DEXTER A. JOHNSON
LEGISLATIVE COUNSEL

STATE CAPITOL BUILDING
900 COURT ST NE S101
SALEM, OREGON 97301-4065
(503) 986-1243
FAX: (503) 373-1043

STATE OF OREGON
Legislative Counsel Committee

May 7, 2015

To: Zena Rockowitz, Administrator, Senate Committee on Health Care

From: Lorey H. Freeman, Senior Deputy Legislative Counsel

Subject: -2 Amendments to House Bill 2638

In a public hearing before the Senate Committee on Health Care on April 29, 2015, the Pharmaceutical Research and Manufacturers of America (PhRMA) provided oral and written testimony in opposition to House Bill 2638. PhRMA asserted that the six-month ban on the coverage of drugs newly approved for marketing by the United States Food and Drug Administration (FDA) is inconsistent with 42 U.S.C. 1396r-8 (the Medicaid statute), which requires the medical assistance program to cover all of a manufacturer's outpatient drugs if the manufacturer has entered into a rebate agreement with the Secretary of the United States Department of Health and Human Services (HHS). According to Joseph Fine of HHS,[1] all manufacturers have rebate agreements that include drugs grandfathered into the program when the agreements were entered into, as well as all of the manufacturer's new drugs. This office agrees that a six-month ban on coverage of new drugs is inconsistent with the Medicaid statute, and the accompanying -2 amendments are intended to avoid that result.

The Medicaid statute contains several exceptions to the requirement that all of a manufacturer's drugs must be covered by a medical assistance program if the manufacturer has entered into a rebate agreement with HHS. One of the exceptions is for drugs that are excluded from coverage by a state formulary.[2] The Medicaid statute also allows a state to require prior authorization for the payment of any covered drug.[3] Both the formulary and the prior authorization process must meet specified requirements of the Medicaid statute.

The Medicaid statute requirements for a state formulary allow a state to exclude a drug "with respect to the treatment of a specific disease or condition for an identified population (if any) only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary."[4] In Oregon, the Pharmacy and Therapeutics Committee is responsible for evaluating drugs and recommending to the Oregon Health Authority which drugs should be included in the state's formulary. However, the evaluation takes some time and may not be available until well after the drug has been approved for marketing by the FDA.

[1] Reached by telephone on May 1, 2015.
[2] 42 U.S.C. 1396r-8(d)(1)(B)(iv).
[3] 42 U.S.C. 1396r-8(d)(5).
[4] 42 U.S.C. 1396r-8(d)(4).

The Medicaid statute requirements for prior authorization require a state to provide a response to a prescriber's request for prior authorization within 24 hours of the request and require a state to provide for the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation.[5] The United States Supreme Court has held the imposition of a prior authorization requirement on any covered outpatient drug to be consistent with the Medicaid statute.[6] ORS 414.325 (4)(c) requires the authority to pay for a drug if the authority fails to respond to a request for prior authorization within 24 hours. However, there is no provision in statute requiring the dispensing of a 72-hour supply of the drug in an emergency situation. This memo does not address whether Oregon's prior authorization requirements satisfy the criteria of the Medicaid statute.

The -2 amendments to House Bill 2638 incorporate the formulary exception to the Medicaid statute and the statute's allowance for states to implement prior authorization processes by amending ORS 414.325 to subject a drug to a prior authorization requirement, imposed in accordance with the Medicaid statute, if the drug has not been evaluated by the Pharmacy and Therapeutics Committee for purposes of the state's formulary and fewer than six months have passed since the FDA approved the drug for marketing. While this will not have the same result as the six-month ban, it will limit the state's liability for the cost of new drugs while preserving the access of Medicaid recipients to medically necessary care.

Encl.

[5] 42 U.S.C. 1396r-8(d)(5).
[6] *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003).