Wednesday, July 18, 2018

CMS Releases Proposed Medicare Payment Rules for 2019

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to update payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP). **Read below.**

Dr. Debra Patt Testifies Before House Panel on 340B Reform

On July 11, Dr. Debra Patt, Executive Vice President of Texas Oncology, testified before the House Energy and Commerce Subcommittee on Health at a hearing examining the 340B program. **Read below.**

The Network Offers Comments to CMS on CAR-T Therapies MS-DRG Assignment

On June 25, The Network submitted comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule, "Chimeric Antigen Receptor (CAR) T-Cell Therapies MS-DRG Assignment for FY 2019." **Read below.**

Groups Submit Comments to Trump Administration Drug Pricing Plan

On July 16, stakeholders from across the health care delivery system submitted comments in response to an RFI requesting feedback on the Trump Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.* **Read below.**

President Trump Nominates Brett Kavanaugh to the Supreme Court

On July 9, President Trump officially nominated Brett Kavanaugh to the U.S. Supreme Court. As a judge on the District of Columbia Circuit Court of Appeals since 2006, Kavanaugh has a robust record on cases that address healthcare issues. **Read below.**

Alex Azar Delivers Remarks at 340B Conference

On July 9, Department of Health and Human Services (HHS) Secretary Alex Azar delivered remarks at the 340B Coalition's Summer Meeting, promising to make "comprehensive changes" to the 340B drug discount program. **Read below.**

Appeals Court Denies Hospital Groups' Challenge to 340B Cuts

On July 17, a federal appeals court upheld a ruling to allow the Department of Health and Human Services (HHS) to begin cutting $1.6 billion from the 340B federal drug discount program. **Read below.**

CMS Announces Demonstration Program to Exempt Doctors in At-Risk Medicare Advantage Programs from MIPS Participation

On July 6, the Centers for Medicare & Medicaid Services (CMS) announced that it will be soon adopt a demonstration program that would allow clinicians who participate in certain Medicare Advantage programs considered to be “at-risk” to be exempt from MIPS reporting requirements and instead be eligible for the 5 percent bonus reserved for those who participate in Alternative Payment Models. **Read below.**

FDA Administrator Gottlieb Delivers Remarks at National Comprehensive Cancer Network Policy Summit

On June 25, FDA Administrator Scott Gottlieb called for more sharing of real-world data in order to modernize the clinical trials process and more quickly bring new therapies to market. **Read below.**

CMS Releases Proposed Medicare Payment Rules for 2019

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to update payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP). CMS will be accepting comments on the rule until September 10, 2018. The final rule is expected by November 1st and will be effective Jan. 1, 2019. Here are the highlights:

Payment Policy Changes
The CY 2019 PFS conversion factor is estimated to be **$36.05 a** slight increase above the 2018 PFS conversion factor of $35.99. Changes in payment policy outlined in the proposed rule result in the overall average impact for the following specialties:

- Hematology/Oncology: -4%
- Radiation Oncology: -2%
- Radiation Therapy Centers: -2%
- Urology: 3%
- Rheumatology: -4%
- Gastroenterology: 1%
- Diagnostic Testing Facility: -4%
- Independent Lab: +4%
- Ophthalmology: -1%

Proposal to Alter Add-on Amount for WAC-Based Payment for Part B Drugs
CMS is proposing that, effective January 1, 2019, WAC-based payments for new Part B drugs during the period first quarter of sales when ASP is unavailable, the drug payment add-on would be 3 percent in place of the 6 percent add-on that is currently being used. If this proposal is finalized, CMS would also update Manual provisions in order to permit Medicare Administrative Contractors to use an add-on percentage of up to 3 percent, rather than 6 percent, when utilizing WAC for pricing new drugs.

Practice Expense (PE): Market-Based Supply and Equipment Pricing Update
CMS is proposing to adopt updated direct PE input prices for supplies and equipment. CMS is proposing to phase in use of the new direct PE input pricing over a 4-year period beginning in 2019 to the final updated prices and payments in CY 2022.

Evaluation and Management Payment
CMS is proposing single, blended payment rates for new and established office or outpatient visits level two to five and add-on codes to reflect additional resources. The proposed rule also includes E&M documentation guidelines by allowing clinicians to choose to document E&M visits using medical decision-making or time, or alternatively continue to use the current framework

CMS is also soliciting comment on how documentation guidelines for medical decision-making might be changed in subsequent years.

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services
CMS is proposing to pay separately for two newly defined physicians' services furnished using communication technology:

- Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVCI1)
- Remote Evaluation of Recorded Video and/or Images Submitted by the Patient (HCPCS code GRAS1)

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging
For CY 2019, CMS proposes to revise the significant hardship criteria in the AUC program to include:

1) insufficient internet access;
2) electronic health record (EHR) or clinical decision support mechanism (CDSM) vendor issues; or
3) extreme and uncontrollable circumstances.

In addition, CMS is proposing to add independent diagnostic testing facilities (IDTFs) to the definition of applicable setting under this program. This will allow the AUC program to be more consistently applied to outpatient settings. CMS is also proposing to allow AUC consultations, when not personally performed by the ordering professional, to be performed by auxiliary personnel.

Request for Information on Price Transparency
CMS is seeking information from the public regarding barriers preventing providers and suppliers from informing patients of their out-of-pocket costs; what changes are needed to support greater transparency around patient obligations for their out of pocket costs; what can be done to better inform patients of these obligations; and what role providers of health care services and suppliers should play in this initiative.

Proposed Changes to the Quality Payment Program Year 3
CMS is proposing the following changes to the MIPS Performance Category Weights:

- Quality: from 50% in Year 2 to 45% in Year 3
- Cost: from 10% in Year 2 to 15% in Year 3
- Improvement Activities (IA) and Promoting Interoperability (PI) remain the same at 15% and 25% respectively

To view the CMS fact sheet on the PFS proposed rule, CLICK HERE.

To view the CMS fact sheet on the QPP proposed rule, CLICK HERE.

To view the proposed rule in its entirety, CLICK HERE.

Dr. Debra Patt Testifies Before House Panel on 340B Reform

On July 11, Dr. Debra Patt, Executive Vice President of Texas Oncology, testified before the House Energy and Commerce Subcommittee on Health at a hearing examining the 340B program. In her testimony, Dr. Patt discussed how the 340B program has led to the closure of many freestanding physician offices, healthcare consolidation into hospital outpatient departments, and a corresponding shift to more expensive sites of service—raising costs for patients and payers alike. She also urged Congress to increase transparency, oversight, and accountability within the 340B program.

Dr. Patt's testimony comes as the committee considers 15 bills intended to reform and modernize the 340B program. Among them is a 340B user fee bill sponsored by Rep. Chris Collins (R-NY) and legislation by Rep. Larry Buchon (R-IN) to require 340B hospitals and other clinics to report their estimated savings, third-party revenue, payer mix and uncompensated-care costs. Another measure sponsored by Rep. Doris Matsui (D-CA) would reverse the $1.6 billion in annual cuts CMS made to 340B hospitals this year and define how drug manufacturers should calculate the ceiling price for the drugs in the program.

Members of Subcommittee also heard from Debra Draper of the Government Accountability Office (GAO) regarding a new report on the need to increase oversight of 340B contract pharmacies. The report, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, found weaknesses in the Health Resources and Services Administration's (HRSA) ability to assess compliance with the 340B program's prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries, understand the methodologies covered entities use to describe the full extent of noncompliance, and require all covered entities to provide evidence that they have taken corrective action.

To view the Energy and Commerce 340B hearing, CLICK HERE.

To read Dr. Patt's testimony, CLICK HERE.

To read the GAO report on the 340B program, CLICK HERE.

The Network Offers Comments to CMS on CAR-T Therapies MS-DRG Assignment

On June 25, The Network submitted comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule, "Chimeric Antigen Receptor (CAR) T-Cell Therapies MS-DRG Assignment for FY 2019." The Network applauded CMS for recognizing that payment methodologies for CAR-T drugs and related services should be site neutral and encouraged CMS to create a new MS-DRG New Technology add-on payment for these breakthrough therapies.

Citing the enormous potential CAR-T therapies offer to patients with cancer, The Network also urged CMS to consider the implications of delivering CAR-T therapies in the community setting.

To read the Network's comment letter, CLICK HERE.

Groups Submit Comments to Trump Administration Drug Pricing Plan

On July 16, stakeholders from across the health care delivery system submitted comments in response to an RFI requesting feedback on the Trump Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.*

The Network's comments focused on proposals that would impact community-based oncology providers and care for cancer patients. The Network raises concerns with some of the Administration's proposals that could limit patient access to cancer treatments and impede providers' ability to deliver patient-centered, appropriate care such as transitioning certain Part B

drugs into Part D and implementation of a CAP-like program for Part B drugs. The comment letter also recognizes many of the blueprint's proposals as positive steps including efforts that aim to increase transparency, reduce patient cost sharing, and mitigate the harmful effects of provider consolidation.

The US Oncology Network joined a coalition of 216 organizations, including patient, physician and industry groups, on a letter to Secretary Azar expressing concern that proposals to create a new Competitive Acquisition Program (CAP) in Medicare Part B and move Part B medicines under Part D coverage would place middlemen between patients and their doctors and create substantial risk of impeding access to needed care, increasing costs for our nation's sick and vulnerable patients, and creating new delays and inefficiencies in care delivery. The groups urged the Administration to reject proposals that could have a damaging impact on access and affordability of Part B medications.

The Alliance for Site Neutral Payment Reform commended specific provisions of the plan, offering support for the site neutral payment provision for physician-administered drugs and urging the Administration to consider further expansion of site neutral payments for outpatient services. The Alliance letter specifically addresses how site neutral payment policies would impact the location of care services, the organization of health systems and competition in the cancer care marketplace.

To read The Network's comment letter, CLICK HERE.

To read the coalition letter on Part B provisions, CLICK HERE.

To read the Alliance for Site Neutral Payment Reform letter, CLICK HERE.

President Trump Nominates Brett Kavanaugh to the Supreme Court

On July 9, President Trump officially nominated Brett Kavanaugh to the U.S. Supreme Court. As a judge on the District of Columbia Circuit Court of Appeals since 2006, Kavanaugh has a robust record on cases that address healthcare issues.

Kavanaugh was in the majority in the *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach* (2007) decision, which ruled that terminally ill patients do not have a constitutional right to try unapproved drugs. Since President Trump signed a right-to-try law in May, the issue may come before the Supreme Court in the future. In *Seven-Sky v. Holder* (2011), he wrote that the court could not rule on the constitutionality of the Affordable Care Act until a taxpayer who paid a penalty for not purchasing coverage under the individual mandate brought suit. Some conservative critics argue that he laid the groundwork for Chief Justice Roberts to consider the mandate a tax, upholding the ACA in 2012.

In a 2013 case against a medical device maker, Kavanaugh sided with the FDA by arguing that "a court is ill-equipped to second-guess that kind of agency scientific judgment" when it comes to federal agency procedures, but later criticized the FDA for not following its own procedures in a 2014 case.

To read President Trump's announcement remarks, CLICK HERE.

Alex Azar Delivers Remarks at 340B Conference

On July 9, Department of Health and Human Services (HHS) Secretary Alex Azar delivered remarks at the 340B Coalition's Summer Meeting, promising to make "comprehensive changes" to the 340B drug discount program including increased transparency surrounding how the discounts are being used and reforms to reduce the gap between discounted prices and the reimbursement provided by government programs.

The Secretary explained how the president's budget proposes broad regulatory authority to help HHS ensure the 340B benefits reach the intended recipients and new funding to support additional oversight activities. He also stated that the gap between prices paid by 340B entities and the compensation they receive has grown far too wide, and was the motivation behind the restructuring reimbursement for 340B drugs under Medicare Part B.

To view Secretary Azar's full remarks, CLICK HERE.

Appeals Court Denies Hospital Groups' Challenge to 340B Cuts

On July 17, a federal appeals court upheld a ruling to allow the Department of Health and Human Services (HHS) to begin cutting $1.6 billion from the 340B federal drug discount program.

The D.C. Circuit Court of Appeals ruled against the American Hospital Association and other hospital groups, meaning HHS can proceed with cuts of nearly 30 percent to certain drugs paid for under the 340B program. According to HHS, payment reductions will bring hospitals' pay more in line with the cost of buying the drugs.

Tuesday's decision is consistent with a lower court decision issued last December.

To read the court's decision, CLICK HERE.

CMS Announces Demonstration Program that Would Exempt Doctors in At-Risk Medicare Advantage Programs from MIPS Participation

On July 6, the Centers for Medicare & Medicaid Services (CMS) announced that it will be soon adopt a demonstration program that would allow clinicians who participate in certain Medicare Advantage programs considered to be "at-risk" to be exempt from MIPS reporting requirements and instead be eligible for the 5 percent bonus reserved for those who participate in Alternative Payment Models (APMs).

The proposed demonstration, to be called Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) , would align with the agency's goal of moving towards a value-based healthcare system and put Medicare Advantage on a more equal footing with traditional Medicare. The decision was supported by several physician's groups, who had argued that MACRA unfairly excluded Medicare Advantage from MIPS bonuses when it was originally implemented.

To view the announcement from CMS, CLICK HERE.

FDA Administrator Gottlieb Delivers Remarks at National Comprehensive Cancer Network Policy Summit

On June 25, FDA Administrator Scott Gottlieb called for more sharing of real-world data in order to modernize the clinical trials process and more quickly bring new therapies to market. In his remarks, Gottlieb said that one of the greatest barriers to the development of new therapies was a lack of availability of clinical data outside of the randomized control trial environment for new therapies. By allowing greater access to this information, providers can more easily make decisions about which treatments may work best for their patients. This information could also help providers and payers establish value-based contracts for emerging treatments – particularly in the oncology specialty – and allow providers to identify patients for whom these new therapies might be most effective.

Dr. Gottlieb's remarks come as the FDA plans to make information about the clinical endpoints of drug treatments available online. The agency is also making significant investments in its own data infrastructure in order to develop a better analytical framework for studying clinical trial results.

To view Dr. Gottlieb's remarks, CLICK HERE.