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BILL ANALYSIS

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Senate Bill 831 (as introduced 11-5-03)
Sponsor: Senator Tom George
Committee: Health Policy

Date Completed: 3-24-04

**CONTENT**

**The bill would add Part 97, the "Michigan Pharmaceutical Best Practices Initiative", to the Public Health Code to allow the Department of Community Health (DCH) to implement a pharmaceutical best practices initiative to control the costs of health care, reduce the costs of prescription drugs, and assure continued access to pharmaceutical services at fair and reasonable prices. The bill would do the following:**

- **Require the initiative to include a preferred drug list, and a prior authorization and appeal process.**
- **Require a prescriber to obtain prior authorization for drugs not included on the preferred drug list, and require the DCH to give authorization for certain drugs, including those prescribed by a specialist and those approved by the Food and Drug Administration.**
- **Allow the DCH to establish disease management and health management programs that would be provided by a pharmaceutical manufacturer, instead of a supplemental rebate for the inclusion of its products on the preferred drug list.**
- **Provide for the membership of the Michigan Pharmacy and Therapeutics Committee and require it to assist the DCH with certain functions.**

Implementation; Prior Authorization & Appeal Process

If implemented, the initiative would have to include the establishment and maintenance of a preferred drug list, and a prior authorization and appeal process.

The prior authorization and appeal process would have to include the establishment of a telephone hotline for prescribers that was accessible 24 hours per day and was staffed to ensure that a response was initiated to each prior authorization request within 24 hours after it was received, and to each appeal of a prior authorization denial within 48 hours after all necessary documentation for reconsideration was received. Each appeal for reconsideration of a previous denial would have to be reviewed and decided by a physician.

The DCH could hire or retain contractors, subcontractors, advisors, consultants, and agents and could enter into contracts necessary or incidental to implement the initiative and carry out its responsibilities and duties.

The DCH could promulgate rules to implement the initiative and to ensure compliance with the published Medicaid bulletin that initiated the initiative.

Disease Management & Health Management Programs

The DCH, in cooperation with a pharmaceutical manufacturer or its agent, could establish disease management and health management programs that would have to be provided, as

negotiated, by the manufacturer or its agent, instead of a supplemental rebate for the inclusion of certain products manufactured by that manufacturer on the DCH's preferred drug list. If the DCH negotiated a plan for the provision of services by the manufacturer instead of a supplemental rebate, the DCH would have to include in a report to the Senate and House Appropriations Subcommittees on Community Health (described below) the effectiveness of the programs and the savings incurred as a result of those programs being provided instead of supplemental rebates.

Pharmacy & Therapeutics Committee

The Michigan Pharmacy and Therapeutics Committee, which was established by Executive Order 2001-8, would be transferred to the DCH as a type II transfer. (Under the Executive Organization Act, a type II transfer means the transferring of an existing department, board, commission, or agency to a principal department. Any department, board, commission, or agency assigned to a type II transfer has all its statutory authority, powers, duties and functions, records, personnel, property, unspent balances of appropriations, allocations or other funds, including the functions of budgeting and procurement, transferred to that principal department.)

The Committee would have to consist of 11 members appointed by the Governor as follows:

-- Six physicians who accepted a significant proportion of Medicaid-eligible patients.
-- Five pharmacists who received a significant proportion of their business from Medicaid-eligible individuals.

The Governor would have to appoint the physicians from a list of physicians recommended by the Michigan State Medical Society and the Michigan Osteopathic Association. The list could include a physician with expertise in mental health, a physician who specialized in pediatrics, and a physician with experience in long-term care. The Governor would have to appoint the pharmacists from a list of pharmacists recommended by the Michigan Pharmacists Association and the Michigan Retailers Association. The list could include a pharmacist with expertise in mental health drugs, a pharmacist who specialized in pediatrics, and a pharmacist with experience in long-term care.

Committee members would serve a term of two years, except that of the first appointed members, three physician members and two pharmacist members would have to be appointed for a one-year term. The Governor would have to designate one member to serve as the chairperson of the Committee, at the pleasure of the Governor.

A member could serve only while maintaining his or her professional license in good standing. A member's failure to maintain his or her license in good standing immediately would terminate his or her membership on the Committee. A member could be reappointed for additional terms.

Committee members would serve without compensation, but would have to be reimbursed for necessary travel and other expenses pursuant to the standard travel regulations of the Department of Management and Budget.

The Committee could promulgate rules governing its organization, operation, and procedures. The Committee would have to meet at the call of the chairperson and as otherwise provided in rules. It could meet at any location within the State and would be subject to the Open Meetings Act. The Committee would have to post a notice of the meetings on the DCH's website 14 days before each meeting date. By January 31 of each year, the Committee would have to make available on the website its regular meeting schedule and meeting locations for that year.

The Committee would have the powers, duties, and responsibilities prescribed in Executive Order 2001-8 and would have to operate pursuant to and in accordance with the Executive Order. The Committee could make inquiries, conduct studies and investigations, hold hearings, and receive comments from the public.

The Committee would be advisory in nature and would have to assist the DCH as follows pursuant to applicable State and Federal law:

-- Advise and make recommendations to the DCH for the inclusion of prescription drugs on the preferred drug list based on the potential impact on patient care, the potential fiscal impact on all Medicaid covered services, and sound clinical evidence found in labeling, drug compendia, and peer-reviewed literature pertaining to use of a drug in the relevant population.
-- Advise the DCH on issues affecting prescription drug coverage for the Department's various health care programs.
-- Recommend to the DCH guidelines for prescription drug coverage under the Department's various health care programs.
-- Recommend to the DCH strategies to improve the initiative.
-- Develop a process to collect and analyze information about new prescription drugs.

The DCH would have to post this process and the necessary forms on its website.

Prior Authorization

Except as otherwise provided by law or in the bill, a prescriber would have to obtain prior authorization for drugs that were not included on the DCH's preferred drug list. If the prescriber's prior authorization request were denied, the DCH or its agent would have to inform the prescriber of his or her option to speak to the agent's physician on duty regarding the request. If immediate contact with the physician on duty could not be arranged, the DCH or its agent would have to inform the prescriber of his or her right to request a 72-hour supply of the nonauthorized drug.

(Under the bill, "prescriber" would mean a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified under the Code to administer and prescribe therapeutic pharmaceutical agents, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.)

The DCH or its agent would have to provide authorization for prescribed drugs that were not on its preferred drug list if the prescribing physician verified that the drugs were necessary for the continued stabilization of the patient's medical condition as initial therapy or following documented previous failures on earlier prescription regimens. Documentation of necessity or previous failures could be provided by telephone, facsimile, or electronic transmission.

The DCH or its agent also would have to provide authorization for a prescribed drug that was not on the preferred drug list if the prescribing physician had achieved advanced specialization training and was certified by the respective specialty board as a specialist and provided documentation of his or her certification. The prescribing physician also would have to provide documentation that the drug was generally recognized as a drug in a class commonly prescribed in that area of specialization or was in a class of drugs that a physician certified in that area of specialization had an advanced level of knowledge about.

A single source covered outpatient drug that was approved by the Federal Food and Drug Administration (FDA) would have to be included by the DCH on the preferred drug list unless the Committee advised the DCH that the drug should be removed from the list.

A patient who was under a court order for a particular prescription drug or who currently was under medical treatment and whose condition had been stabilized under a given prescription regimen before becoming a Medicaid recipient, would be exempt from the prior authorization process and could continue on that medication for the duration of the order or for the current course of treatment.

Annual Report

The DCH would have to provide to the members of the House and Senate Appropriations Subcommittees on Community Health an annual written report on the impact of the initiative on the Medicaid community. The report would have to include the number of appeals used in the prior authorization process and any reports of patients who were hospitalized because of an authorization denial.

The DCH also would have to give those subcommittee members and the House and Senate Fiscal Agencies a report identifying the prescribed drugs that were grandfathered in as preferred drugs and available without prior authorization, and the population groups to which they applied. The report would have to assess strategies to improve the prior authorization process.

Proposed MCL 333.9701-333.9711 Legislative Analyst: Julie Koval

**FISCAL IMPACT**

The Michigan Pharmaceutical Best Practices Initiative was implemented in FY 2001-02 after language was included in the annual appropriations act for the Department of Community Health (Sec. 2204 of Public Act 60 of 2001) allowing the Department to propose changes to pharmacy policies for Medicaid recipients not enrolled in Medicaid HMOs. Nearly $43 million in savings was assumed in the FY 2001-02 budget due this provision, and it is believed that the savings have largely been achieved.

Senate Bill 831 would codify current policy pertaining to the Michigan Pharmaceutical Best Practices Initiative, but would add two provisions that could lead to substantial cost increases for State government. First, the bill would exempt from prior authorization the following: drugs prescribed by a physician specialist that are generally recognized as drugs in a class that are commonly prescribed in the physician's area of specialization; and, drugs that are in a class that the physician specialist has an advanced level of knowledge about. Second, the bill would exempt from prior authorization single source covered outpatient drugs approved by the Food and Drug Administration unless the Pharmacy and Therapeutics Committee advised the Department that the drug be removed from the preferred drug list. Currently, newly FDA-approved drugs are not automatically placed on the preferred drug list. Instead, pharmaceutical manufacturers must notify the Department of their interest in having a newly approved drug reviewed by the Department for consideration of its placement on the preferred drug list.

Both of these provisions would limit the Department's ability to control through the prior authorization process the use of, and therefore expenditures for, prescription drugs for Medicaid clients.

The bill would have no fiscal impact on local units of government.

Fiscal Analyst: Dana Patterson

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