January 5, 2021

Major Legislative and Executive Actions over the Holidays

Over the past two weeks there have been a number of major health policy changes and developments that will make a difference to your bottom line. Here is a summary of the major actions:

Omnibus Appropriations and Covid Relief Package
After threatening to veto the measure, President Trump signed an omnibus spending bill consisting of all 12 fiscal year 2021 appropriations bills, coronavirus relief, and authorizations including: surprise billing reform, Medicare/Medicaid program extensions, Medicare-funded graduate medical education (GME) residency positions, and eliminate Medicaid Disproportionate Share Hospital (DSH) payment reductions through 2027, and a 3-momth extension of the 2% Medicare sequestration pause.

- Click here for the Joint Explanatory Statement of the Appropriations Health Provisions, and here for a summary of the highlights
- Click here for a summary of the authorizations in the package (Surprise Billing begins on page 48, and other health related provisions begins on page 51)
- Click here for the bill (5593 pages!)

Specific Provisions in the Package -

COVID-19 Relief Specific

Click here for a summary of the COVID-19 specific provisions in the package.

- Provider support includes $3B more for the Provider Relief Fund (There is approximately $35B remaining in the fund), a return to the June HHS guidance on use of funds that also allows transfer of PRF funds to the health system for use across the system.
- Extends sequester relief through March 31, 2021.
- $3B for E/M increases in payments to physicians under the Physician Fee Schedule by 3.75% across the board. In other words, no physician payment cuts, as originally proposed.

Surprise Billing
Click here for our Executive Summary of the provisions agreed upon by the four negotiating committees in the last days of the session. These provisions take effect in 2022 and will require extensive rulemaking.

GME

- Section 126 – establishes an additional 1,000 funded Medicare GME positions (200 per year for 5 years) (beginning on page 2206, click here)
- Section 127 – revises the Rural Training Track program to provide greater flexibility for rural and urban hospitals to partner to address workforce needs (beginning on page 2217, click here)
- Section 131 – for hospitals adversely affected by small numbers of resident rotators, provides a 5-year period to re-establish new per resident amounts and GME caps. (Click here for the extracted provision beginning on page 2229)

Telehealth

- Expands access to mental health services through telehealth – click here.
- Includes $250 million for the FCC's COVID-19 Telehealth Program – beginning on page 490, click here.
- Includes $1 million for grants for rural hospitals for telehealth – see page 955, click here.

Medicare Payment for Rural Emergency Hospital Services

Creates a new, voluntary Medicare payment designation that allows either a Critical Access Hospital (CAH) or a small, rural hospital with less than 50 beds to convert to a Rural Emergency Hospital (REH) to preserve beneficiary access to emergency medical care in rural areas that can no longer support a fully operational inpatient hospital. REHs can also furnish additional medical services needed in their community, such as observation care, outpatient hospital services, telehealth services, ambulance services, and skilled nursing facility services. REHs will be reimbursed under all applicable Medicare prospective payment systems, plus an additional monthly facility payment and an add-on payment for hospital outpatient services. Click here for the legislative language.

Executive and Court Actions

Price Transparency Rule

On December 29, 2020, the DC Circuit Court of Appeals affirmed the lower court's ruling upholding HHS' hospital price transparency rule. Click here for the decision. Hospital plaintiffs have the opportunity to petition the appellate court for a rehearing or appeal to the US Supreme Court. However, the Appellate Court dismissed the hospitals' motion to stay enforcement of the rule and the rule became effective January 1, 2021. The rule requires hospitals to make public their standard charges for all items and services, including gross charges and payer-specific negotiated charges through a comprehensive, machine-readable file, as well as a display of 300 shoppable services in a consumer-friendly format. CMS plans to begin audits in January. Click here for additional information from the Medicare Learning Network on audits, penalties and additional information, including the final rule. Click here for a CMS webcast on the final rule.

340B HHS General Counsel Decision on Contract Pharmacies

On December 30, 2020, the HHS Office of the General Counsel released an advisory opinion concluding that drug manufacturers are required to deliver discounts under the 340B Drug Pricing Program, "when contract pharmacies are acting as agents of 340B covered entities." Unfortunately, the advisory opinion only sets forth the agency's view on the issue and does not carry the force of law, as the agency noted. This would mean that the issue could still be a source of litigation and the current

lawsuits that have been filed will still need to go through the motions in the Courts. Click here for the press release from HHS, and here for the advisory opinion.

HIPAA Guidance for Public Health Purposes
HHS' Office of Civil Rights issued guidance on the disclosure of protected health information for public health activities of a public health authority. Click here for the guidance. According to the guidance, HIPAA allows a covered entity or its business associate to disclose public health information to a health information exchange for reporting purposes without an individual's authorization when 1) the disclosure is required by law; 2) when a health information exchange is a business associate of the covered entity (or of another business associate) that wishes to provide public health information to a public health authority for public health purposes; or 3) when a health information exchange is acting under a grant of authority or contract with a public health authority for a public health activity.

CMS Will Allow Medicaid MCO Participation in the Direct Contracting (DC) Demo
In mid-December CMS announced it will allow Medicaid Managed Care Organizations (MCOs) serving dual eligibles to participate in CMMI's Direct Contracting (DC) demonstration, specifically the Global and Professional options. CMS is interested in improving primary, acute, long-term, behavioral, and social care for the current 12.2 million duals who make up 20% of Medicare enrollees but account for 33% of Medicare costs. The CMS fact sheet is here.

CMS Publishes Final Prescription Medicaid Drug VBP Rule
On December 21 December CMS published its final rule titled, "Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third- Party Liability (TPL) Requirements." Essentially, the rule will allow the Medicaid program to engage in value-based drug purchasing programs, i.e., Medicaid programs, beginning in January 2022, will be able to negotiate prices with manufacturers based on outcomes and evidence-based measures such as reduced hospitalizations and physician office visits. The rule will also allow manufacturers to report multiple best prices instead of a single best price when offering their VBP arrangements to all states. The CMS fact sheet is here and the final rule is here.

CMS Publishes Proposed Platelet Rich Plasma NCD
Also, on December 21 CMS published a proposed National Coverage Decision (NCD) concerning use of platelet rich plasma (PRP) for the treatment of non-healing diabetic, venous and pressure (chronic) wounds. The proposed would eliminate the current related Coverage with Evidence Development (CED) and would apply to all PRP coverage determinations for all other chronic non-healing wounds made by Medicare Administrative Contractors (MACs). The comment period runs 30 days from December 21 and a final decision will be issued no later than 60 days after the close of the comment period. The CMS press release is here and the coverage decision memo is here.