

Indiana State DUR Statute

IC 12-15-35

Chapter 35. Drug Utilization Review

IC 12-15-35-1 “Appropriate and medically necessary” defined

Sec. 1. As used in this chapter, "appropriate and medically necessary" means drug prescribing, drug dispensing, and patient medication usage in conformity with the criteria and standards developed under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-2 “Board” defined

Sec. 2. As used in this chapter, "board" refers to the drug utilization review board created under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-3 “Compendia” defined

Sec. 3. As used in this chapter, "compendia" means those resources widely accepted by the medical profession in the efficacious use of drugs, including the following sources:

- (1) The American Hospital Formulary Services Drug Information.
- (2) The U.S. Pharmacopeia-Drug Information.
- (3) The American Medical Association Drug Evaluations.
- (4) The peer-reviewed medical literature.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-4 “Counseling” defined

Sec. 4. As used in this chapter, "counseling" means the activities conducted by a pharmacist to inform Medicaid recipients about the proper use of drugs as required by the board under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-5 “Criteria” defined

Sec. 5. As used in this chapter, "criteria" means the predetermined and explicitly accepted elements that are used to measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-6 “Drug-disease contraindication” defined

Sec. 6. As used in this chapter, "drug-disease contraindication" means an occurrence in which the therapeutic effect of a drug is adversely altered by the presence of another disease condition.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-7 “Drug-drug interaction” defined

Sec. 7. As used in this chapter, "drug-drug interaction" means an occurrence in which at least two (2) drugs taken by a recipient leads to clinically significant toxicity that:

- (1) is characteristic of one (1) or any of the drugs present; or

(2) leads to the interference with the effectiveness of one (1) or any of the drugs.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-8 “Drug utilization review” and “DUR” defined

Sec. 8. As used in this chapter, "drug utilization review" or "DUR" means the program designed to measure and assess on a retrospective and a prospective basis the proper use of outpatient drugs in the Medicaid program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-9 “Intervention” defined

Sec. 9. As used in this chapter, "intervention" means an action taken by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices or utilization of drugs.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-10 “Overutilization or underutilization” defined

Sec. 10. As used in this chapter, "overutilization or underutilization" means the use of a drug in such quantities where the desired therapeutic goal is not achieved.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-11 “Pharmacist” defined

Sec. 11. As used in this chapter, "pharmacist" means an individual who is licensed as a pharmacist in Indiana under IC 25-26.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-12 “Physician” defined

Sec. 12. As used in this chapter, "physician" means an individual who is licensed to practice medicine in Indiana under IC 25-22.5.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-13 “Prospective DUR” defined

Sec. 13. As used in this chapter, "prospective DUR" means the part of the drug utilization review program that:

- (1) is to occur before the drug is dispensed;
- (2) is designed to screen for potential drug therapy problems based on explicit and predetermined criteria and standards that are developed on an ongoing basis with professional input; and
- (3) is to provide for the counseling of recipients about the proper use of drugs.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-14 “Retrospective DUR” defined

Sec. 14. As used in this chapter, "retrospective DUR" means the part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards that are developed on an ongoing basis with professional input.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-15 “Standards” defined

Sec. 15. As used in this chapter, "standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the Medicaid recipient database.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-16 "SURS" defined

Sec. 16. As used in this chapter, "SURS" refers to the surveillance utilization review system of the Medicaid program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-17 "Therapeutic appropriateness" defined

Sec. 17. As used in this chapter, "therapeutic appropriateness" means drug prescribing based on rational drug therapy that is consistent with the criteria and standards developed under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-18

Sec. 18. As used in this chapter, "therapeutic duplication" means the prescribing and dispensing of:

- (1) the same drug; or
- (2) at least two (2) drugs from the same therapeutic class;

where overlapping periods of drug administration are involved and where such prescribing or dispensing is not medically indicated.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-18.5 "Application Chapter

Sec. 18.5. This chapter applies to any contractor or vendor of the state responsible for providing or managing any part of the Medicaid outpatient drug program.

As added by P.L.76-1994, SEC.2.

IC 12-15-35-19 Drug utilization review board; establishment

Sec. 19. The drug utilization review board is established.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-20 "Membership" of board

Sec. 20. The board is composed of the following:

- (1) Four (4) individuals licensed and actively engaged in the practice of medicine or osteopathic medicine in Indiana under IC 25-22.5.
- (2) Four (4) individuals licensed under IC 25-26 and actively engaged in the practice of pharmacy in Indiana.
- (3) One (1) individual with expertise in therapeutic pharmacology who is neither a physician or a pharmacist.
- (4) A representative of the office who shall serve as an ex-officio nonvoting member of the board.
- (5) One (1) individual who:

- (A) is employed by a health maintenance organization that has a pharmacy benefit; and
- (B) has expertise in formulary development and pharmacy benefit administration.

The individual appointed under this subdivision may not be employed by a health maintenance organization that is under contract or subcontract with the state to provide services to Medicaid recipients under this article.

- (6) One (1) individual who is a health economist.

As added by P.L.75-1992, SEC.19

IC 12-15-35-20.1 Board; Conflict of Interest

Sec. 20.1. (a) Each board member shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board for recommendation or other action.

(b) A board member may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

IC 12-15-35-21 Board; appointment; term

Sec. 21. (a) The members of the board shall be appointed by the governor and serve a term of three (3) years.

(b) The governor shall fill a vacancy on the board by appointing a new member to serve the remainder of the unexpired term.

(c) The governor may remove a member for cause.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-22 "Qualifications of board members

Sec. 22. Board members must have expertise in one (1) or more of the following:

- (1) Clinically appropriate prescribing of outpatient drugs.
- (2) Clinically appropriate dispensing and monitoring of outpatient drugs.
- (3) Drug utilization review, evaluation, and intervention.
- (4) Medical quality assurance.

As added by P.L.75-1992, SEC.19

IC 12-15-35-23 Physician appointment; geographic balance

Sec. 23. In making the physician appointments, the governor shall provide for geographic balance.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-24 Reappointment of members

Sec. 24. An individual appointed to the board may be reappointed upon the completion of the individual's term.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-25 Chairman; compensation; expense

Sec. 25. (a) The board shall annually elect a chairman from the members of the board.

(b) The chairman may be re-elected to serve consecutive terms as chairman.

(c) A member of the board who is not a state employee is entitled to the minimum salary per diem as provided by IC 4-10-11-2.1(b). Each member of the board is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties as provided in the state travel policies and procedures established by the Indiana department of administration and the budget agency.

(d) Each member of the board who is a state employee is entitled to reimbursement for traveling expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the Indiana department of administration and approved by the budget agency.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-26 Staff; furnishing

Sec. 26. The secretary shall provide staff to the board.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-27 Retrospective and prospective DUR program responsibility

Sec. 27. The board is responsible for the oversight of the retrospective and prospective DUR program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-28 Duties of board

Sec. 28. The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.3.

IC 12-15-35-29 Quorum; majority vote on DUR criteria and standards for prescribing

Sec. 29. (a) A quorum consists of six (6) voting members of the board.

(b) DUR criteria and standards for appropriate prescribing may only be implemented with the approval of a majority of the quorum of the board. The majority vote must include at least three (3) of the four (4) physician members of the board and may allow the board to accept deviations from the standards on a case-by-case basis.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-30 Local practices; monitoring

Sec. 30. The criteria and standards developed under section 28(3) of this chapter for appropriate prescribing that are implemented must reflect the local practices of physicians to monitor the following:

- (1) Therapeutic appropriateness.
- (2) Overutilization or underutilization.
- (3) Therapeutic duplication.
- (4) Drug-disease contraindications.
- (5) Drug-drug interactions.
- (6) Incorrect drug dosage or duration of drug treatment.
- (7) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-31 Intervention; approval; requisites

Sec. 31. (a) An intervention developed under section 28(4) of this chapter that involves a physician must be approved by at least three (3) of the four (4) physician members of the board before implementation.

(b) An intervention that involves a pharmacist must be approved by at least three (3) of the four (4) pharmacist members of the board before implementation.

(c) Interventions include the following:

- (1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the board's duties and powers.
- (2) Written, oral, or electronic reminders of recipient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care.
- (3) Use of face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention.
- (4) Intensified reviews or monitoring of selected prescribers or pharmacists.
- (5) The creation of an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices.
- (6) The timely evaluation of interventions to determine if the interventions have improved the quality of care.
- (7) The review of case profiles before the conducting of an intervention.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-32 Repealed

(Repealed by P.L.76-1994, SEC.7.)

IC 12-15-35-32.1 Annual report contents

Sec. 32.1. The annual report under section 28 of this chapter shall include information on the following:

- (1) A description of the nature and scope of the prospective drug review program.
- (2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.
- (3) Detailed information on the specific criteria and standards in use and any changes in criteria.
- (4) A description of the nature and scope of the retrospective DUR program.
- (5) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.
- (6) An estimate of the cost savings generated as a result of the DUR program including savings to the Medicaid drug program attributable to the prospective and retrospective DUR.
- (7) An overview of the fiscal impact of the DUR program on other areas of the Medicaid program.
- (8) A quantifiable assessment of how DUR has improved quality of care.
- (9) A summary of the total number of prescriptions reviewed by drug therapeutic class.

As added by P.L.76-1994, SEC.4.

IC 12-15-35-33 Repealed

(Repealed by P.L.1-1993, SEC.132.)

IC 12-15-35-34 Confidential identifying information; release of cumulative non-identifying information

Sec. 34. (a) Information that identifies an individual collected under this chapter is confidential and may not be disclosed by the board.

(b) The board may have access to identifying information for purposes of carrying out intervention activities. The identifying information may not be released to anyone other than a member of the board.

(c) The board may release cumulative non-identifying information for purposes of legitimate research.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-35 Prior approval program for outpatient drugs; standards

Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

- (1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:
 - (A) impede the quality of patient care in the Medicaid program; or

- (B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.
- (2) Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days of notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:
 - (A) a statement of the date, time, and place at which the board meeting will be convened.
 - (B) a general description of the subject matter of the board meeting.
 - (C) an explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after notification.

- (3) Ensure that:
 - (A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and
 - (B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.
- (4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.
- (5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.
- (6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(c) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

- (d) The board shall consider:
 - (1) health economic data;
 - (2) cost data; and
 - (3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office

As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.5.

IC 12-15-35-36 Advisory committees

Sec. 36. The board may establish advisory committees to assist the board in carrying out the board's duties under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-37 Medicaid state plan; inclusion of retrospective and prospective DUR program

Sec. 37. The board shall, in cooperation with the secretary, include in the Medicaid state plan the creation and implementation of a retrospective and prospective DUR program for Medicaid outpatient drugs to ensure that the prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-38 DUR program guidelines and procedures

Sec. 38. The retrospective and prospective DUR program shall be operated under the guidelines and procedures established by the board under section 29 of this chapter.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-39 Retrospective DUR requisites

Sec. 39. Retrospective DUR must:

- (1) be based on the guidelines established by the board; and
- (2) use the mechanized drug claims processing and information retrieval system to analyze claims data to do the following:
 - (A) Identify patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care.
 - (B) Assess data on drug use against explicit predetermined standards that are based on the compendia and other sources to monitor the following:
 - (i) Therapeutic appropriateness.
 - (ii) Overutilization or underutilization.
 - (iii) Therapeutic duplication.
 - (iv) Drug-disease contraindications.
 - (v) Drug-drug interactions.
 - (vi) Incorrect drug dosage or duration of drug treatment.
 - (vii) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-40 Prospective DUR requisites

Sec. 40. Prospective DUR must be based on the guidelines established by the board and must provide that prior to the prescription being filled or delivered a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from the following:

- (1) Therapeutic duplication.
- (2) Drug-drug interactions.
- (3) Incorrect dosage and duration of treatment.
- (4) Drug-allergy interactions.

(5) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-41 Board activities under IC 34-30-15

Sec. 41. The activities of the board in carrying out this chapter are covered under IC 34-30-15.
As added by P.L.75-1992, SEC.19. Amended by P.L.1-1998, SEC.103.

IC 12-15-35-42 Open meetings requirement; executive session purposes

Sec. 42. (a) The board may meet in an executive session for purposes of reviewing DUR data or to conduct or to discuss activity as provided for in IC 5-14-1.5-6.1.

(b) The board shall also conduct regular public meetings to gather input from the public on the operation of the DUR program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-43 Confidentiality; pharmacist data and information

Sec. 43. Confidential data or information obtained by pharmacists as part of prospective DUR are confidential but may be released to prescribers or others according to procedures established by the board.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-44 Confidentiality; violations; penalty

Sec. 44. A person who does not comply with the confidentiality provisions under section 34 of this chapter commits a Class A misdemeanor.
As added by P.L.75-1992, SEC.19. Amended by P.L.1-1993, SEC.133.

IC 12-15-35-45 Outpatient drug formulary

Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make recommendations to the board on the development of a Medicaid outpatient drug formulary.

(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the board.

(c) A formulary used by a Medicaid managed care organization is subject to sections 46 and 47 of this chapter.

As added by P.L.76-1994, SEC.6.

IC 12-15-35-46

Sec. 46. (a) This section applies to a managed care organization that enters into an initial contract with the office to be a Medicaid managed care organization after May 13, 1999.

(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.

(c) The office shall forward the formulary to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will review a Medicaid

managed care organization's proposed formulary at a particular board meeting. The notification shall contain the following information:

- (1) A statement of the date, time, and place at which the board meeting will be convened.
- (2) A general description of the subject matter of the board meeting.
- (3) An explanation of how a copy of the formulary to be discussed may be obtained.
The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.

(e) In reviewing the formulary, the board shall do the following:

- (1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the use of the formulary will not:
 - (A) impede the quality of patient care in the Medicaid program; or
 - (B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.
- (2) Make a determination that:
 - (A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary;
 - (B) a process is in place through which a Medicaid member has access to medically necessary drugs;
and
 - (C) the managed care organization otherwise meets the requirements of IC 27-13-38.

(f) The board shall consider:

- (1) health economic data;
- (2) cost data; and
- (3) the use of formularies in the non-Medicaid markets;

in developing its recommendation to the office.

(g) Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.

(h) The office shall rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.

(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.

(j) The managed care organization must comply with the office's decision within sixty (60) days after receiving notice of the office's decision.

(k) Notwithstanding the other provisions of this section, the office may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.

IC 12-15-35-47

Sec. 47. (a) This section applies to the following changes to a formulary used by a Medicaid managed care organization for Medicaid recipients:

- (1) Removing one (1) or more drugs from the formulary.
- (2) Placing new restrictions on one (1) or more drugs on the formulary.

(b) Before a Medicaid managed care organization makes a change described in subsection (a), the managed care organization shall submit the proposed change to the office.

(c) The office shall forward the proposed change to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will:

- (1) review the proposed change; and
- (2) consider evidence and credible information provided to the board; at the board's regular board meeting before making a recommendation to the office regarding whether the proposed change should be approved or disapproved.

(e) Based on the final recommendation of the board, the office may approve or disapprove the proposed change. If a proposed change is not disapproved within ninety (90) days after the date the managed care organization submits the proposed change to the office, the managed care organization may implement the change to the formulary.

(f) A Medicaid managed care organization:

- (1) may add a drug to the managed care organization's formulary without the approval of the office; and
- (2) shall notify the office of any addition to the managed care organization's formulary within thirty (30) days after making the addition.