House Bill 505 - Senate Health and Human Services Committee
Tuesday, November 29, 2016

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Chairwoman Jones and Vice Chair Lehner, on behalf of the Ohio Association of Health Plans (OAHP), thank you for the opportunity to testify today on House Bill 505. I am Miranda Motter, President and CEO of OAHP.

The Ohio Association of Health Plans is the leading state trade association representing the health insurance industry. OAHP members provide health benefits to more than 9 million Ohioans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare, Medicaid and the Health Insurance Exchange marketplace. Our members offer a broad range of health insurance products to Ohioans in the commercial marketplace and are committed partners in public programs.

House Bill 505 would authorize substitution of an interchangeable biological product for a prescribed biological product under certain circumstances similar to those found in current Ohio law governing substitution of a generically equivalent drug for a prescribed drug. Across the country, states have been working to update laws in lieu of the emergence of biosimilar medications and to allow for pharmacist substitution of interchangeable biologics.

OAHP supports legislation that acknowledges biosimilar medication and allows the FDA-approved substitution of biologic medications. However, our industry opposes unnecessary and burdensome requirements that would impede the dispensing of biosimilar or interchangeable biologic medications. To that end, OAHP believes that legislation addressing this issue must conform to the following principles:

- ***Ohio law should be updated to acknowledge biosimilar dispensing and the substitution of interchangeable biologics as approved by the FDA.*** Ohio law should conform to the FDA definitions of biologics and interchangeable biologics to ensure consistency and reduce confusion in the dispensing of biologic medications.

- ***Ohio law should not include administrative or operational barriers to the dispensing of biosimilar or interchangeable biologics.*** Any dispensing or prescriber notification requirements should not disrupt the physician or pharmacist workflow to dispense biologic medications as appropriate to patients.

As currently drafted, House Bill 505 largely aligns with OAHP's aforementioned position - with one exception. In its current form, the bill gives the Ohio Pharmacy Board discretion to promulgate rules that are inconsistent with FDA standards, while also failing to provide any clear criteria or standards for the state pharmacy board to follow when deviating from the national standard (See Sec. 3715.011).

We have been told that this language is the result of a constitutional issue the Legislative Services Commission raised about Ohio ceding its authority to a regulator. However, we are all aware of a number of examples in Ohio's revised code where the state relies on national law, regulations, and expertise to ensure a consistent standard on various issues. This is not a new concept. We deal with situations like this frequently and across a series of policy areas – including recently enacted prior authorization legislation and pending legislation that would mandate access to abuse deterrent drugs. To that end, House Bill 505, in its current form deviates from most other states' recent legislative activity relative to the substitution of interchangeable biological products.

In hopes of addressing this concern, OAHP has offered language that would clearly define the criteria that the Ohio Pharmacy Board must review if it decides to exclude an FDA-approved interchangeable product. This criteria is consistent with federal law and would align with FDA guidelines. **We believe the amendment addresses the constitutional issue raised by LSC, while at the same time placing "guard rails" around any review the state pharmacy board would undertake that may deviate from the FDA on the subject of interchangeability and biologics.** The language has been shared with the Ohio Pharmacy Board for review and don't have any concerns with the amendment. with it. In advocating for this change, OAHP hopes to the see this one remaining issue remedied so that we can support this bill and the many positive provisions contained within it.

OAHP asks this committee to strengthen HB 505 by incorporating the recommended amendment.

Again, thank you for the opportunity to comment on behalf of OAHP and its member plans. I am happy to answer any questions you might have.