Key Takeaways from the
CY 2021 Medicare Physician Fee Schedule Proposed Rule

Comments due October 5, 2020

On August 3, 2020, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2021 Medicare Physician Fee Schedule (PFS) Proposed Rule, available here.[1] The CMS fact sheet is available here. Key takeaways from the CY 2021 PFS Proposed Rule are summarized below. Please see the end of this document for a glossary of key terms. *Note that due to the delayed release of the Proposed Rule, the Final Rule will be effective 30 days from publication, instead of the usual timeframe of 60 days.*[2]

- **CMS proposes to clarify and revalue code sets related to the finalized policy in the CY 2020 Final Rule, available here, to align changes to E/M payment and coding with recommendations from the American Medical Association (AMA) CPT Editorial Panel.**[3]
  - In the CY 2020 Final Rule, CMS adopted the AMA's recommended updated valuation for E/M visit codes, including recommendations related to times associated with E/M visits.[4]
    - **Current policy:** In the CY 2020 Final Rule, CMS adopted the RUC's recommended total time values for E/M visit HCPCS codes, effective for CY 2021. However, the sum of certain component time findings did not match the RUC's recommended total times.
    - **Proposed change:** CMS would revise the times for the prolonged E/M visit code set to total the RUC's component time findings, as PFS rate setting requires that the component times sum to the total time.
    - **Why it matters:** This revision would decrease the total times associated with four E/M HCPCS visit codes, and increase the total time associated with one E/M HCPCS visit code. These times are used for rate setting of individual E/M visit codes and can have broader PFS rate setting implications, as the total times are used as references for valuing other services under the PFS.
  - CMS proposes to clarify time values for prolonged E/M visits, and proposes revisions for this code set to align total times with the AMA's component time findings (pre-service, intra-service, post-service).[5]
  - The agency proposes to revalue certain code sets that include, rely upon, or are analogous to, E/M visits for CY 2021.[6] The proposed adjustments are intended to accurately account for previously finalized value increases of related E/M visits.[7]

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- **CMS proposes to clarify and refine payment policies for self-administered esketamine by:**
    - Maintaining HCPCS codes G2082 and G2083 and continuing to associate the evaluation and management (E/M) element of the service with CPT code 99212 (incorporating the code's work RVUs, work time, and direct PE inputs);[8]
        - **Current policy:** HCPCS codes G2082 and G2083 have a valuation of 30 minutes of observation time based on the sum of clinical labor for CPT code 99415 (15 minutes) and two billings of CPT code 99416 (8 minutes).
        - **Proposed change:** CMS would revise the valuation from 30 minutes of observation time to 150 minutes, based on the sum of the clinical labor for CPT code 95076 (110 minutes) and CPT code 95079 (40 minutes), in lieu of CPT codes 99415 and 99416.
        - **Why it matters:** The proposed change would take into account clinical staff time and efforts for esketamine, including the acquisition and delivery of the medication to the patient.
    - Increasing the observation time from 30 minutes to 150 minutes by incorporating CPT codes 95076 and 95079, in lieu of CPT codes 99415 and 99416;[9] and
    - Updating payment to reflect the most recent available quarter of wholesale acquisition cost (WAC) data for CY 2021 pricing and to reflect the E/M values (CPT code 99212) for CY 2021.[10]
- **The agency proposes policies related to telehealth and remote services, including:**
    - Adopting certain new services for permanent addition to the Medicare telehealth services list.[11]
        - **Current policy:** CMS adds services to the Medicare telehealth services list if the agency determines that the services are similar to professional consultations, office visits, and office psychiatry services that are currently on Medicare telehealth services list.
        - **Proposed change:** CMS proposes to add nine services to the telehealth services list on a permanent basis.[12]
        - **Why it matters:** When these services are provided through telecommunication and not in-person, they would be eligible for Medicare payment.
    - Creating a third category of criteria for adding services that would be included on a temporary basis to the Medicare telehealth services list.[13] The proposed Category 3 would

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include services that were added during the public health emergency (PHE) for the COVID-19 pandemic.[14] Any service added under this proposed category would remain on the Medicare telehealth services list through the CY in which the PHE ends.[15]

    - CMS requests comment on whether to add these services to the Medicare telehealth list permanently.[16]

  - Clarifying policies related to remote physiologic monitoring (RPM) services, such as payment for certain codes, provider and personnel eligibility for code use, and requirements related to code use, including post-PHE reinstatement of requirements related to established patient-physician relationships and data collection.[17]

- **CMS proposes to extend its existing interim final policy allowing direct supervision for services by a physician or a practitioner using interactive telecommunication technology through CY 2021, in recognition of circumstances that may continue after the PHE ends.[18]** CMS seeks comments regarding this policy, including related risks, possible guardrails, and potential use beyond CY 2021.[19]

- **The agency proposes to remove nine older National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information or that involve items or services that are not used frequently, as shown in the table below.[20]**

NCDs for items and services that were previously covered. Under the proposal, they would no longer be automatically covered. Coverage decisions would be up to the Medicare Administrative Contractors (MACs).
20.5, Extracorpeal Immunoadsorption (ECI) using Protein A Columns
100.9, Implantation of Gastroesophageal Reflux Device
110.14, Apheresis (Therapeutic Pheresis)
110.19, Abarelix Device
190.1, Histocompatibility Testing
190.3, Cytogenetic Studies
NCDS for items and services that were previously barred from coverage. MACs would now be able to cover these items or services.
30.4, Electrosleep Therapy
220.2.1, Magnetic Resonance Imaging
220.6.16, FDG PET

- **CMS would decrease the conversion factor from $36.09 to $32.26 in CY 2021.[21]** The overall payment rate update would be -10.61%. This update would reflect the budget neutrality adjustment.

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- **The agency proposes to establish new payment rates for immunization administration services, intended to better reflect the costs of associated relative resources.[22]** The proposed change would result in payment rates at approximately CY 2017 rates, reversing reductions that began in CY 2018.[23]
    - Specifically, CMS proposes to establish new payment rates for CPT codes 90460, 90461, 90471, 90472, 90473, 90474 and HCPCS codes G0008, G0009, and G0010.[24]
    - These codes were previously crosswalked with a CPT code for which the valuation was reduced beginning in CY 2018.[25] Instead, CMS proposes to crosswalk the valuation of these services to CPT code 36000 (introduction of needle or intracatheter, vein), and to continue to value the add-on codes associated with these services at half of the RVUs of the crosswalk.[26]
    - CMS proposes to apply this valuation to all of these existing vaccine administration codes, using the valuation of CPT code 90471 for base codes and CPT code 90472 for add-on codes.[27]
    - CMS anticipates applying the same approach to valuing administration of a vaccine for COVID-19 or other infectious disease that becomes available during CY 2021, regardless of whether separate coding for such services would need to be introduced.[28]
- **CMS proposes to codify its existing policy of assigning certain 505(b)(2) drug products to existing multiple source drug codes.[29]** This would be limited to 505(b)(2) drug products where a billing code descriptor for an existing multiple source code describes the product and other factors, such as the product's labeling and uses, that are similar to products that are already assigned to the code.[30] The continuation of this policy is intended to maintain payment of similar amounts for comparable products, encourage product competition, and curb drug prices.[31]
- **CMS clarifies that pharmacists may provide services "incident to" the services of billing physicians or nonphysician practitioners (NPPs).[32]** The agency specifies, however, that when pharmacists provide services that are paid under Part D, the services are not reportable or paid for under Part B.[33]
- **The Proposed Rule includes a clarification that physicians and NPPs can review and verify documentation entered into the medical record by members of the medical team (including students) for professional services that they furnish and bill under the PFS.[34]**

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- **The agency proposes that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances using the National Council for Prescription Drug Programs (NCPDP) SCRIPT 2017071 standard by January 1, 2022.[35]** This proposal would delay the original implementation date specified in the SUPPORT Act by one year.[36] On August 4, 2020, CMS separately published a Request for Information regarding electronic prescribing for controlled substances.[37]
    - **Current policy:** Prescribers must use this standard when conducting e-prescribing for covered Part D drugs for Part D eligible individuals. The SUPPORT Act would require use of this standard for e-prescribing for all Schedule II, III, IV, and V controlled substances by January 1, 2021.
    - **Proposed change:** CMS proposes that all prescribers conduct e-prescribing of Schedule II, III, IV, and V controlled substances using the NCPDP standard by January 1, 2022.
    - **Why it matters:** Esketamine is a Schedule III controlled substance, and therefore prescribers of esketamine would need conduct all electronic prescriptions using the NCPDP SCRIPT standard by the January 1, 2022 deadline and CMS requests input on the feasibility of this change.

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Policies Related to the Quality Payment Program

The Proposed Rule also details planned changes to the Quality Payment Program (QPP) established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).[38] CMS also issued a Fact Sheet on the QPP provisions of the Proposed Rule.

- **CMS proposes to reduce the weight of the Quality performance category and transfer it to Cost, while Improvement Activities and Promoting Interoperability would remain the same.**
  - **Current policy:** In 2020, the four performance categories are weighted: Quality (45%); Promoting Interoperability (25%); Improvement Activities (15%); and Cost (15%).[39]
  - **Proposed change:** For 2021, CMS proposes to reduce the weight of the Quality performance category by 5% and to transfer it to Cost,[40] as depicted in Table 1.2A. The other two categories are set in statute and do not change. For 2022, CMS plans to increase it by 10% so that it reaches the statutorily required 30%.[41]
  - **Why it matters:** If finalized, this policy would continue to increase the relative importance of performing well on Cost measures in order to perform well on MIPS overall. While CMS debated delaying this change in light of the COVID-19 PHE, the agency ultimately decided that an additional delay would require too significant of an increase in the Cost category.

Performance Category Weights, by Year						
Performance Category	*2017*	*2018*	*2019*	*2020 (current)*	***2021 (proposed)***	*2022 (by statute)*
Cost	0%	10%	15%	*15%*	***20%***	30%*
Quality	60%	50%	45%	*45%*	***40%***	30%*
Improvement Activities	15%*	15%*	15%*	15%*	**15%***	15%*
Promoting Interoperability	25%*	25%*	25%*	25%*	**25%***	25%*

** Set by statute.*

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- **CMS proposes adding costs associated with telehealth services to the previously established cost measures.**
    - **Current policy:** The Cost category is made up of 2 global, or general, cost measures – total per capita cost and Medicare spending per beneficiary – as well as measures that are specific to discrete episodes of care.[42]
    - **Proposed change:** These newly proposed codes were either recently added to the Medicare telehealth services list through the two interim final rules CMS released as part of its response to the COVID-19 pandemic[43] or were previously not widely billed and therefore had not been considered for inclusion.[44]
    - **Why it matters**: This is a reflection of increased use of telehealth services during the COVID-19 PHE. However, CMS notes that the addition of these new codes to existing measures is not thought to alter the intent of those measures.
- **CMS does not propose changes to the global cost measures, beyond application of telehealth services added to applicable episode-based and TPCC measures.[45]**
- **CMS has not proposed to account for Medicare Part D prescription drug costs in any of the Cost measures, consistent with prior years of MIPS.** Despite the statutory directive to assess the feasibility of including Part D costs, CMS has previously stated that including Part D costs was not operationally feasible,[46] and declines to address the issue in this Proposed Rule.
- **The agency proposes to delay the implementation of the MIPs Value Pathways during the 2021 performance period due to the COVID-19 PHE.[47]** The agency will continue to develop the MVP framework despite the delayed implementation by proposing various updates designed to refine underlying principles.
- **CMS proposes to increase the performance threshold required to avoid a payment reduction <u>from 45 to 50 points</u>,[48] and to keep the bonus threshold at 85 points.[49]**

Performance Thresholds, by Year					
	2017	*2018*	*2019*	*2020 (current)*	*2021 (**proposed**)*
Performance threshold (to avoid cut)	3 points	15 points	30 points	45 points	**50 points**
Additional performance threshold (to earn bonus payment)	70 points	70 points	75 points	85 points	**85 points**

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- **Visit the QPP website, http://qpp.cms.gov, to find information and tools related to QPP.** This is the same website were clinicians go to engage in the program, such as electing various participation options and submitting performance data.

- **Commenting on the Proposed Rule.** The deadline for submitting comments is **5:00 p.m. EDT on October 5, 2020.** Commenters must refer to file code CMS-1734-P when commenting on the Proposed Rule. Interested stakeholders can submit comments electronically by visiting Regulations.gov. Alternatively, comments can be submitted by mail to the following addresses:

  Regular Mail
  Centers for Medicare & Medicaid Services
  Department of Health and Human Services
  Attention: CMS-1734-P
  P.O. Box 8016
  Baltimore, MD 21244-8016

  Express or Overnight Mail
  Centers for Medicare & Medicaid Services
  Department of Health and Human Services
  Attention: CMS-1734-P
  Mail Stop C4-26-05
  7500 Security Boulevard
  Baltimore, MD 21244-1850

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Glossary

Key Term	Definition
CPT	Current Procedural Terminology (CPT) is a medical code set that is developed by the American Medical Association and is used by physicians, hospitals, outpatient facilities, laboratories, and other health care professionals to describe the procedures and services they perform.[50]
E/M	Evaluation and management (E/M) codes classify services provided by physicians and other practitioners in evaluating patients and managing their medical care. E/M codes vary based on level of complexity, site of service, and whether the patient is new or established.[51]
WAC	Wholesale Acquisition Cost (WAC) is the manufacturer's published "list price" for a drug to wholesalers or direct purchasers. WAC is reported in wholesale price guides or other publications of drug pricing data. It does not include discounts or rebates.[52]
Conversion Factor	CMS uses a conversion factor to convert national relative value units (RVUs) into payment rates. For each service, RVUs are established for physician work, practice expense, and malpractice insurance. These RVUs are adjusted for geographic cost variations and multiplied by a conversion factor to convert them into payment rates.[53]
Budget Neutrality Adjustment	The Social Security Act prohibits any increase or decrease in relative value units (RVUs) from causing the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to the conversion factor to preserve budget neutrality.[54]
505(b)(2) Drug Product	A 505(b)(2) application is a New Drug Application (NDA) that contains full reports of investigations of safety and effectiveness, but at least some of the information required for approval comes from studies not conducted by or for the application and for which the applicant has not obtained a right of reference or use.[55]
CPT and HCPCS Codes for Immunization Administration Services	• CPT code 90460 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered) • CPT codes 90461 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered) • CPT code 90471 (Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid))

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	• CPT code 90472 (Immunization administration includes percutaneous, intradermal, subcutaneous, or intramuscular injections) • CPT code 90473 (Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)) • CPT code 90474 (Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)) • HCPCS code G0008 (Administration of influenza virus vaccine) • HCPCS code G0009 (Administration of pneumococcal vaccine) • HCPCS code G0010 (Administration of hepatitis b vaccine)

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[1] Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P), Proposed Rule, 85 Fed. Reg. 50,074 (Aug. 17, 2020), *available at* https://www.govinfo.gov/content/pkg/FR-2020-08-17/pdf/2020-17127.pdf [hereinafter "Proposed Rule"].

[2] *Id.* at 50,336–37.

[3] *Id.* at 50,121–39.

[4] *Id.* at 50,122–23.

[5] *Id.* at 50,123–24.

[6] *Id.* at 50,124–37.

[7] *Id.* at 50,124.

[8] *Id.* at 50,169–70.

[9] *Id.* at 50,170.

[10] *Id.* at 50,171.

[11] *Id.* at 50,095, 50,097.

[12] *Id.* at 50,097.

[13] *Id.* at 50,099.

[14] *Id.*

[15] *Id.*

[16] *Id.* at 50,100–01.

[17] *Id.* at 50,117–20.

[18] *Id.* at 50,115.

[19] *Id.* at 50,116.

[20] *Id.* at 50,380–81.

[21] *Id.* at 50,373.

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[22] *Id.* at 50,162–63.

[23] *Id.* at 50,163.

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.* at 50,264–65.

[30] *Id.*

[31] *Id.* at 50,264.

[32] *Id.* at 50,146.

[33] *Id.*

[34] *Id.* at 50,148.

[35] *Id.* at 50,260–61.

[36] *Id.* at 50,261.

[37] CMS, Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI), 85 Fed. Reg. 47,151 (Aug. 4, 2020).

[38] The Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015) [hereinafter "MACRA"].

[39] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-F), 83 Fed. Reg. 59,452, 59,754–55 (Nov. 23, 2018), *available at* https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions [hereinafter "CY 2019 Final Rule"].

[40] Proposed Rule at 50,313.

[41] *Id.* at 50,294.

[42] CY 2019 Final Rule at 59,773.

[43] 85 Fed. Reg. 19,230 (April 6, 2020); 85 Fed. Reg. 27,550 (May 8, 2020).

[44] Proposed Rule at 50,294.

[45] CMS, Medicare Program; CY 2021 Quality Payment Program Proposed Rule Overview Fact Sheet 27, *available at* https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-4 [hereinafter CY 2021 QPP Fact Sheet].

[46] CY 2018 Final Rule at 53,644–45.

[47] Proposed Rule at 50,276.

[48] *Id.* at 50,318.

[49] CY 2021 QPP Fact Sheet at 29.

[50] AAPC, Medical Coding, What is CPT?, *available at* https://www.aapc.com/resources/medical-coding/cpt.aspx (last accessed Aug. 6, 2020).

[51] Proposed Rule at 50,121.

[52] 42 U.S.C. § 1395w–3a(c)(6)(B).

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[53] Proposed Rule at 50,076.

[54] *Id.* at 50,373.

[55] Federal Food, Drug, and Cosmetic Act § 505(b)(2); FDA, Determining Whether to Submit an ANDA or a 505(b)(2) Application (May 2019) at 2, *available at* https://www.fda.gov/media/124848/download.

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