

Michigan Department of Community Health
Pharmaceutical Programs
FY -2002
September 28, 2001

During discussions on the FY -02 appropriation for the Michigan Department of Community Health, legislative action was taken to allow the Department to submit changes to pharmacy policies for Medicaid that would reflect a composite of pharmacy best practices in use by Health Maintenance Organizations under contract to provide managed medical care for Medicaid beneficiaries. This document is being delivered in compliance with Public Act 60 of 2001 and will outline the proposed policies for pharmacy programs funded by the State of Michigan.

Historical Review

Michigan has covered pharmaceutical products as an optional Medicaid benefit virtually since inception of the Medicaid program in 1966. Since 1992, each annual appropriation bill has included language limiting the Department's ability to apply prior authorization to single-source pharmaceutical products, products which represent 70% of the Medicaid program's pharmacy expenditures. Medicaid currently covers those drugs that have a rebate agreement under Section 1927 of the Social Security Act. During the past few years, the cost of pharmaceuticals has increased dramatically and is one of the driving forces associated with continued medical inflation. During FY -02, it is estimated that the Department will fund over \$1.0 billion in pharmaceutical costs. The Department has attempted for a number of years to obtain the ability to change the methodology used to purchase drugs. With the passage of Public Act 60 of 2001, the Legislature has provided the Department with the opportunity to obtain cost efficiencies by allowing changes in the Department's pharmacy policies.

Background

The FY -02 appropriation for the Michigan Department of Community Health assumes \$42.8 million in savings from implementing various pharmacy efficiencies. The savings were based on a number of initiatives, including rebates obtained on pharmaceutical products provided to beneficiaries in the Elder Prescription Insurance Coverage Program, the State Medical Program, the Children's Special Health Care Services Program, and for Medicaid beneficiaries enrolled in contracted HMOs. The savings also assume the Department will expand the list of "drugs for which prior authorization will be required under the Medicaid fee for service program. In an effort to maximize savings and to promote clinically sound pharmacy programs, the Department has integrated all programs that will be governed by the proposed pharmacy policies. The additional programs include the hospitals and centers operated by the Michigan Department of Community Health, and the non-Medicaid portion of the Community Mental Health Programs.

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Maximizing rebates from pharmaceutical manufacturers is only one piece of the pharmacy program changes being initiated by the Department. In addition to maximizing rebates, the Department will expand its list of drug products for which prior authorization will be required and establish guidelines for implementation in all pharmacy programs funded through its appropriation. The list of drugs requiring prior authorization and guidelines will assist the Department in assuring that the pharmaceutical manufacturers are offering the Department's pharmacy programs their lowest prices. Currently only the Medicaid fee for service program generates rebates, and these rebates are approximately \$80 million per year.

Another area being reviewed as part of this process is the price being paid by Michigan Medicaid. A federal Office of the Inspector General (OIG) report, entitled "Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products", released August 10, 2001, stated that the prices being paid by most states for Medicaid pharmaceuticals is not the lowest price available. Michigan Medicaid pays average wholesale price minus 13.5 -15.1 %. The OIG report indicates that this discount should be in the 20% range. This review will be completed simultaneously with the recommendations in the remainder of this document.

Legislation

As part of the FY -02 budget development process, the Legislature included language that allows the Department to create new pharmacy policies. The boilerplate language included in section 2204 of Public Act 60 of 2001 has several

requirements, including a requirement that the pharmacy policies developed shall not be more restrictive than those developed for the Elder Prescription Insurance Coverage Program. The Legislature also included boilerplate language that provides for a legislative review of the proposed policy changes. Section 2204 (3) of Public Act 60 of 2001 details the legislative review process as follows:

"Any changes described in subsection (1) shall become effective 30 days after the department submits these changes to the chairpersons unless 1 or both of the chairpersons disapprove of the changes. If both of the chairpersons disapprove, the changes do not become effective. If only 1 of the chairpersons disapproves, the chairpersons shall submit the changes to the speaker of the house and the majority leader in the senate, and the changes shall become effective 15 days after that submission to the speaker of the house and the majority leader of the senate unless both the speaker of the house and the majority leader of the senate disapprove."

Since the legislative approval process may take up to 45 days, the Department is continuing with portions of the proposed recommendations in order to assure a December 1, 2001 implementation date.

Pharmacy Policy Changes

>- **Pharmacy and Therapeutics Committee** -The development of the list of drugs for requiring prior authorization will comply with any requirements in Section 1927 of the Social Security Act. The Department will request that Governor Engler appoint a Pharmacy and Therapeutics Committee to assist the Department in developing and

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implementing changes in the Department's pharmacy policies. The Committee will include a minimum of six physicians and four pharmacists representing a cross section of the medical field. One of the tasks of the Committee will be to make the final recommendation to the Department of the specific drugs in selected therapeutic drug classes for which prior authorization should be required. The Committee will also provide recommendations to the Department for pharmaceutical guidelines. While the initial recommendations of the Committee are to be completed by November 1, 2001, the Committee will continue to meet periodically at the call of the chair to consider recommending modifications to the list of drugs requiring prior authorization, including but not limited to adding or deleting classes of drugs to the list, and other changes that may be required to continue with its pharmacy policies.

.. **Supplemental Rebates for Medicaid Pharmacy Program**- It is the intent of the Department to seek supplemental rebates on Medicaid prescriptions from pharmaceutical manufacturers. Section 1927 of the Social Security Act currently requires, as a condition of product coverage, that all manufacturers have a rebate agreement on file with the Secretary of Health and Human Services. In Michigan, rebates are currently being paid by the manufacturers on fee for service drugs as required by the Act. As part of the

~ proposed pharmacy policy changes, the Department will be requesting supplemental rebates from all manufacturers on all drugs utilized by the Michigan Medicaid program. Supplemental rebates are outside of the Social Security Act and, therefore, do not affect the federal rebate issue or price for any other state's Medicaid program. In order to implement supplemental rebates, agreements with manufacturers must receive approval from the Secretary of Health and Human Services. It is the Department's intent to request this approval in October 2001, with an implementation date of December 1, 2001.

>- **Rebates on Medicaid Managed Care Programs** -As part of the move to Medicaid managed care, HMOs under contract to provide services to beneficiaries in the Medicaid program are responsible for the cost of pharmaceuticals for their enrollees. Currently the state is not eligible for rebates for pharmaceuticals purchased by HMOs. Section 1927 G)(i) of the Social Security Act provides that covered outpatient drugs dispensed by HMOs are not subject to the rebate requirement. The federal Centers for Medicare & Medicaid Services (CMS) has interpreted this provision to mean that any outpatient drugs included in a capitation arrangement are excluded from the federal Medicaid Drug Rebate Program. However, at the same time CMS agreed that when a state carves out all Medicaid drugs from the HMO capitated payment and provides them under a fee for service arrangement, the drugs are then covered under the federal rebate program. Therefore, it is necessary to carve out all drug costs from the HMOs in order to obtain rebates. A partial carve out of psychotropic drugs from the HMOs was accomplished during FY -00. The Department intends to implement the proposed carve out by April 1, 2002. In an effort to control utilization, the Department will implement incentives with the HMOs to continue to manage drug utilization.

Rebates on State Funded Program Pharmaceuticals -There are a number of state funded programs that do not currently receive any rebates. These programs include but are not limited to the Elder Prescription Insurance Coverage Program, State Medical Program, Children's Special Health Care Services Program, mental health non-Medicaid

services, and the Department's hospitals and centers. In an effort to gain leverage during discussions with pharmaceutical manufacturers, these programs will be grouped together and will represent over 200,000 lives. Rebates for state funded pharmaceuticals will be part of the negotiation process with pharmaceutical manufacturers. The Department expects to obtain Medicaid level rebates for drugs prescribed under these state funded programs. Rebates under these programs will be phased in, beginning on December 1, 2001.

Pharmaceutical Product List -The Pharmacy and Therapeutics Committee will be asked to identify those therapeutic classes of drugs that represent a majority of the drugs prescribed in all of the pharmacy programs. While the Medicaid pharmacy program will cover all drugs that have a rebate agreement under the Social Security Act, it will require prior authorization for many of the drugs. The non-Medicaid pharmacy programs will include drugs for which pharmaceutical manufacturers sign rebate agreements; and, like the Medicaid program, will require prior authorization for a number of the drugs. It is the Department's intent to utilize a similar pharmaceutical product list for all pharmacy programs.

The end result of the work of the Committee will be the recommendation of the pharmaceutical product list that will contain a limited number of drugs in each

therapeutic class for which prior authorization will be required. Decisions by the Committee will be based on clinical criteria along with the net price of each drug. Once the rebate discussions with the pharmaceutical manufacturers are completed, the net prices for the drugs in each class will be forwarded to the Committee for alignment with their clinical reviews. The Committee will develop the pharmaceutical product prior authorization list with the negotiated net price as a factor in the decision. The Department plans to implement the decisions of the Committee on December 1, 2001.

Implementation Steps

Medicaid Waiver Change -The Department must submit a Medicaid waiver amendment to the Centers for Medicare and Medicaid Services (CMS) for their approval to carve out the drug costs from the Medicaid HMOs. This carve out is necessary to require the pharmaceutical manufacturers to pay the Department rebates under the Social Security Act. A waiver amendment will be submitted to CMS early enough to assure approval prior to implementation.

State Plan Amendment -The Department is consulting with CMS to determine if a State Plan amendment is needed to implement the recommended pharmacy policy changes. The current State Plan for Michigan reads as follows: "Drug Products -the services are covered when prescribed or ordered by a physician or dentist or other licensed practitioner included in the Plan within the scope of his profession, and when obtained at a licensed retail pharmacy. Coverage includes selected legend and over the counter products restricted to only those products sold by manufacturers as required by Section 1927 of the Social Security Act." The Department already has the ability under its current State Plan to implement the proposed pharmacy changes. Based on this existing ability to select drugs for coverage and to require prior authorization, a State Plan amendment may not be needed. If a Plan amendment is needed, it will be developed and submitted to the Centers for Medicare and Medicaid Services by October 12, 2001.

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Manufacturer Discussions -All pharmaceutical manufacturers will be invited within the next three weeks to respond to the Department's proposal for supplemental rebates on Medicaid rebates and for rebates on pharmaceutical products provided to beneficiaries in state funded programs. The Department's contractor will conduct the discussions with staff in attendance from the Department. Manufacturers will be invited to meet with the negotiation team individually over a period of 2-3 days. The manufacturers will be required to respond in writing with their proposals for the net prices on each of their drugs contained in the various therapeutic classes developed by the Department. Discussions are to be completed by October 19, 2001, and the net prices will be forwarded to the Pharmacy and Therapeutics Committee.

Completion of Therapeutic Classifications -The Committee will review the clinical research provided needed to finalize the therapeutic classes that will be used in the pharmaceutical product list.

Development of the Pharmaceutical Product List -Once the therapeutic classes and the manufacturer discussions are completed, the Committee will merge the data to create the Department's list of drugs that will and will not require prior authorization. Included in this process is a review of other drug lists used by Medicaid HMOs. The publication of the pharmaceutical product prior authorization list will be completed by November 1, 2001.

Implementation of the Pharmaceutical Product List -The implementation of the list of drugs that will and will not require prior authorization will occur during the course of FY -02 with many programs starting December 1, 2001. The

Medicaid Program, Elder Prescription Insurance Coverage Program, State Medical Program, and Children's Special Health Care Services Program will begin using the list on December 1, 2001. The carve out will begin by April 1, 2002 as will the non-Medicaid mental health services. All other programs will phase in during the year as timing allows.