

SENATE NO. 428

AN ACT RELATIVE TO PRIOR AUTHORIZATIONS OF PRESCRIPTION MEDICATIONS

*Be it enacted by the Senate and House of Representatives in General Court assembled,
And by the authority of the same, as follows:*

1 SECTION 1. Section 17 of Chapter 118E of the General Laws, as appearing in the 2002 official
2 edition, is hereby amended by striking the words "provision of written documentation by the
3 practitioner to the division that" and inserting in place thereof:- provisions of section 53 of this chapter
4 and

5 SECTION 2. Chapter 118E of the General Laws, as appearing in the 2002 official edition, is hereby
6 amended by adding at the end thereof the following new section:

7 Section 53. Drug prior authorization process

8 (a) The Division shall administer a drug prior authorization process to ensure the timely dispensing of
9 drugs, for any outpatient prescription drug. In administering said process the Division shall meet the
10 following conditions:

11 (1) Provide telephone, fax or other electronically transmitted approval or denial within twenty-four

12 (24) hours after receipt of the prior authorization request;

13 (2) If in the prescribing physician's opinion an emergency situation exists, including a situation in
14 which a response to a prior authorization request is unavailable, allow for the prescribed drug to be
15 dispensed at a physician's discretion and until such time as the prior authorization process and
16 subsequent appeals are determined. Any drug dispensed in said manner shall be eligible for full
17 coverage and payment by the Division of Medical Assistance;

18 (3) Grant authorization of drugs prescribed for a medically accepted use supported by either approved
19 product labeling or peer reviewed literature unless there is a therapeutically equivalent generic drug
20 that is available without prior authorization;

21 (4) Allow any patient that receives benefits under a program of the division, and is receiving
22 maintenance medications for a chronic illness, to receive said medications until the existing
23 prescription expires, or for a period not to exceed six months, whichever is greater, without the need
24 for any prior approvals to be granted.

25 (5) Consult with the Pharmacy and Therapeutics Advisory Committee, established in Section 3 of this
26 act, to develop and implement improvements to the drug prior authorization process and make a report
27 to the advisory committee on the status of the prior authorization list and any changes, related hearings
28 or other proceedings semi-annually.

29 (b) The division shall maintain a process for the evaluation of drugs to be placed on the prior
30 authorization list, which shall include:

31 (1) A public hearing on all medications prior to a decision being made on prior authorization;

32 (2) publishing conspicuous notice in at least one newspaper of general circulation and on the division's
33 website at least thirty (30) days prior to any public hearing on whether such a drug should be placed on
34 prior authorization;

35 (3) consideration of any information provided by any interested party, including but not limited to
36 physicians, pharmacists, beneficiaries, and manufacturers or distributors of the drug;

37 (4) consideration of the potential impact on patient care, safety and other sectors of the state health
38 care systems including emergency room visits and hospitalizations as a result of placement of such
39 drug on prior authorization;

40 (5) receipt of written approval by a physician who is board certified in the specialty that most
41 commonly treats the disease or prescribes the relevant therapeutic class of drugs. Said physician shall
42 not be employed by, nor have any financial relationship with, any pharmacy benefits management
43 company managing Medicaid prescription benefits, nor be a member of the Pharmacy and
44 Therapeutics Advisory Committee. Such written ratification shall be submitted to the commissioner,
45 members of the Pharmacy and Therapeutics Advisory Committee, and shall be available to the public
46 upon request; and,

47 (6) A final decision shall be made within 60 days of the public hearing and published for public
48 comment for a period of no less than 30 days. The effective date of the decision shall not be prior to
49 the close of the comment period and effective notice of the decision's finality is available to
50 prescribers.

51 (c) Notwithstanding any other provision of this section, no drug shall be recommended to require prior
52 authorization by the division and placed on prior authorization, which has been approved or had any of
53 its particular uses approved by the FDA under a priority review classification;

54 (d) The Division shall develop a grievance mechanism for interested parties to appeal the
55 Department's decision to place a drug on prior authorization, which at a minimum shall be concluded
56 within ten days.. After participating in the grievance mechanism developed by the Department on the
57 recommendations of the advisory committee, any interested party aggrieved by the placement of a
58 drug on prior authorization shall be entitled to an administrative hearing before the Department;

59 (e) The Division shall review the prior authorization status of a drug annually;

60 (f) The Division shall make a report to the house and senate committees on ways and means and the
61 house and senate committees on health care at the conclusion of all prior authorization proceedings for
62 each therapeutic class or at least, no less often than annually. Said report shall include but not be
63 limited to the outcomes of all public hearings and prior authorization decisions; a list of drugs which
64 are and are not to be prior authorized along with corresponding information used to make such
65 decisions; sectors of the state health care program that may be affected by the drug's availability for
66 use in treating program beneficiaries; any changes made or proposed to the prior authorization process;
67 and recommendations including legislation that may benefit the prior authorization process and
68 program beneficiaries; said report shall be posted on the division's website.

69 SECTION 3. Chapter 118E of the General Laws, as appearing in the 2002 official edition, is hereby
70 amended by adding at the end thereof the following new section:

71 Section 54. Pharmacy and Therapeutics Advisory Committee

72 (a) There is hereby established a Pharmacy and Therapeutics Advisory Committee for the purpose of
73 advising and making recommendations to the Division of Medical Assistance's prior authorization
74 program. Said advisory committee shall consist of thirteen (13) members to be appointed by the
75 Governor and shall include: five physicians licensed in Massachusetts and actively involved in the
76 practice of medicine; three pharmacists licensed to do business in the commonwealth and actively
77 involved in the practice of pharmacy; a representative of the Massachusetts Medical Society; a
78 representative of the Massachusetts Pharmacy Association; a representative of medical assistance
79 beneficiaries in the commonwealth; and, two patient advocates.

80 In making physician appointments the Governor shall make his selections from a list of nominees
81 provided by the Massachusetts Medical Society. In making pharmacist appointments the Governor
82 shall make his selections from a list of nominees provided by the Massachusetts Pharmacy
83 Association.

84 Advisory committee members shall serve staggered three-year terms. Two physicians, one pharmacist
85 and the representative of medical assistance beneficiaries shall each be appointed for one-year terms.
86 Members may be reappointed for a period not to exceed three, three-year terms. Advisory committee
87 members shall select a chairperson and a vice-chairperson by a majority vote of the committee
88 membership on an annual basis. Said committee shall meet at least monthly and may meet at other
89 times at the discretion of the chairperson. Notice of any meeting of the advisory committee shall be
90 published thirty (30) days before such meeting; and

91 (b) The advisory committee shall have the power and duty to:

92 (1) advise and make recommendations regarding the implementation of a drug prior authorization
93 program for the medical assistance program;

94 (2) advise and make recommendations regarding rules to be promulgated by the division regarding
95 outpatient prescription drug prior authorization;

96 (3) make recommendations for a grievance mechanism for interested parties to appeal any decision
97 made by the Division to place a drug on prior authorization; (4) make recommendations to the
98 Division regarding any inpatient or outpatient prescription drug covered by the medical assistance
99 program that is to be prior authorized as well as which drugs are exempt from the prior approval
100 process. Said recommendation shall be supported by an analysis of prospective and retrospective DUR
101 data demonstrating

102 (a) the expected impact of such a decision on the clinical care likely to be received by beneficiaries for
103 whom the drug is medically necessary;

104 (b) the expected impact on physicians whose patients require the drug;

105 (c) the expected fiscal impact on the medical assistance program;

106 (d) review and make recommendations on a semi-annual basis whether drugs placed on prior
107 authorization should remain on prior authorization; and

108 (e) make recommendations for a list of maintenance medications that are needed for chronic illnesses;