Federal Health Policy: How It May Impact Your Program

ACCC Oncology Reimbursement Meeting
Portland, Oregon
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CURRENT HEALTHCARE LEADERSHIP

Alex Azar II
Secretary
U.S. Department of Health and Human Services

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services

116th UNITED STATES CONGRESS

Nancy Pelosi (D-CA)
Speaker
U.S. House of Representatives

Mitch McConnell (R-KY)
Majority Leader
U.S. Senate

U.S. House of Representatives

U.S. Senate
1. Drug pricing
   - Increased competition in Part B
   - Increased transparency about healthcare costs
   - Reining in 340B and PBMs
   - Promoting access/development of biosimilars

2. Increased flexibility for states and Medicaid programs
   - Medicaid work requirements and waivers
   - Flexibility to offer non-ACA compliant plans
   - Short-term, limited duration health plans

3. Continued push toward value-based payments, using Medicare and Medicaid to drive industry change
   - Site neutral payments
   - CMMI demonstration programs

4. Reducing regulatory burden and increasing interoperability
POLITICAL LANDSCAPE IN WASHINGTON

• Healthcare reform *was* a top priority. The Administration has moved on to Drug Pricing Reform efforts
  
  • With a now divided Congress, the Trump Administration is still seeking to use regulatory power to push for their healthcare agenda as much as possible
  • May 2018 to present, will see a continued push for drug pricing efforts – now with a potential bipartisan legislative push

• What might we see this year?
  
  • Continued focus on Medicare/Medicaid overhaul
    • Part B → Part D → Commercial
    • Healthcare spending comes into spotlight
    • Big changes in Medicaid (more flexibility for states, less coverage)
    • Continued push toward value-based care
Top Threats to Future Cancer Program Growth
(Percentage of respondents that ranked threat in top 5)

68%  Cost of drugs and/or new treatment modalities
47%  Physician alignment around services and program goals
46%  Changes in healthcare coverage
44%  Cuts to fee-for-service reimbursement
43%  Shifting reimbursement from fee for service to value-based care
35%  Marketplace competition
ACCC POLICY PRIORITIES – THE FUTURE OF CANCER CARE

✓ CMMI and value-based payments
✓ Oncology Care Model
✓ Site neutral payment efforts
✓ Reimbursement for supportive care services
✓ Rising healthcare costs & drug pricing reform
✓ Rural healthcare delivery
✓ Access to clinical trials in the community setting
✓ Reimbursement keeping up with innovation
2018-2019: THE YEAR OF DRUG PRICING REFORM

- **May 2018:** Drug Pricing Reform Blueprint Released
- **Summer 2019:** Administration’s public battle with manufacturers, CMS MA step therapy announcement
- **October 2018:** International Pricing Index Model proposal announced
- **December 2018 – January 2019:** Part D proposal reforming Medicare Part D “6 protected classes” & HHS announces proposal to overhaul rebates and safe harbor protections
- **February 2019 – Present:** Congress begins to tackle drug pricing reform – pivoting from the past year’s regulatory agenda
An Advance Notice of Proposed Rulemaking (ANPRM) is advance notice that CMS plans to make a formal proposal in the future through the rulemaking process.

Through the ANPRM, CMS is seeking feedback on the potential parameters of the potential International Pricing Index (IPI) Model.

KEY DATES:

- The ANPRM was issued on October 25, 2018.
- CMS is considering issuing a proposed rule on the IPI Model in the spring of 2019.
- The potential IPI Model would start in spring 2020 and operate for five years, until the spring of 2025.
OVERVIEW

• The IPI is a potential, mandatory model to test Medicare reimbursement for Part B drugs based on an "International Pricing Index."

• Under the IPI Model, U.S. drug prices would be benchmarked against the reportedly lower drug prices in 14 other countries.

• For participating providers, the IPI Model would replace buy-and-bill and the current Average Sales Price (ASP)-based reimbursement for Medicare Part B drugs.
  • Medicare would pay private sector vendors for Part B drugs at rates established using the IPI.
  • Participating physicians and hospitals would receive a fixed "add-on" payment for furnishing the drugs to patients.
  • Participation would be mandatory for approximately 50% of the country.

According to the CMS, the model would save taxpayers and beneficiaries U.S. $17.2 billion over 5 years (2020-2025), with Medicare's total spending on the selected drugs dropping by as much as 30%.
“Something has to change in how Medicare pays for physician-administered drugs.”

“Medicare pays 180% of what other wealthy countries pay for the 27 highest-cost physician-administered drugs.”

“For some drugs, the price differences are even greater. Sometimes we’re not just paying 180%, but 300 or even 500% of what other countries pay.”

“This is a symptom of a completely broken system.”

“Our model would fix the situation by applying a portion of these discounts, which manufacturers voluntarily give to other countries, to what Medicare pays moving forward.”
The mandatory IPI Model would include all physician practices and hospital outpatient departments (HOPDs) that furnish the model's included drugs in the model's selected geographic areas.

CMS anticipates the selected geographic areas would reflect 50% of Medicare Part B spending on separately payable Part B drugs.

CMS is also considering whether to include durable medical equipment (DME) suppliers, ambulatory surgical centers (ASCs), and other Part B providers and suppliers that furnish the included drugs.
ACCC is committed to working with practices across the country in the implementation of various value-based care initiatives – MACRA/MIPS, the Oncology Care Model, etc.

68 percent of ACCC cancer programs are participating in some sort of value-based contract.

ACCC developed the Oncology Care Model Collaborative – an online peer-to-peer forum for OCM participants – that we pair with national and regional workshops to help cancer programs across the country dive into the future of value-based care.
ONCOLOGY CARE MODEL: WHAT WE’RE LEARNING

• Transition to value for all cancer care programs – not just OCM practices.

• Understanding the claims data—let alone using it for continuous quality improvement—continues to be #1 challenge for OCM practices.

• Increased data reporting and cost containment strategies to meet the needs of a value-based healthcare system.

• NON-OCM PRACTICES: Important to do an honest self-assessment – are you financially and operationally ready to participate in something like this? What investments would you have to make? Where are you on these requirements to transform care delivery?
August 2017: The first CAR-T Therapy was approved by the FDA.

June 2018: ACCC submitted comments on the CY 2019 IPPS Proposed Rule to adopt an MS-DRG assignment of 016 and a temporary pass-through on the invoice to account for the cost of the underlying acquisition costs of the biological.

August 2018: CMS approved Medicare technology add-on payments for CAR-T treatments - paying a maximum of $186,500 per case, starting in fiscal year 2019.

February 2019: CMS released a proposed National Coverage Determination (NCD) to provide nationwide consistency in coverage of CAR-T therapy.

May 2019: Finalized NCD was expected to drop. ACCC and many other advocacy stakeholders responded with comments in March.

• Would cover autologous treatment with T-cells expressing at least one chimeric antigen receptor (CAR) under Coverage with Evidence Development (CED) when prescribed by the treating oncologist, performed in a hospital, and all of the listed requirements are met.

  – CED: Medicare coverage for items and services with the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data.

  – CED is an option when CMS believes it lacks evidence to determine whether the item or service is “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

  – CMS does not find the evidence to be sufficient to conclude that CAR T-cell therapy is “reasonable and necessary,” but CMS believes that the therapy “shows promise in improving health outcomes in patients with cancer.”
THE 340B DEBATE CONTINUES

340B Lawsuit: AHA, AMA, AEH

340B Legislation making its way through Congress

Critical review of program eligibility & use – legal battle continues
2019 ACCC Capitol Hill Day Priorities

- Federal Oral Parity
- CLINICAL TREATMENT Act – Medicaid funding for clinical trials
- Healthcare Spending/Drug Pricing Reform
1. ACCC has long advocated for a federal oral parity bill.
2. This bill saw traction on the House side of the 115th Congress, and we are pushing for its reintroduction as well as champions on the Senate side.
3. Requires any health plan that covers chemotherapy to provide coverage for oral chemotherapy drugs at the same out-of-pocket cost as IV chemotherapy drugs.
4. This bill is not a mandate, as it only applies to health plans that already cover chemotherapy!
The CLINICAL TREATMENT ACT (H.R. 913)

1. “The Covering Life-Saving Investigations Needed in Cancer and Other Life-threatening Conditions through Timely use of Resources for Easy and Affordable Treatment from Medicaid for Enrollees in Need Today Act.”

2. Guarantees coverage of routine care costs of participation in an approved clinical trial for Medicaid enrollees with a life-threatening condition.

3. This bill was just recently reintroduced into the 116th Congress after gaining traction on the House and Senate side in 2018.

4. Medicare, private, and commercial payers already guarantee this coverage.

5. Clinical trial participation benefits cancer patients in ways that go beyond the value of the research data generated within the trial, and clinical trials often provide individuals with cancer with their best clinical option.
CONGRESSIONAL ACTION: TACKLING HEALTHCARE COSTS IN THE US SENATE?

1. The Senate Health, Education, Labor, and Pensions (HELP) Committee released a Request for Information (RFI) at the beginning of 2019 to call upon healthcare stakeholder groups to explain to Congress the most pressing issues with the rising cost of healthcare and drug pricing reform.

2. ACCC plans to respond to this RFI with the guidance of our ACCC Governmental Affairs Committee and circulate our response as a Capitol Hill Day priority.

3. With the use of this letter, we hope to develop long-lasting relationships with Hill offices as they create, edit, and take up various healthcare spending and drug pricing reform priorities throughout the remainder of this Congress.
CONTINUE TO EXPECT FROM POLICYMAKERS...

- Continued push to infuse “competition” and “negotiation” into Part B drugs (which will likely mean reduced access).
- Using Medicare and CMMI as a lever to drive big changes.
- Will oncology be treated differently? OCM 2.0?
- Greater transparency in cost and quality.
- Despite unknowns, shift from volume to value here to stay.
THANK YOU!

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