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Proposed Rule on CY 2022 Physician Fee Schedule Addresses Telehealth (Especially Mental Health), Drug Pricing and Reimbursement, Provider Enrollment, Vaccines, and Physician-Owned Distributor Transparency

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On July 13, 2021, the Centers for Medicare & Medicaid Services ("CMS") released the annual Physician Fee Schedule Proposed Rule ("Proposed Rule").[1] Among other things, the Proposed Rule addresses telehealth reform, particularly around mental health services, prescription drug pricing and reimbursement, enhancements to CMS authority over provider enrollment and disenrollment, vaccine coverage, and new transparency reporting for physician-owned distributors of medical devices ("PODs").

This Alert highlights certain aspects of the proposed changes included in the Proposed Rule. Public comments are due on the Proposed Rule by September 13, 2021.

Telehealth Services. The Proposed Rule continues CMS's efforts during the COVID-19 Public Health Emergency ("COVID-19 PHE") to expand telehealth services and related coverage.

- **Extension of Covered Services on Medicare Telehealth List Added Until December 31, 2023 and Solicitation of Comments.** In response to the COVID-19 PHE, Congress passed a series of legislation that gave the Secretary of the U.S. Department of Health and Human Services (the "Secretary") the authority to waive or modify Medicare telehealth coverage requirements during the COVID-19 PHE.[2] The Secretary used this waiver authority to, among other things, remove the requirement to undertake rulemaking to add or delete services from the list of services payable under the Medicare Physician Fee Schedule when furnished via telehealth, known as the Medicare Telehealth Services List ("List"). During the COVID-19 PHE, the Secretary added certain services to the List on an interim basis until the end of the COVID-19 PHE by means of a "Category 3" designation. This Category 3 designation, which was assigned to services such as psychophysiological therapy, eye examinations for new patients, speech and hearing therapy, and a multitude of others, allowed the Secretary to provide coverage for and collect data on the clinical benefit of these services when furnished via telehealth during the COVID-19 PHE. In the Proposed Rule, CMS proposes to allow all services that were temporarily added on a Category 3 basis to remain on the List until December 31, 2023. CMS reasons that the extension will allow for additional data collection and development of support for the permanent addition of appropriate services to the List. CMS also solicits comment regarding certain services added to the list for the duration of the COVID-19 PHE that were not extended on a Category 3 basis, and whether they should similarly be extended.

- **Revision to Interactive Telecommunications System Definition to Include Audio-Only Technology for Mental Health Disorder Services.** During the COVID-19 PHE, the Secretary also used the waiver authority to allow coverage of certain telehealth services furnished through audio-only communications technology. The Secretary's waiver expires when the COVID-19 PHE ends; thereafter, unless otherwise authorized, coverage for telehealth services will again be limited to services furnished through a synchronous, two-way audio and video communication. CMS proposes to amend the regulatory definition of interactive telecommunications system to include audio-only technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. CMS contends that this would increase access to care given the generalized shortage of mental health care professionals. However, coverage would be available only if the beneficiary is not capable of using, or does not consent to the use of, video technology for the services.

- **Implementation of Expansion of Medicare Telehealth Originating Sites for Mental Health Services and Solicitation of Comments.** The Proposed Rule implements provisions of the Consolidated Appropriations Act, 2021 (the "CAA") permitting a patient's home to be an originating site for telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of mental health disorders furnished during or after the end of the COVID-19 PHE. In addition, implementing a requirement of the CAA, CMS proposes that for such services, an in-person, non-telehealth service must be provided at least every six months thereafter and seeks comment on whether a different time interval should be established for mental health services furnished through audio-only technology.

- **Mental Health Visits via Telehealth for Rural Health Clinics ("RHCs") and Federally Qualified Health Centers ("FQHCs").** RHC and FQHC visits are statutorily limited to be face-to-face encounters between a patient and an RHC or FQHC practitioner. Under the CARES Act, the Secretary established a Medicare payment mechanism for telehealth services where RHCs and FQHCs served as distant sites during the COVID-19 PHE. In recognition that the current flexibility only extends through the duration of the COVID-19 PHE, CMS proposes to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face encounter between the patient and practitioner to include visits furnished through interactive, real-time telecommunications technology for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. Additionally, consistent with its policy applicable to other clinicians' use of audio-only technology, CMS proposes to allow RHCs and FQHCs to furnish mental health visits via audio-only technology only when beneficiaries are not capable of or do not consent to the use of video technology.

Payment Provisions. The Proposed Rule includes several proposed updates that aim to codify reimbursement policies reflected both in the CPT guidance and in withdrawn CMS sub-regulatory guidance. These proposals are intended to recognize changes in clinical practice to more team-based medicine and the delivery of care under alternative payment models. Notable proposals include the following:

- **Evaluation and Management ("E/M") Visit Code Updates and Solicitation of Comments.** CMS proposes to refine its policies on E/M visits to better reflect current practices and the evolving and expanding role of non-physician practitioners ("NPPs") within the medical team. Notably, having withdrawn certain provisions of the Medicare Claims Processing Manual addressing split (or shared) billing, CMS attempts to codify its policy on such by clarifying and expanding on the definition provided in the CY2021 Physician Fee Schedule final rule that became effective Jan. 1, 2021.

    - CMS proposes to clarify "split" or "shared" visits through a new section of its regulations at 42 C.F.R. § 415.140. These split (or shared) visits would be defined as an E/M visit in facility settings (for which "incident to" payment is not available) that are performed in part by both a physician and an NPP who are in the same group, and in accordance with applicable law and regulations such that the service could be billed by either the physician or NPP if furnished independently by only one of them. CMS contends this definition will improve clarity and distinguish these services from those furnished "incident to" the professional services of a physician. In addition, CMS solicits comments on the appropriate definition of "same group."

    - As proposed, only the physician or NPP who performs the "substantive portion" (meaning a majority of the time) of the split (or shared) visit would bill for the visit, as determined by summing the distinct time of service spent by each physician or NPP. The billing practitioner with the "substantive portion" would be required to sign the documentation while the other practitioner would need to be identified, and a modifier would be required to identify the split (or shared) services. Further, CMS proposes a list of qualifying activities for purposes of determining the total time and substantive portion of a split (or shared) visit, and solicits comments on a list for such emergency department visits. CMS also proposes to change its prior

policy to allow a practitioner, who furnished the substantive portion, to bill for a prolonged E/M visit as a split (or shared) visit.

- In order to reflect the team-based approach of the current practice of medicine, CMS proposes to allow physicians and NPPs to bill for split (or shared) visits (i) for both new and established patients, (ii) for initial and subsequent visits, (iii) for critical care services and (iv) for skilled nursing facility/nursing facility settings where the physician is not required by regulation to perform the entire service. CMS solicits public comment with regard to the expansion on critical care services.

- With the Proposed Rule, CMS is codifying its policies on critical care services previously addressed in the Medicare Claims Processing Manual and CPT codebook. It proposes that critical care services may be furnished as concurrent care to the same patient on the same day by more than one practitioner in more than one specialty as long as not duplicative. However, no other E/M visit may be billed for the same patient on the same date as a critical care service when such services are furnished by the same practitioner or by practitioners in the same specialty in the same group. CMS also solicits comments on various policies related to critical care services, including (i) reporting critical care services that go beyond midnight, (ii) whether it is appropriate to aggregate time spent by practitioners in a same group in billing initial critical care visits and then subsequent critical care, (iii) critical care visits and same day emergency department, inpatient or hospital outpatient/office visits, and (iv) bundling previously unbundled critical care services with procedures that have a global surgery period.

- CMS proposes changes to payments for teaching physicians, specifically clarifying that when using total time to determine the level of an office/outpatient E/M visit, only the time when the teaching physician was present can be included (with some exceptions such as the so-called "primary care exception" and certain COVID-19 PHE exceptions.

- **Direct Billing for Physician Assistants ("PA").** While nurse practitioners and clinical nurse specialists have been authorized to bill the Medicare program and be paid directly for their professional services, Medicare has been statutorily limited to pay for PA services only to the PA's employer. The CAA removed this requirement effective January 1, 2022 such that PAs will be authorized to bill the Medicare program and be paid directly for their services. CMS proposes to amend certain regulations in order to implement these changes.

- **Concurrent Billing for Chronic Care Management Services ("CCM") and Transitional Care Management ("TCM") Services for RHCs and FQHCs.** Currently, RHCs and FQHCs may not concurrently bill for TCM services if another practitioner or facility has already billed for CCM services for the same beneficiary during the same time-period. CMS proposes to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, noting that such services would be complementary given that TCM services are furnished once within 30 days of a patient's discharge, while CCM services require more frequency.

Drug Pricing and Reimbursement. Consistent with CMS's continued efforts to provide transparency in drug pricing and curb drug prices, the Proposed Rule implements recent reporting requirements related to Average Sales Price ("ASP") data and proposes a framework to determine payment for Section 505(b)2 drugs.

- **Average Sales Price Reporting for Manufacturers Without Medicaid Drug Rebate Agreements.** Manufacturers with Medicaid drug rebate agreements are already required to report ASP data. The CAA amended the ASP reporting statute to also require manufacturers without such agreements to report ASP information to CMS beginning on January 1, 2022 for certain drugs or biologicals payable under Medicare Part B. CMS proposes regulatory changes in order to implement these new reporting requirements.

- **Solicitation of Comments on Proposal to Reimburse Section 505(b)(2) Drugs as Multiple Source Drugs.** Section 505(b)(2) under the Federal Food, Drug, and Cosmetic Act provides an approval pathway for drug applications that contain full reports of investigations for safety and effectiveness, but where at least some of the information comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) drug product is not required to have the same FDA-approved labeling as the labeling for the already-approved drug(s) upon which the Section 505(b)(2) application relied (unlike in the case of generic drugs approved under an Abbreviated New Drug Application). Some Section 505(b)(2) drug products, which are currently assigned to a single source drug code, share substantial portions of labeling with generic drug products that are payable under Medicare Part B as multiple source drugs. With the goals of paying similar amounts for similar services and of reducing drug prices, CMS is soliciting comments on a proposed decision framework through which some Section 505(b)(2) drug products could be assigned to existing multiple source drug codes for payment under Medicare Part B. The proposed framework would compare certain qualities, such as active ingredient and dosage form, of the Section 505(b)(2) drug product with those qualities in drug products already assigned to an existing multiple source drug code, and then further verify the comparability of the products.

Medicare Provider and Supplier Enrollment. The Proposed Rule attempts to strengthen Medicare Program integrity and protection of its beneficiaries through expansion of CMS's bases to deny or revoke provider and supplier enrollment.

- **Expansion of Bases to Deny or Revoke Enrollment.** Under Medicare regulations, CMS may deny or revoke a provider's or supplier's enrollment on various grounds, including if the provider or supplier, or any of its owners, managing employees, authorized or delegated officials, medical directors, supervising physicians, or other health care personnel of the provider or supplier, is excluded by the U.S. Department of Health & Human Services Office of Inspector General ("OIG").

    - To align with existing OIG exclusion guidance, CMS proposes to expand the categories of individuals whose exclusion from federal health care programs could trigger the denial or revocation of enrollment of a provider or supplier entity that employs or contracts such individuals. Specifically, CMS proposes that the OIG exclusion of any administrative or management services personnel who furnish services payable by a federal health care program, such as billing specialists and accountants, would be a basis to deny or revoke a provider's or supplier's Medicare enrollment if the provider or supplier employed or contracted with such individuals to provide those services. Similar to current regulation, if the individual is terminated within 30 days, the provider or supplier may have their revocation reversed.

    - CMS also proposes to expand its authority to deny or revoke a physician's or other eligible professional's enrollment to include surrenders of Drug Enforcement Administration ("DEA") certificates in response to an order to show cause. CMS contends that scenarios in which such professionals *relinquish* their DEA certificate so as to avoid likely suspension or revocation of such are no less a threat to program integrity than a DEA certificate suspension or revocation.

- **Revision of Factors Required to Be Considered in Revocations Involving Abusive Billing.** CMS proposes to revise the factors it must consider in determining whether revocation is appropriate in instances of abusive billing to the following: (i) the percentage of submitted claims that were denied during the period of consideration; (ii) whether the provider or supplier has any history of final adverse actions and the nature of such; (iii) the type of billing non-compliance and the specific facts; and (iv) any other information regarding the specific circumstances that CMS deems relevant to its determination. Other patterns, such as the reasons for claim denials, the length of time over which a pattern has continued and the length of the provider's or supplier's enrollment, would no longer be considered in the determination.

Vaccines and COVID-19 Monoclonal Antibody Products. As the COVID-19 pandemic has brought attention to the importance of vaccination, CMS seeks comments from stakeholders related to its vaccination efforts and associated pricing methods both currently and beyond the COVID-19 PHE, including for that of COVID-19 monoclonal antibody products.

- **Solicitation of Comments on Access to Preventative Vaccines.** As Medicare payment rates for administration of certain preventative vaccines have decreased by roughly 30% in recent years, CMS solicits comments from stakeholders on the costs involved in furnishing preventative vaccines, including for influenza, pneumococcal, hepatitis B virus and COVID-19, and how the agency should update payment rates under Medicare Part B for such vaccines to more accurately reflect the cost and value of these services.

- **Solicitation of Comments on At-Home COVID-19 Vaccine Administration.** As of June 8, 2021, CMS implemented a new add-on payment with a national rate of $35.50 when a COVID-19 vaccine is administered in a beneficiary's home where the beneficiary has difficulty leaving the home to get the vaccine or the patient is hard to reach due to a disability or barriers to getting the vaccine. CMS is seeking feedback on this policy, including its definition of a beneficiary's home and the costs associated with administering COVID-19 vaccines in the home. The agency also is soliciting input on whether the same barriers that could prevent a beneficiary from access to a COVID-19 vaccine may impede access to other vaccines and, relatedly, whether Medicare should offer a similar add-on payment in those circumstances.

- **Solicitation of Comments on Coverage on COVID-19 Monoclonal Antibody Products.** The Food and Drug Administration has approved monoclonal antibody therapy for treatment of certain high-risk patients with mild to moderate COVID-19 in hopes of preventing further deterioration and hospitalization. When these treatments were authorized, CMS decided to cover and pay for them under the COVID-19 vaccine benefit in order to prioritize access by allowing almost all Medicare-enrolled providers and suppliers to furnish and bill for administering the products across different care settings. For vaccines, CMS makes separate payments for the product (when not given to the provider or supplier for free by the government) and for the service to administer it. Covering monoclonal antibody products under the vaccine benefit also led to Medicare beneficiaries being able to access these products without any cost-sharing (whereas other monoclonal antibody therapies furnished under the Medicare Part B benefit would otherwise be subject to 20 percent coinsurance requirements). As the COVID-19 monoclonal antibody market matures, CMS is considering alignment with the approach it takes with other physician-administered drugs and biologicals (including other monoclonal antibodies) under Medicare Part B following the COVID-19 PHE (which would have the effect, inter alia, of adding standard cost-sharing requirements). More broadly, the agency believes it is an important time to "consider a more rational payment framework for the other preventive vaccines covered under Medicare Part B."

Open Payments Financial Transparency Program. The Open Payments program is a statutorily mandated initiative that provides public information regarding financial relationships between the pharmaceutical and medical device industry and certain types of health care providers. It requires manufacturers of covered drugs, devices, biologicals, or medical supplies and applicable group purchasing organizations to submit information annually about certain payments or transfers of value to certain providers. The Proposed Rule includes a number of proposals for the Open Payment program, such as to clarify overlap between reporting of general and ownership payments and to address information gaps in teaching hospital records for reporting verification.

- **Self-identification of PODs When Reporting.** CMS proposes to add a definition of POD as a subset of applicable manufacturers or applicable group purchasing organizations for which Open Payments program reporting is required. This proposed change would not require reporting by an entity that is not already required to report under the existing regulation—PODs have been and would remain obligated to report only if they otherwise meet the definition of applicable manufacturer or applicable GPO, and ownership in publicly traded

companies would remain exempt from reporting—but it would require PODs to self-identify as such when reporting: for example, "applicable manufacturer—physician-owned distributorship," not simply "applicable manufacturer." The Proposed Rule would define a POD for reporting purposes as an entity that:

1. Meets the definition of an applicable manufacturer or applicable group purchasing organization as defined in 42 C.F.R. § 403.902, and

2. Meets at least one of the following two conditions:

    a. Has a minimum of 5 percent direct or indirect ownership or investment interest in the applicable manufacturer or applicable group purchasing organization held by a physician or a physician's immediate family member, or

    b. A physician or a physician's immediate family member receives compensation from the applicable manufacturer or group purchasing organization in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from the sale or distribution of devices by the applicable manufacturer or group purchasing organization in which the physician or physician's immediate family member has ownership.

If you have any questions or would like to comment on any aspect of the Proposed Rule, please contact one of the authors or your usual Ropes & Gray advisor.

1. Medicare Program: CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements *available at* https://www.federalregister.gov/d/2021-14973.
2. *See* Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); Families First Coronavirus Response Act, 2020 (P.L. 116-127); and The Coronavirus Aid, Relief, and Economics Security Act, 2020 (P.L. 116-136) ("CARES Act").