ACE 2020 Annual Meeting

Drug Reimbursement: What's New and What to Expect

Friday, January 24, 2020

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Agenda

- Background
- Recent Developments
- 340B Updates
- Provider Response
- Questions and Discussion

Background

Background

The Unsustainable Path

- Medicaid and Medicare spending is projected to double between 2015 and 2025.[1]
- Oncology spending (across all payers) follows a similar, if not accelerated, trajectory.[2]
- Within oncology care, drugs are the fastest-growing expense category. Between 2004 and 2014, they grew from 15% to 20% of spending.[3]
- Similarly, within the pharmaceutical industry, oncology drugs are the fastest-growing segment.
  - Between 1998 and 2014, they grew from 6.7% to 30.2% of the industry.[4]
  - Oncology products dominate the drug development pipeline, with thousands of products under development.[5]
- Per capita, the US spends significantly more on pharmaceuticals than any other country.[6]
- The current administration included addressing drug spending as one its core 2016 campaign promises.

1 Centers for Medicare & Medicaid Services (CMS), National Health Expenditure Data.
2 Includes diagnosis, surgery, hospitalization, and palliative and end-of-life care. Source: IMS Institute for Healthcare Informatics, "Global Oncology Trend Report: A Review of 2015 and Outlook to 2020" (June 2016).
3 Deloitte Center for Health Solutions, "The Evolution of Oncology Payment Models: What Can We Learn from Early Experiments?"
4 Yossef Lomnicky et al., "Trends in Annual Drug Expenditure: A 16-Year Perspective of a Public Healthcare Maintenance Organization," *Israel Journal of Health Policy Research* (Vol. 5, No. 37, 2016).
5 Analysis Group, "Innovation in the Biopharmaceutical Pipeline: A Multidimensional View" (2013).
6 Organization for Economic Co-operation and Development, "Pharmaceutical Spending Trends and Future Challenges," *Health at a Glance* (2015).

Background

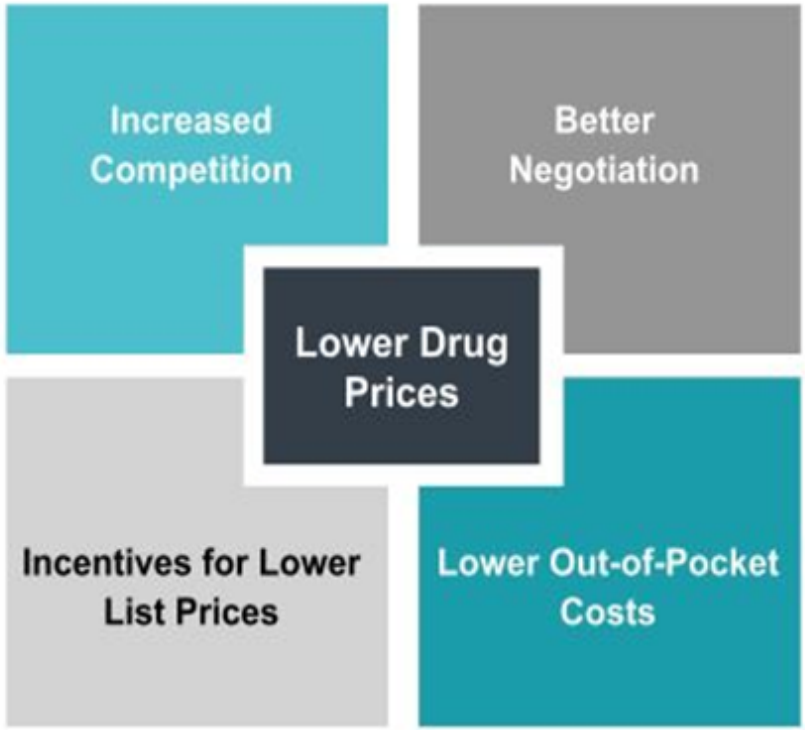
Trump Administration Blueprint

In June 2018, the Trump administration announced a "blueprint" to lower drug prices, citing several system elements that drive prices up.

Issues Driving High Prices

- Overall lack of transparency in drug pricing
- Gaming of the regulatory system by drug companies to keep lower-cost generic drugs out of the market
- The US government's inability to negotiate drug prices
- Concerns over how facilities with access to 340B use savings to facilitate charity care to low-income patients
- Foreign markets' negotiation of low prices from US drug makers, which shifts the burden of financing drug development onto US patients and taxpayers

The Blueprint's Four Pillars



Recent Developments

Recent Developments

International Pricing Index (IPI) Model

CMS is soliciting comments on a proposed model that is designed to test whether changing Part B drug reimbursement leads to higher-quality care for Medicare beneficiaries and reduced spending for the program.

The IPI Model includes a three-pronged approach:

- Phasing down the Medicare reimbursement amount for selected Part B drugs to align with prices paid by foreign countries
- Allowing private-sector vendors to negotiate prices for drugs and compete for physician and hospital business
- Changing the 4.3% (postsequester) drug add-on payment to a flat payment amount

Who Will Participate?	Which Drugs Are Included?	What Is the New Payment Model?	Who Supplies the Drugs?
Physician practices and hospital outpatient departments (HOPDs) in select geographic areas (to be determined by CMS) will participate in the IPI Model.	The IPI Model will initially focus on single-source drugs and biologicals.	If a drug's ASP is higher than international prices, CMS will pay for it based on a target price derived from the IPI Model. The target price will be phased in over five years.	Private-sector vendors will take on the financial risk of acquiring and billing for drugs. Physicians and hospitals would be able to contract with multiple vendors for different drugs and to change vendors.

The model was originally proposed to run from spring 2020 through 2025.

Recent Developments

IPI Model Impact

Impact on . . .

Providers

- The IPI Model covers all physician practices and HOPDs furnishing included drugs in selected geographies.
- CMS plans to transition half of its spending for eligible Part B drugs to the model, which will be adopted in randomly selected regions.
- Participants would continue to receive payment for drug administration and add-on payments.

Physician-Administered and Separately Paid OPPS Drugs

- **Years 1–2:** Certain single-source drugs, biologicals, biosimilars with reliable data, and possibly multiple-source drugs from a single vendor
- **Years 3–5:** Additional single-source drugs, biologicals, and biosimilars when drug pricing data is available
- **Year 5:** CMS expectation that included drugs account for at least 75% of Part B–allowed charges for such drugs

Payments

- Calculate the average international price per HCPCS code.
- Calculate the ratio of domestic ASP spending to ex-US spending (IPI).
- Calculate the target price as the ex-US price multiplied by the IPI, adjusted to not exceed a 30% decrease.
- Phase in the reduction from ASP to the target price over five years.

- Add-on payments would be a set amount, paid per encounter per month.
- The amount would be set by class of drugs, physician specialty, or practice/hospital.
- Payments would reflect approximate revenue realized from the current 6% add-on, based on the most recent claims data.

Rates are phased in over five years:

- **Year 1:** 80% of ASP + 20% of target price
- **Year 4:** 20% of ASP + 80% of target price
- **Year 5:** 100% of target price

Recent Developments

Medicare Advantage (MA) and Part D Rule

CMS finalized the rule on MA and Part D drug pricing on May 16, 2019. The model is intended to improve access to lower-cost options for seniors and provide program sponsors with tools to lower the cost of prescription drugs.

- *Reform to Medicare Part D's Protected Class Drugs:*
  - Part D plans will no longer be required to cover all drugs within the six "protected" categories. At a minimum, plans will have to carry at least two drugs per category.
  - Drugs can be excluded in situations where:
    - A drug's price increases too quickly over a certain period of time.
    - There is no material difference between a new drug and its prior version(s).
  - Plans will use prior authorization and step therapy to manage utilization of protected-class drugs.
- *Real-Time Benefit Tools (RTBTs):* Part D plans will adopt EHR-integrated RTBTs to inform prescribers about lower-cost alternatives for prescription drugs.
- *MA and Step Therapy for Part B Drugs:* Prior authorizations and step therapy will also be used to manage utilization of Part B drugs.
- *Prohibition against Gag Clauses:* Pharmacy gag clauses disallowing pharmacies from disclosing lower cash prices to enrollees will be prohibited.

Protected Drug Categories

- **Antidepressants**
- **Antipsychotics**
- **Anticonvulsants**
- **Immunosuppressants**
- **Antiretrovirals**
- **Antineoplastics**

340B UPDATES

2019-2020 340B Landscape

- Compared to prior years, 2019 was a relatively quiet year for the 340B Program
- Most attention on Medicare payment for 340B drugs
- Several significant policy changes from HRSA
- Limited Congressional attention to 340B Program
- Expect more of the same for 2020, but prepare for more activity in 2021

340B Medicare Litigation

- Effective 1/1/2018, CMS cut Medicare payments to hospitals for most 340B drugs
  - From ASP+6% to ASP-22.5%
- CMS expanded the cuts effective 1/1/2019
  - Expanded cuts to include certain off-campus locations not previously cut
- Hospitals sued HHS to have the cuts reversed
  - Hospitals won at the District Court
  - HHS appealed
- While appeal is pending, CMS continues to pay hospitals at the reduced rate
  - CMS requested comments on possible remedies
  - CMS issued notice of data collection on 340B acquisition costs
    - Proposed implementation of February 2020

340B Policy Changes

- Manufacturer Ceiling Price and Civil Monetary Penalty Rule
  - Effective 1/1/2019- Ceiling Price Website 4/1/2019
- HRSA had been moving towards more oversight and enforcement outside of formal regulatory authority
  - Examples
    - Review of hospital contracts with government entities
    - Imposition of policy requirements through audit "Areas for Improvement"
- Abrupt change in approach mid-year
  - Examples
    - Changes to audit report language
      - Option to dispute findings based on statutory interpretation
  - Withdraw of audit findings in *Genesis* litigation
- Possible Reasons
  - Supreme Court decisions limiting enforcement based on guidance
  - Executive Orders limiting enforcement based on guidance
  - Litigation risk for enforcement based on guidance

340B in Congress

- Significantly less 340B activity in Congress than in prior years
  - Only two fewer bills mentioning 340B, but the attention and focus was significantly less
- Most attention on H.B. 3- “Lower Drug Costs Now Act”
  - Initially excluded drugs subject to negotiated pricing from the 340B Program
  - Provision was removed prior to being finalized by the House
  - Bill was sent to Senate mid-December
    - No further action expected
- No major 340B activity currently expected in 2020
  - But, likely to continue to come up in the context of drug prices

Recent 340B Government Publications

- CMS “Informational Bulletin” to State Medicaid Directors
  - Released January 8, 2020
  - Includes 9 “Best Practices” to prevent 340B/Medicaid Duplicate Discounts
  - Many address Medicaid Managed Care claims
- GAO Report on HRSA Oversight of Nongovernmental Hospital Eligibility
  - Released January 10, 2020
  - Includes 6 “Recommendations” to HRSA to improve oversight
  - May result in increased documentation burdens for nongovernmental hospitals
  - References on-going request for HHS regulatory authority over 340B Program

Provider Response

Provider Response

Impact of Policies

Absent broader payment reform, any efforts to reduce drug acquisition costs will have a direct and negative impact on the bottom line for oncology providers.

Many drug cost reform proposals under consideration target the supply cost of drugs.

In the current environment, providers are paid a “commission” for administering drugs to patients.

If the underlying cost basis decreases, all other factors being the same, the provider’s margin will also decrease.

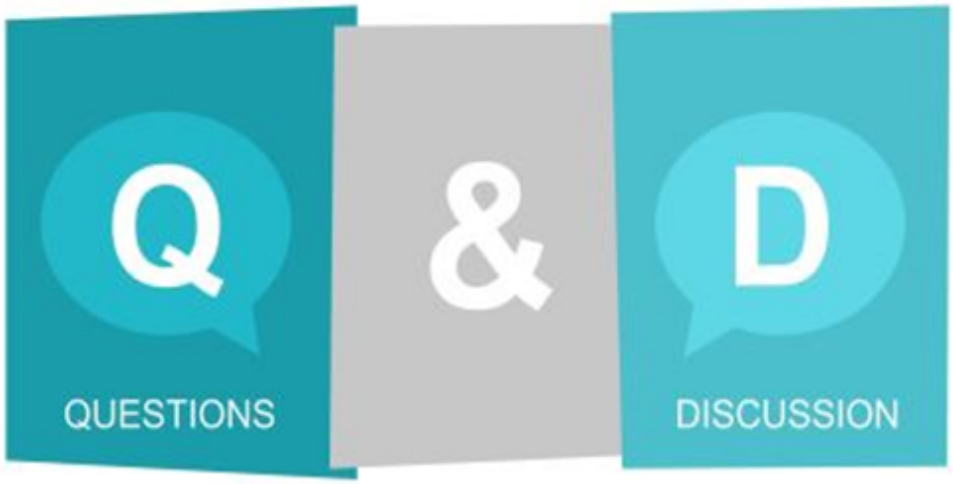
Provider Response

Potential Strategies

Most organizations will fall into one of three categories in terms of how they respond to payment innovation for drugs. Intentionally selecting and maintaining a singular strategy will be important for financial success.

- **Innovators:** Readily jump into new drug reimbursement models as early adopters.
  - Develop processes (pathways, formularies, etc.) to manage drug costs.
  - Approach payers to develop new models or request participation in existing models.
- **Progressives:** Shift into new models after they've been proven and work financially.
  - Carefully assess available models and learn from the results of innovators.
  - Identify and participate in models that align with the realities of your practice.
- **Traditionalists:** Hold on to the cost-plus margin reimbursement structure.
  - Minimize acquisition costs relative to reimbursement.
  - Select therapeutic regimens that maximize reimbursement.
  - Avoid transitioning to new payment models.

Questions and Discussion



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