

MEMORANDUM

To: Members of the Senate Health Care Committee
From: Jim Gardner, Oregon Counsel for PhRMA
Date: May 26, 2015
Re: Legal and Policy Issues with the Dash-3 Amendment to HB 2638

We previously commented on the dash-2 amendment to HB 2638, which was prepared by Legislative Counsel in an attempt to remedy the conceded inconsistency of the original bill with federal law. As we pointed out, the dash-2 amendment contains significant flaws. The dash-3 amendment differs from the dash-2 amendment by only one word: instead of the term “prescribed” (dash-2), the dash-3 amendment substitutes the term “dispensed” (page 3, line 16). This minor wording change does not reduce or mitigate our concerns. For the reason stated below, we recommend that the committee adopt the dash-1 amendment. The dash-1 amendment would eliminate the 6-month window of deniability for newly approved drugs in unevaluated therapeutic classes.

Policy Issues With the Dash-3 Amendment

The dash-3 amendment would permit OHA to bypass, with respect to *all* newly approved drugs not yet evaluated by the Medicaid Pharmacy and Therapeutics Committee (*not simply those new drugs in unevaluated therapeutic classes*), the carefully crafted safeguards currently codified in Oregon law that are designed to protect vulnerable patients against arbitrary denials of authorization for access to needed medications. One of the most important of these safeguards is the “prescriber prevails” language codified in ORS 414.325(4)(d) which provides as follows:

After consultation with the authority or its agent, the prescriber, in the prescriber’s professional judgment, determines that the drug is medically appropriate....

In addition, because of the broad manner in which the new language on page 3, lines 11-17 of HB 2638-3 is drafted, the amendment would have the consequence, perhaps unintended, of authorizing OHA to bypass, with respect to *all* newly approved drugs not yet evaluated by the Medicaid Pharmacy and Therapeutics Committee, all of the remaining and currently applicable safeguards contained in ORS 414.325(1)-(4), including:

- The rural health clinic urgent medical condition safeguard [ORS 414.325(2)(c)];
- The mental health drug carve-out [ORS 414.325(4)(a)]; and
- The refill carve-out for drugs for the treatment of seizures, cancer, HIV or AIDS as well as immunosuppressants [ORS 414.325(4)(e)].

Legal Issue With the Dash-3 Amendment

Under established anti-delegation principles contained in the Oregon Constitution, the Oregon Legislative Assembly may not delegate its legislative power to an external body such as the Congress. When a reference to a federal statute such as 42 U.S.C. 1396r-8(d)(5) is inserted into the Oregon Revised Statutes, the legal effect is to “freeze frame” the referenced federal

statute as it exists at the time of the effective date of the new Oregon law. If the federal law is subsequently amended, the ORS reference will nonetheless continue to constitute a reference to the federal statute as it existed prior to the federal amendment.

Thus, if 42 U.S.C. 1396r-8(d)(5) is amended subsequent to the effective date of HB 2638 to make it more patient-friendly—for instance, by incorporating an Oregon-style “prescriber prevails” provision—the enacted version of HB 2638 will automatically and immediately be out of compliance with federal law.

Conclusion

For these reasons, we recommend that the committee adopt the dash -1 amendment and reject both the dash-2 and dash-3 amendments.