget-neutral.

The rule also:

- Modifies certain licensure requirements for foreign pharmacy school graduates to match those of in-state graduates;
- Modifies registration requirements for certified pharmacy technicians;
- Clarifies the number of experiential hours that a certified pharmacy technician must have worked to staff a remote dispensing site without an on-site pharmacist; and
- Modifies storage requirements for controlled substances in order to prevent theft.

Negotiated rulemaking was conducted, and there is no anticipated fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

The **second proposed rule** clarifies the circumstances under which drugs and devices may be dispensed to inpatients and outpatients of an institutional facility. Inpatients may be prescribed drugs or devices only:

- Upon orders from a licensed facility prescriber;
- Under emergency protocol in life-or-death situations; or

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- For self-administration or use if specifically authorized by the treating or ordering prescriber.

Outpatients may be prescribed drugs or devices for self-administration or use outside of the facility if:

- Standard prescription labeling requirements are complied with; and
- The drug or device is dispensed for a limited and reasonable time to continue or supplement treatment that was administered at the facility.

In order for dispensing to outpatients to be permissible, the outpatient must have received emergency or other care or consultation from the facility, be an employee, a member of the medical staff, or a student at the facility, or be a dependent of an employee, a staff member, or a student. A facility may not dispense refills for former patients or dispense drugs or devices to walk-up customers who have no connection to the facility.

Negotiated rulemaking was conducted, and there is no anticipated fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

The **third proposed rule** defines certain terms, including "hazardous drugs," "USP 795," and "USP 797," for purposes of clarification. The rule also revises language relating to prescriber information and compounding drug products.

Negotiated rulemaking was conducted, and there is no anticipated fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

The **fourth proposed rule** establishes that the Board may:

- Suspend licensing and registration requirements during a national, state, or local emergency for individuals engaged in the scope of practice for which they're licensed in another state;
- Transfer drug outlet licenses and registrations in the event of a national, state, or local emergency; and
- Approve temporary pharmacy facilities and mobile pharmacies and arrange for monitoring and inspection of such facilities.

Additionally, the proposed rule allows existing pharmacies to relocate to a temporary pharmacy or mobile pharmacy in the event of an emergency, provided that the temporary pharmacy or mobile pharmacy is located within the affected area, notifies the Board of its proposed location, is properly secured to prevent the theft of drugs, maintains its records in accordance with the laws and rules of this state, and ceases services when the emergency is over or as otherwise authorized by the Board.

Finally, the proposed rule includes provisions relating to prescription refills during an emergency and to statewide protocol agreements.

Negotiated rulemaking was conducted, and there is no anticipated fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

The **fifth proposed rule** adds the definition of "reconstitution" for purposes of clarification. It also adds language to the existing definition of "pharmaceutical care services," again for purposes of clarification.

Negotiated rulemaking was conducted, and there is no anticipated fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to 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: Alex Adams, Executive Director **Phone:** (208) 334-2356

Date: September 4, 2015

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

Fee Rule Status: Proposed Temporary

Rulemaking Docket Number: 27-0101-1501

STATEMENT OF ECONOMIC IMPACT:

Currently, there are two different non-pharmacy registrations depending on how many over-the-counter products are sold by the outlet. Class A retail non-pharmacy outlets stock more than 50 drug items and pay a registration or renewal fee of \$60. Class B retail non-pharmacy outlets stock fewer than 50 drug items and pay a registration or renewal fee of \$25.

The proposed changes streamline this to just one registration with a \$35 registration or renewal fee, allowing the sale of over-the-counter products. This change was designed to be budget neutral, and will make it easier for Idaho retailers as well as Board staff to complete registrations.

Currently, there are 299 active Class A retail non-pharmacy outlets, and 814 Class B retail non-pharmacy outlets. At current fees, this projects to \$38,290 in revenue. Under the proposal, revenue is projected to be \$38,955. Thus, the proposal is expected to have minimal economic impact.