Substitution allowed? State biosimilars laws are evolving

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Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time. It isn’t just federal law at issue. State law may have a profound impact as well. State law governs the ability of a pharmacist to make substitutions for a prescribed branded drug. Thus, at the end of the day, these laws impact the sales ratio of branded to generic drugs.

State laws governing the substitution of generic versions of small molecule (chemical) drugs primarily divide into two categories: permissive and mandatory. Under permissive regulations, a pharmacist may substitute the generic version, whereas under mandatory laws, the pharmacist must make the substitution if a generic version is available. Both types of laws allow the prescriber to prohibit generic substitution with a “do not substitute” or similar indication on the prescription.

Currently, only eight states have enacted biosimilar substitution laws (Delaware, Florida, Indiana, Massachusetts, North Dakota, Oregon, Utah and Virginia). All these laws are of the permissive type – even where
the same state requires mandatory generic substitution for small-molecule drugs, as in Florida. Many newly
enacted laws also include provisions that further restrict the substitution or place additional requirements on the
pharmacist. For example, Indiana only allows a biosimilar substitution if the prescriber writes “may substitute” on
the prescription. Utah, North Dakota and Oregon all require the pharmacist to notify the prescriber of the
substitution within one to three days (although, ironically, Utah’s notification provision expires in May 2015, likely
before the first biosimilar will enter the US market).

Notification provisions have attracted considerable attention. Some organizations claim these provisions will result
in fewer substitutions, a hypothesis based on the effect pre-dispensation notification requirements had on the
substitution of epilepsy drugs in some states.

An additional 13 states have considered or currently have legislation pending to govern biosimilar substitution,
including Georgia, New Jersey, Pennsylvania, Washington and Vermont, which have newly introduced legislation or
bills under active consideration. While many state efforts have faced an uphill battle, surprisingly, Washington
state’s efforts have garnered support from both the branded biologic and biosimilar manufacturers. The proposed
legislation would require a written prescription form to show two choices – “dispense as written” and “substitution
permitted” – with the prescriber indicating by signature the intended choice. The pharmacist would then have 10
days post-dispensation to notify the prescriber of the substitution. This notification can use an interoperable health
records system shared with the prescriber if the system is available.

In addition to the ongoing debates on substitution legislation, another related debate continues to brew – the
naming of biosimilars. With current small-molecule drugs, pharmacists are generally permitted to make
substitutions for a generic with the same active ingredient, such as those listed as a pharmaceutical equivalent in
the FDAs Orange Book and which carry the same United States Adopted Names (USAN) or International
Nonproprietary Name (INN). Biosimilars may not easily conform to this system because it is still undetermined if
they will carry the same USAN/INN as their branded counterparts.

Unlike small-molecule generic drugs, biosimilar drugs need only be “highly similar” rather than identical
to the branded version. Biosimilars may differ, for example, in post-translational modifications to the protein that
is the drug’s active ingredient (i.e., modifications to chemical groups that are attached to the protein when it is
produced by living cells). Accordingly, differently modified proteins may receive different USAN/INN designations.

The naming convention is likely to impact the rate at which biosimilars are substituted by pharmacists. For
example, the American Medical Association recommends that prescriptions of current generic drugs contain the
USAN assigned name for the drug. Under this recommendation, a biosimilar with a different USAN designation
would not be listed on the prescription, making it less likely to be substituted.

The Federal Trade Commission held a roundtable workshop on naming regulations in February 2014. While these
hearings fleshed out the debate, no consensus has yet emerged.