2020 Pending Federal Health Policy Issues

January 6, 2020

Happy New Year! This memo outlines the health policy issues we expect Congress, the courts and the regulatory agencies to address soon.

Congress:

At the end of the year, Congress passed a $1.4 trillion spending package funding most government programs through September 30, 2020; however, some items were funded only through May 22nd including the $4 billion delay in DSH cuts, funding for community health centers and training for health care providers in underserved areas. Congress will have to pass another health funding bill prior to Memorial Day to get these programs through the calendar year. This funding package is likely to be a vehicle for a prescription drug bill and surprise billing legislation.

Surprise Billing

The House Ways and Means Committee is expected to release its surprise billing legislation soon. Click here for the summary released by the Chairman and Ranking Member in December which encourages providers and insurers to resolve billing disputes on their own and includes an independent mediated negotiated process. The House Education and Labor Committee is also expected to consider legislation. Meanwhile, the agreement between the Chairs of the Senate HELP Committee and the House Energy and Commerce Committee remains in play. Click here for a summary of the agreement. There will be a strong push by both sides of the aisle to move legislation before the Memorial Day recess.

Federal Courts:

HOPD Site Neutral Litigation

Although CMS quietly announced it would begin repaying hospitals the $800 million for the 2019 cuts to hospital outpatient department site neutral payments, it also filed a notice of appeal of the court ruling that CMS had exceeded its statutory authority in making the cuts. Click here for the Notice of Appeal. Additionally, the hospitals' argument that the court's ruling on the 2019 cuts also applied to the 2020 cuts, failed. Click here for the Court's ruling on the 2020 cuts.

340B Litigation

On November 8, the US Court of Appeals for the District of Columbia Circuit heard oral arguments on the government's appeal of the lower court's ruling in the 340B litigation that addressed the cuts for 2018 and 2019. A decision by the appellate court could come at any time. There is no active legislation at this time that addresses the various 340B issues. The major hospital associations are reluctant to pursue a legislative strategy.

Price Transparency

Hospital plaintiffs have filed suit against CMS over the price transparency regulations **that are effective** January 1, 2021 and the court has ordered the parties to file all briefing materials by March 10, 2020. These are the regs that require hospitals to disclose the terms of even privately negotiated contracts with insurers. Click here for the fact sheet on the CMS final hospital rule, and here for the final rule. Click here for the complaint and here for the memorandum in support of summary judgment. Oral argument, which has not yet been scheduled, would occur in March at the earliest. (See more below.)

ACA Litigation

The US Court of Appeals for the Fifth Circuit struck down a central provision of the Affordable Care Act, ruling that the individual mandate is unconstitutional. Click here to read the decision. The appeals court did not invalidate the rest of the law as the lower court did, instead sending the case back to the lower court to conduct a further inquiry into which of the law's parts could survive without the mandate. The Democratic attorneys general who led the states that intervened in the case and argued to preserve the law will petition the US Supreme Court to hear the case before the lower court reconsiders its decision. In its landmark decision in 2012, the US Supreme Court upheld the mandate based on the Congress's power to impose taxes. This new case arose after Congress reduced the penalty for not having insurance to zero dollars, thereby reducing the tax to zero. A final decision by the Courts is not likely until after the 2020 elections, making health care coverage even more prominent in the 2020 elections. For now, the ACA remains in place.

Click here for our December update on the HOPD site neutral, 340B and price transparency litigation.

Regulations:

Medicaid Fiscal Accountability Rule (MFAR)

On November 18, the Federal Register published CMS' proposed "Medicaid Fiscal Accountability Regulation" rule. (The rule is here, the fact sheet here.) This is a far reaching proposal designed to reign in Supplemental Medicaid spending. In sum the proposed attempts to establish requirements to ensure that state plan amendments that address supplemental and based Medicaid payments comply with federal regulations. As we wrote to clients in a memo summarizing the proposed, CMS intends to require all supplemental payments be reauthorized by CMS within two to three years of the final rule's effective date. Intergovernmental Transfers (IGTs) would be required to be derived from state and local taxes or appropriated to a state

university teaching hospital. MFAR proposes new requirements for entities using Certified Public Expenditures (CPEs). The rule proposes modifications regarding assessing whether a provider tax is health care related and whether a proposed tax contains a prohibited hold-harmless provision. Concerning Disproportionate Share Hospital (DSH) payments, the proposed calls for adding a new data element to DSH audits that quantifies the financial impact of any finding including those resulting from incomplete or missing data. The proposed would also require states to report overpayments identified through annual DSH audits. States would be directed to return payments, within two years of the date of discovery, in excess of hospital-specific cost limits to the federal government. **Comments on the proposed MFAR are due January 17. Many groups have asked for a deadline extension; CMS has not yet responded.**

Direct Contracting Demonstration

Last April, CMS' CMMI announced its Direct Contracting (DC) demonstration. (The CMS DC website page is here.) In late November CMMI released its 100-page DC RFA (Request for Applications) document. On November 26th we summarized in a memo to clients numerous DC details as explained in the RFA. These included: allowable participants; model options; reimbursement; benchmark calculation; beneficiary alignment; quality reporting; and, several others. Though non-binding, providers that submitted a Letter of Intent (LOI) **must complete their application by February 25** if they want to participate in the demo's Implementation Period (IP).

Primary Care First Demonstration

Last April, CMMI also announced its Primary Care First demonstration. (The Primary Care First website page is here. A Primary Care First FAQ is here. In late October CMMI released the related RFA.) In brief, building on Comprehensive Primary Care and CPC+ demos, the five-year demo will be offered in 26 regions to primary care practices specializing in caring for complex, chronically ill patients. **Applications for the 2021 start date are due this January 22.**

Proposed Physician Self-Referral (Stark) Rule

On October 17, CMS published its proposed "Modernizing and Clarifying the Physician Self-Referral Regulations" (Stark) rule. (The proposed is here and the October 9 fact sheet is here.) As we wrote in a memo to clients on October 9 summarizing the proposed, the rule attempts to satisfy four primary goals. Create new, permanent exceptions to allow for value-based provider arrangements or those that have a "value-based purpose" including serving a target population, improving care quality and reducing costs or spending growth without reducing quality. The CMS rule proposes to require cost of care information be made known at the point of a referral. This would align with CMS' price transparency efforts more broadly. The proposed discusses guidance to clarify, for example, what is meant by fair market value compensation in instances when one provider is compensating another. The proposed also proposes exceptions that would allow one provider to donate certain IT technology to another provider in order to maintain patient confidentiality and system security. **Comments on the proposed rule were due December 31**.

Proposed Transparency in Coverage Rule

In 2019, CMS proposed two price transparency rules. The first, that requires hospitals to make public standard charges, was finalized on November 15 but does not go into effect until January 1, 2021. The second transparency rule, titled "Transparency in Coverage", proposed November 15, would require most group health plans including self-insured plans to disclose price and cost sharing information to enrollees through an internet-based self-service tool. (The related fact sheet is here.) Plans would also be required under the proposed to make publicly available in-network negotiated rates with their network providers and historical payments of allowed amounts to out of network providers. The deadline for comments **has been extended to January 29.**

Proposed Drug Importation Rule

In late December the FDA published in the Federal Register its proposed "Importation of Prescription Drugs" rule. (The FDA's press release is here.) The proposed, if finalized, would allow states, other non-federal government entities along with a pharmacist, wholesaler or other state or non-federal government entity as cosponsor, to import drugs from Canada with FDA approval under Section 804 of the Food, Drug and Cosmetic Act. Imported drugs would have to be appropriately relabeled and undergo testing for authenticity, degradation and other purposes. The proposed also outlines a regulatory pathway for US drug manufacturers to obtain a National Drug Code (NDC) for FDA approved drugs, including biologics, that were originally manufactured and intended to be marketed in a foreign country. Concerning financial benefit, the proposed is unable to estimate the affect the proposed policy, if finalized, will have on the US market for prescription drugs or to estimate savings to drug distributors, payers, providers and patients. **Comments on the proposed rule are due no later than March 9th.**

For more information on any of these or any issue, please contact any of the following:

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