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BILL ANALYSIS

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Senate Bill 831 (as enrolled) **PUBLIC ACT 250 of 2004**
Senate Bill 832 (as enrolled) **PUBLIC ACT 248 of 2004**
Sponsor: Senator Tom George (S.B. 831)
Senator Bev Hammerstrom (S.B. 832)
Committee: Health Policy

Date Completed: 8-25-04

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 was 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 the 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 added Part 97, the "Michigan Pharmaceutical Best Practices Initiative", to the Public

Health Code to allow the Department of Community Health 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 does the following:

-- Requires the initiative to include a preferred drug list, and a prior authorization and appeal process.
-- Requires a prescriber to obtain prior authorization for drugs not included on the preferred drug list, and requires the DCH to give authorization for certain drugs, including those prescribed by a specialist.
-- Exempts from the prior authorization requirement a patient who, before becoming a Medicaid recipient, is under a court order for a particular prescription drug, or who currently is under medical treatment and whose condition has been stabilized under a given prescription regimen.
-- Provides that the prior authorization requirement does not apply to drugs provided under a contract between the DCH and a health maintenance organization (HMO).
-- Allows the DCH to establish disease management and health management programs that a pharmaceutical manufacturer may provide instead of a supplemental rebate, for the inclusion of its products on the preferred drug list.
-- Provides for the membership of the Michigan Pharmacy and Therapeutics Committee and requires it to assist the DCH with certain functions.

Senate Bill 832 amended the Social Welfare Act to prohibit the DCH from requiring prior authorization for central nervous system anticonvulsant, antidepressant, antipsychotic, and noncontrolled substance antianxiety drugs; drugs cross-indicated for exempted central nervous system drugs; drugs used to treat certain mental disorders; drugs used to treat HIV, cancer, and epilepsy or seizure disorder; or drugs used in organ replacement therapy.

The bills took effect July 23, 2004. They are described below in further detail.

Senate Bill 831

Implementation; Prior Authorization & Appeal Process

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

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

The DCH may hire or retain contractors, subcontractors, advisors, consultants, and agents and may enter into contracts necessary or incidental to implement Part 97 and carry out its responsibilities and duties.

The DCH may promulgate rules or Medicaid policies to implement Part 97 and to ensure compliance with the published Medicaid bulletin that initiated the initiative.

Disease Management & Health Management Programs

In cooperation with a pharmaceutical manufacturer or its agent or another qualified contractor, the DCH may establish disease management and health management programs that may be provided, as negotiated, by the manufacturer or its agent or the contractor, 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 negotiates a plan for the provision of services by the manufacturer instead of a supplemental rebate, the DCH must give the Senate and House Appropriations Subcommittees on Community Health a written report on the effectiveness of the programs and the

savings incurred as a result of those programs' being provided instead of supplemental rebates.

Pharmacy & Therapeutics Committee

Under the bill, the Michigan Pharmacy and Therapeutics Committee, which was established by Executive Order 2001-8, is 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 must consist of 11 members appointed by the Governor. Six members must physicians whose practice includes Medicaid-eligible patients. Five members must be pharmacists whose business includes prescriptions from Medicaid-eligible individuals. Appointees may include physicians and pharmacists with expertise in mental health or mental health drugs, who specialize in pediatrics, and who have experience in long-term care.

No Committee member may be employed by a pharmaceutical manufacturer or have any direct or indirect interest in the business of a pharmaceutical manufacturer that causes a conflict of interest.

Committee members are to serve a term of two years; members serving on the Committee on the bill's effective date, however, are to serve until the date on which their appointment would have expired or until October 1, 2005, whichever occurs first. A member serving on the Committee on the bill's effective date whose term otherwise would have expired after October 1, 2005, may serve the remainder of his or her term if he or she meets the bill's qualifications. The Governor must appoint an additional number of members necessary to reach 11 members as required under the bill. The Governor must designate one member to serve as the Committee chairperson, who serves at the pleasure of the Governor.

A member may 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 will immediately terminate his or her membership on the Committee. The bill specifies that an example of not maintaining a professional license in good standing is if the DCH imposes a disciplinary sanction under the Public Health Code on a Committee member.

A member may be reappointed for additional terms. A vacancy must be filled in the same manner as the original appointment. An individual appointed to fill a vacancy created other than by expiration of a term must be appointed for the unexpired term of the member whom he or she is to succeed in the same manner as the original appointment.

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

The Committee may promulgate rules governing its organization, operation, and procedures. The Committee must review its policies and procedures and consider means to increase and facilitate public comment. The Committee must meet at the call of the chairperson and as otherwise provided in rules. It may meet at any location within the State and is subject to the Open Meetings Act. The Committee must 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 must make available on the website its regular meeting schedule and meeting locations for that year.

A majority of the members serving constitute a quorum for the transaction of business. The Committee must approve a final action by a majority vote. A member must be present at a Committee meeting in order to vote, and may not delegate his or her responsibilities to another person.

The Committee has the powers, duties, and responsibilities prescribed in Executive Order 2001-8 and must operate pursuant to and in accordance with the Executive Order. The Committee may make inquiries, conduct

studies and investigations, hold hearings, and receive comments from the public.

The Committee is advisory in nature and must 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 related Medicaid covered services, and sound clinical evidence found in labeling, drug compendia, and peer-reviewed literature pertaining to use of the 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.
-- Develop a process to collect and review information about new prescription drugs. (The DCH must post this process and the necessary forms on its website.)
-- Recommend to the DCH strategies to improve the initiative.

Prior Authorization

Except as otherwise provided by law or in Part 97, a prescriber must obtain prior authorization for drugs that are provided to Medicaid beneficiaries directly through the Department on a fee-for-service basis or pursuant to a contract for such pharmaceutical services, and are not included on the DCH's preferred drug list. If the prescriber's prior authorization request is denied, the DCH or its agent must 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 cannot be arranged, the DCH or its agent must 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 cannot be arranged within 72 hours due to a legal holiday, the prescriber may request a longer supply of the nonauthorized drug.

(Under the bill, "prescriber" means 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 must provide authorization for prescribed drugs that are not on its preferred drug list if the prescribing physician telephones the DCH's agent or certifies in writing, on a form provided by the DCH, any of the following:

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

The DCH or its agent also must provide authorization for a prescribed drug that is not on the preferred drug list if the prescribing physician has achieved advanced specialization training and is certified by a specialty board recognized by the American Osteopathic Association and the Council on Graduate Medical Education, or their successor organizations, and provides documentation of his or her certification. The prescribing physician must telephone the DCH or certify in writing that the drug is being prescribed consistent with its licensed indications or with generally accepted medical practice as documented in a standard medical reference; that the drug is being used to treat a condition that normally is treated within the physician's specialty

field; and that no other drug or drugs included on the list can provide a comparable benefit, in the physician's professional opinion.

Documentation of necessity or previous failures may be provided by telephone, facsimile, or electronic transmission.

A patient who is under a court order for a particular prescription drug before becoming a Medicaid recipient is exempt from the prior authorization process and may continue on that medication for the duration of the order.

A patient who currently is under medical treatment and whose condition has been stabilized under a given prescription regimen before becoming a Medicaid recipient is exempt from the prior authorization process and may continue on that medication for the current course of treatment if, without that prescription regimen, he or she would suffer serious health consequences. Unless a controlled substance currently is being prescribed under a patient's hospice plan of care, however, a continuing prescription for a controlled substance requires prior authorization. The DCH or its agent may not deny a request for prior authorization of a controlled substance unless the DCH or its agent determines that the controlled substance or the dosage of the controlled substance being prescribed is not consistent with its licensed indications or with generally accepted medical practice as documented in a standard medical reference.

The prior authorization process does not apply to drugs provided under a contract between the DCH and an HMO.

Senate Bill 832

The bill amended the Social Welfare Act to prohibit the DCH, if it develops a prior authorization process for prescription drugs as part of the pharmaceutical services offered under the Medicaid program, from requiring prior authorization for the following single source brand name, generic equivalent of a multiple source brand name, or other prescription drugs:

-- A central nervous system prescription drug that is 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 for the treatment of, and is prescribed to a patient for the treatment of, HIV infections or the complications of the HIV or AIDS; cancer; organ replacement therapy; or epilepsy or seizure disorder.
-- Unless the prescription drug is a controlled substance or is being prescribed to treat a condition that is excluded from coverage under the Act, 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 may not deny a request for prior authorization of a controlled substance, as provided above, unless the DCH or its agent determines that the controlled substance or the prescribed dosage is not consistent with its licensed indications or with generally accepted medical practices as documented in a standard medical reference.

The bill does not apply to drugs provided under a contract between the DCH and an HMO.

The bill defines "prior authorization" as a process implemented by the DCH that conditions, delays, or denies the delivery of particular pharmaceutical services to Medicaid beneficiaries upon application of predetermined criteria by the DCH or its agent for those pharmaceutical services covered by the Department on a fee-for-service basis or pursuant to a contract for those services. The process may 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 require a prescriber to obtain authorization from the DCH or its agent before prescribing or dispensing a

prescription drug that is not included on a preferred drug list or that is subject to special access or reimbursement restrictions.

"Cross-indicated" means 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 Federal Food and Drug Administration's approved labeled indications for that drug.

MCL 333.9701-333.9709 (S.B. 831)
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 from 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 establish in statute what the Department already was practicing, for the most part, and will help ensure that low-income, vulnerable populations continue to have access to necessary prescription medicines. The bills provide for the creation of a financially sound preferred drug list that will not place an undue burden on physicians in their prescription options. By codifying several previous practices, the bills will ensure that these practices are not 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 will help ensure that any future cost containment efforts for the Medicaid prescription drug program are 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 consequences (although patients usually have not required hospitalization). The organization also reported that most of the providers who called had a negative experience with the prior authorization process.

Senate Bill 831 will 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 allows a prescriber to request a supply of a nonauthorized drug in an emergency. While the DCH generally followed these procedures already, it is important to back them up with the force of law. Furthermore, there was some confusion about the appeal process when a prior authorization request was denied. The bill clarifies the process.

Moreover, expediting the prior authorization process will 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 will improve physicians' ability to meet their patients' needs.

Response: The law should include a mechanism to assure medication access through a written declaration of medical necessity by a doctor who goes through the prior authorization and appeal process but is still denied. Perhaps the law 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 law should require extensive monitoring and a program evaluation that includes 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 emergency 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 will 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, for inclusion 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 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. Essential drugs must remain 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 eliminates the broad "fail first" practice, under which some physicians first had to prescribe medication that they knew would 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; these patients lost crucial time taking medication they knew would 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 exempts most drugs used to treat mental illness, cancer, HIV, and epilepsy, and those used by organ transplant recipients.

Response: The law should include several other classes of drugs under the categories that must 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.

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.

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 were largely 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 codifies current policy pertaining to the Michigan Pharmaceutical Best Practices Initiative, but adds a provision that could lead to substantial cost increases for State government. The bill exempts from prior authorization drugs prescribed by a physician specialist that are used to treat a condition that normally is treated within the physician's area of specialization.

Senate Bill 832 includes on the list of prescription drugs 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 epilepsy or seizure disorder also are exempted from prior authorization requirements.

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

Fiscal Analyst: Steve Angelotti

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