

Legislative Analysis



ALLOW DOC PHARMACIES TO REUSE AND REDISPENSE PRESCRIPTION DRUGS

Mitchell Bean, Director
Phone: (517) 373-8080
<http://www.house.mi.gov/hfa>

House Bill 6021 (Substitute H-1)

Sponsor: Rep. Mike Pumford

Committee: Health Policy

First Analysis (6-23-04)

BRIEF SUMMARY: The bill would exempt from the ban on reselling or redispensing prescription drugs pharmacies operated by the Department of Corrections or under contract with the department under certain circumstances.

FISCAL IMPACT: By being able to re-dispense pharmaceuticals that had not left the control of clinic staff, the Department of Corrections would experience cost savings, the extent of which would depend on the costs of the medications involved and the frequency with which they otherwise would have been destroyed, rather than re-dispensed. Early estimates of the costs savings attendant on the ability to re-dispense drugs ranged from \$800,000 to \$1.6 million, and did not assume that only unit-packaged medications could be re-dispensed. The House-passed FY 2004-05 budget for the Department of Corrections assumes savings of \$1.6 million based on prison clinics being able to re-dispense pharmaceuticals.

THE APPARENT PROBLEM:

In general, it is against the law for a pharmacist, doctor, or anyone to sell, dispense, or even give away a prescription drug that has previously been dispensed to someone else. However, under departmental rules, hospitals and nursing homes, and a few other types of medical institutions, are allowed to return to stock and then redispense some prescription drugs under very narrowly specified circumstances. For instance, the drugs must always be under the control of the nursing staff. Used primarily by nursing homes, the ability to redispense drugs has resulted in significant cost savings.

In light of the extreme budget difficulties the state has faced over the last few years, and the cuts in funding to individual state departments, the Department of Corrections has expressed a desire to have the same flexibility as hospitals and nursing homes regarding redispensing drugs. The DOC points out that correctional institutions are closed facilities similar to hospitals and nursing homes, and therefore capable of designing a system that closely matches the ones used by those health facilities. In his committee testimony, a representative from the DOC anticipated annual savings of around \$500,000 to \$1 million; not a huge amount given the size of the DOC budget, but significant in these days of reduced funding. Legislation has been introduced to allow pharmacies operated by or under contract with the DOC, under specified restrictions, to repackage and redistribute prescription drugs.

THE CONTENT OF THE BILL:

The Public Health Code makes it a misdemeanor offense for any person to sell, dispense, or give away a drug, pharmaceutical preparation, or chemical that had previously been dispensed on prescription and that had left the control of the pharmacist.

The bill would amend the code to allow a pharmacy operated by the Department of Corrections (DOC) or under contract with the department to accept for resale or redispensing a prescription drug that had been dispensed and that had left the control of the pharmacist if the drug was being returned from a state correctional facility (the prisoner population is under the jurisdiction of the DOC) that had a registered professional nurse (RPN) or a licensed practical nurse (LPN) who was responsible for the security, handling, and administration of prescription drugs within that facility and if all of the following were met to the satisfaction of the pharmacist:

- The conditions under which the drug was stored, delivered, and handled before and during its return would not have resulted in damage, deterioration, or contamination so as to adversely affect its identity, strength, quality, purity, stability, integrity, or effectiveness.
- The prescription drug did not leave the control of the RPN or LPN responsible for it and the drug did not come into the physical possession of the individual for whom it was prescribed.
- The labeling and packaging of the drug were accurate; were not altered, defaced, or tampered with; and included the identity, strength, expiration date, and lot number.

This would only apply to a prescription drug dispensed in a unit dose package or unit of issue package. “Unit dose package” would mean a package that contained a single dose of a drug with the name, strength, control number, and expiration date of that drug on the label. A “unit of issue package” means 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.

Before a pharmacy operated by the DOC or under contract with the department could accept prescription drugs for return, the pharmacist in charge would have to establish a written set of protocols for accepting, returning to stock, repackaging, labeling, and redispensing. These protocols would have to be kept on the premises and be readily accessible to each pharmacist on duty. At a minimum, the protocols would have to include the following:

- Methods to ensure that damage, deterioration, or contamination had not occurred that could have adversely affected the strength, quality, purity, stability, integrity, or effectiveness or otherwise have rendered the drugs unfit for distribution.
- Methods for accepting, returning to stock, repackaging, labeling, and redispensing the returned drugs. “Repackaging” 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 under a current prescription.

- A uniform system of recording and tracking prescription drugs that were returned to stock, repackaged, labeled, and redistributed.

If the integrity of the drug and its package was maintained, a prescription drug returned under the bill would have to be returned to stock and redistributed as follows:

- A prescription drug originally dispensed and returned in the same manufacturer's unit dose package could be returned to stock, repackaged, and redispensed as needed.
- A drug that had been repackaged into a unit dose package or unit of issue package by the pharmacy, dispensed, and then returned to that pharmacy in the same package could be returned to stock, but could not be repackaged. It could only be redispensed in that same unit dose package or unit of issue package and could only be redispensed once. A pharmacist would be prohibited from adding unit dose package drugs to a partially used unit of issue package.

The bill would not apply to the following:

- A controlled substance.
- A prescription drug dispensed as part of customized patient medication package. The term refers to a package that was prepared by a pharmacist for a specific patient that contains two or more prescribed solid oral dosage forms.
- A drug not dispensed as a unit dose package or a unit of issue package.
- A drug not properly labeled with the identity, strength, lot number, and expiration date.
- A drug dispensed in a medical institution and returned to stock for redistribution in accordance with departmental rules. The rules define "medical institution" as a state-licensed or approved hospital, skilled nursing facility, county medical care facility, nursing home, or other health facility which directly or indirectly provides or includes pharmacy services.

MCL 333.17766

ARGUMENTS:

For:

Prescription drugs account for a significant portion of the health care costs for prisoners in state-operated correctional facilities. Some health care facilities, such as hospitals and nursing homes, under departmental rules, are granted an exception to the ban on reselling or redispensing prescription drugs, and so can save on medications that otherwise would have to be thrown away. In restricted settings and under tight controls, this has proven to be safe for patients and cost-effective for the facilities. The Department of Corrections believes that it could replicate a similar controlled system within its correctional facilities and is seeking the legislative authority to do so.

Reportedly, prisoners are allowed to keep some medications in their cells and are responsible to take those drugs as prescribed, but drugs classified as “restricted” require the prisoner to go to a secured, locked area in the prison where medications are dispensed by a nurse in the prescribed dose. The bill would not apply to any medications that had been in the possession of a prisoner, a corrections officer, or person other than the nurse in charge of managing and dispensing the drugs. The bill would only apply to those drugs that are restricted. Many of the drugs dispensed in this manner are in unit dose packaging, meaning that the package contains the particular dose of the drug that was ordered for the patient. A unit dose package could contain one or even two tablets or capsules of a drug if that was the dose that had been ordered. Since these drugs are packaged according to dosage amounts, and since they never leave the control of the nurse who works in the secure area where the drugs are dispensed directly to prisoners, it is felt that leftover drugs could be safely redispensed to other prisoners. The bill contains many safeguards to ensure that only drugs that were not tampered with and had not passed the expiration date could be returned to a DOC-operated pharmacy or a pharmacy under contract with the DOC for repackaging and redispensing or resale.

The bill does not change the way in which prescribed drugs are administered to prisoners or stored in the correctional facilities and therefore would not pose additional risks in regards to drugs becoming contraband. Furthermore, it is reported that several other states have amended their laws to allow similar practices in their state-operated correctional facilities without causing harm to prisoners or staff.

Against:

Some are concerned that the bill is meant to be a vehicle to privatize the prison pharmacies. If all pharmaceutical services were provided by the Oklahoma pharmaceutical company that dispenses drugs to correctional institutions, there would likely be no pharmacists on duty at the prisons. Pharmacists are uniquely qualified to answer pharmaceutical questions, such as identifying possible drug interactions and adverse reactions, than many doctors and nurses. The state still has a commitment to protect the health and safety of prisoners, and should therefore maintain the current system of having onsite pharmacies and pharmacists.

Against:

The bill should specify that any drugs returned by a prison for redispensing could only be dispensed back to the same or a different prison and not to the general public.

Response:

The concern was discussed by interested parties prior to the committee hearing. However, to do so could limit the ability of pharmacies in the future to bid on state correctional contracts. Currently, the DOC purchases about half of its prescription drugs from an Oklahoma company that only services correctional facilities. Drugs returned to that pharmacy most likely would not end up in the general population. Drugs returned to a prison pharmacy would most likely be repackaged there after proper protocols were established. But, when the contract expires with the Oklahoma company, there may be other companies wishing to bid on the contract who, under the laws of the states they are

domiciled in, may be permitted to cycle the drugs returned from Michigan into the general population in their state or other states. The consensus was that it was improper to try to regulate out-of-state companies in that way. For now, the bill would establish a system by which the drugs would not enter the drug stream for the general population in Michigan, but only for prisoners.

However, the question must be raised that if the system that the bill would create would be safe for prisoners, why wouldn't it be safe for the population in general? The law does mandate that prisoners be afforded the same health precautions and quality of care expected by anyone. If the bill's plan would endanger the health and safety of prisoners in any way, it could not go forward. Therefore, even should the drugs allowed to be redispensed under the bill get into the general population, it should not pose any health concerns.

POSITIONS:

Representative of the Department of Corrections testified in support of the bill. (6-22-03)

A representative of the Department of Community Health indicated support for the bill. (6-22-04)

A representative of the Citizen Alliance on Prisons and Prison Spending indicated support for the bill. (6-22-04)

The Service Employees International Union (SEIU) opposes the bill. (6-22-04)

Legislative Analyst: Susan Stutzky
Fiscal Analyst: Marilyn Peterson

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.