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:

- 1 PART 97.
- 2 MICHIGAN PHARMACEUTICAL BEST PRACTICES INITIATIVE
- 3 Sec. 9701. As used in this part:
- 4 (a) "Committee" means the Michigan pharmacy and therapeutics
- 5 committee established by Executive Order No. 2001-8 and by
- 6 section 9705.
- 7 (b) "Controlled substance" means that term as defined in
- 8 section 7104.
- 9 (c) "Department" means the department of community health.
- 10 (d) "Drug" means that term as defined in section 17703.
- 11 (e) "Initiative" means the pharmaceutical best practices

- 1 initiative established by this part.
- 2 (f) "Medicaid" means the program of medical assistance
- 3 established under title XIX of the social security act, 42 USC
- 4 1396 to 1396v.
- 5 (g) "Pharmacist" means an individual licensed by this state
- 6 to engage in the practice of pharmacy under article 15.
- 7 (h) "Physician" means an individual licensed by this state to
- 8 engage in the practice of medicine or osteopathic medicine and
- 9 surgery under article 15.
- (i) "Prescriber" means a licensed dentist, a licensed doctor
- 11 of medicine, a licensed doctor of osteopathic medicine and
- 12 surgery, a licensed doctor of podiatric medicine and surgery, a
- 13 licensed optometrist certified under part 174 to administer and
- 14 prescribe therapeutic pharmaceutical agents, or another licensed
- 15 health professional acting under the delegation and using,
- 16 recording, or otherwise indicating the name of the delegating
- 17 licensed doctor of medicine or licensed doctor of osteopathic
- 18 medicine and surgery.
- 19 (j) "Prescription" means that term as defined in section
- 20 17708.
- 21 (k) "Prescription drug" means that term as defined in section
- 22 17708.
- 23 (l) "Type II transfer" means that term as defined in section
- 24 3 of the executive organization act of 1965, 1965 PA 380, MCL
- 25 16.103.
- 26 Sec. 9703. (1) The department may implement a
- 27 pharmaceutical best practices initiative for the department's

- 1 various health care programs to control the costs of health care,
- 2 to reduce the costs of prescription drugs, and to assure
- 3 continued access to pharmaceutical services at fair and
- 4 reasonable prices. If implemented, the initiative shall include,
- 5 but is not limited to, the establishment and maintenance of each
- 6 of the following:
- 7 (a) A preferred drug list.
- 8 (b) A prior authorization and appeal process.
- 9 (2) The prior authorization and appeal process established
- 10 under subsection (1) shall include the establishment of a
- 11 telephone hotline for prescribers that is accessible 24 hours per
- 12 day and staffed to ensure that a response is initiated to each
- 13 prior authorization request within 24 hours after its receipt and
- 14 to each appeal of a prior authorization denial within 48 hours,
- 15 excluding Saturday, Sunday, and legal holidays, after all
- 16 necessary documentation for reconsideration is received. Each
- 17 appeal for reconsideration of a previous denial for prior
- 18 authorization shall be reviewed and decided by a physician.
- 19 (3) The department, in cooperation with a pharmaceutical
- 20 manufacturer or its agent, may establish disease management and
- 21 health management programs that shall be provided, as negotiated,
- 22 by the pharmaceutical manufacturer or its agent instead of a
- 23 supplemental rebate for the inclusion of certain products
- 24 manufactured by that pharmaceutical manufacturer on the
- 25 department's preferred drug list. If the department negotiates a
- 26 plan for the provision of services by the pharmaceutical
- 27 manufacturer instead of a supplemental rebate as provided under

- 1 this subsection, the department shall provide a written report on
- 2 the effectiveness of the programs being offered and the savings
- 3 incurred as a result of those programs being provided instead of
- 4 supplemental rebates to the members of the house and senate
- 5 appropriations subcommittees on community health.
- 6 (4) The department may hire or retain contractors,
- 7 subcontractors, advisors, consultants, and agents and may enter
- 8 into contracts necessary or incidental to implement this part and
- 9 carry out its responsibilities and duties.
- 10 (5) The department may promulgate rules or medicaid policies
- 11 to implement this part and to ensure compliance with the
- 12 published medicaid bulletin that initiated this initiative.
- 13 Sec. 9705. (1) The Michigan pharmacy and therapeutics
- 14 committee, established by Executive Order No. 2001-8, is
- 15 transferred to the department as a type II transfer. The
- 16 committee shall consist of 11 members appointed by the governor
- 17 as follows:
- 18 (a) Six physicians whose practice includes patients who are
- 19 eligible for medicaid. The governor shall make this appointment
- 20 from a list of physicians recommended by the Michigan state
- 21 medical society and the Michigan osteopathic association or their
- 22 successor organizations. The list of recommended physicians may
- 23 include, but is not limited to, a physician with expertise in
- 24 mental health, a physician who specializes in pediatrics, and a
- 25 physician with experience in long-term care.
- 26 (b) Five pharmacists whose business includes prescriptions
- 27 from individuals who are eligible for medicaid. The governor

- 1 shall make this appointment from a list of pharmacists
- 2 recommended by the Michigan pharmacists association and the
- 3 Michigan retailers association or their successor organizations.
- 4 The list of recommended pharmacists may include, but is not
- 5 limited to, a pharmacist with expertise in mental health drugs, a
- 6 pharmacist who specializes in pediatrics, and a pharmacist with
- 7 experience in long-term care.
- 8 (2) If the governor declines to appoint, with or without
- 9 cause, any of the individuals recommended under subsection (1)(a)
- 10 or (b), the respective organizations shall, as soon as possible,
- 11 provide the governor with a new list of recommendations for his
- 12 or her consideration.
- 13 (3) No member of the committee shall be employed by a
- 14 pharmaceutical manufacturer or have any interest directly or
- 15 indirectly in the business of a pharmaceutical manufacturer which
- 16 shall cause a conflict of interest.
- 17 (4) Members of the committee shall serve a term of 2 years,
- 18 except as otherwise provided for members currently serving on the
- 19 committee on the effective date of this section. Members serving
- 20 on the committee on the effective date of this section shall
- 21 serve until the date on which their appointment would have
- 22 expired or until October 1, 2005, whichever occurs first. A
- 23 member serving on the committee on the effective date of this
- 24 section whose term would have otherwise expired after October 1,
- 25 2005 may serve the remainder of his or her term if he or she
- 26 meets the qualifications established under this section. The
- 27 governor shall appoint an additional number of members to the

- 1 committee necessary to reach 11 members as required under this
- 2 section. The governor shall designate 1 member of the committee
- 3 to serve as the chairperson of the committee. This member shall
- 4 serve as chairperson at the pleasure of the governor. An
- 5 individual appointed to serve as a physician or pharmacist member
- 6 of the committee may serve only while maintaining his or her
- 7 professional license in good standing. An individual physician's
- 8 or pharmacist's failure to maintain his or her professional
- 9 license in good standing immediately terminates that individual's
- 10 membership on the committee. One example of not maintaining a
- 11 professional license in good standing is if the department
- 12 imposes a sanction under article 15 on a physician or pharmacist
- 13 committee member. A vacancy on the committee shall be filled in
- 14 the same manner as the original appointment. An individual
- 15 appointed to fill a vacancy created other than by expiration of a
- 16 term shall be appointed for the unexpired term of the member whom
- 17 he or she is to succeed in the same manner as the original
- 18 appointment. A member may be reappointed for additional terms.
- 19 (5) The committee has the powers, duties, and
- 20 responsibilities prescribed in Executive Order No. 2001-8 and
- 21 shall operate pursuant to and in accordance with Executive Order
- 22 No. 2001-8.
- 23 (6) Members of the committee shall serve without
- 24 compensation, but shall be reimbursed for necessary travel and
- 25 other expenses pursuant to the standard travel regulations of the
- 26 department of management and budget.
- 27 (7) The committee may promulgate rules governing the

- 1 organization, operation, and procedures of the committee. A
- 2 majority of the members serving constitute a quorum for the
- 3 transaction of business. The committee shall approve a final
- 4 action of the committee by a majority vote of the members. A
- 5 member of the committee must be present at a meeting of the
- 6 committee in order to vote. A member shall not delegate his or
- 7 her responsibilities to another individual.
- 8 (8) The committee shall meet at the call of the chairperson
- 9 and as otherwise provided in the rules promulgated by the
- 10 committee or the department. The committee may meet at any
- 11 location within this state. A meeting of the committee is
- 12 subject to the open meetings act, 1976 PA 267, MCL 15.261 to
- 13 15.275. The committee shall post a notice of the meeting on the
- 14 department's website 14 days before each meeting date. By
- 15 January 31 of each year, the committee shall make available the
- 16 committee's regular meeting schedule and meeting locations for
- 17 that year on the department's website. The committee may make
- 18 inquiries, conduct studies and investigations, hold hearings, and
- 19 receive comments from the public.
- 20 Sec. 9707. The committee shall be advisory in nature and
- 21 shall assist the department with the following functions pursuant
- 22 to applicable state and federal law:
- 23 (a) Advise and make recommendations to the department for the
- 24 inclusion of prescription drugs on the preferred drug list based
- 25 on available information regarding the known potential impact on
- 26 patient care, the known potential fiscal impact on related
- 27 medicaid covered services, and sound clinical evidence found in

- 1 labeling, drug compendia, and peer-reviewed literature pertaining
- 2 to use of the drug in the relevant population.
- 3 (b) Advise the department on issues affecting prescription
- 4 drug coverage for the department's various health care programs.
- 5 (c) Recommend to the department guidelines for prescription
- 6 drug coverage under the department's various health care
- 7 programs.
- 8 (d) Develop a process to collect and review information about
- 9 new prescription drugs. The department shall post this process
- 10 and the necessary forms on the department's website.
- 11 (e) Recommend to the department strategies to improve the
- 12 initiative.
- 13 Sec. 9709. (1) Except as otherwise provided by law or in
- 14 this part, a prescriber shall obtain prior authorization for
- 15 drugs that are not included on the department's preferred drug
- 16 list. If the prescriber's prior authorization request is denied,
- 17 the department or the department's agent shall inform the
- 18 requesting prescriber of his or her option to speak to the
- 19 agent's physician on duty regarding his or her request. If
- 20 immediate contact with the agent's physician on duty cannot be
- 21 arranged, the department or the department's agent shall inform
- 22 the requesting prescriber of his or her right to request a
- 23 72-hour supply of the nonauthorized drug. If contact with the
- 24 agent's physician on duty cannot be arranged within 72 hours due
- 25 to a legal holiday, the requesting prescriber may request a
- 26 longer supply of the nonauthorized drug.
- 27 (2) The department or the department's agent shall provide

- 1 authorization for prescribed drugs that are not on its preferred
- 2 drug list if the prescribing physician telephones the
- 3 department's agent or certifies in writing on a form as provided
- 4 by the department that the drugs are being prescribed consistent
- 5 with its licensed indications, that no other drugs included on
- 6 the preferred drug list would offer a comparable benefit to the
- 7 patient, and that the drugs are necessary for the continued
- 8 stabilization of the patient's medical condition as initial
- 9 therapy or if the prescribing physician telephones the
- 10 department's agent or certifies in writing on a form as provided
- 11 by the department that following documented failures on earlier
- 12 prescription regimens, in the physician's professional opinion,
- 13 no other drug or drugs included on the preferred drug list can
- 14 provide a comparable benefit. Documentation of necessity or
- 15 failures under this subsection or subsection (3) may be provided
- 16 by telephone, facsimile, or electronic transmission.
- 17 (3) The department or the department's agent shall provide
- 18 authorization for a prescribed drug that is not on its preferred
- 19 drug list if each of the following is met:
- 20 (a) The prescribing physician has achieved advanced
- 21 specialization training and is certified as a specialist by a
- 22 specialty board that is recognized by the American osteopathic
- 23 association and the council on graduate medical education or
- 24 their successor organizations and provides documentation of his
- 25 or her certification.
- 26 (b) The prescribing physician described in subdivision (a)
- 27 telephones the department or certifies in writing each of the

- 1 following:
- 2 (i) The prescribed drug is being prescribed consistent with
- 3 its licensed indications or with generally accepted medical
- 4 practice as documented in a standard medical reference.
- 5 (ii) The prescribed drug is being used to treat a condition
- 6 that is normally treated within the prescribing physician's
- 7 specialty field.
- 8 (iii) No other drug or drugs included on the preferred drug
- 9 list can provide a comparable benefit.
- 10 (4) A patient who is under a court order for a particular
- 11 prescription drug before becoming a recipient of medicaid is
- 12 exempt from the prior authorization process and may continue on
- 13 that medication for the duration of the order.
- 14 (5) Except as otherwise provided under this subsection, a
- 15 patient who is currently under medical treatment and whose
- 16 condition has been stabilized under a given prescription regimen
- 17 before becoming a recipient of medicaid is exempt from the prior
- 18 authorization process and may continue on that medication for the
- 19 current course of treatment if without that prescription regimen
- 20 the patient would suffer serious health consequences. Unless a
- 21 controlled substance is currently being prescribed under a
- 22 patient's hospice plan of care, a continuing prescription for a
- 23 controlled substance under this subsection requires prior
- 24 authorization. The department or the department's agent shall
- 25 not deny a request for prior authorization of a controlled
- 26 substance under this subsection unless the department or the
- 27 department's agent determines that the controlled substance or

- 1 the dosage of the controlled substance being prescribed is not
- 2 consistent with its licensed indications or with generally
- 3 accepted medical practice as documented in a standard medical
- 4 reference.