HOUSE SUBSTITUTE FOR

SENATE BILL NO. 831

A bill to amend 1978 PA 368, entitled

"Public health code,"

(MCL 333.1101 to 333.25211) by adding part 97.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

PART 97.

MICHIGAN PHARMACEUTICAL BEST PRACTICES INITIATIVE

Sec. 9701. As used in this part:

(a) "Committee" means the Michigan pharmacy and therapeutics committee established by Executive Order No. 2001-8 and by section 9705.

(b) "Controlled substance" means that term as defined in section 7104.

(c) "Department" means the department of community health.

(d) "Drug" means that term as defined in section 17703.

(e) "Initiative" means the pharmaceutical best practices

initiative established by this part.

(f) "Medicaid" means the program of medical assistance established under title XIX of the social security act, 42 USC 1396 to 1396v.

(g) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy under article 15.

(h) "Physician" means an individual licensed by this state to engage in the practice of medicine or osteopathic medicine and surgery under article 15.

(i) "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 part 174 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.

(j) "Prescription" means that term as defined in section 17708.

(k) "Prescription drug" means that term as defined in section 17708.

(*l*) "Type II transfer" means that term as defined in section 3 of the executive organization act of 1965, 1965 PA 380, MCL 16.103.

Sec. 9703. (1) The department may 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. If implemented, the initiative shall include, but is not limited to, the establishment and maintenance of each of the following:

(a) A preferred drug list.

(b) A prior authorization and appeal process.

(2) The prior authorization and appeal process established under subsection (1) shall include the establishment of a telephone hotline for prescribers that is accessible 24 hours per day and staffed to ensure that a response is initiated to each prior authorization request within 24 hours after its receipt and to each appeal of a prior authorization denial within 48 hours, excluding Saturday, Sunday, and legal holidays, after all necessary documentation for reconsideration is received. Each appeal for reconsideration of a previous denial for prior authorization shall be reviewed and decided by a physician.

(3) The department, in cooperation with a pharmaceutical manufacturer or its agent [or another qualified contractor], may establish disease management and health management programs that may be provided, as negotiated, by the pharmaceutical manufacturer or its agent [or another qualified contractor] instead of a supplemental rebate for the inclusion of certain products manufactured by that pharmaceutical manufacturer on the department's preferred drug list. If the department negotiates a plan for the provision of services by the pharmaceutical manufacturer instead of a supplemental rebate as provided under

this subsection, the department shall provide a written report on the effectiveness of the programs being offered and the savings incurred as a result of those programs being provided instead of supplemental rebates to the members of the house and senate appropriations subcommittees on community health.

(4) The department may hire or retain contractors, subcontractors, advisors, consultants, and agents and may enter into contracts necessary or incidental to implement this part and carry out its responsibilities and duties.

(5) The department may promulgate rules or medicaid policies to implement this part and to ensure compliance with the published medicaid bulletin that initiated this initiative.

Sec. 9705. (1) The Michigan pharmacy and therapeutics committee, established by Executive Order No. 2001-8, is transferred to the department as a type II transfer. The committee shall consist of 11 members appointed by the governor as follows:

(a) Six physicians whose practice includes patients who are eligible for medicaid. A physician appointed under this subdivision may include, but is not limited to, a physician with expertise in mental health, a physician who specializes in pediatrics, and a physician with experience in long-term care.

(b) Five pharmacists whose business includes prescriptions from individuals who are eligible for medicaid. A pharmacist appointed under this subdivision may include, but is not limited to, a pharmacist with expertise in mental health drugs, a pharmacist who specializes in pediatrics, and a pharmacist with

experience in long-term care.

(2) No member of the committee shall be employed by a pharmaceutical manufacturer or have any interest directly or indirectly in the business of a pharmaceutical manufacturer which shall cause a conflict of interest. No more than 2 members appointed to the committee shall be employed by the department.

(3) Members of the committee shall serve a term of 2 years, except as otherwise provided for members currently serving on the committee on the effective date of this section. Members serving on the committee on the effective date of this section shall 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 effective date of this section whose term would have otherwise expired after October 1, 2005 may serve the remainder of his or her term if he or she meets the qualifications established under this section. The governor shall appoint an additional number of members to the committee necessary to reach 11 members as required under this section. The governor shall designate 1 member of the committee to serve as the chairperson of the committee. This member shall serve as chairperson at the pleasure of the governor. An individual appointed to serve as a physician or pharmacist member of the committee may serve only while maintaining his or her professional license in good standing. An individual physician's or pharmacist's failure to maintain his or her professional license in good standing immediately terminates that individual's membership on the committee. One example of not maintaining a

professional license in good standing is if the department imposes a sanction under article 15 on a physician or pharmacist committee member. A vacancy on the committee shall 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 shall be appointed for the unexpired term of the member whom he or she is to succeed in the same manner as the original appointment. A member may be reappointed for additional terms.

(4) The committee has the powers, duties, and responsibilities prescribed in Executive Order No. 2001-8 and shall operate pursuant to and in accordance with Executive Order No. 2001-8.

(5) Members of the committee shall serve without compensation, but shall be reimbursed for necessary travel and other expenses pursuant to the standard travel regulations of the department of management and budget.

(6) The committee may promulgate rules governing the organization, operation, and procedures of the committee. The committee shall review its policies and procedures and consider means to increase and facilitate public comment. A majority of the members serving constitute a quorum for the transaction of business. The committee shall approve a final action of the committee by a majority vote of the members. A member of the committee must be present at a meeting of the committee in order to vote. A member shall not delegate his or her responsibilities to another individual.

(7) The committee shall meet at the call of the chairperson

and as otherwise provided in the rules promulgated by the committee or the department. The committee may meet at any location within this state. A meeting of the committee is subject to the open meetings act, 1976 PA 267, MCL 15.261 to 15.275. The committee shall post a notice of the meeting on the department's website 14 days before each meeting date. By January 31 of each year, the committee shall make available the committee's regular meeting schedule and meeting locations for that year on the department's website. The committee may make inquiries, conduct studies and investigations, hold hearings, and receive comments from the public.

Sec. 9707. The committee shall be advisory in nature and shall assist the department with the following functions pursuant to applicable state and federal law:

(a) Advise and make recommendations to the department 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.

(b) Advise the department on issues affecting prescription drug coverage for the department's various health care programs.

(c) Recommend to the department guidelines for prescription drug coverage under the department's various health care programs.

(d) Develop a process to collect and review information about

new prescription drugs. The department shall post this process and the necessary forms on the department's website.

(e) Recommend to the department strategies to improve the initiative.

Sec. 9709. (1) Except as otherwise provided by law or in this part, a prescriber shall obtain prior authorization for drugs that are being provided to medicaid beneficiaries directly through the department on a fee for service basis or pursuant to a contract for such pharmaceutical services and that are not included on the department's preferred drug list. If the prescriber's prior authorization request is denied, the department or the department's agent shall inform the requesting prescriber of his or her option to speak to the agent's physician on duty regarding his or her request. If immediate contact with the agent's physician on duty cannot be arranged, the department or the department's agent shall inform the requesting 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 requesting prescriber may request a longer supply of the nonauthorized drug.

(2) The department or the department's agent shall provide authorization for prescribed drugs that are not on its preferred drug list if any of the following are satisfied:

(a) The prescribing physician telephones the department's agent or certifies in writing on a form as provided by the department that the drugs are 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 are necessary for the continued stabilization of the patient's medical condition.

(b) The prescribing physician telephones the department's agent or certifies in writing on a form as provided by the department that following documented 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.

(c) The prescribing physician telephones the department's agent or certifies in writing on a form as provided by the department <<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 are being prescribed to a patient for the treatment of any symptoms or side effects that are a direct result of treatment received for any of the following:

(*i*) Human immunodeficiency virus infections or the complications of the human immunodeficiency virus or acquired immunodeficiency syndrome.

(*ii*) Cancer.

(*iii*) Organ replacement therapy.

(*iv*) Epilepsy or seizure disorder.

(3) The department or the department's agent shall provide authorization for a prescribed drug that is not on its preferred drug list if each of the following is met:

(a) The prescribing physician has achieved advanced specialization training and is certified as a specialist by a

specialty board that is 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.

(b) The prescribing physician described in subdivision (a) telephones the department or certifies in writing each of the following:

(*i*) The prescribed drug is being prescribed consistent with its licensed indications or with generally accepted medical practice as documented in a standard medical reference.

(*ii*) The prescribed drug is being used to treat a condition that is normally treated within the prescribing physician's specialty field.

(*iii*) In the physician's professional opinion, no other drug or drugs included on the preferred drug list can provide a comparable benefit.

(4) Documentation of necessity or failures under subsection (2) or (3) may be provided by telephone, facsimile, or electronic transmission.

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

(6) Except as otherwise provided under this subsection, a patient who is currently under medical treatment and whose condition has been stabilized under a given prescription regimen before becoming a recipient of medicaid is exempt from the prior

authorization process and may continue on that medication for the current course of treatment if without that prescription regimen the patient would suffer serious health consequences. Unless a controlled substance is currently being prescribed under a patient's hospice plan of care, a continuing prescription for a controlled substance under this subsection requires prior authorization. The department or the department's agent shall not deny a request for prior authorization of a controlled substance under this subsection unless the department or the department's 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.

[(7) This section does not apply to drugs being provided under a contract between the department and a health maintenance organization.]