Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

House Bill 6021 (Substitute H-1 as reported without amendment)
Sponsor: Representative Mike Pumford
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 7-13-04

RATIONALE

Under the Public Health Code, it is a misdemeanor to possess or control for the purpose of resale, or sell, offer to sell, dispense, or give away a drug, pharmaceutical preparation, or chemical that has been dispensed on prescription and has left the pharmacist's control. Under a Department of Community Health (DCH) rule, however, medical institutions are exempt from the prohibition against redispensing prescription drugs (R 338.436). (The term "medical institution" includes a hospital, skilled nursing facility, county medical care facility, nursing home, or other State-licensed or –approved health facility that provides or includes pharmacy services.) Under the rule, medications in single-unit packages and intravenous solutions that are designed to be tamper-evident and that show no evidence that tampering has occurred may be returned to stock for redispensing, as long as the medications have not left the medical institution or its legal affiliates.

Reportedly, the DCH rule results in significant cost savings to medical institutions. It has been suggested that pharmacies operated by or under contract with the Department of Corrections (DOC) also should be allowed to redispense unused prescription drugs.

CONTENT

The bill would amend the Public Health Code to exempt pharmacies operated by or under contract with the DOC from the prohibition against redispensing prescription drugs after they have left the pharmacist's control, if certain conditions were met.

Under the bill, a pharmacy operated by the DOC or under contract with the DOC could accept for the purpose of resale or redispensing a prescription drug that had been dispensed and had left the pharmacist's control if the prescription drug were being returned by a State correctional facility that had a registered professional nurse or a licensed practical nurse who was responsible for the security, handling, and administration of prescription drugs within the facility, if all of the following conditions were met:

-- The pharmacist was satisfied that the conditions under which the prescription drug had been delivered, stored, and handled before and during its return were such as to prevent damage, deterioration, or contamination that adversely would affect the drug's identity, strength, quality, purity, stability, integrity, or effectiveness.
-- The pharmacist was satisfied that the drug did not leave the nurse's control and did not come into the physical possession of the individual for whom it was prescribed.
-- The pharmacist was satisfied that the labeling and packaging of the drug were accurate; had not been altered, defaced, or tampered with; and included the drug's identity, strength, expiration date, and lot number.
-- The drug was dispensed in a unit dose package or unit of issue package.

A pharmacy operated by or under contract with the DOC could not accept prescription drugs for return until the pharmacist in charge developed a written set of protocols for accepting, returning to stock, repackaging, labeling, and redispensing prescription drugs. The written protocols would have to be maintained on the premises and readily accessible to each pharmacist on duty. The protocols would have to include, at a minimum, all of the following:

-- Methods to ensure that damage, deterioration, or contamination had not occurred during the delivery, handling, storage, and return of the drugs that adversely would affect their identity, strength, quality, purity, stability, integrity, or effectiveness, or otherwise render them unfit for distribution. Methods for accepting, returning to stock, repackaging, labeling, and redispensing the returned prescription drugs.
-- A uniform system of recording and tracking prescription drugs that were returned to stock, repackaged, labeled, and redistributed.

If the integrity of a prescription drug and its package were maintained, a returned drug that originally was dispensed in the manufacturer's unit dose package or unit of issue package and was returned in the same package could be returned to stock, repackaged, and redispensed as needed. A prescription drug that was repackaged into a unit dose package or a unit of issue package by the pharmacy, and dispensed and returned to that pharmacy in that package, could be returned to stock but could not be repackaged. A unit dose package or unit of issue package prepared by the pharmacist and returned to stock could be redispensed only in the same package and could be redispensed only once. A pharmacist could not add unit dose package drugs to a partially used unit of issue package.

The bill specifies that it would not apply to any of the following:

-- A controlled substance.
-- A prescription drug that was dispensed as part of a customized patient medication package.
-- A prescription drug that was not dispensed as a unit dose package or unit of issue package.
-- A prescription drug that was not labeled properly with the identity, strength, lot number, and expiration date.

Under the bill, "customized patient medication package" would mean a package that was prepared by a pharmacist for a specific patient that contained at least two prescribed solid oral dosage forms.

"Unit dose package" would mean a package that contained a single dose drug with the name, strength, control number, and expiration date of the drug on the label. "Unit of issue package" would mean a package that provided multiple doses of the same drug, but each drug was individually separated and included the name, lot number, and expiration date.

"Repackage" would mean a process by which the pharmacy prepared a unit dose package, unit of issue package, or customized patient medication package for immediate dispensing pursuant to a current prescription.

MCL 333.17766 et al.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Hospitals and nursing homes already are exempt from the prohibition against redispensing prescription drugs, subject to safety procedures, and have experienced considerable savings without jeopardizing patient safety. Like hospitals and nursing homes, State correctional institutions are closed facilities and would establish similar safety measures to ensure that the drugs' integrity would not be compromised. In fact, drugs redispensed in a correctional facility probably would be even safer than in a hospital or nursing home due to the extra checks and balances already in place to maintain security.

Sometimes a prisoner is diagnosed and medication prescribed, but due to the rapid progression of his or her disease,

adjustments in his or her drug regimen are needed before the original prescription is administered. When that happens, the unused drugs must be thrown away. According to DOC officials, the bill could generate between $800,000 and $1.6 million in savings--a significant amount in light of reductions in funding. Under the bill, the drugs could not be redispensed if they had left the control of the facility's nurse responsible for the drugs. In a restricted setting and under such tight controls, the DOC would be able to save money in a manner that would be safe for patients.

Legislative Analyst: Julie Koval

FISCAL IMPACT

Allowing the Department of Corrections (DOC) to redispense prescription drugs that had not left the control of clinic staff would result in pharmaceutical savings. The DOC estimates that redistributing unused medications would save approximately $800,000 per year, but the actual extent of the savings would depend on both the costs of the redispensed medications and the frequency with which they otherwise would have been discarded. The DOC's estimate, however, did not assume that only unit-packaged medications could be reused. This provision likely would diminish potential savings.

Fiscal Analyst: Bethany Wicksall