§ 272. Preferred drug program. 1. There is hereby established a preferred drug program to promote access to the most effective prescription drugs while reducing the cost of prescription drugs for persons in state public health plans.

2. When a prescriber prescribes a non-preferred drug, state public health plan reimbursement shall be denied unless prior authorization is obtained, unless no prior authorization is required under this article.

3. The commissioner shall establish performance standards for the program that, at a minimum, ensure that the preferred drug program and the clinical drug review program provide sufficient technical support and timely responses to consumers, prescribers and pharmacists.

4. Notwithstanding any other provision of law to the contrary, no preferred drug program or prior authorization requirement for prescription drugs, except as created by this article, paragraph (a-1) or (a-2) of subdivision four of section three hundred sixty-five-a of the social services law, paragraph (g) of subdivision two of section three hundred sixty-five-a of the social services law, subdivision one of section two hundred forty-one of the elder law and shall apply to the state public health plans.

5. The drug utilization review board shall consider and make recommendations to the commissioner for the adoption of a preferred drug program. (a) In developing the preferred drug program, the board shall, without limitation: (i) identify therapeutic classes or drugs to be included in the preferred drug program; (ii) identify preferred drugs in each of the chosen therapeutic classes; (iii) evaluate the clinical effectiveness and safety of drugs considering the latest peer-reviewed research and may consider studies submitted to the federal food and drug administration in connection with its drug approval system; (iv) consider the potential impact on patient care and the potential fiscal impact that may result from making such a therapeutic class subject to prior authorization; and (v) consider the potential impact of the preferred drug program on the health of special populations such as children, the elderly, the chronically ill, persons with HIV/AIDS and

persons with mental health conditions.

(b) In developing the preferred drug program, the board may consider preferred drug programs or evidence based research operated or conducted by or for other state governments, the federal government, or multi-state coalitions. Notwithstanding any inconsistent provision of section one hundred twelve or article eleven of the state finance law or section one hundred forty-two of the economic development law or any other law, the department may enter into contractual agreements with the Oregon Health and Science University Drug Effectiveness Review Project to provide technical and clinical support to the board and the department in researching and recommending drugs to be placed on the preferred drug list.

(c) The board shall from time to time review all therapeutic classes included in the preferred drug program, and may recommend that the commissioner add or delete drugs or classes of drugs to or from the preferred drug program, subject to this subdivision.

(d) The board shall establish procedures to promptly review prescription drugs newly approved by the federal food and drug administration.

6. The board shall recommend a procedure and criteria for the approval of non-preferred drugs as part of the prior authorization process. In developing these criteria, the board shall include consideration of the following:

(a) the preferred drug has been tried by the patient and has failed to produce the desired health outcomes;

(b) the patient has tried the preferred drug and has experienced unacceptable side effects;

(c) the patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated; and

(d) other clinical indications for the use of the non-preferred drug, which shall include consideration of the medical needs of special populations, including children, the elderly, the chronically ill, persons with mental health conditions, and persons affected by HIV/AIDS.

7. The commissioner shall provide thirty days public notice on the department's website prior to any meeting of the board to develop

recommendations concerning the preferred drug program and any proposed eliminations to the list of drugs reimbursable under subdivision four of section three hundred sixty-five-a of the social services law. Such notice regarding meetings of the board shall include a description of the proposed therapeutic class to be reviewed, a listing of drug products in the therapeutic class, and the proposals to be considered by the board. The board shall allow interested parties a reasonable opportunity to make an oral presentation to the board related to the prior authorization of the therapeutic class to be reviewed. The board shall consider any information provided by any interested party, including, but not limited to, prescribers, dispensers, patients, consumers and manufacturers of the drug in developing their recommendations.

8. The commissioner shall provide notice of any recommendations developed by the board regarding the preferred drug program or elimination to the list of drugs reimbursable under subdivision four of section three hundred sixty-five-a of the social services law, at least five days before any final determination by the commissioner, by making such information available on the department's website. Such public notice may include: a summary of the deliberations of the board; a summary of the positions of those making public comments at meetings of the board; the response of the board to those comments, if any; and the findings and recommendations of the board.

9. Within ten days of a final determination regarding the preferred drug program or elimination to the list of drugs reimbursable under subdivision four of section three hundred sixty-five-a of the social services law, the commissioner shall provide public notice on the department's website of such determinations, including: the nature of the determination; and analysis of the impact of the commissioner's determination on state public health plan populations and providers; and the projected fiscal impact to the state public health plan programs of the commissioner's determination.

10. The commissioner shall adopt a preferred drug program and amendments after considering the recommendations from the board and any

comments received from prescribers, dispensers, patients, consumers and manufacturers of the drug.

(a) The preferred drug list in any therapeutic class included in the preferred drug program shall be developed based initially on an evaluation of the clinical effectiveness, safety and patient outcomes, followed by consideration of the cost-effectiveness of the drugs.

(b) In each therapeutic class included in the preferred drug program, the board shall determine whether there is one drug which is significantly more clinically effective and safe, and that drug shall be included on the preferred drug list without consideration of cost. If, among two or more drugs in a therapeutic class, the difference in clinical effectiveness and safety is not clinically significant, then cost effectiveness (including price and supplemental rebates) may also be considered in determining which drug or drugs shall be included on the preferred drug list.

(c) In addition to drugs selected under paragraph (b) of this subdivision, any prescription drug in the therapeutic class, whose cost to the state public health plans (including net price and supplemental rebates) is equal to or less than the cost of another drug in the therapeutic class that is on the preferred drug list under paragraph (b) of this subdivision, may be selected to be on the preferred drug list, based on clinical effectiveness, safety and cost-effectiveness.

(d) Notwithstanding any provision of this section to the contrary, the commissioner may designate therapeutic classes of drugs, including classes with only one drug, as all preferred prior to any review that may be conducted by the board pursuant to this section.

11. (a) The commissioner shall provide an opportunity for pharmaceutical manufacturers to provide supplemental rebates to the state public health plans for drugs within a therapeutic class; such supplemental rebates shall be taken into consideration by the board and the commissioner in determining the cost-effectiveness of drugs within a therapeutic class under the state public health plans.

(b) The commissioner may designate a pharmaceutical manufacturer as one with whom the commissioner is negotiating or has negotiated a manufacturer agreement, and all of the drugs it manufactures or markets shall be included in the preferred drug program. The commissioner may

negotiate directly with a pharmaceutical manufacturer for rebates relating to any or all of the drugs it manufactures or markets. A manufacturer agreement shall designate any or all of the drugs manufactured or marketed by the pharmaceutical manufacturer as being preferred or non preferred drugs. When a pharmaceutical manufacturer has been designated by the commissioner under this paragraph but the commissioner has not reached a manufacturer agreement with the pharmaceutical manufacturer, then the commissioner may designate some or all of the drugs manufactured or marketed by the pharmaceutical manufacturer as non preferred drugs. However, notwithstanding this paragraph, any drug that is selected to be on the preferred drug list under paragraph (b) of subdivision ten of this section on grounds that it is significantly more clinically effective and safer than other drugs in its therapeutic class shall be a preferred drug.

(c) Supplemental rebates under this subdivision shall be in addition to those required by applicable federal law and subdivision seven of section three hundred sixty-seven-a of the social services law. In order to be considered in connection with the preferred drug program, such supplemental rebates shall apply to the drug products dispensed under the Medicaid program and the EPIC program. The commissioner is prohibited from approving alternative rebate demonstrations, value added programs or guaranteed savings from other program benefits as a substitution for supplemental rebates.

13. The commissioner may implement all or a portion of the preferred drug program through contracts with administrators with expertise in management of pharmacy services, subject to applicable laws.

14. For a period of eighteen months, commencing with the date of enactment of this article, and without regard to the preferred drug program or the clinical drug review program requirements of this article, the commissioner is authorized to implement, or continue, a prior authorization requirement for a drug which may not be dispensed without a prescription as required by section sixty-eight hundred ten of the education law, for which there is a non-prescription version within the same drug class, or for which there is a comparable non-prescription version of the same drug. Any such prior authorization requirement shall

be implemented in a manner that is consistent with the process employed by the commissioner for such authorizations as of one day prior to the date of enactment of this article. At the conclusion of the eighteen month period, any such drug or drug class shall be subject to the preferred drug program requirements of this article; provided, however, that the commissioner is authorized to immediately subject any such drug to prior authorization without regard to the provisions of subdivisions five through eleven of this section.