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The International Pricing Index Model: Breaking Down CMS's Proposed Drug Pricing Model

Emily Cook
John Warren
Drew McCormick
Steven Schnelle

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Overview

- Background
- The International Pricing Index (IPI) Model
- General Considerations
- Requests for Comments

Background

- Growing attention to the rising cost of prescription drugs in the United States
- Increasing political momentum towards regulating prescription drug pricing and reimbursement
  - In May 2018, President Trump released his Administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs"
- The IPI Model proposes to reduce the price Medicare pays for certain prescription drugs
- The IPI Model would also restructure components of the prescription drug supply chain to realign provider incentives

Part B Drugs

- **Medicare Part B Drugs:** Generally include certain drugs furnished "incident to" a physician's service and not usually self-administered by patients
- **Current Part B Drug Supply Chain:**
  - Manufacturer sells a drug to wholesaler, distributor or directly to a provider
  - Wholesaler or distributor sells the drug to health care provider
  - Provider furnishes the drug and bills patient & third-party payors
- **Current Part B Drug Reimbursement:**
  - Average Sales Price (ASP) plus 6% (for most drugs) (minus adjustment for sequestration)

2016 Part B Drug Demonstration

- **March 2016:** The Centers for Medicare and Medicaid Services (CMS) proposes mandatory, nationwide Part B payment model
  - ASP plus 2.5% and flat fee
  - Value-based payment structures
- CMS withdrew the proposal due to “complexity of the issues”

The IPI Model

- **October 25, 2018:** CMS announces Advanced Notice of Proposed Rulemaking with Comment (ANPRM)
- Provides broad framework of possible payment model -- proposals may not be implemented, or may be deeply modified
- Proposes demonstration to evaluate impact of reducing Part B payment rate to align with ex-US country rates
- "Vendors" purchase Part B drugs and claim Medicare reimbursement at new rates
- Providers continue to receive add-on payment, but not purchase and seek reimbursement for drugs (unless vendors)

Model Vendors

- Assume responsibility for negotiating drug prices, purchasing and distributing Part B drugs
- Commercial entities
- Vendor responsibilities:
  - Negotiate drug prices with manufacturers
  - Arrange drug distribution to providers
  - Submit claims to Medicare
  - Develop & implement program safeguards

Model Participants

- All physician practices and HOPDs furnishing included drugs in selected geographies
- May include Durable Medical Equipment (DME) suppliers, Ambulatory Surgery Centers (ASCs), or other providers
- Obtain included drugs from vendors
  - Possibly sent directly from manufacturers
- Submit informational (no-pay) drug claims, claims for drug administration fees, and claims for add-on fees
- Collect cost sharing from beneficiaries

Model Geographic Regions

- CMS suggests randomly assigning geographic regions to the model or to buy-and-bill
- CMS suggests that at least half of spending will be assigned to the model
- Unclear how CMS will define a geographic region

Participant Compensation

- Participants continue to receive payment for drug administration services and add-on payments
- Add-on payment would be a set amount
  - Paid per encounter or per month
  - Set by class of drugs, physician specialty, or practice/hospital
  - Would reflect approximate revenue realized from the current 6% add-on, based on most recent claims data

Included Drugs

- Physician administered and separately paid OPPS drugs
- Years 1 and 2:
  - Single source drugs, biologicals, biosimilars with reliable sources of international pricing data
  - Possibly multiple source drugs from a single vendor
- Years 3 through 5:
  - Additional single source drugs, biologicals and biosimilars when pricing data is available

By year 5, CMS expects the model will include drugs accounting for at least 75 percent of Part B allowed charges for such drugs

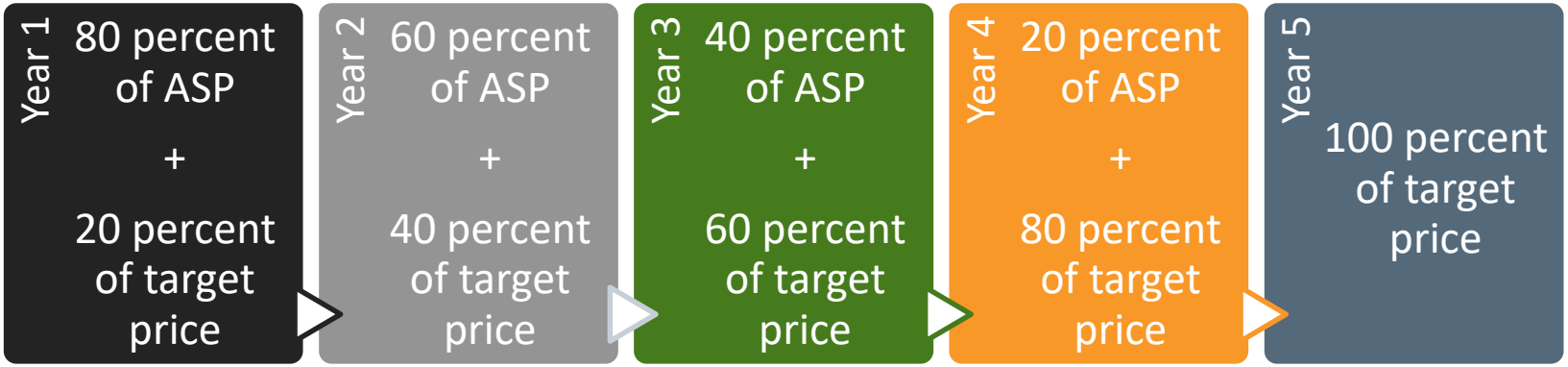
Excluded Drugs

- Part D, Medicaid, End Stage Renal Disease (ESRD) drugs paid under ESRD Prospective Payment System, drugs with OPPS packaged payment
- Multiple source drugs
- New drugs and drugs without international pricing information
- Drugs with FDA identified shortages
- Not Otherwise Classified/miscellaneous code drugs
- Compounded drugs
- Radiopharmaceuticals

Payment for Included Drugs

- Calculate average international price per HCPCS code
- Calculate ratio of domestic ASP spending to ex-US spending
  - Referred to as the IPI
- Calculate Target Price as the ex-US price multiplied by the IPI, adjusted to not exceed a 30% decrease
- Phase in reduction from ASP to Target Price over 5 years
- Frequency of update unsettled

Phase in of Rates



Sources of Data

- Existing data sets, including U.K. Drug Tariff, IQVIA's MIDAS dataset, others
- Manufacturers may be asked to report international prices quarterly with existing ASP data reporting

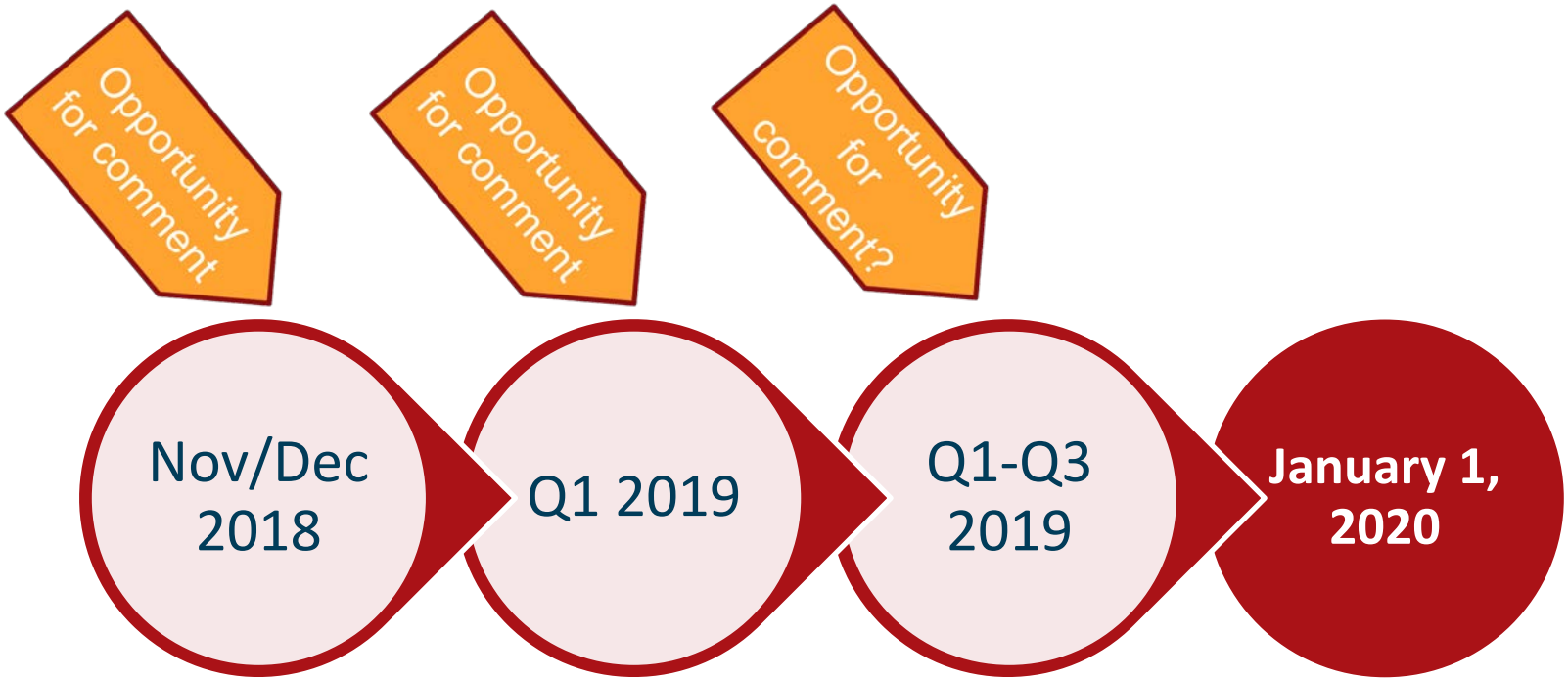
Countries Included

- Austria
- Belgium
- Canada
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Ireland
- Italy
- Japan
- Netherlands
- United Kingdom

Impact on Other Programs

- Potential unintended consequences for other programs:
  - Manufacturer's best price and resulting increase in Medicaid rebates
  - Average Manufacturer Price
  - 340B program
  - Also unclear how IPI Model will affect other Innovation Center programs and how participants in other models may interface with the IPI model.

Timeframe for ANPRM



- Comment period for ANPRM
- Potential publication of Proposed Rule
- Potential publication of Final Rule
- Potential Implementation

General Considerations

- Role of public comments
- Impact on domestic and international drug pricing dynamics
  - Potential impact beyond Medicare Part B
- Legal and compliance concerns
  - Reporting obligations
  - Various legal implications for vendors
- Manufacturer and provider contracting with vendors
  - Potential to shift program compliance risk

Requests for Comment: Vendors

- Who should be permitted to be vendors (in particular, whether health care providers should be allowed to be vendors) and potential "guardrails" for providers and manufacturers who serve as model vendors
- Whether to regulate agreements between vendors and participants and establish "guardrails" to protect the Medicare program and beneficiaries

Requests for Comment: Participants & Geographies

- What responsibilities should be imposed on model participants
- Which health care providers should be included in the model, such as whether small providers should be excluded and whether other providers should be included (e.g., PPS-exempt hospitals, such as cancer hospitals, children's hospitals and Critical Access Hospitals)
- How the add-on payment should be calculated and geographies chosen

Requests for Comment: Drugs & Foreign Markets

- Included Drugs and Drug Payments
  - What drugs to include (e.g., multiple source drugs), and whether to include drugs in all settings in which they may be separately payable
  - The mechanism for manufacturers to report international sales and additional requirements necessary to ensure a feasible process to collect valid international sales
  - What the target reduction to ASP payment should be, how the IPI Model could affect innovation incentives, and methods of calculating payment rates for new drugs
- Foreign Market Considerations
  - How to monitor and address changes in foreign markets

Requests for Comment: Miscellaneous

- What beneficiary outcomes to monitor and how
- How to avoid unintended consequences for other federal programs and how manufacturers would respond with respect to model vendors and Medicaid drug rebates
- Types of quality measures CMS can incorporate to capture patient experience, access and medication management
- How to examine the IPI Model's impact on Medicare spending and quality of care
- Whether prices offered under the IPI Model should be exempt from AMP and best price calculation

Questions?

Emily Jane Cook, McDermott Will & Emery
+1 310 284 6113; ecook@mwe.com

Emily provides counsel to health care providers on complex regulatory and reimbursement matters. Her regulatory experience includes fee-for-service Medicare and Medicaid reimbursement, billing and coding, licensure, survey/certification and accreditation, and compliance with Medicare and state fraud and abuse requirements. She also has significant experience counseling health care providers and other stakeholder entities on issues related to 340B drug pricing program implementation, compliance and advocacy.

John Warren, McDermott+Consulting
+1 202 204 1451; jwarren@mcdermottplus.com

John is a highly experienced Medicare veteran with wide ranging experience in traditional Medicare fee-for-service, program integrity and contracting issues. With over 22 years of experience inside CMS, John brings a unique perspective to clients of all types and sizes. As the former CMS director of the division responsible for clinical laboratory payment policy, John is uniquely qualified to speak on matters related to Medicare payment for clinical laboratory services and fee schedule.

Drew Elizabeth McCormick, McDermott Will & Emery
+1 617 535 4105; dmccormick@mwe.com

Drew advises health care clients on a wide variety of health care regulatory issues, including Medicare and Medicaid regulations, the Federal Anti-Kickback Statute, Ethics in Patient Referral Law, False Claims Act and Health Insurance Portability and Accountability Act (HIPAA), as well as state fraud and abuse laws, privacy laws, licensure regulation, research regulation, and health care compliance matters. Drew also has experience counseling clients who are undergoing government audits and investigations.

Steven J. Schnell, McDermott Will & Emery
+1 212 547 5403; sschnelle@mwe.com

Steven provides counsel on a variety of health care regulatory and transactional matters, primarily focusing on issues involving CMS, the HHS OIG, DOJ and state agencies. He advises clients on complex reimbursement matters involving governmental and commercial payors, and he provides counsel on state licensing and credentialing issues, as well as corporate practice of the health professions. Steven represents clients in False Claims Act *qui tam* matters, investigations and audits, and in matters involving compliance with the federal and state Anti-Kickback statutes.