Generic Substitution: The Science and Savings

D.C. Governors’ Staff Briefing

March 9, 2011

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All 50 States & DC have Generic Substitution Laws

- **State Laws**
  - 15 states have mandatory generic substitution laws
  - 35 states and DC have permissive substitution laws

- **Medicaid**
  - Preferred Drug List (PDL)
    - A list of effective, low-cost prescription drugs within therapeutic drug classes that are the recommended first choice when prescribing for Medicaid patients
  - Mandatory Substitution
    - 40 states and DC require the dispensing of generics
The Facts About Generics

- In 2009, the average price of a brand name prescription was $155 while the average price of a generic was $40.

- Today, generics account for about 75% of all prescriptions filled in the U.S., but comprise just 22% of overall prescription drug costs.

- Each 1 percentage point increase in the market share of generics results in overall drug costs decreasing by approximately 1 percentage point.

- Utilizing generic drugs has saved the American health system $734 billion over the past decade.

Efforts in the States to Impede Generic Substitution

- Carve-outs
  - Epilepsy
  - Immunosuppressants
  - Mental Health
- Continuity of Care
- E-prescribing
Generic Carve-out Legislation

- Seeks to exempt brand drugs in certain classes from state generic substitution laws
- Requires pharmacists to notify and/or obtain additional consent from prescribers and patients
- Ignores that prescribers already have authority to order “dispense as written” or “brand medically necessary”
Carve-outs Negatively Impact Patient Care

- Generic substitution is a well-established practice regulated by state law.
- Difficulty in obtaining consent from prescribers
  - Could lead to delays of hours or even days
  - Particularly problematic for these sensitive patient populations
- Creates barriers to patient access to generic drugs
Proponents of Carve-outs

- Patient Advocacy Groups
  - Epilepsy Foundation
  - National Kidney Foundation
  - American Transplant Foundation

- Brand Drug Manufacturers

- Medical Professional Groups
  - American Academy of Neurology
  - Certain Medical Societies/Colleges
National Generic Carve-out Coalition

- Letterhead coalition members:
  - GPhA (Generic Pharmaceutical Association)
  - AMCP (Academy of Managed Care Pharmacy)
  - APhA (American Pharmacists Association)
  - NACDS (National Association of Chain Drug Stores)
  - NASPA (National Alliance of State Pharmacy Associations)
  - PCMA (Pharmaceutical Care Management Association)

- Other coalition partners:
  - AARP, BCBSA, ASHSP (American Society of Health System Pharmacists)
  - Generic manufacturers: Apotex, Mylan, Sandoz, Teva, Watson, etc.
Generic Carve-out Legislation Contradicted by FDA and AMA

- **FDA:** “It is not necessary for the healthcare provider to approach any one therapeutic class of drug products any differently from any other class when there has been a determination of therapeutic equivalence….” *

- **AMA:** “While concerns still persist among some prescribers about the therapeutic equivalence of generic NTI drugs to their brand name innovator products, scientific evidence to support these concerns either does not exist or is extremely weak.” **

* Letter from U.S. Food and Drug Administration to Iowa Pharmacy Association, (January 11, 2008).
Generic Carve-out and Continuity of Care Legislation Introduced in 2011
New Trend: E-Prescribing Legislation

- Legislation is being introduced around the country that would require immediate implementation of processes that the current platform for e-prescribing cannot support yet.
- It also seeks to prohibit alerts and instant messaging at the point of care, which can include messages related to lower cost generic alternatives or pharmacy choices.
- Additionally, it would require electronic prior authorization in real-time. This function does not exist in e-prescribing platforms in United States at this time, and would have a chilling effect on the adoption of e-prescribing in the states.
E-Prescribing Legislation Introduced in 2011
E-Rx Legislation: A Wolf in Sheep’s Clothing

- Bottom line: Everyone supports e-prescribing. However, proponents of this legislation wish to stifle the adoption of e-prescribing because it will lead to an increase in generic dispensing.
  - State-by-state development of standards that would be created by this legislation will lead to inconsistencies with federal standards, leaving providers with several different and confusing platforms for e-prescribing.
  - Also, pushing the establishment of inconsistent standards may threaten the state’s ability to receive federal grant money that is available to get electronic health record systems, including e-prescribing, up and running.
  - In a time of rising health care costs, generic medications and less expensive pharmacy options can mean the difference between a patient taking their medication or going without critical care that they need. This legislation would prevent prescribers and patients from being made aware of these cost-saving opportunities.
Questions