



Introduction to State Biosimilar Substitution Laws

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Typical Requirements in State Biosimilar Legislation

- ▶ Biosimilar legislation creates requirements for pharmacists and prescribers regarding the interchange of biosimilar drugs, including the following:
 - Requires pharmacists to notify patients and/ or prescribers upon dispensing an interchangeable biosimilar in a specified amount of time.
 - Record-keeping requirements for pharmacists and prescribers for a specified amount of time.
 - BOP to maintain a list of interchangeable biosimilar drugs.



Review of Biosimilar Legislation in 2013

- ▶ 28 bills were introduced in 18 states
 - Rejected in 10 states (AZ, AR, CA (vetoed), CO, DE, IN, MD, MS, TX, WA)
 - Enacted in 5 states (FL, ND, OR, UT, VA)
 - Carried over in 3 states (IL, MA, PA)



Concerns with State Legislative Activity

- ▶ Since the FDA is currently in the process of creating a pathway for the approval of biosimilars and determining interchangeability, state legislation on this issue is extremely premature.
 - There are NO biosimilars in the United States marketplace today that have been approved under section 351(k) of the Public Health Service Act (42 U.S.C. § 262).
 - There is NO patient safety issue because the interchange of biologic products cannot occur without prescriber approval.
- ▶ Concerned that premature legislation will create confusion in state substitution laws.
- ▶ Such legislation attempts to undermine public confidence in biosimilar medicines.



National & State-Specific Opposition Coalitions – 2013

- ▶ National Generic Carve-out Coalition partners include:
 - GPhA (Generic Pharmaceutical Association)
 - AMCP (Academy of Managed Care Pharmacy)
 - NACDS (National Association of Chain Drug Stores)
 - PCMA (Pharmaceutical Care Management Association)

- ▶ Other state-specific partners:
 - AARP state chapters
 - AHIP & state health plan associations
 - Health Insurers
 - Retail/Independent Pharmacies
 - Generic manufacturers
 - Unions
 - State Pharmacy Associations



North Dakota S.B. 2190 - enacted

- ▶ Contains most onerous requirements in the country, including:
 - The pharmacist must notify the prescribing practitioner orally, in writing, or via electronic transmission within 24 hours of the substitution;
 - The pharmacy and the prescribing practitioner shall retain a written record of the interchangeable biosimilar substitution for a period of no less than 5 years;
 - The pharmacist informs the individual receiving the biological product that the biological product may be substituted with a biosimilar product and that the individual has a right to refuse the biosimilar product selected by the pharmacist;
 - The BOP shall maintain on its public website a current list, or an internet link to an FDA-approved list, of biosimilar biological products determined to be interchangeable.



Enacted Bills with Sunset Provisions

State	Patient/ Prescriber Notification	*Sunset Provision	Pharmacy Record-keeping	Prescriber Record-keeping	BOP List Requirements
Oregon	Pharmacist must inform the patient prior to dispensing *Prescriber notified within 3 business days	Prescriber notification requirement expires in 2016. (2 years)	3 years	None	Post & regularly update on a website maintained by the board a list of biosimilar products determined by the FDA to be interchangeable.
Utah	A pharmacist shall communicate the substitution to the purchaser *Prescriber notified within 3 business days	Prescriber notification requirement expires in 2015. (2 years)	In accordance with state/federal laws	None	None
Virginia	Pharmacist must inform the patient prior to dispensing *Prescriber notified within 5 business days	Prescriber notification requirement expires in 2015. (2 years)	2 years	2 years	None



Florida H.B. 365 - enacted

- ▶ The Florida bill was enacted without the prescriber notification provision. Requirements in this law include:
 - The pharmacist notifies the person presenting the prescription of the substitution in the same manner as provided in Fla. Stat. § 465.025(3)(a);
 - The pharmacist retains a written or electronic record of the substitution for at least 2 years;
 - A pharmacist who practices in a class II or modified class II institutional pharmacy shall comply with the notification provisions by entering the substitution in the institution's written medical record system or electronic medical record system;
 - The BOP shall maintain on its public website a current list of biological products that the FDA has determined are biosimilar and interchangeable.



California S.B. 598 - vetoed

- ▶ The enrolled version of this bill that was vetoed by the Governor required the following:
 - Prior to January 1, 2017, the pharmacy must notify the prescriber within 5 business days of the selection of a biological product or an interchangeable biosimilar or enter the information in a patient record system shared by the prescriber. The substitution of a biosimilar shall be communicated to the patient.
 - The bill also required the BOP to maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the FDA to be interchangeable.
- ▶ A coalition of more than 30 organizations, including employer health plans, health insurers, pharmacists, retailers, pharmacy benefit managers, generic drug manufacturers, unions, was organized to stop the bill from becoming law.
- ▶ Ultimately, Governor Brown vetoed the bill, stating the following in his veto message: “The FDA, which has jurisdiction for approving all drugs, has not yet determined what standards will be required for biosimilars to meet the higher threshold for “interchangeability.” Given this fact, to require physician notification at this point strikes me as premature.”



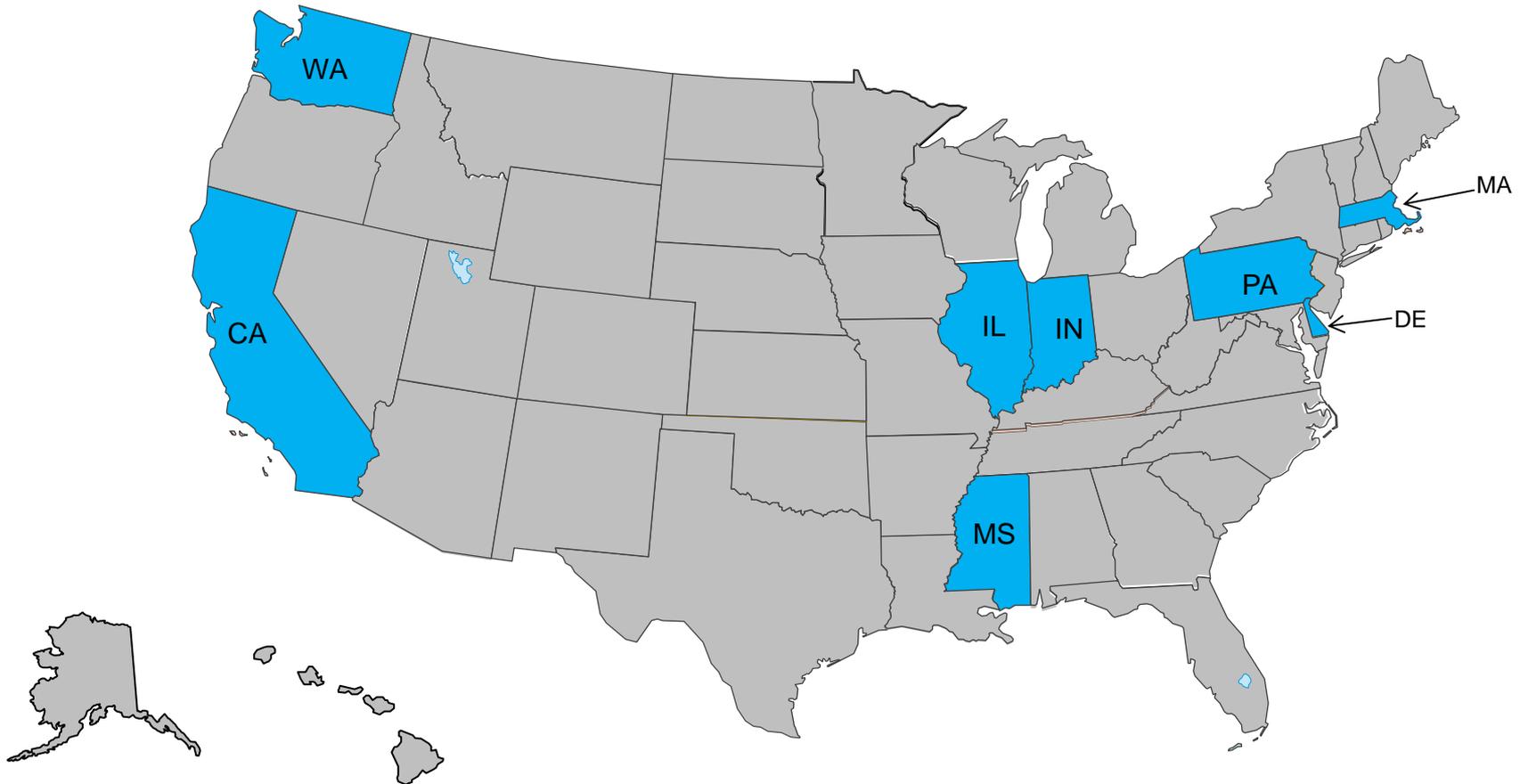
Massachusetts H.B. 3734 - pending

- ▶ Requires prescriber notification within a reasonable time following a substitution of an interchangeable biosimilar. **Notification is not required until full interoperability of electronic health records systems is reached. Entry of the substitution in the patient's electronic health record shall constitute notification.**
- ▶ Requires patient notification following a substitution. Such notification shall be written and may be conveyed by facsimile, electronic transmission, a notation in the patients record system shared with the prescriber, or other means consistent with prevailing pharmacy practice.
- ▶ Upon full interoperability of electronic health records systems, the dispensing pharmacist, the prescribing provider and administering practitioner shall retain a record of any substitution for no less than one year from the date of the last entry in the profile record, of any interchangeable biological product dispensed on the patient's electronic health record. Entry in the electronic health record shall constitute retention of record.



2014 Biosimilar Legislation

(As of 1/30/14)





Summary

- ▶ The FDA is the only U.S. regulatory body with the scientific expertise to determine interchangeability. If the FDA approves a biosimilar as interchangeable, the interchangeable biosimilar should be substitutable as is the case with generics for branded drug products.
- ▶ State legislation that places onerous requirements on the substitution of interchangeable biosimilars is premature and may conflict with the national standards the FDA is currently developing.