Massachusetts Enacts New Biosimilars Substitution Law

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On June 23, 2014, Governor Deval Patrick signed into law House Bill 3734, "An Act Relative to the Substitution of Interchangeable Biosimilars" (now Chapter 143 of the Acts of 2014). The new Act authorizes pharmacists to substitute so-called "interchangeable" biological products when filling a prescription for brand biological products, so long as the substitution complies with five requirements. These five requirements are:

1. Pharmacists may only substitute biosimilars that the Food and Drug Administration (FDA) has determined to be "interchangeable" with the prescribed product;
2. Prescribing doctors retain "dispense as written" authority;
3. Pharmacists must notify prescribing doctors of biosimilars substitutions
4. Pharmacists must notify patients of biosimilars substitutions; and
5. Pharmacists must retain records of biosimilars substitutions for a year.

While no FDA-approved biosimilar products are yet on the market, Massachusetts is in the vanguard of planning ahead for the arrival of interchangeable biological products. With the enactment of the Act, Massachusetts becomes only the seventh state to pass such legislation.

Biosimilar and Interchangeable Products

Biosimilars are biologic drugs that are very similar to — but not identical to — a "reference" (often branded) biological product. In 2010, Congress passed the "Biologics Price Competition and Innovation Act of 2009" (BPCIA), which authorizes a pathway for FDA approval of biological products that are interchangeable with the reference product.

Under BPCIA, the FDA can determine that a product is "interchangeable" with a reference product if (1) the biosimilar product is expected to produce the same clinical result as the reference product in any given patient, and (2) switching between the reference product and the biosimilar product does not increase the safety risk or reduce effectiveness.

In the four years since the enactment of BPCIA, FDA has not yet approved an interchangeable biosimilar. However, FDA officials have recently noted that the agency has met with numerous companies to discuss the submission of biosimilar applications, and several companies have indicated publicly that they expect to submit biosimilar applications to the FDA in the near future.

The Massachusetts Biosimilars Act

The new Massachusetts Act expands pharmacists' authority, allowing them to now substitute interchangeable biosimilars for prescribed branded biologics in addition to exercising their existing authority under G.L. c. 112 § 12D ("Section 12D") to substitute generic drugs for prescribed branded drugs.

As noted above, the Act establishes five requirements that must be met in connection with the substitution of an interchangeable biosimilar. Certain of these requirements are similar to those currently in effect under Section 12D for the substitution of interchangeable generic drugs.

First, the pharmacist may only substitute products that have been determined by the FDA to be interchangeable with the biologic product named on the prescription. Second, if the prescribing practitioner instructs "dispense as written" on the prescription, then the pharmacist may not override the instruction and dispense an interchangeable biological product. Both of these requirements already apply to the substitution of generic drugs under Section 12D.

Third, the pharmacist must notify the prescribing practitioner of the substitution within a reasonable time by either a notation in the patient's electronic health record (or, if an electronic record is not used, by fax, paper record, or electronic transmission). Fourth, the pharmacist must notify the patient or his/her authorized representative of the substitution by fax, by electronic transmission, by notation in the record system, or by another means consistent with the patient notice procedures for the substitution of generic drugs under Section 12D. Finally, the Act requires pharmacists to retain a record of each interchangeable biosimilar substitution for a year — a requirement that is consistent with current state drug dispensing regulations.

The general expectation is that once interchangeable biological products arrive on the market, they will be used interchangeably with branded biological products. Since several of the requirements in the Act already exist in state laws governing the dispensing and substitution of generic drugs, they will likely already be familiar to pharmacists.

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