Part B and the International Pricing Index Model

January 16, 2019
Many of the new innovations today are administered by physicians

<table>
<thead>
<tr>
<th>Then</th>
<th>Now</th>
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<tbody>
<tr>
<td>Medicines made of chemical compounds</td>
<td>Medicines made from living cells</td>
</tr>
<tr>
<td>Medicines treat broad diseases</td>
<td>Medicines targeted to specific patient</td>
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<tr>
<td></td>
<td>based on genetic makeup</td>
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<tr>
<td>Radiation and chemotherapy to treat cancer</td>
<td>Immunotherapy that harnesses body’s</td>
</tr>
<tr>
<td></td>
<td>own immune system to fight disease</td>
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<td></td>
<td>CAR T-cell therapy</td>
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<td>CRISPR</td>
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Progress in Treating Cancer is Leading to Longer Lives and Better Quality of Life

Cancer Death Rates Have Declined 27 percent in 25 Years

U.S. Death Rates from Cancer Decline Over Time

<table>
<thead>
<tr>
<th>Year</th>
<th>Cancer Death Rate (Number of Deaths Due to Cancer per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>215</td>
</tr>
<tr>
<td>2016</td>
<td>156</td>
</tr>
</tbody>
</table>

The Number of Cancer Survivors is Steadily Rising

U.S. Cancer Survivors Over Time

<table>
<thead>
<tr>
<th>Year</th>
<th>U.S. Cancer Survivors (In Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1971</td>
<td>3</td>
</tr>
<tr>
<td>2001</td>
<td>9.8</td>
</tr>
<tr>
<td>2016</td>
<td>15.5</td>
</tr>
<tr>
<td>2026 (Projected)</td>
<td>20.3</td>
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Medicine Costs Growing at Slowest Rate in Years

Spending on Medicine Decelerating

Prices for Brand-Name Medicines Decelerating

Discounts and Rebates Growing

IMS Health & Quintiles are now IQVIA™

0.6%

1.9%

2017

2017

$74B

$153B

2012

2017
Part B Medicines Are A Small Share of Total Medicare Spending with Significant Discounts

Spending on Part B medicines represented just 3% of all Medicare spending in 2016.

The 2018 Average Sales Price represented a volume-weighted average discount of 21.2% off the list price for the 25 medicines with the highest spending under Part B in 2016.

Part B Ensures Access and Predictable Cost Sharing

- Part B beneficiaries have access to new, innovative treatments for some of the most debilitating diseases
- Predictable cost-sharing structure
- Supplemental coverage lowers out-of-pocket costs for more than 80 percent of beneficiaries
U.S. Health Care System Protects Access

<table>
<thead>
<tr>
<th>U.S. System</th>
<th>Foreign Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>96% of new cancer medicines are available in the United States</td>
<td>Just 55% of new cancer medicines are available in the 16 countries referenced in the October ASPE report</td>
</tr>
<tr>
<td>Patients access cancer medicines quickly after FDA approval</td>
<td>Of those new cancer medicines available, patients receive them 17 months later, on average, in the 16 countries referenced in the October ASPE report</td>
</tr>
<tr>
<td>Competitive marketplace with negotiation between manufacturers and payers</td>
<td>Companies have limited leverage in negotiations with foreign governments, most of which run single-payer health care systems</td>
</tr>
</tbody>
</table>

Repeatedly Hear Stories of Access Restrictions Abroad

NICE turns down Opdivo / Yervoy combo for kidney cancer

‘Patients who should live are dying’: Greece’s public health meltdown

NHS will not fund MS drug which can delay need for wheelchair by up to seven years

Despite innovation, Europeans wait years for new cancer drugs
U.S. Cancer Patients’ Survival Rates Could Suffer

U.S. non-small cell lung cancer patients gained nearly 202,000 life years combined due to access to innovative medicines with little to no delay after regulatory approval.

U.S. Patients with Non-Small Cell Lung Cancer Would Lose Life Years If U.S. Government Replicated Flawed Policies of Foreign Governments

- Australia's Access Policies: -74%
- Canada's Access Policies: -54%
- United Kingdom's Access Policies: -54%
- Korea's Access Policies: -52%
- France's Access Policies: -13%

Source: IHS Markit, "Comparing Health Outcome Differences Due to Drug Access: A Model in Non-Small Cell Lung Cancer," December 13, 2018
There Are Right Ways to Address Affordability Challenges

- Promote Value-Driven Health Care
- Fix 340B
- Increase Generic Competition
- Improve Trade Agreements
- Middlemen / Delinking Supply Chain from List Price
- Address the Opioid Crisis
Deep Dive on Medicare Part B
Part B: Medicare’s Medical Insurance

Medicare Part B covers physician office visits, outpatient care, ambulance services and medical equipment like a wheelchair.

Part B also primarily covers physician-administered medicines, like injected or infused chemotherapies.

Care may be delivered in a number of different locations like hospital outpatient departments, physician offices and patients’ homes.
Part B Medicines Help Treat Debilitating Diseases

- CANCER
- RHEUMATOID ARTHRITIS
- HEMOPHILIA
- AUTOIMMUNE DISEASES
- MACULAR DEGENERATION
- OSTEOPOROSIS
- MENTAL ILLNESS
- RARE DISEASES
Part B Uses A Unique Buy & Bill Payment Model

1. Manufacturer sells medicine to wholesaler
2. Wholesaler sells to providers at various negotiated rates
3. Provider administers medicine to patient; patient (or insurer) pays coinsurance
4. Medicare reimburses provider at Average Sales Price plus 4.3% less patient coinsurance
Under the Medicare Modernization Act, Congress changed the reimbursement of Part B medicines from Average Wholesale Price to Average Sales Price (ASP):

- Weighted average of all non-exempt manufacturer sales prices

- Includes rebates and discounts privately negotiated between manufacturers and purchasers

- Updated quarterly to ensure Medicare reimbursement keeps pace with changes in the market

“[T]he MMA tied reimbursement more closely to health care providers’ acquisition costs by paying for a drug’s market price. Under this acquisition process, Medicare has no price-setting power – reimbursement rates lag rather than lead market prices.”

- HHS OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, JUNE 2014

Source: Office of the Assistant Secretary for Planning and Evaluation, “Medicare Part B Reimbursement of Prescription Drugs,” June 1, 2014.
Evidence Shows Market-Based ASP System Works

“[A]mong the top drugs with a decrease, there are a number of competitive market factors at work – multiple manufacturers, alternative therapies or market shifts to lower priced products.”
- Centers for Medicare & Medicaid Services, ASP Drug Pricing Files January 2019 Update

1. Average price growth in Part B is below medical inflation

2. Part B medicines accounted for just 3% of total Medicare spending in 2016.

3. In Q4 2018, on average, payment for the top 50 Part B drugs decreased by 0.8%

2018 Medicare Trustees Report.

Figure 4: Weighted ASP for All Drugs vs. CPI-M

* 2016 and 2017 Weighted ASP numbers are projections.
Understanding the Physician Add-on Payment

<table>
<thead>
<tr>
<th>Add-on Payment Necessary for Number of Reasons</th>
<th>Add-on Payment Doesn’t Drive Physician Prescribing</th>
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</thead>
<tbody>
<tr>
<td>• Currently 4.3% under sequestration</td>
<td>“Our findings indicate that there is no meaningful correlation between drug payment and utilization, challenging the theory that physicians significantly favor drugs with high add-on payments.”</td>
</tr>
<tr>
<td>• Helps cover:</td>
<td>“Overall, treatment choice does not appear to be driven by the margin physicians are paid on a drug, indicating that the ASP+6% payment rate does not drive high-cost drug utilization.”</td>
</tr>
<tr>
<td>− Geographic and provider purchasing variability</td>
<td></td>
</tr>
<tr>
<td>− Shipping fees</td>
<td></td>
</tr>
<tr>
<td>− Ongoing patient monitoring and education</td>
<td></td>
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<tr>
<td>− Overhead for cost of stocking medicines as well as complex storing and handling requirements</td>
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Unlike the ASP System, 340B Has Distorting Impact

GAO: “Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH [disproportionate share] hospitals.”

Average Per Beneficiary Medicare Part B Drug Spending in 2012

- 340B Hospital: $144
- Non-340B Hospital: $60


Site of Care for Breast Cancer Drug Therapies Reimbursed in Medicare Part B

- 2008:
  - 340B Hospitals: 11%
  - Non-340B Hospitals: 73%
  - Physician Offices: 17%
- 2015:
  - 340B Hospitals: 33%
  - Non-340B Hospitals: 49%
  - Physician Offices: 18%
And the 340B Program is Not Always Helping Patients

Experts find the 340B program causes higher health care costs that result in patients paying more out of pocket.

Congressional Budget Office estimates the 340B discount averages 49% off of the list price of outpatient prescription medicines, but there is little evidence patients are seeing any benefit.

GAO has cited the incentives to prescribe more and more expensive drugs at 340B hospitals, which drives up patient out-of-pocket costs.

The program is accelerating consolidation in the health care market, driving up the cost of medical care.
What Is the Proposed IPI Model?
# Proposed Changes to Part B Would Upend Market-Based System

## Proposal Would Cut Part B Payments 30 Percent Over Five Years, Starting in 2020

### Outline of Proposal

- Mandatory demo for half of all Part B drug spend
- Providers must purchase medicines from a vendor
- Government pays vendors based on international reference price index
- Pays providers a flat fee

### Effects of Proposal

- Imports foreign price controls that may ultimately restrict patient access
- Disincentivizes lifesaving research and development
  - $50 billion over eight years – much greater if expanded
- Savings primarily flow to plans
The Model Exceeds Authority Granted to CMMI

The Goal of CMMI:

• Established by the Affordable Care Act to test new models for paying for and delivering health care in the Medicare, Medicaid and CHIP programs

• If model improves quality of care without increasing Medicare spending, CMMI has authority to expand model

• To expand models, statute requires rulemaking

The IPI Model Goes Too Far:

• **Not a True “Test”:** National-scale overhaul of Medicare policy

• **Violates Separation of Powers:** Executive branch would be effectively canceling the effect of existing legislation via broad use of waivers

• **Conflicts with U.S. Patent Law:** Effectively imports foreign regimes for patent protection into the U.S. and would result in the unauthorized, de facto weakening of U.S. patent protection
Administration Has Changed Its Tune on International Reference Pricing

**Before Release of Proposal**

“… God help you if you get cancer in the United Kingdom. You don't have choice or access to the most modern oncology and cancer therapies. You'll be coming to America to get your treatment if you have the money to be able to get here.”

ALEX AZAR, SECRETARY OF HHS, SENATE HELP COMMITTEE HEARING ON THE PRESIDENT’S BLUEPRINT, JUNE 12, 2018

**After Release of Proposal**

“It’s important to understand that this model will expand patient access, through lower prices. This is a pro-patient-access model. … Benefits will not change; formularies will not be imposed. Let’s think about how implausible it is that patient access could be harmed.”

ALEX AZAR, SECRETARY OF HHS, SPEECH AT BROOKINGS INSTITUTE, OCTOBER 26, 2018
IPI Model Would Open Doors to Flawed Foreign Policies

- Set arbitrarily low prices for innovative medicines not aligned with market value
- Apply arbitrarily low thresholds on value of clinical improvements and human life gained from medicines
- Threaten to steal intellectual property as a price negotiating ploy
- Deny due process and a level playing field for U.S. companies
PhRMA Members Predict Significant Impact on R&D

- **77%**
  - Of companies said IPI would affect ability to pursue current or future R&D projects

- **92%**
  - Of companies foresee risk of reductions in Part B R&D investments

- **60%**
  - Of companies expect “significant” cuts in cancer R&D

- **Half of companies said**
  - **20% or more**
  - of current projects could be significantly reduced or terminated

- **66%**
  - Of companies expressed concern about near-term job cuts, eventual closure of facilities or abandonment of expansion plans

Source: Survey of PhRMA members conducted in December 2018.
IPI Model Would Put Patient Access to Treatment at Risk

New Cancer Medicines Available

- Greece: 11%
- Czech Republic: 49%
- Japan: 50%
- Ireland: 51%
- Belgium: 56%
- Canada: 56%
- Italy: 57%
- Netherlands: 62%
- Finland: 65%
- France: 65%
- Denmark: 66%
- Austria: 70%
- United Kingdom: 71%
- Germany: 71%
- United States: 96%

Average Delay in Availability of New Cancer Medicines (in months)

- Greece: -36
- Czech Republic: -23
- Japan: -23
- Ireland: -22
- Belgium: -26
- Canada: -13
- Italy: -9
- Netherlands: -13
- Finland: -19
- France: -11
- Denmark: -12
- Austria: -11
- Germany: -11
- United States: -3

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data. January 2019.
Note: New Active Substances approved by the FDA, European Medicines Agency (EMA) and/or Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) and first launched in any country between January 2011 and September 2018. IQVIA reports only the retail channel for Greece.
IPI Model Would Disrupt Physicians’ Ability to Provide Care

Forces doctors and hospitals in regions representing half of Part B medicine spending to participate in the model

Cuts to provider payment under sequestration are already impacting physicians’ ability to recoup acquisition costs in some markets

Reductions in ASP will lower payments to non-participating providers outside of the model area by 7%

Lower reimbursement outside of model disproportionately impact smaller rural and community practices

HHS Should Instead Address Misaligned Incentives and Seek Market-Based Reforms

**Fix the 340B Program**

- Finalize a new patient definition
- Update eligibility criteria for disproportionate share hospitals
- Revise eligibility criteria for hospitals’ offsite outpatient facilities and implement new reporting requirements
- Revisit guidance on contract pharmacy arrangements

**Continue Shift Toward Value-Driven Care**

- Address barriers to outcomes-based and other value-based contracts
- Provider value-based payment models in Part B
- Better performance measures and incentives for shared decision making
- Better data transparency for value