

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

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.

10 (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

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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 [or another qualified contractor], may
establish disease management and
21 health management programs that may be provided, as negotiated,
22 by the pharmaceutical manufacturer or its agent [or another qualified
contractor] 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. A physician appointed under this
20 subdivision may include, but is not limited to, a physician with
21 expertise in mental health, a physician who specializes in
22 pediatrics, and a physician with experience in long-term care.

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

1 experience in long-term care.

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

7 (3) Members of the committee shall serve a term of 2 years,
8 except as otherwise provided for members currently serving on the
9 committee on the effective date of this section. Members serving
10 on the committee on the effective date of this section shall
11 serve until the date on which their appointment would have
12 expired or until October 1, 2005, whichever occurs first. A
13 member serving on the committee on the effective date of this
14 section whose term would have otherwise expired after October 1,
15 2005 may serve the remainder of his or her term if he or she
16 meets the qualifications established under this section. The
17 governor shall appoint an additional number of members to the
18 committee necessary to reach 11 members as required under this
19 section. The governor shall designate 1 member of the committee
20 to serve as the chairperson of the committee. This member shall
21 serve as chairperson at the pleasure of the governor. An
22 individual appointed to serve as a physician or pharmacist member
23 of the committee may serve only while maintaining his or her
24 professional license in good standing. An individual physician's
25 or pharmacist's failure to maintain his or her professional
26 license in good standing immediately terminates that individual's
27 membership on the committee. One example of not maintaining a

1 professional license in good standing is if the department
2 imposes a sanction under article 15 on a physician or pharmacist
3 committee member. A vacancy on the committee shall be filled in
4 the same manner as the original appointment. An individual
5 appointed to fill a vacancy created other than by expiration of a
6 term shall be appointed for the unexpired term of the member whom
7 he or she is to succeed in the same manner as the original
8 appointment. A member may be reappointed for additional terms.

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

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

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

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

1 and as otherwise provided in the rules promulgated by the
2 committee or the department. The committee may meet at any
3 location within this state. A meeting of the committee is
4 subject to the open meetings act, 1976 PA 267, MCL 15.261 to
5 15.275. The committee shall post a notice of the meeting on the
6 department's website 14 days before each meeting date. By
7 January 31 of each year, the committee shall make available the
8 committee's regular meeting schedule and meeting locations for
9 that year on the department's website. The committee may make
10 inquiries, conduct studies and investigations, hold hearings, and
11 receive comments from the public.

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

15 (a) Advise and make recommendations to the department for the
16 inclusion of prescription drugs on the preferred drug list based
17 on available information regarding the known potential impact on
18 patient care, the known potential fiscal impact on related
19 medicaid covered services, and sound clinical evidence found in
20 labeling, drug compendia, and peer-reviewed literature pertaining
21 to use of the drug in the relevant population.

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

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

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

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

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

5 Sec. 9709. (1) Except as otherwise provided by law or in
6 this part, a prescriber shall obtain prior authorization for
7 drugs that are being provided to medicaid beneficiaries directly
8 through the department on a fee for service basis or pursuant to
9 a contract for such pharmaceutical services and that are not
10 included on the department's preferred drug list. If the
11 prescriber's prior authorization request is denied, the
12 department or the department's agent shall inform the requesting
13 prescriber of his or her option to speak to the agent's physician
14 on duty regarding his or her request. If immediate contact with
15 the agent's physician on duty cannot be arranged, the department
16 or the department's agent shall inform the requesting prescriber
17 of his or her right to request a 72-hour supply of the
18 nonauthorized drug. If contact with the agent's physician on
19 duty cannot be arranged within 72 hours due to a legal holiday,
20 the requesting prescriber may request a longer supply of the
21 nonauthorized drug.

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

25 (a) The prescribing physician telephones the department's
26 agent or certifies in writing on a form as provided by the
27 department that the drugs are being prescribed consistent with

1 its licensed indications, that no other drugs included on the
2 preferred drug list, in the physician's professional opinion,
3 would offer a comparable benefit to the patient, and that the
4 drugs are necessary for the continued stabilization of the
5 patient's medical condition.

6 (b) The prescribing physician telephones the department's
7 agent or certifies in writing on a form as provided by the
8 department that following documented failures on earlier
9 prescription regimens, in the physician's professional opinion,
10 no other drug or drugs included on the preferred drug list can
11 provide a comparable benefit.

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

17 (i) Human immunodeficiency virus infections or the
18 complications of the human immunodeficiency virus or acquired
19 immunodeficiency syndrome.

20 (ii) Cancer.

21 (iii) Organ replacement therapy.

22 (iv) Epilepsy or seizure disorder.

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

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

1 specialty board that is recognized by the American osteopathic
2 association and the council on graduate medical education or
3 their successor organizations and provides documentation of his
4 or her certification.

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

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

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

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

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

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

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

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1 authorization process and may continue on that medication for the
2 current course of treatment if without that prescription regimen
3 the patient would suffer serious health consequences. Unless a
4 controlled substance is currently being prescribed under a
5 patient's hospice plan of care, a continuing prescription for a
6 controlled substance under this subsection requires prior
7 authorization. The department or the department's agent shall
8 not deny a request for prior authorization of a controlled
9 substance under this subsection unless the department or the
10 department's agent determines that the controlled substance or
11 the dosage of the controlled substance being prescribed is not
12 consistent with its licensed indications or with generally
13 accepted medical practice as documented in a standard medical
14 reference.

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