Legislative Analysis



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MAIL ORDER PHARMACIES AND CENTRALIZED PRESCRIPTION PROCESSING

House Bill 4405 as enrolled Public Act 85 of 2005

Sponsor: Rep. Gretchen Whitmer

House Bill 4434 as enrolled
Public Act 72 of 2005

Senate Bill 352 as enrolled
Public Act 73 of 2005

Sponsor: Rep. Scott Hummel Sponsor: Sen. Bill Hardiman

House Committee: Health Policy Senate Committee: Health Policy

Second Analysis (8-25-06)

BRIEF SUMMARY: Together, the bills would enable pharmacies located in Michigan to sell, distribute, and deliver prescription drugs when the prescription is received by mail and allow pharmacies to perform centralized prescription processing services or outsource such services to other pharmacies.

FISCAL IMPACT: Enforcement of the provisions of these bills will be the responsibility of the Department of Community Health's Bureau of Health Professions, thus the bills may have a fiscal impact on the operations of the Bureau. The bills' fiscal impact on the State of Michigan as a payor of health services for Medicaid participants and for employees is not known. The bills will increase access to providers for mail-order pharmaceuticals and increase competition for business which may lead to cost savings for pharmaceutical services paid for by the State.

THE APPARENT PROBLEM:

For decades, the Public Health Code has authorized administrative sanctions against Michigan-based pharmacists who use the mail to sell, distribute, or deliver prescriptions when that prescription is received by mail. Until recently, this prohibition has not been much of an obstacle and community pharmacies have flourished throughout the state. However, driven by ever-increasing health care costs, many employer-sponsored and individual health care plans either require or offer financial incentives to their insureds to utilize pharmacy services via mail-order companies. Since the health code bans this practice for in-state pharmacies, mail-order contracts go to pharmacists domiciled in other states. For example, since the beginning of the 2004-2005 fiscal year, mail-order pharmacies have been able to contract with the state to provide prescription drugs for the Medicaid program.

The result has been that, due to loss of business, hundreds of community pharmacies have either laid off pharmacists or closed their doors over the last several years. According to

information supplied by the Michigan Pharmacists Association, at least 104 pharmacies did not seek license renewal between late 2003 and the end of 2004. Yet, many believe that with newer technologies that increase dispensing efficiency, community pharmacies could compete with out-of-state mail order drug companies if allowed. Many would like to see the law amended so that Michigan companies could bid for and be awarded mail-order contracts, as well as serve individual consumers who rely on receiving medications through the mail.

In a related matter, many believe the state should allow central fill processing. "Central fill" refers to the process by which one retail pharmacy receives a prescription from a consumer (or his or her physician) but a second pharmacy prepares and delivers the prescription drug to the first pharmacy for delivery to the patient. Typically, central fill activities are done by pharmacies that have a contractual arrangement for one pharmacy to prepare the prescriptions for another pharmacy or by pharmacies that share a common owner. Central fill processing utilizes technology that automates the process and so enables a greater volume of prescriptions to be filled. Used by many chain drugstores, central fill services are changing the way the industry operates. In addition, small, independent pharmacies can increase the volume of prescriptions they can handle by contracting with central fill pharmacies. Industry members note that central fill pharmacies reduce the time that pharmacists in retail settings must spend in intensive, administrative tasks, thus providing more time for those pharmacists to spend on patient care. Central fill processing also is believed to reduce the potential for dispensing errors and so improves patient safety.

For these and other reasons, at least 33 states have passed legislation to allow central fill processing. Michigan, however, currently has no mechanism in law to allow such activities. Legislation is needed to establish a framework for central fill pharmacies.

THE CONTENT OF THE BILLS:

Together, the bills would enable pharmacies located in Michigan to sell, distribute, and deliver prescription drugs when the prescription is received by mail and allow pharmacies to perform centralized prescription processing services or outsource such services to other pharmacies. House Bill 4434 and Senate Bill 352 are tie-barred to each other.

<u>House Bill 4405</u> would amend the Public Health Code (MCL 333.17708) to eliminate a provision that subjects a pharmacist licensed in the state to penalties for using the mail to sell, distribute, or deliver a prescription drug when the prescription for the drug is received by mail.

Currently under the code, a disciplinary subcommittee can fine or reprimand a pharmacist licensee, or put a pharmacist licensee on probation, or deny, limit, suspend, or revoke the license of a pharmacist for a mail order violation or for abetting in a violation. The subcommittee can also order restitution or community service.

<u>House Bill 4434</u> would amend the Public Health Code (MCL 333.17753) to allow a pharmacy to perform "centralized prescription processing services," or to outsource those services to another licensed pharmacy, if certain conditions are satisfied.

The term "centralized prescription processing" would be defined to mean the processing by a pharmacy of a request from another pharmacy to prepare a prescription drug order or to perform processing functions such as dispensing, performing drug utilization review, completing claims adjudication, obtaining refill authorizations, initiating therapeutic interventions, and other functions related to the practice of pharmacy.

Under the bill, the following conditions would each have to be satisfied.

- 1) The pharmacies would need to have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state laws and regulations.
- 2) The pharmacies would have to share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to prepare a prescription drug order.
- 3) The pharmacies would have to comply with federal and state law.

Under the bill, a pharmacy that performed, or contracted for, centralized prescription processing services, would have to maintain a policy and procedures manual, along with documentation that implementation was occurring, to be made available to the board for inspection and review on request.

The manual would have to include, at a minimum, a detailed description of how the pharmacies would do the following:

- ** Maintain appropriate records to identify the responsible pharmacist, or pharmacists, in the various stages of drug product preparation, dispensing, and counseling process.
- ** Track the prescription drug order during each step in the drug product preparation, dispensing, and counseling process.
- ** Identify on the prescription label each pharmacy involved in the preparation and dispensing of the prescription drug order.
- ** Provide adequate security to protect the confidentiality and integrity of a patient's protected health information.
- ** Implement and maintain a quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

<u>Senate Bill 352</u> would amend the Public Health Code (MCL 333.17752) to exempt pharmacies that share a real-time, on-line database, or that transferred prescriptions under a contract for centralized prescription processing services, from certain requirements pertaining to refilling a copy of a prescription from another pharmacy.

ARGUMENTS:

For:

As a cost-saving measure, many employers that offer prescription drug benefits to their employees contract with mail-order pharmacies. The state of Michigan began at the beginning of the 2004-2005 Fiscal Year to also enter into contracts with mail-order pharmacies to provide prescription drugs for the Medicaid program; annual savings to the state are expected to be over \$8 million. Since Michigan pharmacists are prohibited from delivering prescriptions through the mail if the prescription was received by mail, these contracts must go to out-of-state companies.

In light of the state's continued sluggish economy, an emphasis has been placed on retaining existing businesses and attracting new business. To prohibit Michigan-based pharmacies from vying for these contracts is counterproductive to the effort to increase business opportunities in the state. The legislation would therefore correct an unfair disadvantage experienced by local pharmacies.

For:

At least 33 states have passed legislation to allow centralized prescription processing services (or "central fill" centers). These services allow a local pharmacy to contract with a larger central processing service for certain services. For example, some drugs are either so rarely requested by customers or so expensive that a local pharmacy may not have them in stock. The pharmacy generally has to order a much larger quantity than the customer's prescription calls for. If the customer has a reaction to the drug or if his or her medical provider changes the prescription to a different drug, the pharmacy may not get another request for that drug before the drug's expiration date. The financial impact to the local pharmacy can be significant, especially in the case of medications used to treat cancer. For example, thalidomide, once banned for causing birth defects but now used in the treatment of some cancers, costs a pharmacist \$8,600 for a bottle containing 120 doses (\$71.66 per dose). If a customer fills a prescription for 30 doses only once, the pharmacist is left with 90 unused doses; this represents a loss of about \$6,450 if the drug expires before another customer requests it.

Under the provisions of House Bill 4434, a local pharmacy could contract with a central fill service for a variety of services. For instance, since a central fill service would be servicing many pharmacies around the state, it would be more likely to be able to use the remaining thalidomide doses before the drug's expiration date in the scenario presented earlier. A local pharmacy that contracted with a central fill service for infrequently used or very expensive drugs would only pay for the doses it dispensed. This would keep prescription drug costs down for local pharmacies, central fill services, and the customers they do business with.

For:

Prescription volumes continue to rise, but there is a nationwide shortage of pharmacists. Small, independent pharmacies find it difficult to compete with large chain drugstores, especially in the ability to stock expensive, rarely used prescription drugs. Pharmacists spend up to two-thirds of their time in administrative tasks when refilling prescriptions

rather than being available to answer patients' questions. For many, the answers are found in central fill processing.

Central fill processing allows a centralized warehouse to utilize new technology to fill a high volume of prescriptions safely and accurately. Whether servicing drugstores owned by a single chain, or contracting with independently owned pharmacies, central fill pharmacies can reduce overall costs associated with filling prescriptions, can free up pharmacists to have more time with patients, and can reduce the potential for dispensing errors. Further, in conjunction with House Bill 4405, which would remove the current prohibition on in-state pharmacies using the mail to receive and deliver prescriptions, the legislation is a necessary piece of the puzzle that would allow in-state pharmacies to compete with out-of-state pharmacies for state contracts to serve the Medicaid population and negotiated contracts that are part of a collective bargaining agreement.

For:

The legislation is much narrower in scale than the pharmacy reform bills offered in the previous session and should not be confused with those efforts. The bills focus on removing the prohibition on pharmacies in the state using the mail and on allowing the creation of central fill processing services. The bills would not have any impact on current, negotiated contracts.

However, with the increased efficiency and volume that central fill processing services can provide, the economic hit experienced by local pharmacies from out-of-state mail order drug companies would be lessened. Also, the playing field would be leveled a bit more by allowing local pharmacies to compete with out-of-state mail order drug companies in submitting bids for state Medicaid contracts and negotiated contracts that are part of a collective bargaining agreement. The bills don't guarantee that such contracts will be awarded to Michigan-based pharmacies, but at least under the bills, they have a shot.

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[■] 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.