



BIOSIMILARS

Background

In 2016, the Oregon Legislature passed HB 4105, amending ORS 689.522 to implement a process for substituting interchangeable biologic products (“interchangeable biosimilars”) for a prescribed biologic and notifying providers when a substitution is made.

“Biosimilars” are akin to generic alternatives for biologic medicines. *Biosimilars* are biologic products manufactured using different cell lines and manufacturing processes than the brand name biologic with the goal of closely mirroring the composition and treatment profile of an innovator product produced by another company. *Interchangeable biosimilars* meet a heightened standard as determined by the U.S. Food and Drug Administration and “can be expected to produce the same clinical result as the [innovator] product in any given patient.”

When HB 4105 passed in 2016, it reflected a negotiated agreement amongst prescribers, pharmacists, insurers, patient groups and manufacturers, and mirrors language enacted in nearly every other state. Earlier this year, the first interchangeable biosimilars were approved by the FDA for use in the U.S. The biosimilars language in ORS 689.522 expires 1/1/2022 (See Section 3 of HB 4106 (2016)).

Oregon’s Biosimilar statute, ORS 689.522, addresses the need for communication between health care providers and pharmacies when substituting interchangeable biosimilars. Biologic products can be dynamic in how they work with each individual patient. The unique characteristics of biologics, biosimilars, and interchangeable biosimilars require a heightened focus on maintaining medical records that capture continued efficacy or any immunological reactions. The current statute ensures that providers and patients have the best access to information when substituting one product for another and is critical as more interchangeable biosimilar products are approved for use.

2021 Ask

With the expiration of the current biosimilars language in ORS 689.522, our organizations are seeking to re-institute the original language approved by HB 4105, and extending the sunset to 1/1/2026.

For Questions, Contact:

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