

# Return of Unused Medications from Assisted Living Facilities

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Federal Mandate Review  
January 2003

Office of Performance Evaluations  
Idaho State Legislature



Review 03-01HHW



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## Return of Unused Medications from Assisted Living Facilities

### Executive Summary

Current Idaho statutes and rules do not authorize assisted living facilities to return unused medications to pharmacies for credit and redistribution. Instead, Department of Health and Welfare rules call for assisted living facilities to dispose of medications if they are not used within 30 days.

In contrast, the Board of Pharmacy's rules *allow* hospitals and nursing homes to return unused medications. In addition, the Department of Health and Welfare's Medicaid program rules *require* nursing homes to return unused medications that were paid for through Medicaid.

With the exception of controlled substances, federal requirements do not appear to prohibit the return of unused medications from assisted living facilities as long as certain conditions are met. These conditions include compliance with storage, handling, and record keeping requirements established by the federal Food and Drug Administration.

Authorization for return of unused medications from assisted living facilities in Idaho could be accomplished through modification of existing state statutes and rules. Allowing the return of unused medications from assisted living facilities could result in cost savings to the state's Medicaid program, assisted living facility residents, insurance carriers, and other programs such as Medicare. However, should the Legislature choose to authorize the return of medications from these facilities, it may wish to consider several issues that could affect the implementation of this change. These issues include pharmacist liability for redistribution of returned medications and state oversight of medication handling practices at assisted living facilities.

*Federal mandate reviews examine federal legal requirements made of the state, associated federal funding, and state compliance with the requirements. Unlike performance evaluations, these reviews do not follow audit procedures and do not conclude with findings and recommendations. This review was completed at the request of the Chairman of the House Health and Welfare Committee. Questions may be directed to the Office of Performance Evaluations, P.O. Box 83720, Boise, Idaho 83720-0055, or phone (208) 334-3880. The review is also available on our website at <http://www.state.id.us/ope/>.*

## At Issue. . .

Representatives of the Department of Health and Welfare, the Board of Pharmacy, and the assisted living industry are currently discussing possible regulatory changes that would allow the return of unused medications from assisted living facilities in Idaho. Currently, there are 257 assisted living facilities in the state with the capacity to serve nearly 6,000 individuals. These facilities, which are sometimes referred to as residential care facilities, provide 24-hour care to adults who need (1) assistance with daily living activities, and (2) supervision to help ensure their safety. The Office of Performance Evaluations was directed to review state and federal requirements that could impact the return of medications from assisted living facilities. We asked:

- Do current Idaho statutes or regulations prohibit or restrict the return of unused medications from assisted living facilities?
- To what extent do federal requirements limit the return of medications from these facilities?
- What are the potential implications of establishing a medication return program for assisted living facilities in Idaho?

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## State Legal Requirements

The Idaho Board of Health and Welfare and the Idaho Department of Health and Welfare have statutory and regulatory responsibilities regarding nursing homes and assisted living facilities.<sup>1,2</sup> Additionally, the Idaho Board of Pharmacy is required to enforce the provisions of the Idaho Pharmacy Act.<sup>3</sup> Idaho statutes do not specifically address the return of unused medications from either nursing homes or assisted living facilities. However, Idaho Board of Pharmacy and Department of Health and Welfare rules do address this issue.

### **Idaho Administrative Code 27.01.01.156.05. Rules of the Idaho State Board of Pharmacy**

The Board of Pharmacy's rules were modified in April 2000 to allow nursing homes and hospitals to return unopened "unit dose" medications to the dispensing pharmacy for credit, provided that specific conditions are satisfied.<sup>4</sup> These conditions include:

- The facility returns unused medications with tamper-evident packaging intact;
- In the professional judgment of a pharmacist, the returned medications meet all federal and state standards for product integrity;
- The facility has implemented policies and procedures for the appropriate storage and handling of medications and for the

transfer, receipt, and security of medications returned to the dispensing pharmacy;

- The pharmacy has a system in place to track restocking and reuse to allow recall of medications if required; and
- No controlled substance may be returned except those delivered by unit dose on a daily delivery system.<sup>5</sup>

**Idaho Administrative Code 16.03.09.817.07. Department of Health and Welfare, Rules Governing the Medical Assistance Program**

The Department of Health and Welfare's rules were modified in March 2002 to require nursing homes to return unused medications dispensed in unit dose packaging to the dispensing pharmacy. The pharmacy provider must then credit the department the amount billed for the cost of the medication less the dispensing fee.

**Idaho Administrative Code 16.03.22.428.04. Department of Health and Welfare, Rules for Licensed Residential and Assisted Living Facilities in Idaho**

Although agency rules allow return of unused medications from nursing homes and hospitals, there are no statutes or agency rules that allow the return of medications from *assisted living facilities*. Instead, Department of Health and Welfare rules governing assisted living facilities require the facilities to dispose of unused medications that accumulate for more than 30 days. These rules also require the facilities to keep detailed records of the type and amount of unused medications and the method of their disposal.

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**Federal Legal Requirements**

There is no single set of federal laws, rules, regulations, or policy guidance that directly addresses the return of unused medications from either nursing homes or assisted living facilities. Rather, several laws and policies provide direction on how and when medications from nursing homes can be returned to pharmacies. The rules and regulations identified do not, however, address the return of medications from assisted living facilities.

Based on our review of the Controlled Substances Act, the Drug Enforcement Administration website, and an interview of a federal Drug Enforcement Administration official, it appears that the Controlled Substances Act does not provide for the return of controlled substances to registered pharmacies once prescriptions have been dispensed.<sup>6</sup> Controlled substances (e.g., narcotics, stimulants, depressants, and hallucinogens) are carefully regulated because of their potential for abuse. Federal requirements call for careful

tracking of controlled substances that are used for medical purposes. Tracking is required from manufacture through distribution to the end user.

The Food and Drug Administration established a policy in October 1980 discouraging pharmacists from accepting returned medications that have been out of their possession.<sup>7</sup> However, in February 2000 the Food and Drug Administration issued an informal opinion in response to an inquiry by the American Medical Association clarifying that it would not object to the return of medications from nursing homes to the dispensing pharmacy for reuse, provided that the returned medications met the Food and Drug Administration conditions, which are:

- The dispensing pharmacy is affiliated by contract with the nursing home.
- The pharmacy and pharmacist are licensed and in good standing.
- The dispensed medications have not left the control of the nursing home after they are received from the pharmacy.
- The storage, handling, and record-keeping systems of the nursing home are adequate to document how the returned medications have been handled. Special attention must be given to storage conditions.<sup>8</sup>
- Only medication that has been dispensed in the original manufacturer's packaging may be returned.<sup>9</sup>

*However, the Food and Drug Administration's opinion does not specifically address the return of medications from assisted living facilities.*

A subsequent letter written by a commissioner from the Food and Drug Administration stated that the "FDA has concluded that individual states, which have direct responsibility for regulating pharmacies, nursing homes, and LTCFs [long-term care facilities], are in a better position to make a determination on a case-by-case basis for the protection of their citizens."<sup>10</sup> Overall, the commissioner underscored the importance of having specific processes in place to maintain the integrity of the pharmaceuticals and the possibility of illegal reuse of the prescriptions, but gave states the authority to make the final decision.

We also reviewed federal Medicaid requirements to determine if they contained provisions regarding the return of medications purchased with Medicaid funds. We found that federal Medicaid statutes and regulations do not address the return of prescription drugs for credit.<sup>11</sup>

## Financial Implications

Prescription drug costs are substantial. According to Department of Health and Welfare publications, Idaho's overall Medicaid expenses for prescription medications totaled approximately \$114.2 million during fiscal year 2002, more than double the \$52 million spent on prescription drugs in fiscal year 1998. During the same period, prescription drugs as a percentage of all Medicaid expenditures increased from 12 to 15 percent. Other public and private funds are also used to purchase prescription drugs.

Representatives of the assisted living facility industry reported instances where assisted living facilities were required by current rules to destroy medications. For example, according to industry representatives:

- Four facilities with a total of 32 residents were required to destroy a total \$2,700 worth of medications over a three-month period.
- Another facility with 97 residents had to destroy approximately \$5,400 in medications in one week.
- A third facility with 49 residents was required to destroy \$10,357 in medications over a two-month period.

However, it is difficult to determine what portion of these medications were initially purchased through Medicaid and what portion was paid for by facility residents, their insurance carriers, or other programs such as Medicare. In addition, it is unclear whether these medications were packaged, stored, and handled in such a way that would permit their return and reuse.

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## Potential Implementation Issues

In conducting our review, we identified a number of issues that could impact implementation of a medication return program that legislators may wish to consider.

- ***Potential pharmacist liability when reissuing returned medications.*** A 1980 Food and Drug Administration policy indicates that pharmacists may be held liable for reissuing returned medications. The policy states "(t)he pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his shelf stocks."<sup>12</sup>
- ***Pharmacist compensation for processing medication returns.*** Under Medicaid, pharmacists receive a fee for dispensing medications to program recipients. Currently, pharmacists receive \$4.94 per Medicaid prescription filled.<sup>13</sup> This fee is intended to cover the cost of the pharmacist's time and expertise in filling

prescriptions. However, pharmacists may incur additional costs when processing medication returns that were not intended to be covered by the fee.

- ***Oversight of assisted living facility handling of medications.*** While there is some regulation of assisted living facilities by the state (e.g., Department of Health and Welfare licensure and annual facility surveys), oversight of medication handling at these facilities may need to be strengthened if the return of medications is authorized or required.

Currently, the Board of Pharmacy registers and inspects nursing homes, but does not oversee assisted living facilities. The board appears to have authority to regulate medication handling at assisted living facilities, but has not exercised it.<sup>14</sup> If the board were to use this authority, it may incur costs for registering and inspecting facilities. However, the board could charge registration fees to these facilities to help cover its costs. According to the Executive Director of the Board of Pharmacy, non-pharmacy institutional drug outlets (e.g. clinics and nursing homes) currently pay a \$35 annual registration fee. Assessing this fee from the 257 assisted living facilities in Idaho would generate approximately \$9,000 annually. In addition, should additional funding be needed, statutes authorize the Board of Pharmacy to assess this fee at a maximum of \$100 annually.<sup>15</sup>

Alternatively, the Department of Health and Welfare could be directed to expand its oversight of assisted living facilities. As noted earlier, the department conducts annual surveys of these facilities. Department officials have indicated that reviewing facilities' medication handling procedures would add one to two hours to each survey.<sup>16</sup>

- ***Facility and pharmacy compliance with medication return requirements.*** Other states (Oregon and Connecticut) have found that compliance with return requirements has been limited. In Idaho, at a meeting of the Medication Rules Review Committee for Residential and Assisted Living Facilities on January 17, 2003, committee members indicated that some nursing homes are not aware of the Medicaid return requirements that went into affect in 2002 and others have apparently not complied with these requirements. Additionally, at the same meeting, it was noted that at least one pharmacy was not complying with the requirements to credit the state for returned medications.

## **Legislative Options**

Should the Legislature wish to pursue authorizing the return of medications from assisted living facilities, several steps could be taken:

- Direct the Board of Pharmacy and the Department of Health and Welfare to request the federal Food and Drug Administration to provide a clarification of its position regarding the return of medications from assisted living facilities. While the Food and Drug Administration has issued an informal opinion supporting the return of medications under certain conditions, this opinion focused on nursing homes and did not specifically address assisted living facilities.
- Direct the Board of Pharmacy and the Department of Health and Welfare to amend their rules to specifically allow the return of unused medications from assisted living facilities. This could be accomplished by:
  - a) Modifying Idaho Administrative Code 27.01.01.156.05 (Board of Pharmacy rules) to add assisted living facilities to those facilities that are authorized to return unused medications. Adding assisted living facilities to this section of the rules would ensure that medication returns from these facilities would be subject to the same conditions that apply to medication returns from hospitals and nursing homes.
  - b) Modifying Idaho Administrative Code 16.03.09.817.07 (rules governing the Department of Health and Welfare's Medicaid program) to require return of unused medications from assisted living facilities that were purchased through Medicaid.
  - c) Modifying Idaho Administrative Code 16.03.22.428.04 (Department of Health and Welfare rules governing assisted living facilities) to allow medications that meet the requirements set forth in Board of Pharmacy rules to be returned for credit rather than being destroyed as currently required.
- Amend Idaho statutes to specifically authorize the return of prescription medications from assisted living facilities.

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## **Endnotes**

<sup>1</sup> IDAHO CODE §§ 39-1302, 39-3305, and 39-3505 (2002). The Idaho Board of Health and Welfare and the Idaho Department of Health and Welfare have the responsibility to establish and enforce rules necessary to promote safe and adequate treatment of individuals within nursing homes and assisted living facilities.



- <sup>2</sup> Nursing homes, sometimes referred to as skilled nursing care or long-term care facilities, generally provide a higher level of care than assisted living facilities. In addition to the services provided at assisted living facilities, nursing homes provide skilled medical supervision, rehabilitative care, and care for unstable chronic health problems.
- <sup>3</sup> IDAHO CODE §§ 54-1706, -1717 (2000). Idaho Board of Pharmacy is authorized to develop rules and regulations for the proper administration and enforcement of the Idaho Pharmacy Act.
- <sup>4</sup> Unit dose is defined as medications packaged in individually sealed doses with tamper-evident packaging (e.g., single unit of use, blister packaging, unused indictable vials and ampules).
- <sup>5</sup> A daily delivery system provides a single day's dosage of medication. This appears to allow for the return of a controlled substance if it is in unit dose packaging and it has not been dispensed. However, the opportunity to return controlled substances appears to be quite limited due to strict federal regulations.
- <sup>6</sup> 21 U.S.C. §§ 801–889 and 901–971 (2000).
- <sup>7</sup> The policy also states that a pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he or she mix returned portions of drugs to his or her shelf stock. U.S. Department of Health and Human Services, Food and Drug Administration, *Return of Unused Prescription Drugs to Pharmacy Stock*, Section 460. 300, Compliance Policy Guide 7132.09 (1 October 1980).
- <sup>8</sup> 42 C.F.R. pt. 483.60 (2002) outlines requirements for states and long-term care facilities. Specifically, facilities must store medications in locked compartments under proper temperature controls with limited access. Also, 21 C.F.R. pts. 210–226 (2002) set out the minimum practices for packing and holding of drugs to assure that such drugs meet the requirements of the Food, Drug, and Cosmetic Act (21 U.S.C. § 301 (2001)) as to safety, identity, strength, quality, and purity characteristics. This section of code requires the medication to be destroyed if the packaging has been damaged, if the safety of the medication has been compromised, or if the medication has been stored improperly.
- <sup>9</sup> Janet Woodcock, M.D., *U.S. Department of Health and Human Services, Food and Drug Administration*, informal opinion (25 February 2000).
- <sup>10</sup> Jane E. Henney, M.D., *U.S. Department of Health and Human Services, Food and Drug Administration*, informal opinion (21 August 2000).
- <sup>11</sup> 42 U.S.C. §§ 1396–1396v (2002) and 42 C.F.R. pts. 400–498 (2002).
- <sup>12</sup> U.S. Department of Health and Human Services, Food and Drug Administration, *Return of Unused Prescription Drugs to Pharmacy Stock*, Policy Section 460. 300, Compliance Policy Guide 7132.09 (1 October 1980).
- <sup>13</sup> A 2000 report on Idaho's Medicaid program found the dispensing fee paid to pharmacies that fill Medicaid prescriptions was almost twice the average commercial rate, and recommended reducing the fee by \$0.50. Idaho Office of Performance Evaluations, *Idaho's Medicaid Program: The Department of Health and Welfare Has Many Opportunities for Cost Savings*, Report 00-05 (2000), 39.
- <sup>14</sup> The Idaho Pharmacy Act, IDAHO CODE §§ 54-1701–1750 (2000 and Supp. 2002) charges the Board of Pharmacy with regulating pharmacies and drug outlets (including assisted living facilities) that dispense, deliver, or distribute drugs in Idaho. The board's statutes and rules provide it authority to register drug outlets and inspect them.
- <sup>15</sup> IDAHO CODE § 54-1730(1) (2000).
- <sup>16</sup> According to Department of Health and Welfare officials, on-site surveys generally require 8 to 18 hours to complete.

## Performance Evaluations Completed 1998–Present

<u>Pub. #</u>	<u>Report Title</u>	<u>Date Released</u>
98-01	Public School Use of Tobacco Tax Funds	January 1998
98-02	Medicaid Reimbursement for Outpatient Occupational and Speech Therapy	June 1998
98-03	Management of State Agency Passenger Vehicles	October 1998
98-04	Management Review of the Idaho Commission for the Blind and Visually Impaired	October 1998
99-01	The State Board of Pharmacy's Regulation of Prescription Controlled Substances	June 1999
99-02	The State Board of Medicine's Resolution of Complaints Against Physicians and Physician Assistants	October 1999
99-03	Employee Morale and Turnover at the Department of Correction	October 1999
00-01	A Limited Scope Evaluation of Issues Related to the Department of Fish and Game	March 2000
00-02	The Department of Fish and Game's Automated Licensing System Acquisition and Oversight	June 2000
00-03	Passenger Vehicle Purchase Authority and Practice in Selected State Agencies, Fiscal Years 1999–2000	September 2000
00-04	A Review of Selected Wildlife Programs at the Department of Fish and Game	November 2000
00-05	Idaho's Medicaid Program: The Department of Health and Welfare Has Many Opportunities for Cost Savings	November 2000
01-01	Inmate Collect Call Rates and Telephone Access: Opportunities to Address High Phone Rates	January 2001
01-02	Idaho Department of Fish and Game: Opportunities Exist to Improve Lands Program and Strengthen Public Participation Efforts	January 2001
01-03	Improvements in Data Management Needed at the Commission of Pardons and Parole: Collaboration With the Department of Correction Could Significantly Advance Efforts	May 2001
01-04	The State Board of Medicine: A Review of Complaint Investigation and Adjudication	June 2001
01-05	A Review of the Public Works Contractor Licensing Function in Idaho	November 2001
01-06	A Descriptive Summary of State Agency Fees	November 2001
02-01	The Department of Environmental Quality: Timeliness and Funding of Air Quality Permitting Programs	June 2002
02-02	Management of State Agency Passenger Vehicles: A Follow-up Review	November 2002
02-03	A Review of the Idaho Child Care Program	November 2002
03-01	Programs for Incarcerated Mothers	February 2003

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