NCSL PRESCRIPTION DRUG POLICY RESOURCE CENTER

10/4/2018
NCSL Reports, Tracking, TAs, Meetings and more

Laws Addressing Prescription Drug Prices

- Ban "gag clauses" thus allowing pharmacists to disclose price options
- Enhance transparency in drug pricing
- Allow drug makers to market "off-label" drugs for treatments not approved by the FDA

Source: NCSL, 2018
Prescription Drugs: What Can States Do?

Meeting of the National Conference of State Legislatures  Updated 10/11/18

Shawn Bishop, MPP
Vice President, Advancing Medicare and Controlling Health Care Costs
October 12, 2018
Growth in US Drug Spending is Expected to Stay Above Growth in Economy

Rx Spending Growth (aggregate)

GDP Growth

Source: CMS, CBO. Note: Spending for drugs purchased through retail outlets such as pharmacies
Branded Drug Prices Have Nearly Tripled Since 2008

Adapted from Peterson-Kaiser Health System Tracker. Data source: Express Scripts Prescription Price Index.
What is Driving Drug Spending Growth? 2011-16

Contribution to growth in drug spending, $US billions

- New Brands
- Protected Brands
- Lost Patent
- Generics
- Total

Adapted from Peterson-Kaiser Health System Tracker. Data source: IQVIA, National Sales Perspectives, Dec 2016; IQVIA Institute of Human Data Science.
Framework of Drug Spending and Solutions

\[
\text{PER PERSON COST} = \text{VOLUME} \times \text{MIX} \times \text{PRICE}
\]

**DRIVERS:**
- Prescriptions filled
- Population age
- Disease burden
- Generics vs. brand
- Biologic vs. biosimilar
- Specialty drugs
- Genetic therapy
- Lack of competition/leverage
- Monopolies
- Market exclusivities
- Consolidation
- Anticompetitive behaviors!
- Lack of transparency
- Lack of comparative effectiveness research/value

**SOLUTIONS:**
- Reduce disease burden
- Increase use of low cost substitutes
  - Pharmacy substitute generics/biologics
  - Formularies/PDLs
  - Utilization mgmt.
  - Value assessments
- Fix patent gaming
- Boost generic/biosimilar entry
- Ban/deter anticompetitive acts
- Boost payer leverage
  - Open pricing practices
  - Assess/use drug value data
- Rebate mandates
- Payment rate setting

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- Specialty drugs
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**PRICE =**
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- Payment rate setting
- Deter generic sample blocks
- “Pay-for-delay” reporting
- Medicaid “line extension”
- Extend Medicare “donut” discount to biosimilars, branded generics

CONGRESSIONAL ACTION (2018):
- Medicaid “line extension”
- Extend Medicare “donut” discount to biosimilars, branded generics

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ADMINISTRATIVE ACTION (2017-18):
- FDA:
  - Competition Action Plan
  - Provider education on biosimilars
- CMS:
  - Medicare plan flexibility on substitution
- FDA:
  - Biosimilar Action Plan
  - Provider education on biosimilars
- CMS:
  - Medicare plan flexibility on substitution
- FDA:
  - Competition Action Plan
    - Guidances on sample blocking, generics without competition, or orphan drugs, etc
  - Biosimilar Action Plan
- CMS:
  - Medicare plan flexibility on substitution
- HHS:
  - Indication specific pricing in MA
  - WAC prices for new Part B drugs
  - Approved OK Medicaid waiver
  - Drug price dashboards

The Administration’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

**Proposals/In Progress**

- Add drug price in DTC ads
- Reform rebate safe harbors
- HHS drug importation group
- FDA Drug Shortages Task Force
- (340B reform)

**Ideas**

- Further value-based purchasing in federal programs
- Medicare Part B and D reforms
- Rebate system reform
- Copay discount reform
- Increase transparency of lower-cost alternative and price increases in Medicare
- “Foreign freeriding”

**Questions (133)**

Four major themes...

- Improve competition and end regulatory gaming?
- Support better negotiation through government insurance programs?
- Incentivize drug companies to lower list prices?
- Reduce consumer out-of-pocket spending?
Framework of Drug Spending and Solutions

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**SOLUTIONS:**
- Reduce disease burden
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  - Pharmacy substitute generics/biologics
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  - Utilization mgmt.
  - Value assessments
- Substitution laws - biosimilars
- PDLs/MCO contracting
- Utilization mgmt.
- Fix patent gaming
- Boost generic/biosimilar entry
- Ban/deter anticompetitive acts
- Boost payer leverage
  - Open pricing practices
  - Assess/use drug value data
- Rebate mandates
- Payment rate setting
- Transparency, anti-gouging laws
- APCDs, data analysis
- Commissions
- PDLs and MCO contracting terms
- Medicaid waivers on value (OK)
- Cap total drug spend and renegotiate price (NY)
- Negotiate fixed price/access (LA)
- Drug importation (VT)
- Sample blocking ban (ME)

**RECENT STATE ACTIONS:**
- Transparency, anti-gouging laws
- APCDs, data analysis
- Commissions
- PDLs and MCO contracting terms
- Medicaid waivers on value (OK)
- Cap total drug spend and renegotiate price (NY)
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Resources

Getting to the Root of High Prescription Drug Prices
Drivers and potential solutions

Waxman Strategies, *Getting to the Root of High Prescription Drug Prices*

NASEM’s *Making Medicine’s Affordable: A National Imperative*
STATE MEDICAID CHALLENGES AND AUTHORITY TO MANAGE DRUG COSTS

OCTOBER 2018 - FOR NCSL
HOW CAN WE FIX THIS?

https://www.learning4kids.net/category/sensory/
Diagram from President Trump’s America Patients First
MEDICAID CHALLENGES WITH CONTROLLING DRUG SPEND

- Medicaid Drug Rebate Program
  - Broad coverage requirements
  - Perverse incentives to prefer brand over generic Drugs
  - Lack of commercial tools to control spending
- Medicaid members, particularly those in expansion populations have a preponderance of chronic conditions; therefore appropriate utilization often means adherence and increased drug spending
- Dynamics of specialty drugs
- Medicaid quality measures are tied to appropriate drug utilization
- The Outpatient Drug rule provided parameters for Medicaid FFS reimbursement
- The Medicaid managed care “mega-reg” requires managed care plans to follow Section 1927 of the Social Security Act
Medicaid rebate funds often have their own line item and are transferred to the general fund.
 Manufacturers must sign a rebate agreement with CMS to ensure Medicaid coverage of their outpatient prescription drugs.

 They must also agree to participate in the 340B and Veteran’s Administration programs.

 600 companies, including all large ones, have agreements.

 States can negotiate supplemental rebates with companies in which they get a higher rebate than the federally mandated amount.

### Rebates offset a substantial portion (50% in FFS for 2015) of Medicaid drug spending:

<table>
<thead>
<tr>
<th>Annual Medicaid Prescription Drug Spending and Rebates, FFY 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed Drugs</td>
</tr>
<tr>
<td>Drug Rebate Offset - National</td>
</tr>
<tr>
<td>Drug Rebate Offset - State Sidebar Agreement</td>
</tr>
<tr>
<td>MCO - National Agreement</td>
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<td>MCO - State Sidebar Agreement</td>
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</table>

ACA increased minimum rebate amounts. CMS gets a portion of the difference, rather than states. Approximately $1.4 billion in FFY2015.

Sources: Centers for Medicare and Medicaid Services, “Medicaid Drug Rebate Program;” CMS 64 Reports.
MINIMUM REBATE REQUIREMENTS

+ Brand Drugs = Greater of 23.1% of AMP or difference between BP & AMP

+ Generic Drugs = 13% of AMP

+ Clotting factor or solely pediatric = 17.1% of AMP or diff. between BP & AMP.

+ Rebates are capped at 100% of AMP

CONSUMER PRICE INDEX PENALTY

Adds to the rebate amount

+ Penalizes for AMP increases faster that change in CPI-U

+ Was brand only, beginning 1st Quarter 2017 applies to generics

+ CPI-U penalty uses a baseline AMP and CPI-U to calculate penalty compared to current AMP and change in CPI-U

Because of the CPI Penalty, the amount of the rebate can equal the price of the drug or in some cases even exceed it.
• Either negotiated by individual states or by groups of states
• Drugs with supplemental rebates are “preferred” and not subject to prior authorization
• Many states use a contractor to perform the PDL management and/or perform supplemental rebate negotiations
• Supplemental rebates account for 7-8% of total rebates collected on FFS claims
• Since MCO drug utilization is eligible for federal drug rebates, MCO supplemental rebates are de minimus for the most part
The movement towards statewide PDLs and pricing transparency are impacting contracting for States and MCOs

+ States are increasingly requiring MCOs to follow statewide PDLs or a common formulary to maximize their supplemental rebates
+ States are prohibiting MCOs from negotiating supplemental rebates and instead are negotiating directly with manufacturers for supplemental rebates for both FFS and MCO utilization (sometimes for certain drug classes only)
+ CMS is encouraging single PDLs and carve out classes for developing value-based purchasing (VBP) arrangements similar to what commercial plans are doing
+ Transparent pricing may become more prevalent because of Medicaid medical loss ratio (MLR) regulations effective during contract periods beginning in 2017.
+ There is potential for states to move to single PBMs for all health plans or carving back out after recent carve ins (TennCare)
+ Recent managed care RFPs require plans to disclose all contracting arrangements in the supply chain or require full pricing transparency
+ A few states are requiring MCOs to follow state FFS NADAC/Actual Acquisition Cost (AAC) pharmacy reimbursement to encourage pricing transparency on the pharmacy side
Impact of Medication Adherence on Health Services Utilization in Medicaid

Mark C. Roebuck; Robert J. Kaestner; Julia S. Dougherty

Abstract

Objective: To examine the impact of adherence to chronic disease medications on health services utilization among Medicaid enrollees.

Subjects: Eligibility, claims, and encounter data from the Medicaid Analytic Extract files from 10 states (Alabama, California, Florida, Illinois, Indiana, Louisiana, New Hampshire, New Mexico, New York, and Virginia) were used to construct a 3-year (2008–2010), longitudinal dataset of Medicaid recipients 18–64 years of age, including 656,646 blind/disabled individuals and 704,368 other adults. Patients were classified as having ≥1 of 7 chronic conditions: (1) congestive heart failure; (2) hypertension; (3) dyslipidemia; (4) diabetes; (5) asthma/chronic obstructive pulmonary disease; (6) depression; and (7) schizophrenia/bipolar.

Methods: Poisson regression was used to estimate associations between medication adherence [continuous and categorical proportion of days covered (PDC)] and 3 dependent variables: number of inpatient hospitalizations, emergency department visits, and outpatient physician/clinic visits.

Results: Full adherence was associated with 8%–26% fewer hospitalizations and 3%–12% fewer emergency department visits among those with congestive heart failure, hypertension, diabetes, and schizophrenia/bipolar. In all analyses, full adherence was associated with up to 15% fewer outpatient physician/clinic visits. Moreover, low and moderate levels of adherence were also related to less health care use.

Conclusions: Substantial reductions in health services utilization and costs may be realized with improved medication adherence in Medicaid. These benefits begin to accrue at adherence levels below the common 0.80 PDC threshold. Therefore, interventions should focus not just on perfecting moderate adherers, but also on encouraging Medicaid patients with chronic conditions to initiate pharmacotherapy.

Medical Care. 56(3):266-273, MAR 2018
MEDICAID MEASURES IMPACTED BY MCOS/PBMS/PHARMACISTS

✓ Adherence to Antipsychotic Medications for Individuals With Schizophrenia
✓ Annual Monitoring for Patients on Persistent Medications - ACE or ARB
✓ Annual Monitoring for Patients on Persistent Medications - Digoxin
✓ Annual Monitoring for Patients on Persistent Medications - Diuretics
✓ Annual Monitoring for Patients on Persistent Medications - Total
✓ Antidepressant Medication Management - Effective Acute Phase Treatment
✓ Antidepressant Medication Management - Effective Continuation Phase Treatment
✓ Asthma Medication Ratio (5-11)
✓ Asthma Medication Ratio (12-18)
✓ Asthma Medication Ratio (18-50)
✓ Asthma Medication Ratio (50-64)
✓ Asthma Medication Ratio Total
✓ Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis
✓ Controlling High Blood Pressure
✓ FU Care for Children Prescribed ADHD Medication - Continuation & Maintenance Phase
✓ FU Care for Children Prescribed ADHD Medication - Initiation
✓ Reducing multiple anti-psychotics in children under age 18
Specialty drug spending as a percentage of total drug spending will increase from 17% in 2011 to 42% in 2021.

50% of specialty drug spending is billed to the medical benefit rather than the pharmacy benefit.

Effective April 2017, Medicaid agencies had to submit a State Plan Amendment to comply with the Medicaid Outpatient Drug Rule (42 CFR Part 447)

- Pay pharmacies off an acquisition cost model
- Maximum Allowable Cost (MAC) lists are replaced by AAC methodologies
- National Average Drug Acquisition Cost (NADAC), or other specific actual acquisition cost methodology plus a dispensing fee developed through a specific study
- Dispensing fees range from about $4 to $18, with an average of $10.24
- Compare dispensing fees paid before of $.50 to $1.50

Medicaid managed care plans are not subject to this rule, but some states require plans to pay according to the rule or Medicaid fee schedule (IA, KS, and, NC)

MCOs can negotiate their own rates with pharmacies and health plan clients

- Brand (discounts off of AWP) and Generic (MAC)
- Transparent pricing
- Spread pricing
- Maximum Allowable Cost Pricing
- Pharmacies also make “spread”
- MAC transparency laws
Generic Competition and Drug Prices

Average Relative Price
(Avg Generic / Brand)

Source: FDA, analysis of retail sales data from IMS Health. Data National Sales
Descriptive CUC, 1998-2004, updated February 2005
Washington OIC Study of the Pharmacy Supply Chain
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HEALTH MANAGEMENT ASSOCIATES
CONTACT ME

ANNE WINTER
Principal

Phoenix, AZ

awinter@healthmanagement.com
www.healthmanagement.com

HEALTH MANAGEMENT ASSOCIATES
**FEDERAL MEDICAID REBATE PROGRAM TERMS OF ART**

| Best Price (BP): Lowest price per unit provided to (almost) any purchaser |
| Average Manufacturer Price (AMP): Price calculated by the manufacturer that represents sales by wholesalers to retail pharmacies (with some exclusions) |
| Single Source (S) – marketed under an original new drug application (NDA) |
| Innovator Multiple Source (I) – multiple source drug that was originally marketed under an original NDA |
| CPI Penalty = Rebate penalty ($) added when manufacturer increases AMP faster than the Consumer Price Index – Urban (CPI-U) |
| Non-Innovator Multiple Source (N) – marketed pursuant to an abbreviated new drug application (ANDA) |
Pharmaceuticals & Public Health Crises: State Strategies to Improve Access While Ensuring Fiscal Sustainability

For National Conference of State Legislatures
New Orleans, LA
October 12, 2018
NGA Project – Overview

Launched: November 2017

States: Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia and Washington

Goal: Identify potential strategies for states to address public health crises by increasing access to pharmaceuticals while ensuring fiscal sustainability of public programs

Structure:
- Intensive work with states to collect data and identify potential strategies
- Series of roundtable discussions with states and key stakeholders to vet strategies
Defining “Public Health Crisis”

“Public health crises include morbidity and mortality arising from hazards and vulnerabilities whose scale, rapid onset, or unpredictability stresses or overwhelms the routine capabilities of government, the private sector, and individuals. Addressing such crises requires proactive efforts by all sectors designed to prevent, detect, and mitigate threats by deploying and adapting plans and resources to meet the emerging needs of the situation.”
Public Health Crisis: Hepatitis C

Annual number of hepatitis C-related deaths vs. other nationally notifiable infectious conditions in the US, 2003-2013

Source: Centers for Disease Control and Prevention
Roll Up of State Data: Hepatitis C

Ranges and Averages Across States

• **Prevalence**: 1% - 4.85%; Average: 2.15%

• **Medicaid average cost per treatment**: ~ $25,000
  - **Percentage of Medicaid budget** necessary to treat all enrollees with Hepatitis C in select states: **3.2%, 5.8%, 8.8%**

• **Corrections average cost to treat**: $58,000
  - **Percentage of corrections services budget** necessary to treat all incarcerated with Hepatitis C in select states: **4.3%, 8.0%**
Pharmacy Spending in Corrections

Drug Spending as a Share of Total Health Care Spending in Departments of Corrections, 2015

Source: 49-state surveys of DOCs developed and administered by The Pew Charitable Trusts.
Pharmacy Spending in Corrections

Most expensive drugs by unit price in DOCs, 2015

- Hepatitis C: 37
- Oncology: 25
- Inflammatory conditions: 21
- Multiple Sclerosis: 15
- Respiratory Disease: 5
- Hemophilia: 5
- Antipsychotic: 5
- HIV: 2
- Other: 4

Source: 49-state surveys of DOCs developed and administered by The Pew Charitable Trusts.
Trend: Specialty Medicines

Specialty Medicines

• In the past five years, proportion of overall pharmacy spend rose from 24.7 percent in 2008 to 46.5 percent in 2017.

• In 2017, accounted for $9.8 billion of $12 billion net growth in brand-name drug spending

• Account for 0.9 percent of claims and 32 percent of Medicaid drug spending

• Spending will reach $400 billion by 2020, or about 9.1 percent of all health care spending (just shy of current spending on all drugs)
Trend: Price Increases

Price Increases

• Price increases on existing drugs is common practice - occurring for hundreds of products every year

• Example: Naloxone
  • One product rose from $690 to $4,500 in two years
  • One product was priced at less than $1 as recently as 10 years ago

• Medicaid is uniquely protected from significant price increases, but other state programs are not
# Naloxone Pricing

## Recent and Current Prices for Naloxone

<table>
<thead>
<tr>
<th>Naloxone Product</th>
<th>Manufacturer</th>
<th>Previous Available Price (yr)</th>
<th>Current Price (2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injectable or intranasal, 1 mg-per-milliliter vial (2 ml) (mucosal atomizer device separate)</td>
<td>Amphastar</td>
<td>$20.34 (2009)</td>
<td>$39.60</td>
</tr>
<tr>
<td>Injectable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.4 mg-per-milliliter vial (10 ml)</td>
<td>Hospira</td>
<td>$62.29 (2012)</td>
<td>$142.49</td>
</tr>
<tr>
<td>0.4 mg-per-milliliter vial (1 ml)</td>
<td>Mylan</td>
<td>$23.72 (2014)</td>
<td>$23.72</td>
</tr>
<tr>
<td>0.4 mg-per-milliliter vial (1 ml)</td>
<td>West-Ward</td>
<td>$20.40 (2015)</td>
<td>$20.40</td>
</tr>
<tr>
<td>Auto-injector, two-pack of single-use prefilled auto-injectors (Evizio)</td>
<td>Kaleo</td>
<td>$690.00 (2014)</td>
<td>$4,500.00</td>
</tr>
<tr>
<td>(approved 2014)</td>
<td></td>
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<tr>
<td>Nasal spray, two-pack of single-use intranasal devices (Narcan)</td>
<td>Adapt</td>
<td>$150.00 (2015)</td>
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## The cost to reverse an overdose

Price of naloxone hydrochloride, per 1 ml

Source: Truven Health Analytics | Graphic by Nicholas Wells

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National Governors Association
NGA Project – Strategies

• Establish a Medicaid Spending Cap for Pharmaceuticals
• Pursue Alternative Payment Mechanisms (Subscription Model)
• Consider Options for Excluding Select Drugs from Medicaid Coverage
• Engage in Bulk and Pooled Purchasing
• Determine and Pay Value-Based Prices
• Maximize Discounts for the Incarcerated Population through the 340B Drug Discount Program
• Explore Whether the Federal Government Would Invoke Section 1498 of Title 28 of the United States Code (U.S.C.)
• Pursue Legal and Regulatory Options to Foster Greater Transparency in the Pharmaceutical Market
• Explore Whether the Federal Government Would Allow Nominal Pricing for Correctional Facilities
Pipeline

• Continued focus on specialty medicine development, especially for rare/orphan diseases (e.g. hemophilia and cystic fibrosis) and cancer (CAR-T)

• Increasing focus on gene therapies that will have large price tags

• Primary therapy classes in the specialty drug pipeline: migraine, inflammatory conditions, MS (Multiple Sclerosis), cancer, HIV, and autism

• Biosimilars offer opportunity for cost reduction, but have faced significant approval hurdles