

Statement of Opposition to Oregon House Bill 2638

Hogan Lovells provides legal counsel to the Pharmaceutical Research and Manufacturers of America (“PhRMA”). PhRMA opposes Oregon House Bill 2638, which would authorize the Oregon Health Authority (“OHA”) to deny access to innovative and potentially life-saving treatments to Oregon residents for as long as six months after those prescription drugs are approved by the U.S. Food and Drug Administration, in contravention of federal law.

PhRMA represents America’s leading biopharmaceutical research and biotechnology companies. Our members are committed to finding tomorrow’s cures and treatments for some of the most serious diseases. We share the goals of Oregon and OHA to provide meaningful access to prescription medications for all Oregonians. Oregon House Bill 2638 runs counter to those objectives.

The bill would allow the OHA to deny access to certain prescription drugs in drug classes that have not yet been evaluated by the OHA for inclusion on the Practitioner Managed Prescription Drug Plan for the first six months following approval by the US Food and Drug Administration.

That is not consistent with the federal Medicaid statute, which requires a state Medicaid program to cover all of a manufacturer’s covered outpatient drugs if that manufacturer has entered into an agreement to participate in the Medicaid Drug Rebate Program. Section 1927(d) of the Social Security Act lists the only permissible restrictions on the coverage of “covered outpatient drugs”—that is drugs or biologicals approved by the FDA when used for any medically accepted indication—and a six-month denial period for newly approved drugs is not among them. At a minimum, OHA must make a newly approved drug available through a prior authorization process that complies with the requirements specified in § 1927(d)(5) of the Social Security Act, just as any other drug not on the state’s Preferred Drug List would need to be made available via a prior authorization process. That requirement cannot be waived by the Centers for Medicare & Medicaid Services.

PhRMA therefore opposes House Bill 2638 and urges the Oregon legislature to protect access to innovative therapies for all Oregonians.