Extending Discounted Drug Pricing to Correctional Facilities

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Overview

• Undiscounted correctional pricing has two causes:
  – Manufacturer barriers to discounts
  – Limited negotiating power

• Extending discounts requires addressing each

• Case studies – HIV, HCV, and HBV
Barriers

• Federal price reporting programs generally include discounts given directly to correctional facilities
  – Average Manufacturer Price – not a barrier for most drugs, limited impact even when correctional sales included
  – Best Price – perceived as barrier by manufacturers, single sale can trigger

• Because manufacturers hold the power to extend discounts, need to rebut their stated concerns

Barriers

• 42 CFR § 447.505 - Determination of best price.

• (c) Prices excluded from best price. Best price excludes the following:

  – (2) Any prices charged to a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

  – (15) Nominal prices to certain entities as set forth in § 447.508.

  – (17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.
Sales to 340B Entities

• “Any prices charged to a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).”

• All sales excluded – regardless of whether the patient meets the patient definition

• Provision requested by manufacturers for compliance purposes

• Manufacturers are not required to provide discount unless the patient definition is met, but they can provide other voluntary discounts

Nominal Prices

• “Nominal prices to certain entities as set forth in § 447.508.”

• (5) An entity that:
  – (i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and
  – (ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but does not receive funding under a provision of law referred to in such section.

• Nominal price means a price that is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.
PBM Rebates

• “(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.”

• May offer the most flexibility, but could require additional contracting

• “Provider means a hospital, HMO, including an MCO, or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.”

— Need to ensure that rebates are not considered to adjust prices at the “provider” level

Negotiating Power

- In 2016, 1.9M adults incarcerated in state and local prisons and jails
- In 2013, 70.2M Medicaid enrollees
- CVS Caremark – 94M PBM members
- Express Scripts – 39.5M covered lives
Negotiating Power

- Medicaid Preferred Drug Lists can be a tool to achieve other policy outcomes
- Example: Texas price reporting for pharmacy reimbursement
An Alternative

- Rather than encourage manufacturers to provide voluntary discounts, achieve mandated discounts under the 340B program
- Texas model – on-site medical facilities meet 340B program requirements
- Additional compliance requirements, liability borne by 340B entity, not correctional facility
Louisiana Model

• “Corrections: The successful Manufacturer will utilize the 340b Drug Pricing Program to effectively limit the Total State Spend for DAAs in the Corrections population. The 340B program was established by the federal government to allow covered entities to stretch scarce federal dollars by exempting deeply discounted prices negotiated with pharmaceutical manufacturers from the Medicaid ‘best price’ calculation. The ‘best price’ requirement ensures low drug prices for state Medicaid programs, but also creates a negative incentive for manufacturers to grant any one entity a deep discount as it would then become the ‘best price’ for all Medicaid programs. Negotiations with a 340B program covered entity are exempt from this requirement, protecting the DAA manufacturer contracting with the State from affecting their ‘best price’ through participation in the subscription model. For example, this could be achieved by having LSU Lallie Kemp Regional Medical Center, a 340B covered entity providing clinical services to inmates on behalf of the Department of Corrections, purchase DAAs for the Corrections population at a Medicaid Best Price Policy-exempt negotiated price. Much like the SRAs in Medicaid, the price for the Corrections DAA purchases would be adjusted over time to ensure it does not exceed the 2018 Total State Spend for the Corrections population.”

Case Studies

- HIV, HCV, and HBV

<table>
<thead>
<tr>
<th>Disease</th>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Price</th>
<th>Base Rebate</th>
<th>Inflation Rebate</th>
<th>Total Discount</th>
<th>Discount %</th>
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<tbody>
<tr>
<td>HIV</td>
<td>Atripla</td>
<td>efavirenz/emtricitabine/tenofovir</td>
<td>$84</td>
<td>$19</td>
<td>$32</td>
<td>$51</td>
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<tr>
<td>HCV</td>
<td>Zepatier</td>
<td>elbasvir/grazoprevir</td>
<td>$21,840</td>
<td>$5,045</td>
<td>$0</td>
<td>$5,045</td>
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<tr>
<td>HBV</td>
<td>Viread</td>
<td>tenofovir disoproxil fumarate</td>
<td>$35</td>
<td>$8</td>
<td>$18</td>
<td>$26</td>
<td>74%</td>
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</tbody>
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## Case Studies

<table>
<thead>
<tr>
<th>State</th>
<th>Incarcerated Population, 2016</th>
<th>HIV-1.3%</th>
<th>HCV-9.8%</th>
<th>HBV-2.7%</th>
<th>HIV Savings</th>
<th>HCV Savings</th>
<th>HBV Savings</th>
<th>Total Savings</th>
<th>% Savings</th>
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<tbody>
<tr>
<td>Alaska</td>
<td>4,400</td>
<td>57</td>
<td>431</td>
<td>119</td>
<td>$1,060,602</td>
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<td>California</td>
<td>202,700</td>
<td>2635</td>
<td>19865</td>
<td>5473</td>
<td>$48,860,024</td>
<td>$100,216,907</td>
<td>$142,295</td>
<td>$149,219,227</td>
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<tr>
<td>District of Columbia</td>
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<td>23</td>
<td>176</td>
<td>49</td>
<td>$433,883</td>
<td>$889,938</td>
<td>$1,264</td>
<td>$1,325,084</td>
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<td>43,200</td>
<td>562</td>
<td>4234</td>
<td>1166</td>
<td>$10,413,187</td>
<td>$21,358,512</td>
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<tr>
<td>Michigan</td>
<td>56,500</td>
<td>735</td>
<td>5537</td>
<td>1526</td>
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<td>$27,934,165</td>
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<td>Tennessee</td>
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<td>Wisconsin</td>
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<td>3489</td>
<td>961</td>
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<td>$17,600,996</td>
<td>$24,991</td>
<td>$26,207,225</td>
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