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BILL ANALYSIS

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Senate Bills 831 and 832 (as reported without amendment)
Sponsor: Senator Tom George (S.B. 831)
Senator Bev Hammerstrom (S.B. 832)
Committee: Health Policy

Date Completed: 4-13-04

RATIONALE

In 2001, then-Governor John Engler issued Executive Order 2001-8 to establish a Michigan Pharmacy and Therapeutics Committee, made up of physicians and pharmacists, to advise the Department of Community Health (DCH) on issues affecting prescription drug coverage for, and recommend to the DCH guidelines for prescription drug coverage in, its various health care programs. The resulting program, described below, is known as the Michigan Best Practices Initiative. It has been suggested that the Best Practices Initiative be written into statute, and that certain drugs, such as those used to treat psychiatric conditions and specific chronic physical illnesses, be exempted from the program's prior authorization process.

In an effort to control the cost of prescription drugs for the State's Medicaid program, the Pharmacy and Therapeutics Committee was charged with developing a preferred drug list, called the "Michigan Preferred Product List" (MPPL). The Committee reviewed approximately 40 classes of therapeutic prescription drugs and identified at least two medications as "best in class", based on clinical data, effectiveness studies, and peer-reviewed literature, and placed them on the MPPL for availability without prior authorization from the State's pharmacy benefits manager. Manufacturers of drugs not designated as "best in class" then were given the opportunity to gain placement on the MPPL without prior authorization by offering the State supplemental rebates, in addition to the rebates already negotiated by the Secretary of the United States Department of Health and Human Services (HHS). Drugs whose manufacturers did not offer supplemental rebates were listed with a notation that physicians wishing to prescribe those drugs would have to obtain prior authorization in order for those drugs to be eligible for Medicaid reimbursement. (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.

CONTENT

Senate Bill 831 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 U.S. Food and Drug Administration.**
- **-- Allow the DCH to establish disease management and health management programs that a pharmaceutical manufacturer would provide 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.**

Senate Bill 832 would amend the Social Welfare Act to prohibit the DCH from requiring prior authorization for all antianxiety, anticonvulsant, antidepressant, or antipsychotic central nervous system drugs; drugs used to treat certain mental disorders; drugs used to treat HIV, cancer, and hepatitis C; and drugs used in organ replacement therapy.

The bills are described below in further detail.

Senate Bill 831

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 U.S. 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.

Senate Bill 832

The bill would amend the Social Welfare Act to prohibit the DCH, if it developed a prior authorization process for prescription drugs as part of the pharmaceutical services offered under the medical assistance program administered under the Act, from requiring prior authorization for the following single source brand name, multiple source brand name, or other prescription drugs:

-- A prescription drug that was classified as an antianxiety, anticonvulsant, antidepressant, or antipsychotic central nervous system drug in the most recent publication of "Drug Facts and Comparisons" published by the facts and comparisons division of J.B. Lippincott Company.
-- A prescription drug that was cross-indicated for an antipsychotic central nervous system drug exempted above according to the most recent publication of "American Psychiatric Press Textbook

of Psychopharmacology", "Current Clinical Strategies for Psychiatry", "Drug Facts and Comparisons", or any other similar publication approved by the DCH.

-- A prescription drug that was prescribed for the treatment of mental disorders that met criteria specified in the most recent diagnostic and statistical manual of mental disorders published by the American Psychiatric Association.

-- A prescription drug that was approved by the FDA for the treatment of human immunodeficiency virus (HIV) infections or the complications of the HIV or acquired immunodeficiency syndrome (AIDS); cancer; organ replacement therapy; or hepatitis C.

If the publications were amended after the bill's effective date, the DCH would have to determine whether those changes would apply to the prescription drugs exempt from the prior authorization process under the bill. In making this determination, the DCH would have to consider whether the amendments furthered the goal of the exemption of those categories of prescription drugs from the prior authorization process.

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 upon application of predetermined criteria by the DCH or its agent for that service. 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.

Proposed MCL 333.9701-333.9711 (S.B. 831)
Proposed MCL 400.109h (S.B. 832)

BACKGROUND

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. The suit was brought against Tommy Thompson, Secretary of the U.S. Department of Health and Human Services, and Thomas Scully, Administrator of the Centers for Medicare and Medicaid Services. The National Urban Indian Coalition (NUIC) joined PhRMA as an intervenor-plaintiff. The DCH joined the suit as an intervenor-defendant.

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

(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

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.

Supporting Argument

The prior authorization process sometimes can cause two- or three-week delays. In some situations, this may be an unnecessary, potentially devastating barrier to access to medication. Parkinson's Disease patients who do not take their medications in a timely manner can fall, freeze up, shake uncontrollably, or fall into a deep sleep in an instant. A patient diagnosed with depression can have a relapse and become despondent waiting for the proper medication. For patients with certain brain disorders, delayed access to medication potentially can result in hospitalization or contact with the criminal justice system. According to testimony from a representative of the Mental Health Association of Michigan, two-thirds of the 400 consumer and family calls the organization has received involved delays or denials with negative consequence, (although patients usually have not required hospitalization). The organization also reports that most of the providers who have called have had a negative experience with the prior authorization process.

Senate Bill 831 would alleviate these concerns by requiring that prior authorization requests be addressed within 24 hours, and each appeal of a request denial within 48 hours. The bill also would allow a prescriber to request a 72-hour supply of a nonauthorized drug in an emergency. While the DCH generally follows these procedures already, it is important to back them up with the force of law. Furthermore, confusion around the appeal process when a prior authorization request is denied continues to exist. The bill would clarify the process.

Moreover, expediting the prior authorization process would save time for physicians and their staff and help make treating Medicaid patients more cost-effective. Many doctors see treating Medicaid patients as a moral obligation to the communities in which they practice. Reportedly, some doctors who treat Medicaid patients are reimbursed for less than 50% of their costs. The prior authorization process requires extra communication between physicians and pharmacists and takes up a significant amount of time for physicians and their staff, which leads to increased office costs. Ideally, a physician should be able to prescribe the medication necessary to treat a patient properly, with no restrictions. If a prior authorization process is necessary, it must be as easy as possible for health care providers. The requirements for the process under Senate Bill 831 would provide physicians with a greater ability to meet their patients' needs.

Response: The bill should include a mechanism to assure medication access through a written declaration of medical necessity by a doctor who went through the prior authorization and appeal process but was still denied. Perhaps the bill also should require that one of the physician Committee members come from the board of a nonprofit health care advocacy organization so that consumer interests would have stronger representation. A pain management specialist also could be beneficial to the Committee.

In addition, the bill should require extensive monitoring and a program evaluation that would include the number of prior authorization requests; the percentage of requests denied; response times from, and the costs of running prior authorization through, each pharmacy benefit administrator; the number of requests for 72-hour prescriptions; the accuracy of information in pharmacists' computer systems; changes in utilization levels for various drugs; changes to State drug costs; any adverse effect on hospitalization and emergency room usage and costs; and categorization of reporting data across different populations that receive State-funded health care. This information would provide a more complete view of the Initiative's impact than the information required in the annual reports to the Legislature would supply.

Supporting Argument

It is critical that a physician have complete control over his or her patients' drug regimens, particularly in cases of mental illness and chronic disease. When the Committee was created several years ago, it chose two medications in each of

approximately 40 classes of therapeutic drugs, usually if the manufacturers agreed to give the State rebates, to include on the preferred drug list. As a result, patients who had been stabilized with certain drugs were required to switch to other drugs on the list. The DCH amended the program and allowed some essential medications, including nearly all psychiatric drugs, to be grandfathered in. Eventually, organ transplant drugs also were exempted from the prior authorization process. It is important to ensure that these categories of drugs, as well as the others mentioned in Senate Bill 832, remain exempt from the prior authorization process for several reasons.

First, there is great variation in response to medicines among individual patients due to multiple genetic factors, the specific nature of the illness, the side effects of the drugs, and, commonly, the presence of multiple health problems or impairments that make treatment more difficult. Often, the only way to "test" the best treatment for a specific patient is through a very complex period of trial and error. Furthermore, it is critical to optimize treatment as soon as possible in the case of a potentially chronic and debilitating physical or mental illness. Early treatment can improve the course of the disease, which ultimately is more cost effective for the State.

Advances in therapeutic medications have been the greatest factor in successfully facilitating the deinstitutionalization of mental health patients. Most of the State-owned psychiatric hospitals have been closed, and there has been a 40% drop in private psychiatric hospital beds since 1993. The State should take steps to ensure that essential drugs continue to be available with minimal limitation. Compared with many other drugs, psychotropic medication tends to take longer to start working and longer to get out of the system if a switch is needed, and has a greater variability in response.

Also, in expanding the exempted categories of drugs, Senate Bill 832 would eliminate the broad "fail first" practice, under which some physicians must first prescribe medication that they know will not most effectively treat an individual patient, before being able to obtain prior authorization for the appropriate prescription. In one reported incident, a woman was not properly diagnosed with bipolar disorder for seven years, and then had to show that the authorized medication failed to treat her condition before getting the correct treatment. Some Medicaid patients do not have regular doctors, and so cannot produce documentation of previous failures on specific drugs and have lost crucial time taking medication they know will not work.

Finally, an overly restrictive preferred drug list results in untold costs to the State. According to one recipient of a kidney transplant, his prescription drugs cost $12,500 annually, or a total of $225,000 since he received the transplant 18 years ago. Without these drugs, his body could have rejected the transplanted organ, forcing him to undergo dialysis to stay alive at a cost of $60,000 per year, or $1,080,000 over the last 18 years. Furthermore, he would not have been able to work and would have continued drawing disability payments.

Since the preferred drug list and prior authorization process sometimes can interfere with a physician's ability immediately to prescribe the necessary drugs for the patient, Senate Bill 832 would exempt most drugs used to treat mental illness, cancer, HIV, hepatitis C, and those used by organ transplant recipients.

Response: The bill should include several other classes of drugs under the categories that would have to be covered without prior authorization. Although the bill mentions diseases of the central nervous system, drugs used in the treatment of Parkinson's Disease should be cited explicitly. As with many of the other illnesses mentioned in the bill, the symptoms of and treatment approaches to Parkinson's vary greatly among individuals, and treatment choices often require careful, frequent adjustments to drug regimens.

The bill also should exempt drugs used in the treatment of epilepsy or seizure disorders. The term "epilepsy" refers to as many as 100 different seizure types, which occur for different reasons, affect different parts of the brain, and are most appropriately treated with different drugs and combinations of drugs. In addition, pain management drugs should be exempt from the prior authorization requirement in order to prevent unnecessary suffering. Particularly during end-of-life care, the need for pain management can be acute.

Opposing Argument

Senate Bill 831 is unnecessary because the Pharmacy and Therapeutics Committee already exists under Executive Order 2001-8, and the State has implemented the Best Practices Initiative. Senate Bill 832 is unnecessary because, with the exception of the HIV, hepatitis C, and cancer drugs, all of the drugs listed in the bill already are exempt from the prior authorization process under current practice. The vast majority of doctors have been able to comply with the prior authorization process, and patients almost always receive what their physicians have ordered. According to the DCH, of the 250,000 prior authorization requests it receives every week, only 30 are denied.

Furthermore, under Senate Bill 832, if a new, expensive drug were developed and fell into an exempted class, the DCH would have to pay for it with no additional funding. No private insurer, or Blue Cross and Blue Shield of Michigan, must operate under the restrictions the bill would impose upon the DCH. The bill could jeopardize the savings generated by the MPPL.

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 to this provision, and it is believed that the savings have largely been achieved.

Beginning in FY 2003-04, the Department of Community Health appropriations act (Public Act 519 of 2003) included language requiring the Department to continue its practice of placing all atypical antipsychotic medications on the Medicaid preferred drug list, thereby exempting those drugs from prior authorization requirements of the Michigan Pharmaceutical Best Practices Initiative.

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.

Senate Bill 832 would include on the list of prescription drugs to be exempted from prior authorization requirements not only atypical antipsychotics, but effectively all prescription drugs used for the treatment of mental disorders. In addition, prescription drugs used for the treatment of HIV/AIDS, cancer, organ replacements, and Hepatitis C also would be exempted from prior authorization requirements.

As a result, the bills 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 bills would have no fiscal impact on local units of government.

Fiscal Analyst: Dana Patterson