



2021 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule Summary

On August 4th, the Centers for Medicare & Medicaid Services (CMS) released a [proposed rule](#) for the 2021 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP). Comments are due to CMS no later than October 5, 2020. The AMA plans on sharing its draft comments with the Federation prior to the due date. CMS usually publishes the final rule 60 days prior to its effective date, which would be around November 1. However, due to the COVID-19 public health emergency (PHE), the agency is waiving this requirement and replacing it with a 30-day notification timeline. This means the final rule will be effective on January 1, 2021, even though it may not be published until December 1, 2020.

The proposed rule covers diverse topics including the calendar year (CY) 2021 Conversion Factor, Evaluation/Management (E/M) office visit services, telehealth and other services involving communications technology, scope of practice, and updates to the Quality Payment Program through Merit-based Incentive Payment System (MIPS) activities, methodology, payment adjustments, and the Promoting Interoperability performance category. Key points of the proposed rule include:

- The proposed CY 2021 Medicare Physician Fee Schedule (PFS) **conversion factor is \$32.26**, which represents an almost **11% reduction** from the CY 2020 conversion factor of \$36.09.
- Similarly, the proposed CY 2021 **anesthesia conversion factor is \$19.96**, down 10% from the CY 2020 anesthesia conversion factor of \$22.20.
- **The AMA/Specialty Society RVS Update Committee (RUC)'s recommendations account for only half of the reduction. The remaining spending increases and resulting conversion factor reduction is attributed to various CMS proposals to increase valuation for specific services.**
- CMS proposed to accept approximately 75% of the RUC recommendations for Physician Work RVU Updates. Updates to the direct practice expense inputs are proposed for individual codes based on RUC recommendations. The proposed rule **does not include the 1.0 work geographic practice cost index (GPCI) floor.**
- CMS proposes to implement finalized CPT descriptors, guidelines and payment rates effective on January 1, 2021, which will be a **significant modification to the coding, documentation, and payment of evaluation and management (E/M) services for office and outpatient visits**: retain 5 levels of coding for established patients, reduce to 4 levels for new patients, and revise code definitions. CMS revalues services analogous to office outpatient E/M visits.
- CMS proposes to allow the three G-codes used to report **opioid use disorder (OUD) to also be used for monthly treatment reporting for patients with substance use disorder (SUD) as well.** So that they could be used to report monthly treatment of patients with any SUD, not just OUD.
- Due to statutory constraints, CMS **does not propose to permanently extend the Medicare telehealth geographic and site of service originating site restrictions** (Section 1834(m)), which temporarily allows Medicare beneficiaries across the country to receive care from their homes.

- CMS has proposed to **permanently keep several codes that were temporarily added to the Medicare telehealth list, including the prolonged office or outpatient E/M visit code and certain home visit services**. CMS also proposes to keep additional services, including certain emergency department visits, on the Medicare telehealth list until the end of the calendar year in which the PHE ends to allow more time to study the benefit of providing these services using telecommunications technology outside the context of a pandemic.
- CMS proposes to add a **third temporary category (Category 3) of criteria for adding services to the telehealth list during a PHE**. Medicare telehealth visits to nursing facility settings are expanded from once every 30 days to once every 3 days.
- CMS made a number of care management services and **remote physiologic monitoring (RPM) proposals** including allowing RPM services only to an established patient, allowing consent for RPM to be obtained at the time services are furnished, and allowing auxiliary personnel to furnish RPM under general supervision of the billing physician or practitioner.
- **Scope of practice** issues are prevalent in the CMS Medicare PFS.
 - CMS proposes to allow a **teaching physician** to use two-way audio/video communications technology to provide **direct supervision to a resident** through the later of the end of the COVID-19 PHE or December 31, 2021. CMS seeks comment on guardrails or limitations if this policy were to continue temporarily or were made permanent.
 - During the COVID-19 PHE, CMS expanded the list of services included in the primary care exception to allow Medicare PFS payments to certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. CMS is considering whether this expansion should be made permanent.
 - CMS is proposing to specify that **the supervision of diagnostic psychological and neuropsychological testing services** can be done by Nurse Practitioners (NP), Clinical Nurse Specialists (CNS), and Certified Nurse Midwives (CNM) to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and clinical psychologists (CP) who are currently authorized to supervise these tests. Moreover, CMS is proposing to specify that diagnostic tests performed by a Physician Assistant (PA) in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests.
 - **Pharmacists**, who come under the category of auxiliary personnel, may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or nonphysician practitioners (NPP), if payment for the services is not made under the Medicare Part D benefit.
 - CMS is proposing to make the policy established during the COVID–19 PHE permanent which allows a physical therapist (PT) or occupational therapist (OT) who establishes a maintenance program to assign the **duties to a physical therapist assistant (PTA) or occupational therapy assistant (OTA)**, as clinically appropriate, to perform **maintenance therapy services**.
- CMS proposes to require **electronic prescribing for controlled substances** for Medicare prescriptions beginning in 2022 instead of 2021.

- CMS proposes to allow all **Medicare Diabetes Prevention Program (MDPP)** services to be delivered virtually during the current COVID-19 PHE as well as future declared emergencies if suppliers are unlikely to be able to deliver classes in-person. However, the proposed rule stops short of allowing providers of virtual-only DPP services to enroll as MDPP suppliers. Exceptions to the once-per-lifetime policy are made for those who do not continue through virtual classes.
- CMS will develop a new model to test innovative payment mechanisms to allow **rural healthcare providers** to provide the necessary level and quality of care related to the establishment of predictable financial payments and high-quality, value-based care.
- CMS is postponing Merit-based Incentive Payment System (**MIPS**) **Value Pathways (MVP)** implementation and plans to propose an initial set of MVPs and detailed policies for the 2022 performance period.
- CMS proposes to **increase the performance threshold** to avoid a penalty from 45 points in 2020 to 50 points in 2021, which is a more gradual increase than the previously finalized increase to 60 points. CMS proposes to maintain **the exceptional performance threshold** at 85 points in 2021. CMS proposes **no changes to the complex patient bonus** for the 2021 performance period. However, CMS proposes to retroactively increase the maximum complex patient bonus from five points to ten points for the 2020 performance period in response to the COVID-19 pandemic.
- CMS proposes to **lower the weight of the Quality Category performance score** from 45 percent to 40 percent of the MIPS final score and increase the weight of the Cost performance category from 15 percent of the MIPS final score to 20 percent. Promoting Interoperability and Improvement Activities categories would remain at 25 percent and 15 percent of the MIPS final score, respectively. CMS proposes to **increase the weight of the Cost Performance Category** from 15 to 20 percent of the MIPS final score.
- CMS proposes to **add telehealth services to the previously established cost measures**. These services were not previously included in the measures because they were newly included on the Medicare telehealth list during the COVID-19 public health emergency (PHE) or not billed widely enough to be found in empirical claims-based data.
- CMS proposes changes to the way the agency distributes **Alternative Payment Model (APM) incentive payments** to qualified participants (QPs) and to update the methodology for calculating QP thresholds. In response to the COVID-19 PHE, CMS does not plan to amend the list of Advanced APMs in 2020 and would not revoke QP status in certain circumstances, such as when an APM terminates its participation early due to the pandemic.
- CMS estimates approximately 930,000 clinicians will be **MIPS eligible in 2021**: approximately 92.5 percent of eligible clinicians who submit data will receive a positive or neutral payment adjustment, the mean final score would be 76.75, the median would be 81.32, the maximum positive payment adjustment would be 6.9 percent, and the maximum penalty would 9 percent (subject to variations from final calculations and COVID-19 impacts).
- For performance year 2021, CMS is proposing that Accountable Care Organizations (ACOs) participating in the **Medicare Shared Savings Program** would be required to report quality measure data for purposes of the Shared Savings Program via the APP, instead of the CMS Web Interface.

Medicare Physician Fee Schedule

PAYMENT ISSUES

CY 2021 Conversion Factor

The proposed CY 2021 Medicare Physician Fee Schedule (PFS) conversion factor is \$32.26 (CY 2020 conversion factor was \$36.09). The conversion factor update of almost -11 percent (-10.61 percent actual calculation) reflects a budget neutrality adjustment for reductions in relative values for individual services in 2021 and a zero percent statutory adjustment factor.

The proposed CY 2021 anesthesia conversion factor is \$19.96 (CY 2020 anesthesia conversion factor was \$22.20). The anesthesia conversion factor update of -10 percent reflects the same -10.61 percent RVU budget neutrality adjustment and the zero percent statutory adjustment factor as the Medicare PFS conversion factor above, but is also includes a +0.59 anesthesia fee schedule practice expense and malpractice adjustment.

The drastic 11% reduction in the Medicare conversion factor is necessitated by proposed additional spending of \$10.2 billion. The AMA/Specialty Society RVS Update Committee (RUC)'s recommendations account for only half of this additional spending, and therefore, half of the reduction. The remaining spending increases and resulting conversion factor reduction is attributed to various CMS proposals to increase valuation for specific services, as described in this table.

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| Increases to E/M Office Visits (99202-99215; 99XXX) | \$ 5,600,000,000 |
| GPC1X E/M Office Visit Primary Care Add-on* | \$ 3,300,000,000 |
| Immunization Administration (CPT codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS codes G0008, G0009, and G0010) | \$ 320,000,000 |
| End Stage Renal Disease Services (90951-90970) | \$ 270,000,000 |
| Psychiatric Diagnostic Evaluation and Psychotherapy (90791, 90792, 90832, 90834, 90837) | \$ 245,000,000 |
| Initial Preventive Physical Exam and Annual Wellness Visits (G0402, G0438 and G0439) | \$ 194,000,000 |
| Emergency Department Visits (CPT codes 99281-99285) | \$ 174,000,000 |
| Physical and Occupational Therapy Evaluation (97161-97164, 97165-97168) | \$ 72,000,000 |
| Transitional Care Management (99495-99496) | \$ 58,000,000 |

**Increase in Utilization Assumptions for GPC1X for CY2021 NPRM Relative to CY2020 Final Rule \$800 million*

Table 90: CY 2021 PFS Estimated Impact on Total Allowed Charged by Specialty is included at the end of this document.

Relative Value Unit (RVU) and Geographic Practice Cost Index (GPCI) Updates

Physician Work RVU Updates

CMS has proposed to accept approximately 75% of the RUC recommendations. The RUC recommendations, voting report, and minutes are publicly available at <https://www.ama-assn.org/about/rvs-update-committee-ruc/ruc-recommendations-minutes-voting>. AMA staff will work with the specialty societies to provide comments to urge that CMS will accept a greater number of these recommendations in the Final Rule.

Practice Expense RVU Updates

Updates to the direct practice expense inputs are proposed for individual codes based on recommendations from the RUC. CMS continues to transition to updated pricing for medical supplies and equipment with CY2022 being the final year of the 4 -year phase-in period. Several updates are proposed for supplies and equipment based on invoices supplied by specialty societies. The RAND Corporation continues its CMS-commissioned study to identify potential improvements to CMS' practice expense allocation methodology. RAND has issued a new report on its latest phase of research, available at www.rand.org/t/RR3248. Concurrently, the AMA has engaged in a pilot study to determine the best practices and methodology to collect practice expense data. The AMA will convene meetings with CMS and with the national medical specialty societies and other health care organizations to share lessons learned from the pilot study and to discuss the potential for a large-scale data collection effort.

Geographic Practice Cost Indices (GPCI) Updates

For CY 2021, the proposal does not include the 1.0 work GPCI floor, as the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 only extended the floor through November 30, 2020.

Office and Outpatient Evaluation and Management (E/M) Services

CMS proposes to implement finalized CPT descriptors, guidelines and payment rates on January 1, 2021, which will be a significant modification to the coding, documentation, and payment of evaluation and management (E/M) services for office and outpatient visits. The CPT coding changes will retain 5 levels of coding for established patients, reduce the number of levels to 4 for new patients, and revise the code definitions. A new CPT code for extended office visit time will also be implemented. History and physical exams should continue to be performed as medically appropriate; however, these elements will no longer be a consideration for code level selection. Physicians can choose the E/M visit level based on either medical decision making or time.

CMS previously adopted the RUC recommended values, times, and practice costs for the stand-alone E/M office visits. CMS proposes to modify the time values for the codes by adopting the sum of the pre-service, intra-service, and post-service times. The RUC recommendations contribute to an approximate 5 percent reduction between those physicians who routinely provide office visits and those physicians or other health professionals who do not report office visits.

In addition to the CPT and RUC recommended changes, CMS previously finalized separate payment for a Medicare-specific add-on for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition. CMS seeks comment about how to address concerns with the lack of clarity in the definition of this add-on code. CMS impact tables indicate that approximately \$3.3 billion will be redistributed between specialties if this code is implemented.

Revaluing Services that are Analogous to Office/Outpatient E/M Visits

CMS proposes to revalue the following services to reflect the increased value of the office/outpatient E/M services:

- ESRD monthly capitation payment services,
- transitional care management services,
- cognitive impairment assessment and care planning services,
- maternity care global services,
- initial preventive physical examinations,
- annual wellness visits,
- emergency department visits,
- therapy evaluation services, and
- psychiatric diagnostic evaluation services.

Although the surgical specialties participated in the RUC survey and their data were similar to other specialties, CMS proposes not to apply the office visit increases to the visits bundled into global surgery packages.

Substance Use Disorder (SUD) Treatment

Effective in 2020, CMS established three G-codes to report monthly treatment of patients with opioid use disorder (OUD). The codes include development of a treatment plan, care coordination, and individual and group therapy and counseling. Medications to treat OUD are paid separately. For 2021, CMS proposes to modify the three codes so that they could be used to report monthly treatment of patients with any SUD, not just OUD. The codes were also added to the Telehealth List in 2020 and will remain on the list in 2021. CMS seeks comment on whether the resource costs involved in treating different SUDs are different and whether more stratified coding is needed to reflect these differences. CMS also is proposing a new G-code for initiation of medication-assisted treatment for OUD in the emergency department including assessment, referral to ongoing care, and arranging access to supportive services. Also effective in 2020, CMS began providing weekly payments to opioid treatment programs. For 2021, CMS proposes to add naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and allow Opioid Treatment Programs (OTPs) to be paid for dispensing naloxone to patients receiving OUD treatment services. CMS also seeks comments on whether a new code should be established for OTPs to educate patients about preventing overdose.

TELEHEALTH ISSUES

During the COVID-19 PHE, pursuant to authority granted in the CARES Act, CMS waived the geographic and site of service originating site restrictions for Medicare telehealth services, allowing Medicare beneficiaries across the country to receive care from their homes. These flexibilities remain in effect as Health and Human Services Secretary Azar recently extended the PHE declaration through October 23, 2020. CMS does not propose to permanently waive these restrictions in the PFS because it lacks authority to make this adjustment. The AMA has been aggressively lobbying Congress to remove the geographic and site of service originating restrictions, and is closely monitoring a variety of bills that would make changes to 1834(m). Permanent changes to the geographic and originating site of service restrictions will require Congressional legislation.

Medicare telehealth services have been dramatically expanded during the COVID-19 PHE. CMS has proposed to permanently keep several codes that were temporarily added to the Medicare telehealth list, including the prolonged office or outpatient E/M visit code and certain home visit services. CMS also proposes to keep additional services, including certain emergency department visits, on the Medicare telehealth list until the end of the calendar year in which the PHE ends to allow more time to study the benefit of providing these services using telecommunications technology outside the context of a pandemic. This new Category 3 would provide a basis for adding or deleting services from the Medicare

telehealth list on a temporary basis where there is likely clinical benefit, but where there is not yet sufficient evidence available to permanently consider the services under Category 1 or 2 criteria. CMS requests comments on the Category 3 approach.

Category 3 Addition

CMS solicits comments on Medicare telehealth services which were added on an interim basis during the COVID-19 PHE that it is not proposing to retain after the PHE ends. Although planning to let these interim telehealth services expire at the conclusion of the PHE, comments will help inform final decisions on whether the services should be added to Category 3, and inform CMS' future thinking on these services. (See Table 11: Telehealth services for the PHE that are not CY 2021 Medicare Telehealth Proposals)

Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations

CMS seeks comment on whether it is appropriate to maintain the COVID-19 PHE flexibilities which allow physicians and NPPs to perform required visits for nursing home residents via telehealth using two-way, audio/visual communications technology. CMS also proposes to allow more frequent follow-up Medicare telehealth visits for nursing home residents, allowing a Medicare telehealth visits to be covered once every 3 days instead of once every 30 days. This is intended to put more autonomy in the hands of clinicians to decide the frequency of necessary visits via Medicare telehealth, and to afford nursing home residents more care if necessary.

CMS is not proposing to continue payment for Medicare audio-only visits after the conclusion of the COVID-19 PHE. CMS does not have the authority to permanently waive the requirement for two-way, audio/video communications. CMS will receive comments on whether it should develop coding and payment for a service similar to a virtual check-in, but for a longer unit of time and with a higher value. CMS seeks comments on appropriate guardrails or limitations on telehealth services to ensure patient safety, clinical appropriateness, and to prevent fraud and abuse.

Care Management Services and Remote Physiologic Monitoring (RPM)

CMS proposes several code refinements for remote physiologic monitoring, transitional care management (TCM) and psychiatric collaborative care model (CoCM) services:

- The medical device should digitally (automatically) upload patient physiologic data;
- RPM may be used to remotely collect and analyze physiologic data from patients with acute conditions as well as from patients with chronic conditions;
- Interactive communication must total a least 20 minutes of interactive time over the calendar month to be reported;
- Consent for RPM services may be obtained at the time the RPM services are furnished;
- Auxiliary personnel may furnish RPM services under the general supervision of the billing physician or practitioner; and
- At the end of the COVID-19 PHE, RPM services must be furnished only to an established patient.

SCOPE OF PRACTICE and RELATED ISSUES

CMS' policies on scope of practice continue from Executive Order 13890, which modifies supervision requirements in Medicare that "limit healthcare professionals from practicing at the top of their license." CMS believes "physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure ..." and proposes policies from that position. CMS seeks information and comments on a number of issues related to scope of practice:

1. Which states that have licensure or scope of practice laws in place, as well as any facility-specific policies, that would impact the ability of clinicians to exercise the flexibilities CMS is proposing. This includes understanding the scope of practice of auxiliary staff (some of whom are not licensed) who might provide tests under the supervision of a NPP, including RNs, LPNs, medical assistants, radiologic technicians and others. CMS seeks information about specific services (service-level information).
2. Whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities if CMS were to adopt the policies proposed in this section, and to what extent practitioners would be permitted to exercise these proposed flexibilities, such as for all diagnostic tests or only a subset.

Teaching Physician and Resident Moonlighting Policies

CMS is considering whether the teaching physician and resident moonlighting policies enacted during the COVID-19 PHE should be extended on a temporary basis (that is, through December 31, 2021 if the PHE ends in 2021) or whether the flexibilities should be made permanent. During the COVID-19 PHE, CMS allowed the teaching physician to satisfy supervision requirements using audio/video real-time communications technology to direct the care furnished by a resident, and to review the services furnished by the resident during or immediately after a visit, remotely. CMS pays for the interpretation of diagnostic radiology and other diagnostic tests if when performed by a resident as long as the teaching physician is present through audio/video real-time communications technology. CMS also permits a teaching physician to direct a resident during psychiatric service using audio/video real-time communications technology.

CMS proposes to allow a teaching physician to use two-way audio/video communications technology to provide direct supervision to a resident through the later of the end of the COVID-19 PHE or December 31, 2021. CMS seeks comment on guardrails or limitations if this policy were to continue temporarily or made permanent. CMS has raised concerns that extending these teaching physician-resident flexibilities past the PHE may decrease the quality of patient care and fail to provide residents with the necessary teaching that comes with in-person training. CMS pointed out that once the PHE concludes, the patient would need to be located at a telehealth originating site, and the teaching physician would need to furnish the service as the distant site practitioner with the involvement of the resident. Telehealth rules at Section 1834(m) would apply.

Primary Care Exception Policies

CMS raised concerns that “primary care exception” policies during COVID-19 PHE may be inappropriate to extend on a temporary basis or to permanently add once the PHE ends. Under the primary care exception, Medicare makes PFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. In the March 31st COVID-19 Interim Final Rule with Comments (IFC), CMS allowed all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. In the May 1st COVID-19 IFC, CMS further expanded the list of services included in the primary care exception during the PHE for COVID-19. CMS also allowed PFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services. These services included CPT codes: 99204, 99205, 99214, 99215, 99495, 99496, 99421, 99422, 99423, 99452 G2012, and HCPCS code G2010.

Supervision of Diagnostic Tests by Certain NPPs

Effective January 1, 2021, CMS is proposing to amend the basic rule under the regulation at § 410.32(b)(1) to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as

allowed by state law and scope of practice. Prior to the COVID-19 PHE, physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who were treating a Medicare beneficiary for a specific medical problem could order diagnostic tests when they used the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests. In the May 1st COVID-19 IFC, CMS permitted, during the COVID-19 PHE, PAs, NPs, and certain other NPPs to supervise diagnostic tests. CMS is proposing to make this supervision practice permanent.

These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or "incident to" their own professional services, to the extent authorized under state law and scope of practice. CMS is proposing to permanently amend the regulation to specify that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and CPs who are currently authorized to supervise these tests.

CMS is also proposing to permanently amend the regulation to specify that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians would continue to apply. CMS is also proposing to permanently eliminate the requirement that a general level of physician supervision is necessary for diagnostic tests performed by a PA.

Pharmacists Providing Services Incident To Physicians' Services

CMS reiterated its clarification that pharmacists fall within the regulatory definition of auxiliary personnel. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law. CMS believes this clarification may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training, licensure, and scope of practice.

Provision of Maintenance Therapy by Therapy Assistants

During the COVID-19 PHE, CMS allow the physical therapist (PT) or occupational therapist (OT) who established the maintenance program to assign the duties to a physical therapy assistant (PTA) or occupational therapy assistant (OTA), as clinically appropriate, to perform maintenance therapy services. CMS proposes to make permanent the Part B policy for maintenance therapy services. If adopted, the policy would dovetail with the amended policy set forth during the COVID-19 PHE that grants PTs and OTs the discretion to delegate maintenance therapy services to PTAs and OTAs, as clinically appropriate, for the duration of the PHE. If the PHE is ended prior to January 1, 2021, the therapist would need to personally furnish the maintenance therapy services until the proposed policy change takes effect.

CMS proposes to allow, on a permanent basis, therapists to delegate performance of maintenance therapy services to an OTA or PTA for outpatient occupational and physical therapy services in Part B settings beginning January 1, 2021. CMS seeks to clarify that PTs and OTs no longer need to personally perform maintenance therapy services, and specifically removes the prohibitions on PTAs and OTAs from furnishing such services.

Medical Record Documentation

Any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record

for the services they bill, rather than re-document the notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. The broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team also applies to therapists.

OTHER PROVISIONS

Electronic Prescribing for Controlled Substances (EPCS)

The Support for Patients and Communities Act (SUPPORT Act) included a requirement that Medicare Part D prescriptions for controlled substances be electronically prescribed starting in 2021 and that the U.S. Drug Enforcement Administration (DEA) update its EPCS regulations pertaining to the biometric component of two-factor authentication. Recently, to facilitate this update, the DEA reopened the comment period on its 2010 EPCS interim final rule. The current CMS proposed rule outlines the advantages of EPCS over paper prescriptions, but also describes a number of hurdles to greater physician adoption of EPCS, including the existing DEA requirements for two-factor authentication. The proposed rule also indicates that the COVID-19 public health emergency presents additional difficulties for medical practices that wish to adopt EPCS. As a result, CMS proposes to require EPCS for Medicare prescriptions beginning in 2022 instead of 2021.

There are at least 25 states with an EPCS requirement for some or all controlled substances, with a majority of those taking effect on January 1, 2021.

Part B Drug Payment for Drugs Approved Under Section 505(b)(2) of the FDCA

CMS is proposing to codify existing policy related to drug products approved under section 505(b)(2) of the Food, Drug, and Cosmetic Act (FDCA). Section 505(b)(2) establishes FDA's abbreviated approval pathway for new drug products. For reimbursement purposes, these products can be defined as either a single source drug or a multiple source drug; depending on the definition, the products are assigned to either a single source or multiple source drug code. CMS is proposing to codify policy allowing for an expansive reading of the definition of multiple source drug, which would allow the agency to assign to a multiple source drug code any new drug product approved under the 505(b)(2) pathway that aligns with an existing code descriptor for a multiple source. CMS notes this codification will help combat high drug prices, as drug manufacturers frequently seek single source code for new drug products as a way to ensure higher reimbursement. CMS also seeks to limit opportunities for manufacturers to game the approval and reimbursement systems.

Clinical Laboratory Fee Schedule – Reporting Period and Data Collection Conforming Regulatory Changes

The Further Consolidated Appropriations Act of 2020 (FCAA) and Coronavirus Aid, Relief, and Economic Security Act (CARES) of 2020 both made legislative changes to the Clinical Laboratory Fee Schedule (CLFS) data reporting and data collection periods to provide some relief to laboratories required to report data on services on the CLFS to CMS. In this proposed rule, CMS proposes regulatory changes to conform to the statutory requirements of the FCAA and CARES Act. The changes to the data collection period, data reporting period, and payment reduction schedule would be as follows:

- Data reporting for labs required to report begins January 1, 2021, and is required every three years beginning January 1, 2022;
- For the data reporting period beginning January 2022, the data collection period is January 1, 2019 through June 30, 2019;
- There is no phased-in payment reduction for CY 2021, and payment reductions are not to exceed 15 percent for CY 2022 – CY2024. Previously, payment reductions were capped at 10 percent.

Payment for Specimen Collection for COVID-19 Clinical Diagnostic Tests

CMS seeks comment on whether the HCPCS codes created for COVID-19 specimen collection by independent laboratories should be deleted once the public health emergency ends.

Medicare Diabetes Prevention Program (MDPP)

Although CMS has permitted many MDPP services to be provided virtually during the COVID-19 public health emergency, it has continued to require the first core session to be provided in-person, which has effectively prevented new patient cohorts from starting the program during the pandemic. The AMA had urged CMS to lift this restriction, and effective in 2021 the proposed rule would drop that requirement and allow all MDPP services to be delivered virtually during the current emergency as well as future declared emergencies if suppliers are unlikely to be able to deliver classes in-person. The proposed rule stops short of allowing providers of virtual-only DPP services to enroll as MDPP suppliers, however. CMS also proposes to allow patients to report their weight through virtual means, such as Bluetooth-enabled scales. As it would be possible for patients participating in MDPP virtually during an emergency to submit their weight, the minimum weight loss requirements for maintenance session eligibility would be reinstated. As is permitted during the COVID-19 emergency, CMS proposes to allow exceptions to the once-per-lifetime limit on patients obtaining the set of MDPP services for future emergencies for patients who do not continue in the program through virtual classes.

Rural Health Model with Payment Innovation

On August 3rd, the White House issued an Executive Order on improving rural health and telehealth access. Under the Executive Order, CMS will develop a new model to test innovative payment mechanisms with flexibilities from existing Medicare rules to allow rural healthcare providers to provide the necessary level and quality of care. The Executive Order calls for the establishment of predictable financial payments and encourages the movement into high-quality, value-based care. The model is to be announced within 30 days of the Executive Order.

Quality Payment Program

MIPS Value Pathways (MVPs)

In light of the COVID-19 pandemic, CMS is postponing the 2021 MVP implementation and plans to propose an initial set of MVPs and detailed policies for the 2022 performance period. CMS previously finalized a broad framework for MVPs, which would consist of a set of measures tailored to an episode of care or condition and would be developed by specialty societies and other stakeholders. The MVP approach responds to some of the recommendations made to CMS by the AMA after significant consultation with specialty and state medical societies about opportunities to improve MIPS and move away from the current check-the-box reporting requirements.

CMS proposes additions to the MVP guiding principles and MVP candidate development and submission process. For instance, CMS proposes that stakeholders consult patients and/or patient representatives as part of the MVP development process as a pre-requisite for CMS to consider the candidate MVP and must include the full set of Promoting Interoperability measures in their MVP. Stakeholders would formally submit their MVP candidates using a standardized template on a rolling basis throughout the year. CMS and its contractors would then review, vet, and evaluate MVP candidates, reaching out to the stakeholders as needed to answer questions. For MVP candidates that are deemed feasible, CMS proposes to schedule a feedback loop meeting with the stakeholders to discuss any recommended modifications to the MVP candidate. MVPs must then be established through rulemaking. CMS seeks comment on this process, as well as ways to make the process more transparent in future years.

Performance Threshold and Complex Patient Bonus

CMS proposes to increase the performance threshold to avoid a penalty from 45 points in 2020 to 50 points in 2021, which is a more gradual increase than the previously finalized increase to 60 points. CMS also proposes to maintain the exceptional performance threshold at 85 points in 2021, the same threshold as in 2020. The exceptional performance threshold is the minimum score needed to be eligible to receive a MIPS bonus outside of budget neutrality from a separate \$500 million fund.

CMS proposes no changes to the complex patient bonus for the 2021 performance period. However, CMS proposes to retroactively increase the maximum complex patient bonus from five points to ten points for the 2020 performance period in response to the COVID-19 pandemic. CMS believes the existing complexity indicators, HCC risk score and dual Medicare and Medicaid eligibility, serve as a proxy for capturing the increased complexity due to the pandemic.

Performance Category Weights

CMS proposes to increase the weight of the Cost performance category from 15 percent of the MIPS final score to 20 percent. Promoting Interoperability and Improvement Activities categories would remain at 25 percent and 15 percent of the MIPS final score, respectively.

Quality Performance Category

CMS proposes to lower the weight of the Quality Category performance score from 45 percent to 40 percent of the MIPS final Score. CMS also proposes a total of 206 quality measures for the 2021 performance period, which reflects proposed changes on the following:

- Substantive changes to 112 existing MIPS quality measures;
- Changes to specialty sets;
- Removal of measures from specific specialty sets;
- Removal of 14 quality measures;
- 2 new administrative claims outcome quality measures

The 2 administrative claims measures are:

- (1) a new Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups, and
- (2) Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians.

The HWR measure would replace to the existing All-Cause Hospital Readmission measure and continue to only apply to groups or virtual groups with 16 or more clinicians that meet the case minimum of 200 cases over a one-year measurement period. The new Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA)/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians is proposed to apply to individual clinicians, groups and virtual groups that meet the 25 case minimum over a three year measurement period.

CMS also proposes to eliminate the GPRO web-interface as a collection type and submission type for groups and virtual groups beginning with the 2021 performance period. All other collection types for individuals, groups and virtual groups would remain the same in 2021. In addition, CMS proposes to revise and expand their scoring flexibility policy that may be triggered due to updates to clinical guidelines or measures specifications, such as revisions to medication lists, codes and clinical actions. Therefore, based on the timing of the change and the availability of data, CMS may either:

- Truncate the performance period to 9 consecutive months, if there were no concerns with potential patient harm and 9 consecutive months of data were available; or
- Suppress the measure from scoring (0 achievement points and total measure achievement points reduced by 10 for each measure submitted that is impacted) if 9 consecutive months of data were not available.

Due to COVID-19, CMS intends to use performance period benchmarks for the CY 2021 MIPS performance period rather than baseline period historic data. CMS is concerned they may not have a representative sample of historic data for CY 2019 because of the national public health emergency for COVID-19 (which impacted data submission in 2020), which could skew benchmarking results.

Qualified Clinical Data Registry (QCDR) Measure Requirements:

Beginning with the 2022 performance period, QCDR measures must be fully tested at the clinician level in order to be considered for inclusion in an MVP. CMS originally finalized and required QCDR measures to be tested starting with the 2021 performance year, but delayed the requirement due to the COVID-19 pandemic.

Cost Performance Category

CMS proposes to increase the weight of the Cost Performance Category from 15 to 20 percent of the MIPS final score. By statute, CMS is required to increase the weight of the Cost Performance Category to 30 percent of the MIPS final score beginning in the 2022 performance period.

CMS proposes to add telehealth services to the previously established cost measures. These services were not previously included in the measures because they were newly included on the Medicare telehealth list during the COVID-19 PHE or not billed widely enough to be found in empirical claims-based data. Proposed updates to the measure specifications are available to download on the CMS [website](#).

Promoting Interoperability (PI) and Certified Health Information Technology (health IT) proposed changes

For the CY 2021 Medicare PI Program, CMS is proposing the following:

- Maintaining the continuous 90-day period EHR reporting period in CY 2022;
- Maintaining the Electronic Prescribing objective's Query of PDMP measure as optional but increasing the bonus points from five to 10 points;
- Adding a new Health Information Exchange (HIE) Bi-Directional Exchange measure to the HIE objective as an optional alternative to the two existing measures. Physicians either may report the two existing measures and associated exclusions OR may choose to report the new bi-directional exchange measure. The HIE Bi-Directional Exchange measure would be worth 40 points. The HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response. And
- Physicians participating in PI or QPP would be required to use only technology that is considered certified under the ONC Health IT Certification Program according to the timelines finalized in the 21st Century Cures Act final rule. Physicians may use the current 2015 Edition EHRs and/or 2015 Edition Update EHRs until August 2, 2022. After August 2, 2022, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

As the AMA reviews the Promoting Interoperability and health IT proposals, we do note initial concerns with the last proposal which would de-certify existing technology and force physicians to use only ONC certified technology.

Improvement Activities

For the CY 2021 Medicare PI Program, CMS is proposing the following:

- Changes to the Annual Call for Activities: An exception to the nomination period timeframe such that during a PHE, stakeholders can nominate improvement activities (IAs) outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, CMS would accept nominations for the duration of the PHE as long as the IA is still relevant. CMS would also establish a new criterion for nominating new IAs, "Activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible."
- HHS-nominated IAs: This change would establish a process to allow CMS to consider HHS-nominated improvement activities all year long in order to address HHS initiatives in an expedited manner.
- Modifications: CMS proposes to modify two existing IAs: (1) Engagement of patient through implementation of improvements in patient portal, and (2) Comprehensive Eye Exams.

Advanced Alternative Payment Model (APM) Proposals

CMS proposes changes to the way the agency distributes APM incentive payments to qualified participants (QPs). Because there is a two-year lag between when a group participates in an Advanced APM and when the payment is made, the agency has identified several challenges distributing these payments. CMS also proposes to update the methodology for calculating QP thresholds by excluding beneficiaries who are prospectively aligned to an APM Entity from the pool of attribution-eligible beneficiaries for other APM Entities in order to prevent diluting the QP threshold scores for participants in APMs that use retrospective attribution. CMS proposes to establish a targeted review period for correcting QP determination errors made by CMS. Finally, in response to the COVID-19 PHE, CMS does

not plan to amend the list of Advanced APMs in 2020 and would not revoke QP status in certain circumstances such as when an APM terminates its participation early due to the pandemic.

Projected 2021 QPP Participation and 2023 Payments Adjustments

CMS estimates approximately 930,000 clinicians will be MIPS eligible in 2021. Based on its proposals, CMS estimates approximately 92.5 percent of eligible clinicians who submit data will receive a positive or neutral payment adjustment. The mean final score would be 76.75 and the median would be 81.32. The maximum positive payment adjustment is estimated to be 6.9 percent, while the maximum penalty is 9 percent. CMS cautions that these estimates may change due to service and payment disruptions caused by the COVID-19 public health emergency.

CMS estimates between 196,000 and 252,000 clinicians will become QPs in 2021 and therefore be excluded from MIPS and qualify for the 5 percent incentive payment. This number is lower than estimates for 2019 and 2020. In 2021, the QP threshold is set to increase to at least 75 percent of Part B covered professional services or at least 50 percent of Medicare beneficiaries furnished Part B covered professional services through an APM Entity.

Medicare Shared Savings Program

For performance year 2021, CMS is proposing that Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program would be required to report quality measure data for purposes of the Shared Savings Program via the APP, instead of the CMS Web Interface. Under this new approach, ACOs would only need to report one set of quality metrics that would meet requirements under both MIPS and the Medicare Shared Savings Program. The total number of measures in the ACO quality measure set would be reduced from 23 to 6 measures. The redesign also raises the quality performance standard for ACOs under the Shared Savings Program. ACOs would now be required to receive a Quality performance score equivalent to or above the 40th percentile across all MIPS Quality performance category scores in order to share in savings or avoid owing maximum losses.

For performance year 2020, all ACOs are deemed affected by the COVID-19 pandemic Public Health Emergency (PHE), and thus, the Shared Savings Program extreme and uncontrollable circumstances policy applies. In addition, for performance year 2020 only, CMS is proposing to waive the requirement for ACOs to field a Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey. Consequently, ACOs would receive automatic full credit for the patient experience of care measures. The AMA will continue to monitor the impact of the COVID-19 pandemic on the MSSP program and assess whether additional flexibilities and changes are needed for 2020 or 2021 performance years

| (A) Specialty | (B) Allowed Charges (mil) | (C) Impact of Work RVU Changes | (D) Impact of PE RVU Changes | (E) Impact of MP RVU Changes | (F) Combined Impact |
|--|---------------------------------|--|--|--|---------------------------|
| Allergy/Immunology | \$246 | 5% | 4% | 0% | 9% |
| Anesthesiology | \$2,011 | -7% | -1% | 0% | -8% |
| Audiologist | \$74 | -4% | -2% | 0% | -7% |
| Cardiac Surgery | \$264 | -6% | -2% | -1% | -9% |
| Cardiology | \$6,849 | 1% | 0% | 0% | 1% |
| Chiropractor | \$759 | -7% | -3% | 0% | -10% |
| Clinical Psychologist | \$824 | -1% | 1% | 0% | 0% |
| Clinical Social Worker | \$851 | -1% | 1% | 0% | 0% |
| Colon And Rectal Surgery | \$168 | -4% | -1% | 0% | -5% |
| Critical Care | \$376 | -6% | -2% | 0% | -8% |
| Dermatology | \$3,758 | -1% | -1% | 0% | -2% |
| Diagnostic Testing Facility | \$813 | -1% | -5% | 0% | -6% |
| Emergency Medicine | \$3,065 | -5% | -1% | 0% | -6% |
| Endocrinology | \$506 | 11% | 6% | 1% | 17% |
| Family Practice | \$5,982 | 9% | 4% | 1% | 13% |
| Gastroenterology | \$1,749 | -3% | -1% | 0% | -5% |
| General Practice | \$405 | 5% | 2% | 0% | 8% |
| General Surgery | \$2,041 | -4% | -2% | 0% | -7% |
| Geriatrics | \$190 | 2% | 2% | 0% | 4% |
| Hand Surgery | \$245 | -2% | -1% | 0% | -3% |
| Hematology/Oncology | \$1,702 | 9% | 5% | 1% | 14% |
| Independent Laboratory | \$639 | -3% | -2% | 0% | -5% |
| Infectious Disease | \$653 | -4% | -1% | 0% | -4% |
| Internal Medicine | \$10,654 | 2% | 2% | 0% | 4% |
| Interventional Pain Mgmt | \$932 | 4% | 3% | 0% | 7% |
| Interventional Radiology | \$497 | -3% | -5% | 0% | -9% |
| Multispecialty Clinic/Other Phys | \$152 | -3% | -1% | 0% | -4% |
| Nephrology | \$2,213 | 4% | 2% | 0% | 6% |
| Neurology | \$1,513 | 3% | 2% | 0% | 6% |
| Neurosurgery | \$806 | -4% | -2% | -1% | -7% |
| Nuclear Medicine | \$56 | -5% | -3% | 0% | -8% |
| Nurse Anes / Anes Asst | \$1,316 | -9% | -1% | 0% | -11% |
| Nurse Practitioner | \$5,069 | 5% | 3% | 0% | 8% |
| Obstetrics/Gynecology | \$633 | 4% | 3% | 0% | 8% |
| Ophthalmology | \$5,328 | -4% | -2% | 0% | -6% |
| Optometry | \$1,349 | -2% | -2% | 0% | -5% |
| Oral/Maxillofacial Surgery | \$78 | -2% | -3% | 0% | -5% |
| Orthopedic Surgery | \$3,796 | -3% | -1% | 0% | -5% |
| Other | \$47 | -3% | -2% | 0% | -5% |
| Otolamgology | \$1,264 | 4% | 3% | 0% | 7% |
| Pathology | \$1,257 | -6% | -4% | 0% | -9% |
| Pediatrics | \$66 | 4% | 2% | 0% | 6% |
| Physical Medicine | \$1,157 | -3% | 0% | 0% | -3% |
| Physical/Occupational Therapy | \$4,946 | -5% | -5% | 0% | -9% |
| Physician Assistant | \$2,888 | 5% | 3% | 0% | 8% |
| Plastic Surgery | \$378 | -4% | -3% | 0% | -7% |
| Podiatry | \$2,111 | -1% | 0% | 0% | -1% |
| Portable X-Ray Supplier | \$94 | -2% | -4% | 0% | -6% |
| Psychiatry | \$1,099 | 4% | 3% | 0% | 8% |
| Pulmonary Disease | \$1,647 | 0% | 0% | 0% | 1% |
| Radiation Oncology And Radiation Therapy Centers | \$1,803 | -3% | -3% | 0% | -6% |
| Radiology | \$5,253 | -6% | -5% | 0% | -11% |
| Rheumatology | \$546 | 10% | 6% | 1% | 16% |
| Thoracic Surgery | \$350 | -5% | -2% | -1% | -8% |
| Urology | \$1,803 | 4% | 4% | 0% | 8% |
| Vascular Surgery | \$1,287 | -2% | -5% | 0% | -7% |
| TOTAL | \$96,557 | 0% | 0% | 0% | 0% |

* Column F may not equal the sum of columns C, D, and E due to rounding.