CMS Proposes Significant and Far-Reaching Hospital Price Transparency Requirements in CY 2020 OPPS Proposed Rule

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On Monday, July 29, 2019, the Centers for Medicare & Medicaid Services (CMS) released the 2020 Outpatient Prospective Payment System (OPPS) Proposed Rule (the Proposed Rule). In it, CMS proposes an anticipated but extraordinarily burdensome price transparency rule that would require hospitals to publicly disclose negotiated prices with third party payers in connection with their disclosure of "standard charges" under section 2718(e) of the Public Health Services Act.

The Proposed Rule also contains notable proposals concerning supervision of therapeutic services in hospital outpatient departments; prior authorization requirements for a limited set of outpatient procedures; continuation of the 340B price reduction; implementation of the second phase of site-neutral payment for clinic visits at off-campus, provider-based departments; and the certification of organ procurement organizations.

Price Transparency

CMS describes the Proposed Rule as "bold action . . . to empower patients with price transparency," and the Proposed Rule certainly includes significant and far-reaching proposals to advance the Administration's goal of furthering price transparency in healthcare. The Administration has made price transparency a priority this year, as underscored by President Trump's June 24, 2019 Executive Order on the topic. Although the statute only requires "a list" of "standard charges," the proposed rule would require hospitals to include negotiated rates with third party payers alongside its charges in two publicly available files—a machine-readable file with charges for all items and services and a consumer friendly list that focuses on 300 "shoppable services."

- ***Statutory Background and Current Requirements.*** Under section 2718(e) of the Public Health Services Act, all hospitals are required to "establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups." Based on 2014 guidance, hospitals could comply with the statute by "either mak[ing] public a list of their standard charges, or their policies for allowing the public to view a list of those charges in response to an inquiry." Under guidance released last year, however, hospitals are currently required to make their chargemasters public in machine-readable format, which should include all items

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and services (including drugs) provided by the hospital as well as diagnosis-related group information (e.g., data in the Inpatient Utilization and Payment Public Use File). CMS indicated that future rulemaking would address "[s]pecific additional future enforcement."

- ***The Price Transparency Executive Order.*** CMS' proposals follow from President Trump's direction in a June 24, 2019 executive order (EO) to increase health care price and quality transparency. The EO's stated goal was to help patients "know the price and quality of a good or service in advance of [receiving] care." The EO directs the Department of Health and Human Services ("HHS") and other agencies to issue rules, guidance, or reports, including rules requiring "hospital[s] to publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable items and services, in an easy-to-understand, consumer-friendly, and machine-readable format." The EO also requires advance notice of proposed rulemaking to obtain comments on how providers, insurers, and self-insured group health plans could be required to share anticipated out-of-pocket cost information with patients and a report on barriers to price and quality transparency resulting from federal government and private sector actions, and proposals to eliminate such barriers and increase competition.

- ***"Payer-Specific Negotiated Charges."*** Under the Proposed Rule, payer-specific negotiated charges would mean "the charge that a hospital has negotiated with a third party payer for an item or service." Although the Proposed Rule uses the term "charges," it is referencing the rates negotiated between hospitals and third party payers. This data would need to be included in both the machine-readable file of all items and services provided by the hospital, as well as in the consumer-friendly list of at least 300 shoppable services.

- ***"Shoppable Services."*** CMS proposes a list of 70 "shoppable" services that would be required to be included in the consumer-friendly list of "standard charges." These include various evaluation and management services, laboratory and pathology services, radiology services, and medicine and surgery services. In addition, providers would be required to include additional "shoppable" services for a total of 300 items for inclusion on the consumer-friendly list.

- ***Civil Monetary Penalties.*** The proposed rule would permit CMS to initiate enforcement actions and to impose civil monetary penalties (CMPs) of up to a maximum of $300 a day where a provider fails to comply with the price transparency regulations. The CMP would generally follow a written warning and the failure to either submit or comply with a corrective action plan. CMS is also proposing to publicize each notice of imposition of a CMP online, even while such CMP is being appealed, only removing the public notice if the CMP is overturned by a final and binding decision. CMS is requesting comments on imposing stronger penalties or limiting the maximum amount of a penalty, as well as the unintended consequence of the proposed penalties and whether other penalties should be applied.

The foregoing price transparency proposals raise a number of significant legal and practical problems, some of which are summarized below:

- ***Limits of Statutory Authority.*** These proposals may exceed CMS' statutory authority under Section 2718(e) of the Public Health Service Act, which only speaks to public disclosure of "standard charges" rather than competitively negotiated rates. CMS may also lack authority to promulgate rules relating to the enforcement of the new price transparency rules. CMS relies upon Public Health Services Act section 2718(b)(3), which contains ACA's provisions relating to the medical loss ratio and rebate requirements that ACA imposed upon health insurers. It does not address enforcement of the requirement to disclose standard charges pursuant to Section 2718(e).

- ***Impact on Competition.*** The disclosure of negotiated discounts from a hospital's charges are likely to have significant, adverse impacts on competition. Such discounts are widely recognized to be competitively sensitive by providers and payers alike. CMS admits "the impact resulting from the release of negotiated rates is largely unknown" and that doing so "may have the unintended consequence of increasing health care costs" and/or encouraging "anticompetitive behaviors"—along the lines of the oft-discussed "Danish cement" case study. (See Section XVI.D.2. of the Proposed Rule) The Proposed Rule does not indicate any consultation with the Antitrust Division of the

Department of Justice or the Federal Trade Commission.

- ***Operational Difficulties*.** The Proposed Rule appears to underestimate the amount of data to be disclosed and the amount of work involved for hospitals. Notably, CMS assumes that "it presents little burden for a hospital to electronically pull and display" negotiated rates for individual payers. But data about negotiated rates for individual payers may or may not be stored in a hospital's billing software in a format that can be readily extracted. Such rates are not "routinely used for billing," as CMS contends. Rather, bills submitted by a hospital typically list the hospital's gross charges for services provided, and the payer determines payment during the claim adjudication process. CMS further assumes that the charge for each item or service on a hospital's chargemaster can be readily tied to a dollar amount by the hospital and that hospitals and consumers will be able to map between individual items and services and the various configurations of "service packages" (e.g., per diem stays, diagnosis-related groups) used by different payers.

- ***Disconnect with Trends in Managed Care.*** Over the past decade, managed care has continued to move toward shared-risk arrangements and value-based payments. The Proposed Rule does not acknowledge or address how providers that receive capitation payments, bundled care payments, shared savings or shared risk pool distributions, or quality incentive bonuses could comply with the regulations. It is possible that such arrangements are excluded from the proposed definition of "standard charge" ("the regular rate established by the hospital for an item or service provided to a specific group of paying patients"), but it is puzzling that there is no discussion of the consumer confusion that might result or the other impacts of the exclusion of these types of arrangements.

- ***Identifying the Payer.*** CMS also assumes that the third party payer can be identified in every instance, and that each discount is "payer-specific." This is not true where, for example, the hospital has signed a "rental" or "network access" agreement and may not know the identities of all the payers who may "access" such an agreement.

These price transparency proposals will almost certainly prompt significant public comment. For now, serious questions remain about whether Public Health Services Act section 2718(e) gives CMS sufficient authority to promulgate these rules; whether the agency has or can sufficiently address trade secret and antitrust considerations; whether it is even operationally feasible to comply with the Proposed Rule; and, even if so, whether much of this information is more efficiently obtained from payers than from hospitals.

Other Issues of Note

Prior Authorization Process Proposal. CMS proposes for the first time in the fee-for-service context a prior authorization process for five categories of hospital outpatient department services: (1) blepharoplasty, (2) botulism toxin injections, (3) panniculectomy, (4) rhinoplasty and (5) vein ablation. This prior authorization proposal stems from CMS' stated goals of managing the growth of Medicare spending for outpatient department services, and CMS claims that the prior authorization requirement is permissible as "a method for controlling unnecessary increases in the volume" of covered outpatient department services under 42 U.S.C. § 1395l(t)(2)(F). CMS indicates that volume increases for these services were higher than expected and notes that the specified services are likely to be cosmetic surgical procedures and/or are directly related to cosmetic procedures that are not medically necessary.

CMS proposes that as a condition of Medicare payment for services that fall within the five specified categories, a provider must submit a prior authorization request that includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. This request must be submitted before the service is furnished to the beneficiary and before the claim is submitted. The Proposed Rule sets a ten or two business day deadline (depending on the severity that any delay would have on the beneficiary) as the deadline for CMS or its contractor to review and issue a decision on authorization requests. The Proposed Rule also gives CMS the option of exempting a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding and payment rules. Any such exemption would remain in effect until CMS withdraws it.

Level of Supervision. CMS is proposing to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by hospitals and critical access hospitals (CAHs). General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. This proposal is motivated by CMS' desire for a uniform enforceable supervision standard for all hospital outpatient therapeutic services,[1] as well as by CMS' recognition that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers. CMS also notes that, in its experience, Medicare providers will provide a similar quality of services, regardless of the supervision required. CMS is seeking public comments on this proposal, as well as specific comments on whether there are any types of services that should be excepted from the proposal.

340B Drug Payment and Litigation. CMS proposes to continue to pay ASP minus 22.5 percent for 340B-acquired drugs, as it has since CY 2018, when the rate was reduced from ASP plus 6 percent to ASP minus 22.5 percent. In the Proposed Rule, CMS acknowledges the federal district court rulings in *American Hospital Association. v. Azar*, No. 18-cv-2084 (D.D.C.), within the last year, wherein the court concluded that the Secretary exceeded his statutory authority when imposing those rate reductions for 340B-acquired drugs in CY 2018 and CY 2019. While the Secretary has appealed the case to the D.C. Circuit, in this Proposed Rule, CMS seeks public comments as it takes steps to craft a remedy in the event of an adverse decision for the agency on appeal. CMS states that in the event of such an adverse appellate decision, it anticipates proposing the specific remedy for CYs 2018 and 2019, and, if necessary, changes to the CY 2020 rates, in the next available rulemaking vehicle, which is the CY 2021 OPPS proposed rule. Those proposals will be informed by the comments solicited in this Proposed Rule.

CMS first seeks comments on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP plus 3 percent could be an appropriate payment amount for 340B-acquired drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. CMS also is soliciting comments on how to structure the remedy for CYs 2018 and 2019. More specifically, CMS seeks comments on: (1) whether such a remedy should be retrospective in nature (for example, made on a claim-by-claim basis), (2) whether such a remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past), and (3) whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting what CMS describes as a "budget neutrality mandate." Finally, CMS asks for comments on the most appropriate treatment of beneficiary cost-sharing responsibilities under any proposed remedy.

Organ Procurement Organizations Changes and Request for Information . The Proposed Rule revises the Organ Procurement Organization (OPO) Conditions for Certification (CfC) as a step toward the Administration's Advance Kidney Health Initiative launched from President Trump's recent Executive Order to increase utilization of available organs. Currently, OPOs are required to meet two of three outcome measures. The Proposed Rule revises the definition of "expected donation rate" that is included in the second outcome measure to make it consistent with the definition used by the Scientific Registry of Transplant Recipients (SRTR)—a definition that was adopted in 2009. The revision would define the expected donation rate per 100 eligible deaths as "the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations."

The Proposed Rule also includes a Request for Information regarding the OPO CfCs and the Conditions of Participation (CoPs) for transplant centers that must be met for payment. The RFI seeks comments in six areas covering the impacts, consequences and reliability of OPO outcomes measures. The Proposed Rule also solicits public comments on two potential OPO outcome measures: (1) the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation; and (2) the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. Lastly, in addition to the public comments of these two listed outcome measures, CMS is also interested in public comments on the appropriate parameters for these measures. CMS indicates it will use this feedback in a comprehensive proposal in future rulemaking expected later this year.

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The foregoing is a sampling of key highlights found among the more than 819 pages of the Proposed Rule. Comments on CMS' proposals are due on September 27, 2019. The Proposed Rule will be published in the Federal Register on August 9, 2019 at https://federalregister.gov/d/2019-16107. In the interim, the unpublished version is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16107.pdf.

For more information on the OPPS and price transparency, please contact, Katrina Pagonis in the San Francisco office, Eric Chan, Alicia Macklin or Sansan Lin in the Los Angeles office, or Kelly Carroll, Marty Corry, Kelly Delmore or Monica Massaro in the Washington, DC office or your regular Hooper, Lundy & Bookman contact.

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[1] Since approximately 2010, CMS has instructed all MACs not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs or small rural hospitals having 100 or fewer beds. These enforcement instructions created a two-tiered system of supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program: for most hospital outpatient therapeutic services in most hospital providers, direct supervision is required, but for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds, only general supervision is required.

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