

# MAINE STATE LEGISLATURE

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# 122nd MAINE LEGISLATURE

## FIRST REGULAR SESSION-2005

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Legislative Document

No. 1404

S.P. 493

In Senate, March 22, 2005

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**An Act To Increase the Quality of Care and Reduce Administrative  
Burdens in the Pharmacy Prior Approval Process**

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Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script that reads "Joy J. O'Brien".

JOY J. O'BRIEN  
Secretary of the Senate

Presented by Senator BRENNAN of Cumberland.  
Cosponsored by Representative BRAUTIGAM of Falmouth and  
Senators: MAYO of Sagadahoc, MILLS of Somerset, MITCHELL of Kennebec, STRIMLING  
of Cumberland, Representatives: BARSTOW of Gorham, NUTTING of Oakland, PERRY of  
Calais, TARDY of Newport.

2  
3 **Be it enacted by the People of the State of Maine as follows:**

4 **Sec. 1. 22 MRSA §254, sub-§11-A**, as enacted by PL 2001, c.  
691, §1 and affected by §6, is amended to read:

6 **11-A. Retention of eligibility.** A person who was eligible  
7 for the program at any time from August 1, 1998 to July 31, 1999  
8 and who does not meet the requirements of subsection 10 retains  
9 eligibility for the program if that person is a member of a  
10 household of an eligible person; and

12 **Sec. 2. 22 MRSA §254, sub-§12**, as enacted by PL 1999, c. 731,  
Pt. TT, §10, is amended to read:

14 **12. Funds not to lapse.** Funds appropriated from the  
15 General Fund to carry out the purpose of this section may not  
16 lapse but must carry from year to year; and

18 **Sec. 3. 22 MRSA §254, sub-§13** is enacted to read:

20 **13. Procedures.** Procedures for prior authorization of  
22 benefits under the program or preferred drug lists within the  
23 program must meet the requirements established for prior  
24 authorization and preferred drug lists in the MaineCare program  
25 under section 3174-GG.

26 **Sec. 2. 22 MRSA §§3174-GG and 3174-HH** are enacted to read:

28 **§3174-GG. Pharmacy benefit procedures**

30 The requirements set out in this section apply to procedures  
32 for prior authorization of pharmacy benefits or preferred drug  
33 lists under the MaineCare program and the elderly low-cost drug  
34 program under section 254. As used in this section "member"  
35 means a person receiving benefits under the MaineCare program or  
36 the elderly low-cost drug program. The department shall adopt  
37 rules to implement this section. Rules adopted pursuant to this  
38 section are routine technical rules as defined in Title 5,  
39 chapter 375, subchapter 2-A.

40 **1. Preferred drug lists.** In the adoption of any preferred  
42 drug lists, the provisions of this subsection apply.

44 A. The department shall adopt rules specifying the number  
45 and classes of preferred drugs that must be determined to be  
46 clinically inappropriate or ineffective before permitting  
47 the use of a nonpreferred drug.

48 B. The department shall adopt rules establishing preferred  
50 drug lists for off-label use of prescription drugs for

2 children through an approval process that is determined in  
3 accordance with the requirements of 42 United States Code,  
4 Section 1396(r)(5).

5 2. Prior authorization. In the adoption of any prior  
6 authorization process for pharmacy benefits, the provisions of  
7 this subsection apply.

8 A. The department shall adopt rules providing clinical  
9 exemptions from the prior authorization process for at least  
10 the following groups of persons:

11 (1) Members who are unable to adequately communicate  
12 their health condition as a result of dementia or other  
13 cognitive or physical impairment;

14 (2) Members who reside in health care or residential  
15 care facilities;

16 (3) Members who have acute psychiatric conditions that  
17 have been stabilized on a nonpreferred drug and who, in  
18 the judgment of the treating health care provider,  
19 would suffer an adverse health effect as a result of  
20 changing that drug;

21 (4) Members whose medical condition has been  
22 stabilized on a nonpreferred drug during  
23 hospitalization or who have been prescribed a  
24 nonpreferred drug upon discharge so that they may  
25 continue to receive the drug following hospitalization  
26 for a transition period of at least 90 days;

27 (5) Members for whom the abrupt termination of a  
28 certain prescribed drug may cause serious harm; and

29 (6) Members who are frail or medically vulnerable,  
30 including those diagnosed with HIV or AIDS, for whom  
31 exclusion from prior authorization is clinically  
32 appropriate.

33 B. The department shall adopt rules that provide for  
34 dispensing drugs on an emergency basis.

35 (1) The rules must apply if a prescribing provider  
36 fails to submit a completed application for prior  
37 authorization or to attach the required documentation.

38 (2) The rules must authorize the pharmacy to dispense,  
39 in accordance with applicable licensing standards and

2           professional judgment, a one-time supply for 34 days of  
3           the prescribed drug.

4           (3) The rules must allow the department to authorize  
5           refills of the drug on a case-by-case basis at the end  
6           of the 34-day dispensed supply if the prescribing  
7           provider has not submitted the required information at  
8           that time.

10          (4) The rules must provide that receipt of a 34-day  
11          supply under this subparagraph does not relieve the  
12          prescribing provider of the duty to submit all required  
13          information and does not entitle the member to receive  
14          benefits pending appeal in the event a request for  
15          prior authorization is ultimately denied.

16          C. The department shall adopt rules to minimize the  
17          administrative burdens imposed on prescribing providers.

20          (1) The rules must allow a provider to sign a  
21          statement on the prior authorization form certifying  
22          that the prescribed drug is medically necessary, is  
23          supported by the clinical records of the provider and  
24          does not exceed the medical needs of the member. The  
25          rules must provide for acceptance of this certification  
26          and may not require attachment of clinical records if  
27          certification has been completed. The rules must allow  
28          the department's surveillance and utilization review  
29          unit to determine, on a case-by-case basis, whether a  
30          provider is not subject to this provision.

32          (2) The rules must provide for the adoption of a prior  
33          authorization form that clearly indicates all of the  
34          clinical criteria required for approval of a  
35          nonpreferred drug and must solicit the information  
36          necessary to determine whether the clinical criteria  
37          have been met.

38          (3) The rules must prohibit disapproval by the  
39          department solely because the department does not have  
40          a record in its files of a prior prescription for a  
41          nonpreferred drug if a provider certifies that the drug  
42          has previously been prescribed for or provided to the  
43          member.

44          (4) The rules must establish procedures to advise  
45          providers of changes in the preferred drug list within  
46          48 hours of the change, by electronic or facsimile  
47          notice.

2           (5) The rules must establish a method of electronic  
4           submission of prior authorization forms,  
          certifications, documentation and necessary information.

6           (6) The rules must define "clinical records."

8           (7) The rules must provide an exemption to the prior  
10          authorization process for a period of 6 months for a  
12          provider if the provider routinely prescribes drugs  
          from the preferred drug list or if the provider's  
          requests for prior authorization have been routinely  
          approved in the past.

14          D. The department shall adopt rules to streamline the  
16          appeals process for the prior authorization process.

18           (1) The rules must provide for a decision by the  
          commissioner or the commissioner's designee.

20           (2) The rules must provide that the decision of the  
22          commissioner or the commissioner's designee is final  
          agency action.

24           (3) The rules must provide for final decision on a  
26          request for a fair hearing within 90 days of the date  
28          of request for the hearing and, if a decision is not  
30          made within 90 days and the delay past 90 days is not a  
          result of a request, fault or consent of the member,  
          for temporary approval of a prior authorization request  
          until a final decision is made.

32           (4) The rules must provide for approval of the prior  
34          authorization request if the hearing officer determines  
36          that the notice of decision provided by the department  
38          fails to substantially comply with the department's  
          rules regarding the content of notices and the hearing  
          officer determines that further delay would prejudice  
          the rights of the member.

40          E. The department shall adopt rules establishing a consumer  
42          information sheet on prior authorization of pharmacy  
44          benefits. The information sheet must include a telephone  
46          number for the member to call for assistance in accessing  
48          pharmacy benefits. The rules must require the information  
          sheet to be available at pharmacies and to be given to a  
          member when the department refuses to grant prior  
          authorization.

50          §3174-HH. Drug utilization review committee

2 The drug utilization review committee, referred to in this  
3 section as "the committee," is established to review data,  
4 maintain a best practices protocol and analyze department,  
5 provider, pharmacy and member experience with the preferred drug  
6 lists adopted by the department under the MaineCare program and  
7 the elderly low-cost drug program. The committee shall review on  
8 a quarterly basis nonpreferred drugs for which the prior approval  
9 rate is high to determine whether they should be categorized as  
10 preferred drugs. The committee shall meet at least twice per  
11 year.

12 **1. Membership.** The Director of the Bureau of Medical  
13 Services shall appoint the committee from nominations solicited  
14 from the appropriate interest groups by the director when  
15 vacancies exist. At least half of the membership must be  
16 appointees under paragraphs A and B, not including a physician  
17 employed by or under contract with the State. The membership  
18 must include:

20 A. At least 4 allopathic physicians who are licensed and  
21 actively practice medicine in the State. Nominations for  
22 these members must be solicited from a statewide association  
23 of allopathic physicians, the committee, other statewide  
24 medical societies and an association of nursing facility  
25 medical directors;

26 B. At least one osteopathic physician who is licensed and  
27 actively practices medicine in the State. Nominations for  
28 this member must be solicited from a statewide association  
29 of osteopathic physicians, the committee and other statewide  
30 medical societies;

31 C. Three community pharmacists who are licensed and  
32 actively practice in the State. Nominations for these  
33 members must be solicited from the committee or a statewide  
34 association of pharmacists;

35 D. The Director of the Bureau of Medical Services or a  
36 person designated by the director as a pharmacy physician  
37 consultant;

38 E. A hospital pharmacist who is licensed and actively  
39 practices in the State or a pharmacist with pharmacy benefit  
40 management experience. The required level of hospital  
41 pharmacy background must be determined by the Director of  
42 the Bureau of Medical Services. Nominations for this member  
43 must be solicited from a statewide association of hospital  
44 pharmacists;

2 F. The pharmacy programs manager for the Bureau of Medical  
3 Services;

4 G. An assistant pharmacy programs manager for the Bureau of  
5 Medical Services;

6 H. A pharmacist employed by the entity that holds the  
7 contract with the department for drug utilization review;

10 I. Two consumers of MaineCare services. Nominations for  
11 these members must be solicited from the committee that  
12 advises the commissioner on the MaineCare program; and

14 J. A psychiatrist who is licensed and actively practices in  
15 the State. Nominations for this member must be solicited  
16 from a statewide association of psychiatrists, other  
17 statewide medical societies and the committee.

18 **2. Specialty committees.** The committee may appoint members  
19 to specialty committees to offer advice to the committee as  
20 needed.

22 **3. Conduct of meetings.** The department shall adopt rules  
23 governing the conduct of meetings of the committee. The rules  
24 must require that all meetings be open to the public unless they  
25 are permitted to be held in executive session by Title 1, section  
26 405. The rules must provide for an adequate period of time for  
27 public comment during the meetings of the committee, to be  
28 divided equally among attendees from the general public,  
29 MaineCare members and their representatives, MaineCare providers  
30 and representatives of the pharmaceutical industry.

32 **4. Notice of action.** The department shall provide notice  
33 to committee members within 48 hours of taking action regarding a  
34 matter on which the committee has provided a recommendation to  
35 the department.

38 **5. Rulemaking.** The department shall adopt rules to  
39 implement this section. Rules adopted pursuant to this  
40 subsection are routine technical rules as defined in Title 5,  
41 chapter 375, subchapter 2-A.

42 **Sec. 4. MaineCare handbook.** The Department of Health and  
43 Human Services shall develop a MaineCare handbook for applicants  
44 for and recipients of benefits under the MaineCare program. The  
45 handbook must provide current basic program information including  
46 information about the prior authorization process. The  
47 department shall provide easy access to the handbook on the  
48 department's publicly accessible site on the Internet. The



2 department shall provide the handbook to MaineCare providers in  
sufficient numbers for their patients.

4 **Sec. 5. Prior authorization study and survey.** The Department of  
Health and Human Services shall contract with an independent  
6 entity to study the efficacy and impact of the prior  
authorization process on program benefits and costs and conduct a  
8 survey of MaineCare members.

10 **1. Study.** The study shall examine at a minimum the  
following issues:

12 A. The number of prescriptions not being filled by  
14 recipients of prescription drug benefits under the MaineCare  
program as a result of the prior authorization process;

16 B. The percentage of denied requests from providers who do  
18 not later file an additional request for prior authorization;

20 C. The percentage of denied requests for which a generic  
drug was substituted;

22 D. The percentage of denied requests for which no drug was  
24 substituted; and

26 E. The extent to which adverse health effects or the use of  
additional MaineCare services resulted from not receiving a  
28 nonpreferred drug.

30 **2. Random sample survey.** By October 1, 2005, the  
department shall conduct a random sample survey of MaineCare  
32 members to examine the impact of the prior authorization process  
on members. The survey must be designed to determine whether  
34 members are receiving clinically appropriate, medically necessary  
drugs with reasonable promptness and must explore the extent to  
36 which, as a result of the prior authorization process, members  
may have encountered barriers to care or adverse health effects  
38 or may have incurred additional health care costs for the  
MaineCare program.

40 **3. Report.** By March 1, 2006, the department shall report  
42 to the Joint Standing Committee on Health and Human Services on  
the results of the study and the survey under this section.

## 46 SUMMARY

48 This bill establishes prior authorization pharmacy benefit  
procedures for the MaineCare and elderly low-cost drug programs.  
50 The bill establishes a drug utilization review committee within

2 MaineCare. The bill requires the Department of Health and Human  
Services to publish a MaineCare handbook and to contract for a  
4 MaineCare study and survey and to report the results to the Joint  
Standing Committee on Health and Human Services by March 1, 2006.