# Virginia Enacts Nation's First Biosimilar Substitution Law

On March 21, 2013, Virginia governor Bob McDonnell signed into law the nation's first state law concerning substitution of biosimilars. The law's requirements that pharmacists keep records of substitutions, give notice of substitution to prescribers, and give notice of retail cost to patients differ significantly from the state's existing law applicable to substitution of small-molecule drugs. The biosimilar substitution provisions requiring notice to prescribers and notice of retail cost expire in July 2015. A copy of the law as passed is available here.

The biosimilar substitution provisions permit pharmacists to dispense a biosimilar in place of a prescribed biological product, but only if the biosimilar meets the safety standards for interchangeability pursuant to federal law. This provision is similar to the requirement that a substituted chemical drug be "therapeutically equivalent" to the prescribed drug. Under Virginia law, therapeutically equivalent drug products are those that contain the same active ingredient, are identical in strength or concentration, dosage form, and route of administration, and are classified as "therapeutically equivalent" in FDA's "Orange Book."

Substitution of an interchangeable biosimilar for a prescribed biological product, or a therapeutically equivalent chemical drug for a prescribed drug, is prohibited if the prescriber has specified "brand medically necessary" on the prescription or if the prescriber has given specific oral dispensing instructions. Substitution is also prohibited if the patient "insists" on the dispensing of the prescribed biological product or chemical drug.

The biosimilar substitution provisions are similar to the small-molecule drug substitution provisions in other ways, as well. In both cases, the pharmacist must inform the patient of the substitution. Pharmacists must also indicate in their records and on the "prescription label" the name of the manufacturer or distributor of the interchangeable biosimilar or generic drug. In the case of an interchangeable biosimilar, the pharmacist must also include the "product name." In addition, the name of a substituted generic drug must be followed by the words "generic for" and the name of the brand drug, while the name of a substituted interchangeable drug must be followed by the words "substituted for" and the name of the prescribed biological product.

There are, however, two key differences between the new biosimilar substitution provisions and existing drug substitution provisions:

- If a pharmacist substitutes an interchangeable biosimilar, the pharmacist or pharmacist's designee must provide electronic, written, or telephonic notice to the prescriber or the prescriber's staff within five business days or within such time as set forth in a collaborative agreement between the pharmacist and prescriber. No such notice is required for small-molecule drug substitution.
- If the pharmacist substitutes an interchangeable biosimilar, the pharmacist or pharmacist's designee must provide the patient with retail cost information for both the prescribed product and the interchangeable biosimilar, where "retail cost" is defined as "the actual cost to be paid by a retail purchaser to a pharmacy for a drug at the prescribed dosage and amount." When a pharmacist substitutes a therapeutically equivalent chemical drug for a prescribed drug, however, the pharmacist need only ensure that the dispensed drug product have a lower retail price than that of the drug prescribed and no notice to the patient is required. The provisions requiring notice to the prescriber and notice of retail cost to the patient expire on July 1, 2015.

A number of other states are considering similar legislation, including Indiana, Maryland, Colorado, Texas, Florida, and Pennsylvania.

For more information, please contact Joy Liu or your regular Ropes & Gray attorney.