Drug Pricing

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US Drug Expenditure

- In 2017, Total Part D Expenditures was $100 billion on 40.5 million beneficiaries (Average of $2,409 per beneficiary)

- Prescriptions for chronic therapy areas are biggest drivers of prescription growth particularly hypertension and mental health.

- In 2016, US spending on prescription medicines increased by 5.8 percent over 2015 levels to $450 billion and 4.8 percent to $353 billion when adjusted for discounts and rebates.

- It is predicted that US spending on prescription medicines will increase 4 percent to 7 percent through 2021, reaching $580 billion to $650 billion, according to a report released by Quintiles IMS Hold.
American Patients First—Proposal to Reduce Drug Costs

The Administration’s Blueprint to lower drug prices and reduce out-of-pocket costs

- Lower Out-of-Pocket Costs
- Increased Competition
- Better Negotiation
- Incentives for Lower List Prices

HHS Response

HHS has identified four challenges in the American drug market:

- High list prices for drugs
- Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools
- High and rising out-of-pocket costs for consumers
- Foreign Governments free-riding off of American Investment in innovation
### HHS Actions and Proposals

#### Increased Competition
- Approved, through FDA, a record number of generic drugs in July
- Approved first product designated as a "competitive generic therapy" under a pathway created to expedite development and review of products that lack competition
- Launched a working group on how safe, short-term importation of certain medically necessary drugs could address price spikes
- Announced an FDA Biosimilar Action Plan to spur competition among expensive biologic drugs
- Took action to stop drug companies from gaming certain FDA safety programs to block cheaper competition

### HHS Actions and Proposals

#### Lower Out-of-Pocket Costs
- Put industry on notice that "gag clauses" causing seniors to pay more at the pharmacy are unacceptable
- Proposal to decrease the price paid by taxpayers and patients for certain new drugs in Medicare
- Clarified tools that Part D plans have to help patients access low-cost generics
- Proposed lower payments for certain discounted drugs,
- Announced that the average Part D premium would drop for the second year

### HHS Actions and Proposals

#### Better Negotiation
- Gave Medicare Advantage new negotiation tools to drive down prices for patients
- Solicited comment on ways to use private-sector competitive acquisition for Medicare Part B drugs
- Approved first-of-its-kind waiver for a state to negotiate pricing contracts with drug makers to secure more value

#### Incentives for Lower List Prices
- Supporting the introduction of legislation to undo the subsidy to drug companies on Medicaid rebates
- Began publishing individual drug price increases on CMS's drug dashboard
- Worked with drug companies to secure historically unprecedented rollbacks or cuts in list prices
**Very Early Results- 100 Days**

- Two drug companies lowering drug prices or rolled back of drug prices
- 13 drug companies committed to price freezes for rest of 2018
- Four drug companies canceled planned price increases
- Sixty percent fewer brand-drug price increases than the same period in 2017
- Fifty four percent more generic and brand-drug price decreases than the same period in 2017
- 20 million seniors on Medicare Advantage plans that will now have new tools to negotiate
- Record Breaking 146 generics approved in July 2018
- 3,028 comments on Presidents blueprint

**Most Recent HHS Proposal**

- On January 31, 2019, HHS proposed a rule to lower prescription drug prices and out-of-pocket costs by encouraging manufacturers to pass discounts directly on to patients and bringing new transparency to prescription drug markets.
- Under the proposed rule, prescription drug rebates that today amount to, on average, 26 to 30 percent of a drug’s list price may be passed on directly to patients and reflected in what they pay at the pharmacy counter. By encouraging negotiated discounts that are reflected in cost-sharing methods like co-insurance, used for many expensive drugs in Medicare Part D, the proposal is projected to provide the greatest benefits to seniors with high drug costs.

**CMS’s Role in Lowering Drug Costs**

Letter to Part D Plans eliminating “gag clause”

A reduction in the maximum amount that low-income beneficiaries pay for certain innovative medicines known as “biosimilars”

Allowing for certain low-cost generic drugs to be substituted onto plan formularies at any point during the year

Increasing competition among plans by removing the requirement that certain Part D plans have to “meaningfully differ” from each other, making more plan options available
### Indication-Based Formulary Design Beginning in Contract Year (CY) 2020

**What is Indication-Based Formulary Design?**
Indication-based formulary design is a formulary management tool that allows health plans to tailor on-formulary coverage of drugs predicated on specific indications. Under this type of formulary design, health plans have the ability to negotiate formulary coverage based on specific indications.

**How is this Different from Existing Policy?**
Existing CMS policy requires that if a Part D plan includes a particular drug on its formulary, the plan must cover that drug for every indication approved by the U.S. Food & Drug Administration, except for those uses that are statutorily excluded from Part D coverage, even if the plan would otherwise cover a different drug for a particular indication.

### Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)

- **Part D Explanation of Benefits** - CMS proposes to amend regulations related to the Part D Explanation of Benefits to require the inclusion of drug pricing information and lower cost therapeutic alternatives in the Explanation of Benefits that Part D plans send members.

- **Pharmacy Price Concessions in the Negotiated Price (DIR fees)** - CMS is also considering for a future plan year, which may be as early as 2020, a policy that would re-define negotiated price as the baseline, or lowest possible, payment to a pharmacy. The policy we are considering would reduce beneficiary out-of-pocket costs, and improve price transparency and market competition under the Part D program.

### Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)

- **Providing Plan Flexibility to Manage Protected Classes** - proposal would provide Part D plans with greater flexibility to negotiate discounts for drugs in "protected" therapeutic classes, so beneficiaries who need these drugs will see lower costs.

- **E-Prescribing and the Part D Prescription Drug Program** - CMS is proposing that each Part D plan adopt a provider (i.e. EHR-integrated) Real Time Benefit Tools (RTBT) of its choosing beginning on or before January 1, 2020. RTBTs have the capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary’s prescription drug benefit.
Making EHRs More Interoperable Schematic

https://go.cms.gov/MedicareRequirementsLookup

Drug Spending Dashboards

Dashboards show changes in spending per drug over time
Medicare Part D Drug Spending Dashboard
Medicare Part B Drug Spending Dashboard
Medicaid Drug Spending Dashboard
Part D Manufacturer Rebate Summary Report

No personally identifiable information included

High Annual Increases in 2016 Spending Medicare Part D

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Annual Growth Rate (2015-2016)</th>
<th>Avg Monthly Spending/ Beneficiary</th>
<th>MFgs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remvela</td>
<td>Sevelamer</td>
<td>21.8% (-53 to 56)</td>
<td>$630 Genzyme</td>
<td></td>
</tr>
<tr>
<td>Lantus</td>
<td>Insulin-Glargine, hum. rec. Animag</td>
<td>16.6% (-513 to 525)</td>
<td>$209 Sanofi-Aventis</td>
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<tr>
<td>Zetia</td>
<td>Esetibine</td>
<td>18.3% (-55 to 59)</td>
<td>$181 Merck Sharp &amp; D</td>
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<tr>
<td>Enfrel</td>
<td>Enfentanil</td>
<td>18.2% (-5498 to 5912)</td>
<td>$2,741 Genentech</td>
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<tr>
<td>Humira Pen</td>
<td>Adalimumab</td>
<td>18.0% (-51,019 to 55,970)</td>
<td>$2,835 Abbvie US LLC</td>
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<tr>
<td>Lyrica</td>
<td>Predesatin</td>
<td>17.4% (-51 to 56)</td>
<td>$705 Pfizer US Pharm</td>
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<tr>
<td>Lantus Solostar</td>
<td>Insulin-Glargine, hum. rec. Animag</td>
<td>14.2% (-514 to 525)</td>
<td>$196 Sanofi-Aventis</td>
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<tr>
<td>Crestor August 2018</td>
<td>Rosuvastatin Calcium</td>
<td>19.2% (-55 to 590)</td>
<td>$524 AstraZeneca</td>
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</tbody>
</table>
High Annual Increases in 2016 Spending Medicare Part B

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Annual Growth Rate (2012-2016)</th>
<th>Avg Monthly Spending/Beneficiary</th>
<th>Mfg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocrevus</td>
<td>Alemtuximab</td>
<td>16.2% ($222 to $340)</td>
<td>$2,186</td>
<td>BMS</td>
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<tr>
<td>Neulasta</td>
<td>Pegfilgrastim</td>
<td>8.5% ($2,788 to $3,869)</td>
<td>$1,395</td>
<td>Amgen</td>
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<tr>
<td>Xolair</td>
<td>Omalizumab</td>
<td>8.0% ($222 to $330)</td>
<td>$1,823</td>
<td>Genentech, Inc.</td>
</tr>
<tr>
<td>Vaccine Influenza</td>
<td></td>
<td>6.9% ($39 to $59)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Sandostatin LAR</td>
<td>Octreotide</td>
<td>6.8% ($123 to $160)</td>
<td>$9,202</td>
<td>Novartis</td>
</tr>
<tr>
<td>Prevnar 13</td>
<td>Pneumococcal 13-Valent Vaccine</td>
<td>6.1% ($332 to $567)</td>
<td>N/A</td>
<td>Wyeth Pharm</td>
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<tr>
<td>Remicade</td>
<td>Infliximab</td>
<td>6.0% ($63 to $80)</td>
<td>$1,930</td>
<td>Janssen Biotech</td>
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<tr>
<td>Sitaxsent</td>
<td>Tumor necrosis factor</td>
<td>5.6% ($615 to $765)</td>
<td>$1,985</td>
<td>Genentech, Inc.</td>
</tr>
</tbody>
</table>

CMMI Models

International Pricing Index (IPI) Model

- The IPI Model would test whether increasing competition for private-sector vendors to negotiate drug prices, and aligning Medicare payments for drugs with prices that are paid in foreign countries, improves beneficiary access and quality of care while reducing expenditures.

- CMS envisions that the model would initially focus on single source drugs and biologicals, as they encompass a high percentage of Part B drug spending and are frequently used by physicians that bill under Medicare Part B.

- Initially, the model would include drugs and biologicals that we identify from international pricing data. The model would begin with these two broad groups of drugs — single source drugs and biologicals — but could over time include multiple source drugs and Part B drugs provided in other settings.
**Part D Enhanced Medication Therapy Management (MTM) Model**

Enhanced MTM, when implemented correctly, can improve health care and outcomes for patients and has the potential to lower overall health costs. The model will assess whether additional incentives and flexibilities to design and implement programs will achieve:

- Improving compliance with medication protocols
- Reducing medication-related problems
- Increasing patients' knowledge of their medications
- Improving communication among prescribers, pharmacists, caregivers, and patients

*Began January 1, 2017 with a 3 year performance period

*CMS is testing the model in 5 Part D regions:
  - Region 7 (Virginia, West Virginia, Ohio, Indiana, Illinois, Wisconsin, Michigan, and Minnesota)
  - Region 11 (Alaska, Hawaii, and Washington, Oregon, Idaho, Nevada, Utah, Arizona, New Mexico, and Arizona)
  - Region 21 (Louisiana, Mississippi, Alabama, Georgia, South Carolina, North Carolina, Florida, Tennessee, Arkansas, and Kentucky)
  - Region 25 (Utah, Colorado, New Mexico, Arizona, Nevada, and California)
  - Region 28 (Arizona, New Mexico, and Utah)

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**Current Medication Management Issues: Prescribers**

- Currently prescribers face barriers to ensuring proper medication management:
  - Prescribers often lack a complete picture of a patient's prescriptions.
  - They lack the time to educate patients on proper medication management.

- Potential prescriber benefits for participating in the model:
  - Access to up-to-date accurate prescription records that reduce prescription of duplicative or contraindicated medications.
  - Synergies with ACO model
  - Linkages between clinical care, consultations, and data to improve patient quality of care.

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**Current Medication Management Issues: Pharmacists**

- A primary goal of the model is to promote stronger linkages between PDPs, pharmacists, and prescribers.

- Limitations of current MTM programs:
  - Pharmacists are often not utilized fully or effectively.
  - Information exchange between pharmacists and prescribers is often lacking.

- The Enhanced MTM model does not directly pay pharmacists; they can be paid only through a participating PDP or MTM vendor.
Part D Defined Standard Benefit

- The Part D standard benefit consists of four phases:
  - Deductible Phase
  - Initial Coverage Phase
  - Coverage Gap Phase
  - Catastrophic Coverage Phase

- The negotiated price of the medication determines:
  - movement through the different phases of the Part D benefit
  - cost-sharing for non-low-income subsidy (non-LIS) enrollees

- When enrollees reach a set out-of-pocket threshold, they enter the catastrophic coverage phase


Part D Sponsor Payments

Part D sponsor payments consist of:

- Enrollee Premiums
- Direct Subsidy (Sponsor Risk):
  - Initial Coverage: 75% of costs (net liability)
  - Coverage Gap: 5% (brand) and 75% (generic) of costs
  - Catastrophic Coverage: 15% of costs (net liability)
- Federal Reinsurance Subsidy (No Sponsor Risk)
  - Catastrophic Coverage: 80% of costs (after any DHR)

Part D sponsors also receive federal low-income cost-sharing subsidies and low-income premium subsidies, as well as other payments through direct and indirect remuneration (DIR)
Part D Payment Modernization Model

Part D Payment Modernization Model Eligibility

- Eligible: PDP and MA-PD plans, including those that offer standard or alternative Part D coverage, may apply to participate.
- Not eligible: Special needs plans, private fee-for-service plans, employer/union only direct contract plans, section 1876 cost contract plans, section 1831 health care prepaid plans, PACE, Medicare-Medicaid plans, and religious fraternal benefit plans.
- Part D sponsors will be required to submit all Plan Benefit Packages (PBPs) in the PDP regions for which they are applying for participation.
- Medicare Advantage Organizations (MAOs) that apply with an MA-PD must include all of the eligible MA-PD PBPs offered in or across the Part D region(s) that the MA-PD serves.

Spending Target Benchmark

Intended to represent the amount of federal reinsurance subsidy spending that CMS would have paid model participants in the absence of the model.
- Calculated at an aggregate level for participating organizations.
- Calculated separately for PDPs and MA-PD.
- Calculated after the performance year.
- Includes necessary benchmark adjustment factors.

Based on performance relative to the spending target benchmark, model participants will be eligible for performance-based payments or will be accountable for losses.
Part D Rewards and Incentives Programs

- CMS is permitting model participants to propose Part D Rewards and Incentives (RI) programs that, in connection with medication use, focus on promoting improved health, medication adherence, and the efficient use of health care resources.

- The goals include rewarding and incentivizing enrollees:
  - Participation in a disease state management program
  - Engaging in medication therapy management with pharmacists or providers
  - Receipt of preventive health services, such as vaccines
  - Active engagement with their plans in understanding their medications, including clinically-equivalent alternatives that may be more cost-accessible

Value-Based Insurance Design Model

Greater Value Based Insurance Design Scope for 2020

- Bipartisan Budget Act of 2018 (BBA) allows eligible MAOs in all 50 states and territories to apply for one or more of the health plan innovations being tested in the VBID model.

- Coordinated care plans (CCPs) – including HMOs and local PPOs - may apply to VBID currently.

- Regional Preferred Provider Organizations (RPPCs) may apply to VBID for 2020.

- Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs) may apply to VBID for 2020.

CY 2021: Hospice Benefit in MA
### VBID Model Design Elements

- VBID by chronic condition and/or socioeconomic status
- Rewards and Incentives
- Telehealth Networks
- Wellness and Health Care Planning
- CY 2021: Hospice Benefit in Medicare Advantage

### Value-Based Insurance Design – Chronic Condition and/or Socioeconomic Status

- To test the impact of value-based insurance design, MAOs may propose reduced cost-sharing and/or additional supplemental benefits, including non-primarily health related supplemental benefits, for targeted enrollees.
- MAOs may propose reducing costs for covered Part D drugs
  - For example, based on chronic condition(s) and/or low-income subsidy status, MAOs may propose generic drug(s) with $0 cost-sharing.
- MAOs may propose additional conditions for eligibility
  - For example, a conditional requirement may be participation in a disease state management program or seeing a high-value provider.

### Rewards and Incentives Programs

- Participating MAOs that offer Prescription Drug Plans (MA-PDs) may also propose RI programs for enrollees who take covered Part D prescription drugs.
- Generally, these RI programs should do one or more of the following:
  - Reward and incentivize participation in a disease state management program
  - Reward and incentivize engaging in medication therapy management with pharmacists or providers
  - Reward and incentivize receiving preventive health services, such as vaccines
  - Reward and incentivize active engagement between MAOs and their enrollees in understanding their medications, including clinically-equivalent alternatives that may be more cost-accessible.
References
