Research Protocol for State Drug Product Selection Laws

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State Drug Product Selection Laws

I. Date of Protocol: April 2016

II. Scope: To collect and code all state drug product selection laws—statutes and regulations enumerating conditions for pharmacist-led substitution of prescriptions for brand-name products with generic equivalents.

III. Primary Data Collection

a. Project dates: The National Association of Boards of Pharmacy Law (NABPLAW) and WestLawNext databases were searched between December 2014 and April 2015. Collected laws were coded concurrently. Results were reassessed in November 2015 using the WestLawNext database.

b. Law Current As Of: November 2015

c. Data Collection Methods: Data collection was performed by a two-person team consisting of the principal investigator and a research assistant. The NABPLAW and WestLawNext databases were each searched by one team member. Collected statutes and regulations were coded independently. Differences in coding were resolved through discussion and joint evaluation of the statute or regulation in question.

d. Databases Used: NABPLAW and WestLawNext.

e. Search Terms: “drug,” “generic”, “biologic”, “biosimilar”, “follow-on biologic”, “product”, “selection”, and “substitution”, as well as variations and combinations of these terms.

f. Additional Search Criteria: Additional material was scanned in the section of code featuring the search result using the WestLawNext table of contents tool.

IV. Coding

a. Development of Coding Scheme: An iterative process was used to develop the coding scheme. Collected statutes and regulations for ten states were first read and discussed, focusing on the following issues: 1) aspects of the laws that could impact
whether a brand-name or generic product was dispensed, and 2) variation of each aspect between the states.

b. Coding Methods: Collected drug product selection laws were ultimately coded with regard to the following variables.

i. Obligation to Perform Substitution
   2: Permissive, no duty to inform of possibility of substitution
   1: Permissive, duty to inform of possibility of substitution
   0: Mandatory

ii. Steps to Ensure Prescription Dispensed as Written
    1: Handwritten signature or words—not just initials or mark—not required
    0: Handwritten signature or words—not just initials or mark—required

iii. Duty to Notify Patients of Substitution
    2: Consent (an explicit opportunity to refuse) required
    1: Notification independent of label required
    0: Notification independent of label not required or specified

iv. Resource for Determining Interchangeability
    3: Pharmacist discretion (with or without resource recommendations)
    2: State board (including ability to remove state board listings)
    1: Orange Book (including ability to remove Orange Book listings)
    0: Orange Book + other additions (by board or pharmacists)

v. Cost Savings
    1: Substituted product must not be more expensive
    0: No cost requirement

vi. Liability for Performing Substitution
    1: Nothing stated
    0: No greater liability than dispensing brand-name product

vii. Product-Specific\(^1\) Carve-Outs
    6: Heightened requirement-substitution prohibited
    5: Heightened requirement-permissive rather than mandatory
    4: Heightened requirement-physician and patient consent
    3: Heightened requirement-physician or patient consent
    2: Heightened requirement-physician and patient notification
    1: Heightened requirement-physician or patient notification
    0: No heightened requirement

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\(^1\) Carve outs existed in some states for all drug refills, narrow therapeutic index drug refills, antiepileptic drugs, post-transplant immunosuppressant drugs, and follow-on biologics.
V. **Quality Control**: Coding was performed independently by two team members, with differences resolved through consensus discussion. Results were subsequently reassessed and compared with prior mapping projects.