Legislative Analysis

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MICHIGAN BEST PRACTICES INITIATIVE AND MEDICAID PRESCRIPTION DRUGS

Senate Bill 831 (Substitute H-1)
Sponsor: Sen. Tom George

Senate Bill 832 (Substitute H-2)
Sponsor: Sen. Bev Hammerstrom

House Committee: Health Policy
Senate Committee: Health Policy

First Analysis (6-16-04)

BRIEF SUMMARY: Senate Bill 831 would codify current policy pertaining to the Michigan Pharmaceutical Best Practices Initiative. 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, but also require the DCH to give authorization under certain conditions when specified criteria were met.
- Exempt from the prior authorization process a patient who was under a court order for, or whose condition had been stabilized under, a particular drug or drug regimen, before becoming a Medicaid recipient.
- Allow the DCH to establish disease management and health management programs that would be provided by a pharmaceutical manufacturer, in lieu of providing a supplemental rebate for the inclusion of its products on the preferred drug list; and require the DCH to report to the legislature on the effectiveness of the programs and the savings incurred.
- Provide for the membership of the Michigan Pharmacy and Therapeutics Committee and endow it with the powers, duties, and responsibilities prescribed in Executive Order 2001 - 8.

Senate Bill 832 would prohibit DCH from requiring preauthorization for certain drugs.

FISCAL IMPACT: Senate Bill 831. The bill would place in statute provisions related to the Pharmaceutical Best Practice Initiative, many of which are currently specified in the Department of Community Health annual appropriations act and in department policies. The initiative has resulted in annual savings to the Medicaid program of about $40.0 million per year, according to the Department, through a preferred drug list, supplemental rebates and prior authorization requirements that limit the use of more costly prescription drugs.

It is not anticipated that SB 831 would have a significant fiscal impact on the state's Medicaid budget.

Senate Bill 832. The bill would prohibit the Department of Community Health from requiring prior authorization for certain prescription drugs through the Pharmaceutical Best Practice Initiative. This would include medications prescribed to patients with mental disorders, HIV/AIDS, cancer, organ replacement, and epilepsy or seizure disorders.

The bill would maintain the exemptions from prior authorization that are in current policy, and there would be no significant fiscal impact on state Medicaid expenditures.

THE APPARENT PROBLEM:

In an attempt to contain an ever-increasing strain on the state Medicaid budget due to rising prescription drug costs, then-Governor John Engler established the Michigan Pharmacy and Therapeutics Committee (P & T Committee). The committee, made up of physicians and pharmacists, was charged with advising the Department of Community Health on issues affecting prescription drug coverage, and recommending guidelines for prescription drug coverage, for its various health care programs. The resulting program is known as the Michigan Best Practices Initiative.

The P & T Committee was also charged with developing a preferred drug list, called the Michigan Preferred Product List (MPPL), of medications that physicians could prescribe for their Medicaid patients without prior authorization from the state's pharmacy benefits manager. Manufacturers of drugs not chosen to be on the MPPL were given the opportunity to gain placement on it by offering the state supplemental rebates, in addition to the rebates already negotiated by the secretary of the U.S. Department of Health and Human Services. If a manufacturer did not offer a supplemental rebate on a drug, that drug could only be reimbursed by Medicaid if the physician obtained prior authorization to prescribe it. (In order for their drugs to be included on the MPPL without prior authorization, the manufacturers also had to provide rebates on drugs for two other State programs, the Elder Prescription Insurance Coverage (EPIC) program, and the Maternity Outpatient Medical Service (MOMS) program.)

Subsequently, a combination of executive action and boilerplate language in appropriation bills amended the MPPL to exempt from the prior authorization requirements specific classes of psychotropic drugs, such as selective serotonin reuptake inhibitors (antidepressants) and atypical antipsychotics, as well as anticonvulsants and drugs used by organ donation recipients. Guidelines for the timely response to prior authorization requests also were adopted, along with a provision allowing a physician to request a 72-hour supply of a nonauthorized drug when necessary.

The Best Practices Initiative was challenged in federal court and upheld by the U.S. District Court in March 2003 and by the U.S. Circuit Court of Appeals on April 2, 2004.

Now that the constitutionality of the Initiative has been upheld, and savings to the state has been realized, some feel that the Best Practices Initiative should be codified.

THE CONTENT OF THE BILLS:

The bills would codify current policy pertaining to the Michigan Pharmaceutical Best Practices Initiative. The Initiative was implemented in FY 2001-02 after language was included in the annual appropriations act for the Department of Community Health allowing the DCH to propose changes to pharmacy policies for Medicaid recipients not enrolled in Medicaid HMOs.

Senate Bill 831 would add Part 97, entitled the "Michigan Pharmaceutical Best Practices Initiative", to the Public Health Code (MCL 333.9701-333.9709) to allow the DCH to implement a pharmaceutical best practices initiative for the department's various health care programs to control the costs of health care, to reduce the costs of prescription drugs, and to assure continued access to pharmaceutical services at fair and reasonable prices.

The bill would do the following:

Implementation; Prior Authorization and Appeal Process. If implemented, the initiative would have to include, but not be limited to, 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 (excluding weekends and holidays) 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 or Medicaid policies to implement the initiative and to ensure compliance with the published Medicaid bulletin that initiated the initiative.

Disease Management and 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 provide a written report to the Senate and House Appropriations Subcommittees on Community Health on the effectiveness of the programs and the savings incurred as a result of those programs being provided instead of supplemental rebates.

Pharmacy and 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 whose practice included Medicaid-eligible patients.
- Five pharmacists whose business included prescriptions from Medicaid-eligible individuals.

The committee could include, but not be limited to, a physician or pharmacist with expertise in mental health, who specialized in pediatrics, and who had experience in long-term care.

The bill would specify how committee members would serve their terms and would provide for current members to complete their appointments or serve until October 1, 2005, whichever came first.

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. It would have to review its policies and procedures and consider means to increase and facilitate public comment. 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 web site 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 available information regarding the known potential impact on patient care, the known 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 review information about new prescription drugs.

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

Prior Authorization. Except as otherwise provided by law or in the bill, a prescriber would have to obtain prior authorization for drugs provided to Medicaid beneficiaries directly through the department on a fee for service basis or under contract for such pharmaceutical services and 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. If contact with the agent's physician on duty could not be arranged within 72 hours due to a legal holiday, the prescriber could request a longer 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 any of the following were satisfied:

- The prescribing physician verified that the drugs were being prescribed consistent with its licensed indications, that no other drugs included on the preferred drug list, in the physician's professional opinion, would offer a comparable benefit to the patient, and that the drugs were necessary for the continued stabilization of the patient's medical condition.
- The prescribing physician verified that following documented previous failures on earlier prescription regimens, in the physician's professional opinion, would offer a comparable benefit to the patient.
- The prescribing physician verified that the drugs were being prescribed to a patient for the treatment of any symptoms or side effects that were a direct result of treatment received for HIV infections or complications from AIDS or acquired immunodeficiency syndrome; cancer; organ replacement therapy; epilepsy or seizure disorder.

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 being prescribed consistent with its licensed indications or with generally accepted medical practice as documented in a standard medical reference; was being used to treat a condition normally treated within that physician's specialty field; and that in the physician's professional opinion, no other drug included on the preferred drug list could provide a comparable benefit.

Documentation to verify all of the above could be provided by telephone, facsimile, or electronic transmission.

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.

Senate Bill 832 would add a new provision to the Social Welfare Act (MCL 400.109h) to prohibit the Department of Community Health (DCH), if it developed a prior authorization process for prescription drugs under the medical assistance program, from requiring prior authorization for the following:

- A central nervous system prescription drug classified as an anticonvulsant, antidepressant, antipsychotic, or noncontrolled substance antianxiety drug in a generally accepted standard medical reference.

- A prescription drug that is cross-indicated for a central nervous system drug exempted above as documented in a generally accepted standard medical reference.
- A prescription drug that is recognized in a generally accepted standard medical reference as effective in the treatment of conditions specified in the most recent diagnostic and statistical manual of mental disorders published by the American Psychiatric Association. The DCH or its agent could not deny a request for prior authorization under this provision unless it was determined that the controlled substance or the dosage of the drug was not consistent with its licensed indications or with generally accepted medical practice as documented in a standard medical reference.
- A prescription drug that is recognized in a generally accepted standard medical reference for the treatment of HIV infections or the complications of the HIV or AIDS; cancer; organ replacement therapy; or epilepsy or seizure disorder.

The bill would define "prior authorization" as a process implemented by the DCH that conditions, delays, or denies the delivery of a particular pharmaceutical service to Medicaid beneficiaries upon application of predetermined criteria by the DCH or its agent for those services covered by the department on a fee-for-service basis or under a contract for those services. The process could require a prescriber to verify with the DCH or its agent that the proposed medical use of a prescription drug being prescribed for a patient meets the predetermined criteria for a prescription drug that is otherwise covered under the act, or requires a prescriber to obtain authorization from the DCH or its agent before prescribing or dispensing a prescription drug that is included on a preferred drug list or that is subject to special access or reimbursement restrictions.

"Cross-indicated" would mean a drug that is used for a purpose generally held to be reasonable, appropriate, and within community standards of practice even though the use is not included in the FDA's approved labeled indications for that drug.

HOUSE COMMITTEE ACTION:

The committee substitute for Senate Bill 831 made the following changes:

- Eliminated the requirement that the governor appoint physicians and pharmacists to the Michigan Pharmacy and Therapeutics Committee from lists provided by physicians associations and the Michigan Pharmacists Association and Michigan Retailers Association, respectively.
- Restricted membership on the committee to no more than two department employees.
- Clarified that the preauthorization process applies to drugs being provided to Medicaid beneficiaries directly through a fee-for-service basis or under a contract for such pharmaceutical services and that are not included on the department’s preferred drug list.
- Excluded from preauthorization drugs used to treat symptoms or side effects that are a direct result of treatment received for certain listed diseases or conditions.

- Required the committee to review its policies and procedures and consider means to increase and facilitate public comment.
- Eliminated the restriction that a drug be exempt from preauthorization if used as initial therapy for a patient to continue his or her continued stabilization.
- Exempt from the preauthorization requirement drugs, in the physician's professional opinion, for which there are no other drugs that would give a comparable benefit to the patient.

The committee substitute for Senate Bill 832 clarified that the prior authorization process pertained to services delivered to Medicaid beneficiaries who received those services on a fee-for-service basis or under a departmental contract for those pharmaceutical services. The committee substitute also specified that a request for prior authorization of a controlled substance could not be denied unless the drug or the dosage of the drug was not consistent with licensed indications or documented accepted medical practice. In addition, the substitute bill replaced the phrase "multiple source brand name or its generic equivalent" with "generic equivalent of a multiple source brand name" and made a few other minor changes in wording.

BACKGROUND INFORMATION:

The following information was supplied by the Senate Fiscal Agency in an analysis on earlier versions of the bills.

In March 2003, the United States District Court for the District of Columbia ruled on a suit brought by the Pharmaceutical Research and Manufacturers of America (PhRMA) challenging the Michigan Best Practices Initiative.

PhRMA claimed that the DCH had created a formulary under the federal Medicaid statute but did not comply with all the requirements for a formulary under the statute; that the HHS secretary improperly had approved the DCH's supplemental rebate requirement; that the Initiative's requirement that manufacturers provide rebates with respect to two non-Medicaid programs as a condition of ensuring exemption from the prior authorization process violated a provision of the statute requiring that a prior authorization process be implemented in the "best interests" of Medicaid recipients; and that the pricing aspect of the Initiative amounted to state action that had the effect of regulating trade outside the state in violation of the Commerce Clause of the U.S. Constitution.

PhRMA argued that in excluding certain drugs from the preferred drug list based upon price, rather than solely upon the absence of a "clinically meaningful therapeutic advantage", as required by the Medicaid statute, the DCH created an illegal formulary. Furthermore, the DCH had not offered a written explanation for its exclusion of particular drugs, as also required by the Medicaid statute.

The court disagreed, citing language in the statute that, "[a] State may subject to prior authorization any covered outpatient drug", and "[a] prior authorization program

established by a State...is not a formulary subject to" specific requirements of the statute for establishing a drug formulary and excluding drugs form it. The court concluded that the statute "could not be clearer in specifying that states need not follow the procedures for excluding drugs from formularies in order to subject drugs to prior authorization."

PhRMA also asserted that the HHS secretary improperly approved the DCH's requirement that manufacturers offer supplemental rebates in exchange for designation as a preferred drug. PhRMA interpreted statutory language to mean that the DCH could enter into "separate state agreements as alternatives to, rather than in addition to, the Secretary's agreement". PhRMA argued that the statute did not allow a state to use the rebate amount negotiated by the HHS secretary as a "floor" from which to negotiate higher rebates. The court rejected PhRMA's interpretation, stating that the HHS secretary's rebate level would be a default rebate if negotiations between a manufacturer and a state fell through. "This default rebate level is thus necessarily a 'floor'...".

Third, the NUIC claimed that the DCH violated a provision in the Medicaid statute requiring a state plan to "provide such safeguards as may be necessary to assure that...care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients", by requiring manufacturers to provide rebates with respect to two non-Medicaid programs (EPIC and MOMS) in order to avoid the prior authorization requirement for their products. The plaintiff alleged that prior authorization unnecessarily would subject Medicaid recipients to harm for the purpose of saving money only in the non-Medicaid realm.

The court agreed with the federal defendants' response to this argument, which was that the projected savings would provide for increased coverage through the EPIC and MOMS programs of people who otherwise would be diverted to the Medicaid program. Therefore, although the prior authorization process could result in delays in obtaining first-choice medications for some individuals, it would protect the "best interests" of the Medicaid program as a whole.

Finally, PhRMA claimed that the pricing aspect of the Initiative had the effect of regulating interstate commerce in violation of the dormant Commerce Clause of the U.S. Constitution (which prohibits states from unduly burdening interstate or foreign commerce even where Congress--which has the power to regulate such commerce--has not enacted legislation). According to the plaintiff, the manufacturer agreements for supplemental rebates and non-Medicaid rebate agreements effectively reduced the prices of drugs the manufacturers sold in Michigan for the Medicaid program, to the lowest prices available within the United States for the "best in class" drugs, and thus established out-of-state "benchmarks" for regulating prices.

Invoking an earlier U.S. Supreme Court decision that the Commerce Clause places no limitation on a state's activities if the state is acting as a market participant, the district court found that, since the state of Michigan itself was the purchaser of the drugs, and since the prices were affected not through state legislation but through voluntary agreements, the state was acting purely as a market participant. Furthermore, the court

held, "[I]t is plain that there is no dormant Commerce Clause violation in any event. "The court determined that any effect on interstate prices would be sporadic and incidental, and that the burden imposed on interstate commerce was not clearly excessive in relation to the putative local benefits of the Initiative.

The court entered judgment in favor of the federal defendants and the DCH director on all claims. PhRMA then appealed to the U.S. Circuit Court of Appeals for the District of Columbia, which upheld the lower court's decision on April 2, 2004.

ARGUMENTS:

For:

The bills would establish in statute what already is, for the most part, current practice, and help ensure that low-income, vulnerable populations continue to have access to necessary prescription medicines. The bills would provide for the creation of a financially sound preferred drug list that would not place an undue burden on physicians in their prescription options. By codifying several current practices, the bills would ensure that these practices would not be changed in the future when different people are appointed to the Pharmacy and Therapeutics Committee. Furthermore, an issue as significant as the prior authorization process should be regulated in the compiled laws, not reauthorized in the boilerplate language of the DCH's budget bill every year. These bills would help ensure that any future cost containment efforts for the Medicaid prescription drug program were based on scientific, medically sound principles.

Response:

As written, Senate Bill 832 could still impede physicians who treat children and cancer patients as well as psychiatrists, as many of the drugs used to treat their patients are used according to protocol established in peer review literature and not necessarily documented in a standard medical reference. For instance, according to information provided by the Michigan Psychiatric Society, unlicensed indications that are good standard practice for child psychiatry are not always found in standard medical references. Therefore, the prescribing physician would have to seek prior authorization, resulting in an unnecessary burden on the physician and possible delay in receiving medication for the patient. The Society suggests that there are myriad approaches and information regarding an appropriate solution to address specific off-label use.

For:

The House committee substitutes clarify that the prior authorization process and the exclusions apply to the Medicaid fee-for-service population or where the state contracts with pharmaceutical companies for non-HMO enrollees. The bills do not apply to services provided to the Medicaid beneficiaries enrolled in HMOs. The state is able to negotiate reasonable prices for services through their HMO contracts for those Medicaid recipients. However, the fee-for-service population often represents the sickest patients and those who have multiple ailments. Therefore, it is all the more important to codify the current practices of the Best Practices Initiative, including excluding certain drugs from needing prior authorization, so that the state can continue to offer critically needed

health care services at a reasonable cost. Already the state is saving about $40 million a year.

Against:

Some feel that Senate Bill 831 should be amended to require at least one member of the Pharmacy and Therapeutic Committee to be a consumer, preferable one who has been or is currently a Medicaid beneficiary. A consumer representative could offer a different perspective and insight that could help the committee formulate better and more consumer-friendly policies. Even if the consumer member did not have voting rights, he or she could still prove a valuable asset to the committee.

POSITIONS:

The Department of Community Health supports the bills. (6-15-04)

A representative of each of the following groups testified in support, submitted written testimony in support, or indicated support for the bills on 6-15-04):

The Epilepsy Foundation of Michigan
The Mental Health Association in Michigan
The HIV AIDS Alliance of Michigan
The Michigan Psychiatric Society
The National Association for the Mentally Ill – Michigan (NAMI)
The Michigan Pharmacists Association
The Michigan Academy of Physician Assistants
The National Kidney Foundation
Gift of Life Michigan
The ARC Michigan
The Michigan Hospice and Palliative Care Organization
The Barbara Ann Karmanos Cancer Institute
The American Cancer Society – Michigan Division
The American College of Cardiology

The Michigan Medical Society indicated support for Senate Bill 831.

Legislative Analyst: Susan Stutzky
Fiscal Analyst: Bill Fairgrieve

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