

Health Policy Update – August 6, 2019

HHS Announces New Plan to Import Prescription Drugs

On July 31, the Department of Health and Human Services (HHS) published a Safe Importation Action Plan that outlines two potential pathways for the safe importation of certain drugs originally intended for foreign markets. In coordination with the U.S. Food and Drug Administration (FDA), the Safe Importation Plan is designed to lay the foundation for importing drugs safely into the United States with the goal of helping promote competition and ultimately lower costs.

Under the first pathway outlined in the plan, states, wholesalers, or pharmacists could submit plans for demonstration projects to import drugs from Canada that have been approved by Health-Canada and are in compliance with Section 505 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs would be excluded from this pathway.

Under the second pathway, manufacturers of FDA-approved drug products would be allowed to import versions of these FDA-approved drugs that they sell in foreign countries into the U.S. under a different NDC number.

HHS is seeking comments on the proposed pathways as it works to develop a final proposal. In recent years, four states have passed laws to import drugs into the U.S., but none have received HHS authority to do so.

To read the Safe Importation Plan, [CLICK HERE](#).

To read a press release about the Safe Importation Plan, [CLICK HERE](#).

Legislation to Reduce Prior Authorization Barriers Introduced in House

In June, Reps. Suzan DelBene (D-WA), Mike Kelly (R-PA), Roger Marshall, MD (R-KS), and Ami Bera, MD (D-CA) introduced H.R. 3107, the Improving Seniors' Timely Access to Care Act of 2019, which aims to streamline the prior authorization process in Medicare Advantage. The bill would require HHS to establish a process for "real-time decisions" for items and services for which prior authorization requests are routinely approved, improve electronic transmissions, and increase transparency and oversight over how prior authorization is used. According to the bill's sponsors, the legislation is intended to improve access to care for patients and reduce administrative burdens on physicians.

To read the text of the bill, [CLICK HERE](#).

To read a joint statement from the bill's sponsors, [CLICK HERE](#).

CMS Issues 2020 Physician Fee Schedule Proposed Rule

On July 29, the Centers for Medicare & Medicaid Services (CMS) released the CY 2020 Physician Fee Schedule proposed rule, which proposes to adopt the American Medical Association's recommendation to reform evaluation and management (E/M) codes instead of the changes CMS had finalized in last year's rule. CMS is now proposing to retain five levels of coding for established patients, reduce the number of levels to four for new patients, revise the code

definitions, and allow providers to choose the E/M level based on either medical decision-making or time. If finalized, the policy would take effect in 2021.

CMS is also proposing to adopt the AMA RUC-recommended values for the office/outpatient E/M visit codes for CY 2021 and the new add-on CPT code for prolonged service time. According to CMS, the AMA RUC-recommended values would increase payment for office/outpatient E/M visits.

Additionally, the proposed rule creates a MIPS Value Pathways framework that is expected to reduce reporting requirements for clinicians by only requiring reporting on a smaller set of specialty-specific measures, more closely aligning it with alternative payment model requirements. Other provisions in the proposed rule include a new Part B coverage benefit for opioid treatment programs and increased payments for transitional care for beneficiaries recently discharged from an inpatient hospital setting.

To view the PFS proposed rule, [CLICK HERE](#).

To view a CMS fact sheet on the proposed rule, [CLICK HERE](#).

CMS Issues 2020 Outpatient Prospective Payment System Proposed Rule

On July 29, CMS released the Calendar Year 2020 Outpatient Prospective Payment System (OPPS) Proposed Rule, which continues site neutral payment reforms and 340B drug discount program cuts, as well as proposes hospitals list negotiated prices.

CMS is completing a two-year phase-in of site neutral payments for clinic visits. Under the policy, Medicare would pay the physician fee schedule-equivalent rate for clinic visits furnished in the off-campus hospital outpatient setting. According to CMS, this policy is estimated to save beneficiaries \$160 million in lower copays and save the Medicare program \$650 million in 2020.

For CY 2020, CMS is proposing to continue to pay an adjusted amount of the ASP, minus 22.5 percent for certain separately payable drugs or biologicals that are acquired through the 340B Program. CMS also acknowledges the ongoing litigation pertaining to the 340B payment adjustment and solicits comment on alternative payment options for CY 2020 and potential remedies for CY 2018 and CY 2019 payments in the event of an adverse ruling on the 340B payment policy by the United States Court of Appeals.

The rule also implements a recent executive order signed by the President requiring HHS to develop regulatory guidance to require hospitals to post pricing information online in a consumer-friendly format. Hospitals would be required to make public all of their standard charges for all items and services, revealing payer-specific negotiated charges. It would also require hospitals to make the charges of "shoppable services" – services selected in advance that includes x-rays, tests and bundled services like cesarean sections – public and available to consumers online.

To view the OPPS proposed rule, [CLICK HERE](#).

To view a CMS fact sheet on the proposed rule, [CLICK HERE](#).

Congressional Action to Lower Drug Prices

On July 25, the Senate Finance Committee approved their much-anticipated bipartisan plan to lower the cost of drugs in the Medicare and Medicaid programs. If passed into law, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019 is projected to save more than \$100 billion over 10 years for both the government and Medicare beneficiaries. The bill

includes changes to the ASP calculation under Medicare Part B, changes to the Medicare Part D benefit structure, a requirement for drug manufacturers to pay rebates to Medicare if they increase prices on Part B and Part D drugs above inflation, as well as several PBM and DIR fee transparency measures.

Despite the Trump Administration's support for the package, Senate Republicans largely expressed strong opposition to parts of the bill, especially the inflationary caps. Senator Pat Toomey (R-PA) also offered an amendment to prohibit implementation of the International Pricing Index (IPI); the amendment failed after a tied vote, with nearly every Republican on committee voting to support the amendment. Ultimately, the package passed out of committee on a 19-9 vote.

The Senate HELP Committee passed legislation to lower healthcare prices and address surprise medical bills in June. While the House and Senate have adjourned for the August recess, congressional staff is expected to continue working through August and into September to set up a Senate floor vote on drug pricing legislation this fall.

In addition, Speaker of the House Nancy Pelosi (D-CA) announced on July 22 that House Democrats would release a major bill designed to lower drug prices in September. The bill is expected to include provisions that would allow Medicare to directly negotiate drug prices. In the event that negotiation breaks down, drug companies would face higher levies to encourage them to strike a deal with Medicare.

To read a summary of the Senate Finance Committee's Prescription Drug Pricing Reduction Act (PDPRA) of 2019, [CLICK HERE](#).

To view the Congressional Budget Office's score for the Prescription Drug Pricing Reduction Act (PDPRA) of 2019, [CLICK HERE](#).

To read the text of the Senate HELP Committee bill, [CLICK HERE](#).

Budget Deal Will Extend Medicare Sequestration To 2029

Congress has passed a two-year budget deal to lift the budget caps established by the Budget Control Act of 2011 and suspend the debt limit until July 31, 2021. The deal, negotiated between the White House and congressional leaders, will also extend sequestration on Medicare to 2029 in order to help cover the cost of increasing the budget caps. It passed the House on July 25 and the Senate on August 1 and was signed into law by the president on August 2.

To read more about the budget deal and Medicare sequestration, [CLICK HERE](#).

Site Neutral Payment Update

On July 22, Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, touted the Trump Administration's implementation of site neutral policies. In a speech at the Better Medicare Alliance policy summit, Verma decried hospitals for suing to roll back the site neutral payment rule CMS finalized in 2018. In criticizing the ability of hospitals to charge higher prices for the exact same services than if they were performed in a community-based or freestanding setting, Verma also blasted the resulting vertical consolidation in the healthcare industry.

"Hospitals are buying up physician practices, and mergers of large health systems and health plans are a common occurrence," she said. "But without competition in a market, consumers have fewer choices, prices go up, and incentives to improve quality go down."

Days after Verma's remarks, the Alliance for Site Neutral Payment Reform issued a press release praising the Senate for proposing site neutral payment policies in the Senate Finance Committee's Prescription Drug Pricing Reduction Act (PDPRA) of 2019. Specifically, the Alliance applauded the inclusion of Section 611, which would remove the exception for "grandfathered" off-campus HOPDs and ensure that the payment for administering a Medicare Part B drug would be made at the physician office rate rather than the HOPD rate. The Alliance also praised the proposed modification of the transparency tool created by the 21st Century Cures Act of 2015 to include information for services furnished in a physician office.

To read the Alliance statement commending site neutral provisions in the Senate drug pricing package, [CLICK HERE](#).

To read a transcript of CMS Administrator Seema Verma's remarks, [CLICK HERE](#).