DEVELOPING NEW STATE LEGISLATIVE HEALTH LEADERS

Prescription Drugs: Overview and Update

Richard Cauchi, Program Director, NCSL Health Program
Prescription Drugs (Rx) – Fast Facts

- More than half of all Americans use prescription drugs
- About 10% of total U.S. health spending
  - $371 billion annually. Latest annual increase now at 14+% (2014)
- Many products, both unique and competing:
  - FDA Approved (dosages; delivery method) = 10,000+
  - Total FDA different “molecules” = 2090
- 86% of prescriptions filled now are generics (total use, 2014)
- Medicaid Rx spending
  (brands = $2/3$rd of spending; generics = $1/3$rd of spending)
Generics share of prescriptions

Generics now account for 86% of all dispensed retail prescriptions

Source: IMS Health, National Prescription Audit, Jan 2014
(Virtually) ALL FDA-approved prescription drugs must be available*

Very active state roles in assuring access and controlling costs

- Medication adherence programs
- Preferred drug lists (PDL) or formularies
- Generic substitution, with physician “override” for brand
- Sliding-scale cost-sharing or copayments
- Prior authorization
- Step therapy or “fail first” requirements
- Drug utilization review (DUR)
- Multi-state purchasing
- Pharmacy benefit managers (PBMs)
- State-set dispensing fees to pharmacies
- Ingredient reimbursements (AAC, EAC, MAC, AWP, AMP, ASP)
- Supplemental rebates from manufacturers, (Hep C example)
- Disease management

* See handout toolkit for process and exceptions
Sample Medicaid PDL (Preferred Drug List)

Example: anti-diabetes drugs
Complete list = 55 pages

<table>
<thead>
<tr>
<th>Hypoglycemics, Incretin MIMETICS/Enhancers</th>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HYPOGLYCEMICS, INCRETIN ENHANCERS</strong></td>
<td>JANUMET (metformin)</td>
<td>GLYXAMBI (empagliflozin/linagliptin)</td>
</tr>
<tr>
<td></td>
<td>JANUMET XR (metformin/metformin)</td>
<td>KAZANO (alogliptin/metformin)</td>
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<tr>
<td></td>
<td>JANUVIA (sitagliptin)</td>
<td>KOMEGLYZE XR ( saxagliptin/metformin)</td>
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<tr>
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<td>JENTADUETO (sitagliptin/metformin)</td>
<td>NESINA (alogliptin)</td>
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<td></td>
<td>TRAQUENTA (linagliptin)</td>
<td>ONCELYZA (saxagliptin)</td>
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<tr>
<td></td>
<td>BYDURECON (exenatide ER)</td>
<td>OSENI (alogliptin/plagliptin)</td>
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<tr>
<td></td>
<td>BYETTA (exenatide) 5%</td>
<td>TRULIQUITY (albigludide)</td>
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<tr>
<td></td>
<td>SYMLIN (pramlintide)</td>
<td>VICTOZA (liraglutide)</td>
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<td></td>
<td>TANZELM (albigludide)</td>
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| Incretin MIMETICS | TRULIQUITY (albigludide) 5% | VICTOZA (liraglutide) |

<table>
<thead>
<tr>
<th>Hypoglycemics, Insulin</th>
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<tr>
<td><strong>HYPOGLYCEMICS, INSULIN</strong></td>
<td>HUMALOG (insulin lispro)</td>
<td>AFREZZA (insulin, rDNA-derived)</td>
</tr>
<tr>
<td></td>
<td>HUMALOG MIX (insulin lispro/protamine)</td>
<td>APEXPA insulin glulisine)</td>
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<td>TOUJEO (insulin glargine)</td>
<td>NOVOLIN (insulin)</td>
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<th>Prior Authorization/Class Criteria</th>
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<tr>
<td>Link to PA Form for Hypoglycemics - Incretin Enhancers</td>
</tr>
<tr>
<td>Non-preferred agents will only be approved if a patient has tried and failed therapy with a preferred agent within the last 6 months.</td>
</tr>
<tr>
<td>Link to PA Form for Hypoglycemics - Incretin MIMETICS (for all products except Symlyn)</td>
</tr>
<tr>
<td>Non-preferred agents will be approved only after documented failure of a preferred agent.</td>
</tr>
<tr>
<td>Link to PA Form for Symlyn</td>
</tr>
<tr>
<td>Symlyn will be approved for patients with diabetes who are currently on insulin therapy.</td>
</tr>
<tr>
<td>Symlyn will not be approved for pediatric patients 5 years of age or for patients with a diagnosis of gastroparesis, or who require the use of medication to stimulate gastric motility.</td>
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<tr>
<td>Link to PA Form for Insulin (required for non-preferred drugs)</td>
</tr>
<tr>
<td>Apipla will be approved for participants with documented hyperglycemia with hemoglobin A1c &gt;9.0%.</td>
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<tr>
<td>Aprezzi requires medical necessity documentation for any injectable insulin cannot be used.</td>
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<tr>
<td>Non-preferred agents will be approved after documented failure of a</td>
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Health Insurance Covering Pharmaceuticals
ACA Essential Health Benefits, Contracts and Beyond

2013 Analysis by Avalere:
States Defining Biologics and Biosimilar Substitution

- **Biologics and Interchangeable Biosimilars: Typical Provisions**
  - Products must have FDA approval as “biosimilar” and as “interchangeable”
  - Prescriber may block change/substitution (virtually all 50 states)
  - “Communication” or “Notification” from pharmacist to prescriber
  - Patient or purchaser information
  - Substitute costs less or “lowest cost” choice
  - Retaining records of any substitution
  - Pharmacists not liable once state laws complied with
  - Public list of interchangeable choices

*State policies vary; recent laws emphasize easy “communication”*
States Respond to Pharmacy Compounding Errors

- For past 60 years, states regulated pharmacies; Feds regulated manufacturers
- 2012: 750 sick, 64 die from contamination at Mass. facility
- 2013: New federal law; divides responsibility; 2014 regs. explain state options
  - New section (503B) of the Food Drug and Cosmetic Act (FDCA), defines how a compounder can become an “outsourcing facility”
- 2015: States can rewrite sterile compounding pharmacy safety and oversight standards, also conform to new FDA regulations

See NCSL & Pew resources:  
2015-16 Additional Pharmaceutical Issues

- Medication adherence
- Medication Therapy Management (MTM)
- Step therapy or fail-first
- Price transparency
- Limits on out-of-pocket consumer costs
- Direct state assistance (SPAPs); allow “return and reuse”
- Reference pricing
- Academic detailing – objective facts generic and brand
- Preventing prescription drug abuse and illegal sales
Pharmaceuticals

REGULATING PHARMACY SAFETY
When almost 750 patients were infected and more than 50 died from contaminated drugs made in compounding pharmacies, state regulators and legislators and federal officials moved to create more enforceable oversight to assure safety of the drug supplies. A federal law, signed November 2013, creates updated standards and safeguards while the FDA also is examining nationwide regulation.

BIOLOGICS & EXPERIMENTAL RX REPORTS (2015)
State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars - an NCSL report on bills in 31 states, with new laws in 13 states.

"Right to Try" Experimental Prescription Medicines State Laws and Legislation, 36 states considered, more new laws for 2015 - [NCSL report]

Provision for "Sunshine Rule" Brings Disclosure by Drug and Device Manufacturers. An ACA provision (Section 6002), the "National Physician Payment Transparency Program "

http://www.ncsl.org/research/health/pharmaceuticals.aspx
NCSL’s 2015 Rx Database
Funded by a grant from PEW Charitable Trusts

PRESCRIPTION DRUG STATE DATABASE
10/27/2015

2015 State Legislation on Prescription Drugs

Use this new 2015 state legislative database to learn about and analyze what states are considering and enacting in current topic areas of prescription drugs. The bill listings include four broad categories of state regulation and involvement:

- Specialty pharmaceuticals | 2015 Overview
- Biologics and biosimilar substitutions
- Compounding pharmacies and patient safety | 2015 Overview
- Pharmaceutical access and affordability

Using the search box below, you can search legislation by state, year, topic, keyword, current status, and/or primary legislative sponsor. For more information on the topics covered in the database, please see the guide section below the database.

New and updated bills: All state legislative material is updated for actions through Monday of the current week. (Status updates and additions occur every Tuesday by 8 a.m.) New measures will be added as they are filed and identified. Members are invited to submit suggested updates for recently filed or amended bills, by email.

- There are now 980 bills and resolutions filed and listed across all 50 states, D.C. and Puerto Rico
- So far for 2015, 215 laws have been signed or enacted in 45 states and Puerto Rico, six states also adopted non-statutory resolutions. (As of 10/27/2015)

Selections: To view all items click on the “All Topics” or “All States” box. To select multiple items (e.g., state or topic) in the database lists, click the boxes next to your desired selections.
NCSL’s 2015 Rx Database

225 new laws in 45 states and P.R.

2015 Prescription Drug Enacted Laws

Updated 10/15/2015 - (c) NCSL

For upcoming sessions, consider:

- What state policy changes can affect 1) access 2) affordability 3) informed consumer choice 4) innovation
- Hold a briefing or hearing on Medicaid pharmaceutical policies
- Examine cost containment policies in use and future alternatives
- State definitions for generic substitution and “biosimilar” interchange
- What level of regulation of specialty pharmacy and sterile compounding pharmacies
- Compare your state to your neighbors
DEVELOPING NEW STATE LEGISLATIVE HEALTH LEADERS

La Jolla, California | November 2-4, 2015