August 7, 2019

CMS Releases Proposed Rules on PFS, QPP and Price Transparency

On July 29, 2019, the Centers for Medicare & Medicaid Services (CMS) issued two significant proposed rules: (a) a Proposed Rule that addresses changes to the Physician Fee Schedule (PFS) and updates to the Quality Payment Program (QPP), and (b) a Proposed Rule that addressed changes to the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System (collectively, the Proposed Rules). If enacted, CMS contends that the Proposed Rules will, among other changes, reduce burdens on clinicians, allowing them to spend additional time with patients, and increase transparency regarding hospital charges for patients.

To reduce clinician burden, the PFS and QPP proposed rule outlines CMS' plan to transition from the Merit-based Incentive Payment System (MIPS) to "MIPS Value Pathways" (MVPs), a model that will allow participating physicians and groups to report on a smaller set of specialty-specific measures. In addition, CMS proposes to implement regulations regarding a new Medicare Part B benefit for opioid use disorder treatment services, pursuant to requirements in Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. Finally, hospitals will have new public disclosure requirements, because the OPPS Proposed Rule outlines, among other developments, provisions to implement Section 2718(e) of the Public Health Service Act, which would implement certain price transparency disclosure mechanisms for hospitals' standard charges.

Initial industry public feedback was mixed regarding the efficacy of these proposals in reducing burdens on clinicians. Industry reaction to the hospital public disclosure requirements was generally negative. These proposed changes and subsequent industry reaction are highlighted in this client alert. Public comments are due on the Proposed Rules by September 27, 2019.

CY 2020 Physician Fee Schedule and Quality Payment Program Proposed Rule

- **Transition from Merit-based Incentive Payment System (MIPS) to MIPS Value Pathways (MVPs).** Beginning in the 2021 performance period, CMS is proposing to eliminate the current MIPS framework, which requires clinicians to report on many measures across the Quality, Cost, Promoting Interoperability and Improvement Activities performance categories.[1] In its place, CMS proposes MVPs, which would allow clinicians to report on a smaller set of specialty-specific measures.[2] Under the proposed MVPs, a participating clinician or group would be in one MVP associated with their specialty or with a condition (e.g., surgery or diabetes), reporting on the same measures and activities as other clinicians and groups in that MVP.[3] CMS explained that its proposal responds to feedback that the QPP, and specifically MIPS, remains overly complex, despite CMS' attempts to streamline program requirements over the last few years.[4] The MVP framework proposal also requested comments on providing clinician feedback on administrative claims-based quality and cost measures. An initial response from the American Medical Group Association criticized the proposal,[5] noting that while the statutory framework for the Medicare Access and CHIP Reauthorization Act offers providers an opportunity to earn an adjustment of up to 9% of on their Medicare Part B payments in 2022 based on their 2020 performance, the proposed rule estimates an overall payment adjustment of only

[1] Ctrs. for Medicare & Medicaid Srvs., "Trump Administration's Patients over Paperwork Delivers for Doctors," Press Release, (July 29, 2019).
[2] *Id.*
[3] Centers for Medicare & Medicaid Services, "2020 Quality Payment Program Proposed Rule Overview Factsheet with Request for Information for 2021," Fact Sheet, p.2.
[4] *Id.*
[5] Am. Medical Grp. Ass'n, "AMGA Concerned MIPS No Longer a Pathway to Value Under Proposed Physician Fee Schedule," Press Release, (July 29, 2019).

1.4%.[6] However, the President of the American Medical Association issued a statement generally supporting the PFS Proposed Rule, and called the MVPs proposal "a simplified option that would give physicians the choice to focus on episodes of care rather than following the current, more fragmented approach."[7]

- **Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs.** CMS is proposing regulations to implement requirements in Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) that established a new Medicare Part B benefit for opioid use disorder (OUD) treatment services. This benefit would include medications for medication-assisted treatment (MAT) furnished by opioid treatment programs (OTPs).[8] OTPs are programs or providers that provide a range of services to people with OUD, including medication-assisted treatment and counseling.[9] There are currently approximately 1,700 OTPs nationwide.[10] Approximately 74% of patients receiving services from OTPs receive methadone for MAT, with the vast majority of remaining patients receiving buprenorphine.[11] To meet the statutory requirement, CMS has proposed regulations including: definitions of OTP and OUD treatment services; enrollment policies for OTPs; methodology and estimated bundled payment rates for OTPs that vary by the medication used to treat OUD and service intensity, and by full and partial weeks; adjustments to the bundled payment rates for geography and annual updates; flexibility to deliver the counseling and therapy services described in the bundled payments via two-way interactive audio-video communication technology as clinically appropriate; and zero beneficiary copayment for a time-limited duration.[12] CMS intends to implement this benefit beginning January 1, 2020, as required by the SUPPORT Act.[13]

- **Proposed bundled payment under the PFS for Substance Use Disorders (SUDs).** CMS is proposing to create new coding and reimbursement for a monthly bundled episode of care for management and counseling treatment for SUDs.[14] Services would include overall management, care coordination, individual and group psychotherapy and substance use counseling.[15] CMS is proposing that the individual psychotherapy, group psychotherapy, and substance use counseling included in these bundles could be furnished as Medicare telehealth services as clinically appropriate.[16] CMS is also seeking comment on bundles describing services for other SUDs and on the use of MAT in the emergency department setting.[17]

- **Payment for Evaluation and Management (E/M) Services.** CMS is proposing to change E/M coding to align with changes by the CPT Editorial Panel for office/outpatient E/M visits. The CPT coding changes maintained

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[6] Ctrs. for Medicare & Medicaid Servs., "Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations," Federal Register (July 29, 2019), Table 114 (scheduled to be published on Aug. 14, 2019).
[7] Am. Medical Ass'n, "Relief from Administrative Burden Key to Proposed Medicare Fee Schedule," Press Release (July 30, 2019).
[8] Ctrs. for Medicare & Medicaid Servs., "Physician Policy, Payment and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2020," Fact Sheet (July 29, 2019).
[9] *Supra* n.1.
[10] *Supra* n.6, § III.G.1.
[11] *Id.*
[12] *Supra* n.7.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

five levels of coding for established patients, reduced the number of levels to four for office/outpatient E/M visits for new patients and revised the code definitions.[18] The CPT coding changes also revised the times and medical decision making process for all of the codes, required performance of history and exam only as medically appropriate and allowed clinicians to choose the E/M visit level based on either medical decision making or time.[19] CMS is also proposing to adopt the American Medical Association Relative Value Scale Update Committee (RUC)-recommended values for the office/outpatient E/M visit codes for CY 2021, which would increase the payment for office/outpatient E/M visits.[20]

- **Changes to Requirements for Review and Verification of Medical Record Documentation.** In response to feedback CMS received in response to the "Patients Over Paperwork" initiative request for information, CMS is proposing broad modifications to regulations regarding medical record documentation, to allow physicians and non-physician practitioners who furnish and bill for professional services to "review and verify" (or sign and date) rather than re-document notes included in the medical record by physicians, residents, nurses, students or other members of the medical team.[21] Because CMS intends this proposal to apply broadly (including across all Medicare-covered services paid under the PFS), CMS proposes to amend regulations specifying medical record documentation requirements for professional services furnished by physicians and non-physician practitioners in all settings.

- **Physician Supervision Requirements for Physician Assistant (PA) Services.** CMS is proposing to modify Medicare benefit regulations regarding the supervision required for PA services (42 C.F.R. § 410.74(a)(2)). Specifically, the proposed rule provides that a statutory physician supervision requirement for PA services (§ 1861(s)(2)(K)(i) of the Social Security Act) is met when a PA furnishes services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed.[22] In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services.[23] To date, CMS has interpreted 42 C.F.R. § 410.74(a)(2)(iv) to require PA services to be furnished under the "general supervision" of a physician (as defined under 42 C.F.R. § 410.32(b)(3)(i)).[24] CMS indicated that this change responds to recent changes in practice of medicine for PAs that allow PAs to practice more autonomously, like nurse practitioners and certified nurse specialists, and changes to scope of practice laws for PAs regarding physician supervision across some states.[25]

- **Increased Payment for Care Management Services.** CMS is proposing a series of measures to increase payment for care management services, including:

    - Increasing payment for "Transitional Care Management" (TCM) services, a care management service provided to beneficiaries after discharge from an inpatient stay or certain outpatient stays;

[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Supra* n.6, § III.J.2.
[22] *Id.* § II.I.2.
[23] *Id.*
[24] *Id.*
[25] *Id.*

- Proposing a set of Medicare-developed HCPCS G codes for certain "Chronic Care Management" (CCM) services, services for providing care coordination and management services to beneficiaries with multiple chronic conditions over a calendar month service period;

- Proposing to replace a number of the CCM codes with Medicare-specific codes to allow clinicians to bill incrementally to reflect additional time and resources required in certain cases and to better distinguish complexity of illness as measured by time;

- Adjusting certain billing requirements and elements of care planning services, so as to reduce the burden associated with billing the complex CCM codes; and

- Creating new coding for "Principal Care Management" (PCM) services, which would pay clinicians for providing care management for patients with a single serious and high risk condition (e.g., diabetes).[26]

CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule

- **Price Transparency of Hospital Standard Charges.** The proposed CY 2020 OPPS/ASC rule proposes regulations to implement Section 2718(e) of the Public Health Service Act, which requires each hospital operating within the United States to establish and make public a yearly list of the hospital's standard charges for items and services.[27] President Trump signed an Executive Order on June 24 directing the Secretary of Health and Human Services (HHS) to propose a regulation to require hospitals to publish standard charge information. Specifically, CMS proposes requirements for hospitals to make public both (1) a machine-readable file online that includes all standard charges (both gross charges and payer-specific negotiated charges) for all hospital items and services, and (2) payer-specified negotiated charges for a limited set of at least 300 "shoppable" services (defined as a service that can be scheduled by a health care consumer in advance) that the hospital provides in a "consumer-friendly" form and manner.[28] The hospital must update the information at least annually and display it prominently on a publicly available webpage that clearly identifies the hospital (or hospital location), is easily accessible, without barriers, and searchable. CMS also proposes to monitor and enforce hospital noncompliance by evaluating complaints made by individuals or entities and auditing hospitals' websites, to take actions to address hospital noncompliance (including issuing a warning notice, requesting a corrective action plan and imposing civil monetary penalties not in excess of $300 per day), and to provide a process for hospitals to appeal the civil monetary penalties before an Administrative Law Judge.[29]

- Industry reaction to the price transparency provisions was swift. The same day as the OPPS/ASC Proposed Rule was introduced, hospital industry groups including the Association of American Medical Colleges (on behalf of itself and the American Hospital Association, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, and the Federation of American Hospitals) issued a joint press release calling the proposed rule "a misguided attempt to improve price transparency for patients because it fails to give them the information they need."[30] Separately, the President of the American Hospital Association issued a statement denouncing the rule and stating that "mandating the disclosure of negotiated rates between insurers and hospitals is the wrong approach" and "could seriously limit the choices available to patients in the

[26] *Id.*
[27] Centers for Medicare & Medicaid Services, "CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule," Fact Sheet (July 29, 2019).
[28] *Id.*
[29] *Id.*
[30] Ass'n of Am. Medical Colleges, "Joint Statement from National Hospital Associations on Proposed CY 2020 OPPS Rule," (July 29, 2019).

private market and fuel anticompetitive behavior among commercial health insurers in an already highly concentrated insurance industry."[31]

Please contact any member of Ropes & Gray's health care practice group with any questions concerning this Alert or for assistance in preparing any comments to the Proposed Rules.

[31] Rick Pollack, Am. Hosp. Ass'n, "AHA Statement on Proposed CY 2020 OPPS Rule," (July 29, 2019).