Medicare Physician Payment Schedule
Detailed Summary

OVERVIEW

On December 1, the Centers for Medicare & Medicaid Services (CMS) released a final rule for the 2021 Medicare Physician Payment Schedule (PFS) and Quality Payment Program (QPP). While the final rule is effective on January 1, 2021, CMS is implementing on an interim final basis the provisions on coding and payment of virtual check-in services and the coding and payment for personal protective equipment (PPE) and other infection control costs during the COVID-19 public health emergency (PHE). The AMA will issue comments on these provisions by the February 1, 2021 deadline.

The following is an executive summary of the calendar year (CY) 2021 Conversion Factor, telehealth and other services involving communications technology, scope of practice, various other provisions, and updates to the Quality Payment Program.

Following the executive summary is a more detailed summary on the following topics:

EXECUTIVE SUMMARY

PAYMENT PROVISIONS

CY 2021 Physician Fee Schedule Ratesetting and Conversion Factor

- The final CY 2021 Medicare Physician Fee Schedule (PFS) **conversion factor is $32.4085**, which represents a **10.2% reduction** from the CY 2020 conversion factor of $36.09.
- Similarly, the final CY 2021 **anesthesia conversion factor is $20.0547**, down 9.61% from the CY 2020 anesthesia conversion factor of $22.20.
- The most widespread specialty impacts of the relative value unit (RVU) changes are generally related to the changes to RVUs for specific services resulting from the E/M office visit increases and other changes made by CMS. The AMA/Specialty Society RVS Update Committee's (RUC) recommendations account for a 5.5 percent reduction to the conversion factor. The remaining spending increases and resulting conversion factor reduction is attributed to various CMS proposals to increase valuation for specific services, including the E/M visits and the new G2211 visit complexity add-on code.
    - E/M visits billed using CPT codes comprise approximately 45 percent of allowed charges for PFS services. Office and outpatient E/M visits comprise approximately 25 percent of allowed charges for PFS services.

    - There is considerable variability within the specialties of the Federation in terms of E/M level of visits and volume. Physicians such as family practitioners who do not provide procedural interventions or diagnostic tests have most of their allowed charges from E/M visits. Therefore, these practitioners and other primary care providers should expect to see increases for their E/M visits.
- CMS finalized Current Procedural Terminology® (CPT) descriptors, guidelines, and payment rates effective on January 1, 2021, which are a **significant modification to the coding, documentation, and payment of E/M services for office and outpatient visits**. In the final rule, CMS retained five levels of coding for established patients, reduced to four levels for new patients, and revised code definitions. CMS revalued services analogous to office outpatient E/M visits.

TELEHEALTH

- CMS **did not 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, citing a lack of statutory authority to do so. Therefore, the waivers in place will last only during the COVID-19 PHE.
- CMS **finalized its proposals to permanently add several codes to the Medicare telehealth list** and **certain home visit services**. CMS also kept over 150 additional services 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 via telehealth.
- Medicare telehealth visits to nursing facility settings are expanded from once every 30 days to **once every 14 days**.
- Telehealth rules do not apply when the beneficiary and the practitioner are in the same location, even if audio/visual technology assists in furnishing a service.
- CMS finalized its proposal to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE for COVID-19 ends or December 31, 2021.
- CMS finalized a number of care management services and **remote physiologic monitoring (RPM)** proposals including allowing RPM services for both new and established patients during the COVID-19 PHE, and only for an established patient after the PHE ends. CMS will allow the medically necessary services associated with all the medical devices for a single patient to be billed by only one practitioner, only once per patient per 30-day period, and only when at least 16 days of data have been collected.

SCOPE OF PRACTICE

- CMS finalized that **a teaching physician** can 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. This excludes audio-only technology.

- 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 made this policy permanent only for teaching physician supervision of services provided by residents that are furnished in rural areas (those areas outside of Office of Management and Budget (OMB)-defined metropolitan statistical areas).
- For all teaching settings and for the duration of the PHE for COVID-19, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present during the key portion of the service.
- A teaching physician may not only direct the care furnished by residents, but may also **review the services provided with the resident**, during or immediately after the visit, remotely **through interactive, audio/video real-time communications technology (excluding audio-only)**.
- CMS will allow **the supervision of diagnostic psychological and neuropsychological testing services** by Nurse Practitioners (NP), Clinical Nurse Specialists (CNS), Physician Assistants (PA), Certificate Registered Nurse Anesthetists (CRNA) and Certified Nurse Midwives (CNM) to the extent that they are authorized to perform the tests under applicable state law and scope of practice.
- CMS reiterated that **pharmacists** come under the category of auxiliary personnel and may provide "incident to" services under the appropriate level of supervision of a billing physician or nonphysician practitioner (NPP), if payment for the services is not made under the Medicare Part D benefit. The pharmacist must be able to carry out the "incident to" services under state scope of practice and applicable state law.
- CMS finalized its proposal and will allow 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**.

OTHER PROVISIONS

- CMS finalized that **electronic prescribing for controlled substances** for Medicare prescriptions will begin in 2021 and compliance will be required beginning in 2022.
- In the **Medicare Diabetes Prevention Program** (MDPP), CMS finalized flexibilities through the COVID-19 PHE and for future 1135 waivers, should they occur. Specifically, CMS will:
    - Allow MDPP suppliers to either deliver MDPP services virtually or suspend in-person MDPP services and resume MDPP services at a later date;
    - Allow MDPP beneficiaries who begin the set of MDPP services virtually, or who change from in-person MDPP services to virtual during the COVID-19 PHE (or subsequent 1135 waiver event) to continue the MDPP set of services virtually, even after the emergency event has concluded;
    - Permit certain MDPP beneficiaries to obtain the set of MDPP services more than once per lifetime, and allow suspension in service to allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in service; and

- Add virtual weight measurement methods and MDPP beneficiary self-reporting of their weights by submitting a time and date-stamped photo or video of their home scale with their current weight measurement, or online video technology (such as video chatting or video conferencing) with an MDPP coach.

QUALITY PAYMENT PROGRAM

- CMS extended the Extreme and Uncontrollable Circumstances Hardship Exception due to COVID-19 through 2021, allowing eligible clinicians to apply to be held harmless from Merit-based Incentive Payment System (MIPS) or to have certain categories reweighted to zero if they experience disruptions related to the public health emergency.
- CMS postponed the **MIPS Value Pathways (MVP)** implementation for the 2022 performance period.
- CMS **increased the performance threshold** to avoid a penalty from 45 points in 2020 to 60 points in 2021. CMS maintained **the exceptional performance threshold** at 85 points for 2021.
- CMS finalized its proposal to lower the weight of the **Quality Category** performance score from 45 percent to 40 percent and to **increase the weight of the Cost Performance Category** from 15 to 20 percent of the MIPS final score.
- CMS estimates approximately 92.5 percent of eligible clinicians who submit MIPS data will receive a positive or neutral payment adjustment and between 196,000 and 252,000 eligible clinicians will be Qualifying APM Participants (QPs), will be excluded from MIPS, and will receive a five percent incentive payment in 2023.
- For performance year 2021, CMS finalized that Accountable Care Organizations (ACOs) participating in the **Medicare Shared Savings Program** is optional in 2021 and mandatory starting in 2022. ACOs will be required to report quality measure data for purposes of the Shared Savings Program via the APP, instead of the CMS Web Interface.

PAYMENT ISSUES

CY 2021 Conversion Factor

On December 1, 2020, the Centers for Medicare & Medicaid Services (CMS) released the Final Rule for the calendar year (CY) 2021 Medicare Physician Payment Schedule (MFS). To calculate the CY 2021 Medicare conversion factor (CF), CMS applied a budget-neutrality adjustment of -10.20%. This reduction is necessitated by proposed additional spending of $9.9 billion due to changes in coding and payment for:

- Evaluation and Management (E/M) office visits, representing $5.6 billion of the redistribution.
- A CMS-created office visit complexity add-on code G2211, representing $3 billion of the redistribution.
- CMS revaluation of certain services relative to the new E/M office visit values including: end-stage renal disease (ESRD) monthly capitation payment services, transitional care management (TCM) services, cognitive impairment assessment and care planning services, and emergency department (ED) visits, maternity care services. In total, these modifications represent $1.3 billion of the redistribution.

The 2021 Medicare CF, effective January 1, 2021, is $32.4085, $3.6811 lower than in 2020. The anesthesia CF, effective January 1, 2021, is $20.0547 which reflects the same overall MFS adjustments with the addition of anesthesia-specific practice expense (PE) and malpractice (MP) adjustments.

The CY 2021 MFS will cause a significant redistribution in payments beginning on January 1, 2021. CMS estimates the range of impacts on specialties between -10% and +16%, depending on the mix of services provided. The Agency adopted the significant changes in office visit coding definitions and guidelines made by the CPT Editorial Panel, as well as the RUC-recommended relative value recommendations for implementation in 2021. These coding changes and payment increases represent a substantial improvement over the existing coding structure. Under current law, however, payment increases must be implemented in a budget neutral manner which leads to steep negative adjustments for many physicians and other health care professionals who report no or few office visits.

Organized medicine has been advocating to waive the budget neutrality requirement, or at least postpone it during the COVID-19 pandemic, given the pandemic's severe negative impact on practice costs and revenue. The AMA is also pursuing legislative relief; for example, supporting H.R. 8702, "Holding Providers Harmless from Medicare Cuts During COVID-19 Act of 2020," which would effectively freeze payments at 2020 rates for services scheduled to be cut in 2021 for a period of two years, while allowing the planned E/M payment increases to be implemented as scheduled. In addition, the AMA has advocated for CMS to fully adopt the AMA/Specialty Society RVS Update Committee (RUC) recommendations for the office visit codes by including the payment increases to the post-operative office visits bundled in the global surgical packages.

The drastic 10.2% reduction in the Medicare conversion factor is necessitated by proposed additional spending of $9.9 billion in coding and payment as summarized below:

Coding Policy Change	Fiscal Impact
Evaluation and Management (E/M) office visits	$5.6 billion
A CMS-created office visit complexity add-on code G2211	$3.0 billion
CMS revaluation of certain services relative to the new E/M office visit values including: - end-stage renal disease (ESRD) monthly capitation payment services, - transitional care management (TCM) services, cognitive impairment assessment and care planning services, and - emergency department (ED) visits, - maternity care services	$1.3 billion
TOTAL	**$9.9 billion**

Table 106: CY 2021 PFS Estimated Impact on Total Allowed Charged by Specialty is included at the end of this document and illustrates the average impact on the conversion factor on each specialty.

Coding Changes and Work Relative Values

Over the last 30 years, the RUC has reviewed nearly all services paid through the MFS, accounting for 98% of spending. For the 2021 MFS, the RUC submitted 154 recommendations for individual CPT codes, and CMS implemented the recommended work values for 77% of these services. The services for which RUC made recommendations for the CY 2021 payment schedule included breast reconstruction, hip and knee arthroplasty, and remote retinal imaging. Of note was the creation of numerous new CPT codes for COVID-19 testing, vaccines, immunization administration, and development of CPT code 99072 to help physicians pursue payment for additional supply and infection control costs associated with caring for patients during the COVID-19 public health emergency.

The RUC recommendations, minutes, voting records and other supporting documentation are available at www.ama-assn.org/about/rvs-update-committee-ruc/ruc-recommendations-minutes-voting.

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

Last year, CMS finalized an important policy change in the 2020 Medicare Physician Fee Schedule final rule when it adopted CPT guidelines to report office and outpatient E/M visits based on either medical decision making or physician time and reduce unnecessary documentation. These changes were made effective on Jan. 1, 2021 to allow for extensive education on use of the new guidelines and revised codes.

CMS also adopted the relative value recommendations made by the RUC for the office and outpatient E/M visits, which will lead to significant payment increases for these services in 2021.

The final 2021 E/M policies differ from the RUC recommendations in one important respect: although the surgical specialties participated in the RUC survey and their data and vignettes were incorporated into the RUC recommendations, CMS did not apply the RUC recommended values to the visits bundled into global surgical payments.

In addition, despite concerns about a lack of clarity in its definition and estimated utilization, CMS finalized a new code, G2211, to be reported in addition to the CPT codes for office visits. The AMA had urged CMS to postpone implementation, allowing the CPT Editorial Panel to better define the service to meet its intended purpose.

The January 2021 office visit guidelines and descriptions; an AMA Ed Hub tutorial; detailed RUC recommendations, data, and a vote report are all posted on the AMA website and may be obtained via www.ama-assn.org/cpt-office-visits.

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

CMS revalued 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.

Substance Use Disorder (SUD) Treatment

Effective in 2021, CMS finalized its proposal to modify the three G-codes used to report monthly treatment of patients with opioid use disorder (OUD) so the codes can be used to report monthly treatment of patients with any SUD, not just OUD. When reported, these codes provide monthly bundled payments for treatment of patients with OUD, including development of a treatment plan, care coordination, and individual and group therapy and counseling. Medications to treat OUD are paid separately. CMS clarified that the codes should not be reported more than once per month for each patient as they will now apply comprehensively to the treatment of "one or more" SUDs.

CMS added naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and will allow Opioid Treatment Programs (OTPs) to be paid for dispensing naloxone to patients receiving OUD treatment services. In finalizing its policy, CMS will allow patients being treated at OTPs to receive take-home supplies of nasal naloxone on an as-needed basis from their OTP with no cost-sharing (G2215 is the naloxone code). CMS also sought comments on whether a new code should be established for OTPs to educate patients about preventing overdose. It has adopted a policy of adding payment for patient education about overdose and use of naloxone to the payment for the medication instead of establishing a separate education code.

CMS also proposed 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. The agency has finalized payment for this code, G2213, as proposed, to be reported in addition to the code for the primary procedure done in the emergency department. The AMA was supportive of these changes and urged their inclusion in the final rule.

Practice Expense for Personal Protective Equipment (PPE)

To address the financial impact of the additional supplies and new staff activities required to provide safe patient care during the PHE, the CPT Editorial Panel approved CPT code 99072 and the RUC submitted extensive research and analysis describing the direct costs for the code. Organized medicine advocated that CMS immediately implement and pay for CPT code 99072 with no patient cost-sharing during the PHE and fully fund these codes using remaining money from the CARES Act Provider Relief Fund or by recognizing the decreased expenditures during the early months of the pandemic to waive budget neutrality.

CMS is finalizing CPT code 99072 as a bundled service on an interim basis, rather than recognize the increased expenses due to intensive infection control practices by implementing CPT code 99072, CMS instead finalized, on an interim basis, supply pricing increases, such as an increase in the price of surgical masks and surgical masks with face shields that are bundled into few office-based procedure codes. CMS seeks comment about this interim final policy, as well as how to account for services that do not include these specific PPE items but for which there are increased costs.

Immunization Administration

CMS did not finalize its proposal to crosswalk the valuation of the immunization administration codes to CPT code 36000, which many stakeholders agreed would better recognize the resources needed to cover the costs of purchasing, storing, monitoring, and administering vaccines. Instead, CMS will maintain the 2019 payment rates for all nine of the services in this family, including the add-on codes.

In a separate Interim Final Rule with Comment, CMS established Medicare coverage and payment policies for a future COVID-19 vaccine and its administration. The RUC will review the COVID immunization administration valuation and submit recommendations to CMS this month. A comprehensive review of all immunization administration valuation will be planned for April 2021.

The AMA is also working collaboratively with CMS and the Centers for Disease Control and Prevention (CDC) on a new approach to report use of COVID-19 vaccines. More information is available here.

Physician Practice Expense (PE) Data Collection

While not currently proposing or finalizing changes to the practice expense relative values (PE RVUs) methodology or data collection process, CMS solicited comments about the RAND Corporation's ongoing research and analysis and a January 2020 Technical Expert Panel (TEP). CMS believes updates are necessary as the current comprehensive source for PE data, the Physician Practice Information (PPI) Survey, was conducted by the AMA with the participation and cooperation of CMS and 72 national medical specialty societies and other health care professional organizations in 2007-2008 and precedes the widespread adoption of electronic

health records, quality reporting programs, billing codes that promote team-based care, and hospital acquisition of physician practices. The AMA provided details comments about RAND's findings and reiterated our strong opposition to translating the practice cost relativity of hospitals to the practice cost relativity of physician offices.

In 2020, the AMA conducted an in-depth, multi-stage Practice Expense Pilot Study to determine whether a new PE data collection effort would be successful and to inform a large-scale study. Ideally, a 2021 AMA Practice Expense Survey would be planned. However, the COVID-19 pandemic has dramatically altered physician practice revenue, staffing and expense in 2020. Querying physicians and their financial experts in 2021 on their 2019 data may also be problematic. The AMA recommends that a 2022 survey be planned and fielded, collecting 2021 data, using lessons learned from the AMA pilot survey. Discussions with CMS, AMA, and other stakeholders should begin in 2021 to work toward this important goal.

The AMA strongly urges CMS to refocus all efforts on a new practice expense data collection effort. CMS should convene a Town Hall meeting with stakeholders and immediately begin working with the AMA, the RUC, and other stakeholders to launch a new physician practice expense survey in 2022.

TELEHEALTH

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 into January 2021. CMS does not propose to permanently waive these restrictions, citing its lack of authority to make this adjustment. The AMA strongly supports legislative proposals before Congress that would remove these restrictions permanently and allow telehealth services to be delivered to Medicare patients wherever they are located.

The list of services that Medicare covers when delivered via telehealth has been dramatically expanded during the COVID-19 PHE. CMS proposed to permanently add several codes to the Medicare telehealth list that had been temporarily added during the PHE. CMS has now finalized this policy, which permanently adds the prolonged office or outpatient visit code, certain home visit services, assessment and care planning for patients with cognitive impairment, group psychotherapy, and several other codes. CMS also finalized its proposed policy allowing physicians to provide direct supervision via telehealth until the end of the year in which the PHE ends or December 31, 2021.

CMS proposed a new category of telehealth services, Category 3, which it would keep 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 via telehealth outside the context of a pandemic. An additional set of services would no longer be covered as telehealth services after the PHE ends. In the final rule, consistent with AMA comments, CMS has finalized the addition of the new Category 3 and has added significantly to the codes included in this category. For

example, CMS had proposed to only include three of the five emergency visit codes on the list but has finalized the inclusion of all five emergency visit codes, and it has added critical care, observation care, and hospital discharge services.

CMS has also finalized its proposal to remove the prohibition on the use of telephones for telehealth services. Telephones, such as smart phones, that fit the definition of "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication" may be used for Medicare telehealth services. CMS did not propose to continue payment for Medicare audio-only visits after the conclusion of the COVID-19 PHE as the agency does not believe it has the authority to waive the requirement for two-way, audio/video communications beyond the PHE. Within this final rule, CMS has included an interim final rule with comment in order to receive information regarding provision of lengthier audio-only services outside of the COVID-19 PHE, if not as substitutes for in-person services, then as a tool to determine whether an in-person visit is needed, particularly as patients may still be cautious about exposure risks associated with in-person services. In the interim, CMS has established a new code, G2252, describing a virtual check-in of 11-20 minutes, for which it has established a 60-day comment period.

Remote Physiologic Monitoring (RPM)

CMS finalized several code refinements for remote physiologic monitoring:

- Physicians and other qualified healthcare providers may furnish RPM services to remotely collect and analyze physiologic data from patients with acute conditions as well as patients with chronic conditions.
- CMS clarified, as AMA recommended, that 20 minutes of time required for 99457 and 99458 can include time for furnishing care management services as well as interactive communication.
- CMS will allow for RPM services furnished to new and established patients for the duration of the PHE and only to an established patient after the COVID-19 PHE ends.
- The flexibilities related to RPM were extended through the end of the COVID-19 PHE. The AMA asked for these flexibilities to continue to end of the year in which the PHE ends or, preferably, an additional year to allow for more data to be collected and a smoother transition. CMS declined to extend these flexibilities beyond the PHE.
- As a result, at the end of the COVID-19 PHE, RPM services must be furnished only to an established patient and must include at least 16 days of data collection in a 30-day period.

SCOPE OF PRACTICE and RELATED ISSUES

CMS' policies on scope of practice continue from Executive Order 13890, which directs HHS to modify supervision requirements in Medicare that "limit healthcare professionals from practicing at the top of their license." CMS believes "physicians, non-physician practitioners (NPPs), and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure…" and finalized policies from that position.

Teaching Physician and Resident Moonlighting Policies

CMS finalized its policy for all inpatient teaching settings. CMS made permanent that services of residents unrelated to their approved GME program and that are performed in the outpatient department, emergency department, or inpatient setting of a hospital where their training program is based are able to separately bill for physicians' services and receive payment under the PFS, provided that the services are identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries in providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and the services are not performed as part of the approved GME program. The AMA sought this permanent resident moonlighting policy.

Primary Care Exception Policies

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 31 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.

A key point for the primary care exception involved whether the policy would be made permanent and if so, for which services. Three key aspects of the primary care exception were finalized. While the AMA sought permanent policies, overall, CMS is moving in the right direction with its primary care exceptions in the final rule related to telehealth.

1. CMS finalized a permanent policy to permit an expanded primary care exception, but only for services furnished in residency training sites that are located in rural areas (those areas outside of an OMB-defined metropolitan statistical area (MSA)).
2. CMS permanently expanded only a limited array of services under the primary care exception to include communication-technology based services and interprofessional consults (CPT codes 99421-99423, and 99452, and HCPCS codes G2010 and G2012).
3. CMS will continue the interim policy of an expanded set of services under the primary care exception for the duration of the PHE, which will provide flexibility for communities that may experience resurgences in COVID-19 infections. At the end of the COVID-19 PHE, CMS will terminate the inclusion of CPT codes 99204, 99214, 99205, 99215, 99495 and 99496 from the primary care exception for all settings.

Supervision of Residents in Teaching Setting through the Audio/Video Real-Time Communications Technology

CMS finalized a permanent policy to permit teaching physicians to meet the requirements to bill for their services involving residents through virtual presence, but only for services furnished in residency training sites that are located in rural areas. For all other settings, CMS is allowing supervision of residents in teaching settings through audio/visual real-time communications technology to remain in place for the duration of the PHE to provide flexibility for communities that may experience resurgences in COVID-19 infections. The AMA sought supervision of residents in all teaching settings through audio/visual real-time communications technology to be permanently adopted.

Supervision of Diagnostic Tests by Certain NPPs

CMS finalized, as it originally proposed, a significant amendment to permanently allow NPs, CNSs, PAs, CRNAs, and CNMs to supervise diagnostic tests on a permanent basis as allowed by state scope of practice laws.

The AMA vehemently opposed this proposal, citing serious concerns about proper training of NPPs for the services proposed. However, CMS deferred to state laws that allow NPPs to furnish diagnostic tests to determine whether these NPPs are qualified to supervise the performance of the enumerated diagnostic tests. The power remains with the states to maintain appropriate supervision amidst scope of practice expansion.

OTHER PROVISIONS

Electronic Prescribing for Controlled Substances (EPCS)

Congress passed legislation in 2018 requiring Medicare Part D prescriptions for controlled substances to be electronically prescribed starting in 2021, with some exceptions. The 2021 proposed rule outlined the advantages of EPCS over paper prescriptions, but also described hurdles to greater physician adoption of EPCS, including two-factor authentication requirements. CMS indicated that the COVID-19 public health emergency is making it even more difficult for medical practices that wish to adopt EPCS. It therefore proposed to require EPCS for Medicare prescriptions beginning in 2022 instead of 2021, which AMA comments strongly supported.

In the final rule, CMS reiterates the rationale for its proposal to defer the EPCS mandate until 2022, but also notes that some commenters urged the agency to require EPCS for Medicare Part D controlled substance prescriptions in 2021 even if it declines to enforce the requirement until 2022. Attempting to balance these divergent views, the final rule states that the Medicare EPCS requirement will take effect on January 1, 2021, but no compliance action will be taken until 2022 and physicians who do not implement EPCS "until January 1, 2022 will still be considered compliant with the requirement." CMS also observed that EPCS will soon be required in 31 states.

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

CMS proposed to codify an existing policy related to drug products approved under section 505(b)(2) of the Food, Drug, and Cosmetic Act (FDCA), 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. In the final rule, CMS declined to finalize a decision. Instead, CMS will respond to requests for more details about its proposed approach in future rulemaking.

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 the final rule, CMS made changes to conform to the statutory requirements of the FCAA and CARES Act. Specifically, CMS changed the data collection period, data reporting period, and payment reduction schedule as follows:

- The next data reporting period runs from January 1, 2022 through March 31, 2022 and will be based on the data collection period of January 1, 2019 through June 30, 2019. This applies to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests;
- After the data reporting period in 2022, there will be a three-year data reporting cycle for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests. The future cadence for reporting will be 2025, 2028, 2031, etc.; and
- There is no phased-in payment reduction for CY 2021, and payment reductions are not to exceed 15 percent for CY 2022 – CY2024.

Payment for Specimen Collection for COVID-19 Clinical Diagnostic Tests

CMS received feedback but made no final determination on whether CPT code 99211 created for COVID-19 specimen collection by independent laboratories when furnished incident to a practitioner's other services should be deleted once the public health emergency ends.

Medicare Diabetes Prevention Program (MDPP)

CMS made a number of flexibilities to the MDPP during the COVID-19 PHE, and in the final rule, has noted that these flexibilities will extend to future 1135 waiver events that could cause a disruption to in-person MDPP services. CMS has established an MDPP Emergency Policy focused on the minimization of disruption of MDPP services that applies broadly during the current COVID-19 PHE and for future similar emergencies. That being said, CMS declined to make the flexibilities offered permanent, as the AMA had urged.

In order to furnish virtual services during the Emergency Period, a MDPP supplier must already have preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) recognition for in-person services. CMS continues to bar virtual-only suppliers from furnishing MDPP services, either virtually or in-person, during the Emergency Period. CMS cites that virtual suppliers are not able to enroll in Medicare and are not in position to deliver MDPP services in-person at the conclusion of the Emergency Period. CMS will require MDPP providers to resume in-person services at the conclusion of the Emergency Period. Against AMA urging, CMS declines to allow virtual providers to participate in MDPP to the fullest extent either during or after the PHE.

During the COVID-19 PHE, CMS initially adopted policy allowing MDPP beneficiaries to be exempt from the once-per-lifetime limit on receiving MDPP services. CMS has since changed course to limit those who choose to continue to receive MDPP virtually during an Emergency Period to receiving MDPP only once, but those who discontinue receiving services due to an 1135 waiver situation could restart their MDPP services at the first core session after the Emergency Period. For those who are in the first 12 months of the MDPP and choose to stop receiving services, they may restart later at the beginning of the program, or to resume where they left off. Those who are in the second year of the program may only restart the ongoing maintenance portion of the MDPP and may not restart the entire MDPP. Beneficiaries are

eligible to restart or resume services regardless of their weight measurement or glucose level as of the date on which they elect to restart or resume services.

CMS will allow MDPP suppliers to provide engagement incentives including Bluetooth-enabled scales to support weight measurement program goals for those who lack the ability to otherwise collect and transmit their weekly weights. These virtual weight measurement methods may be self-reported by submitting a time and date-stamped photo or video, or by using a synchronous, online video technology such as video chatting or video conferencing with a MDPP coach. These are developments for CMS and MDPP, as the methods allowed have not been accepted previously by the Agency and may signal greater flexibilities using audio/visual tools.

QUALITY PAYMENT PROGRAM

MIPS Extreme and Uncontrollable Circumstances Hardship Exception Due to COVID-19

CMS responded to the AMA's concerns about the worsening COVID-19 public health emergency (PHE) and extended the MIPS Extreme and Uncontrollable Circumstances hardship exception policy through 2021. Physicians, in need of flexibility and minimal administrative burdens to continue to meet the needs of patients during this once-in-a-century pandemic, can plan and determine the best way to allocate their resources toward patient safety, treating patients diagnosed with COVID-19, and participating in MIPS in 2021.

The 2021 hardship exception process is expected to mirror the 2020 process. Eligible clinicians and group practices will be able to submit a brief application listing "COVID-19" as the cause for requests to re-weight any or all MIPS performance categories. For instance, a physician can request a hardship on just the Cost Category and Quality Category and only be held accountable for Promoting Interoperability and Improvement Activity Categories. A physician can also request a hardship on all four categories to be held harmless from a MIPS penalty, if approved.

CMS finalized its proposal to allow APM Entities to apply to reweight MIPS performance categories as a result of extreme and uncontrollable circumstances, such as the public health emergency resulting from the COVID-19 pandemic. This policy will apply beginning with the 2020 performance period.

In response to AMA advocacy efforts, CMS separately announced an extension of the 2020 hardship exception application deadline until February 1, 2021. The AMA recommends applying for a hardship exception if your practice experienced disruptions due to COVID-19 in 2020. At a minimum, the AMA suggests physicians apply to have the Cost performance category re-weighted to zero percent of the final score due to significant changes in care delivery and resource use during the PHE. More information is available here.

MIPS Value Pathways (MVPs)

Due to the COVID-19 pandemic, CMS postponed MVP implementation and will propose an initial set of MVPs and detailed scoring policies in future rulemaking for the 2022 performance period. CMS previously finalized a broad framework for MVPs, which consisted of a set of measures tailored to an episode of care or condition, 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 updated the MVP guiding principles to include the patient voice, subgroup reporting, and digital quality measures. CMS also finalized the MVP development criteria to include quality and cost measures, as well as improvement activities, that are clinically appropriate and linked to the intent of the MVP. Importantly, CMS clarified that QCDR measures may be included in MVPs. Despite significant concerns raised by the AMA and others, CMS moved ahead with requiring the claims-based Hospital-Wide, 30-Day, All-Cause Unplanned Readmission measure and the full set of Promoting Interoperability measures as foundational components of all MVPs. CMS expects specialty societies and other MVP developers to engage patients or patient representatives during the development of MVPs.

Specialty societies and other MVP developers will submit their MVP candidates using a standardized template, which can be downloaded here. CMS and its contractors will 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 will meet with the developers to discuss any recommended modifications to the MVP candidate. MVPs must then be established through rulemaking.

MIPS Performance Threshold and Complex Patient Bonus

Despite proposing a lower performance threshold in response to the disruption of the COVID-19 pandemic, CMS instead finalized an increase from 45 points in 2020 to 60 points in 2021. CMS acknowledged the AMA's concerns that a performance threshold of 60 points will be challenging for clinicians affected by the PHE and extended the hardship exception application due to COVID-19 through 2021. By law, CMS must set the MIPS performance threshold at the mean or median of final scores beginning in 2022, which CMS estimates will be 74.01 points.

The additional performance threshold for 2021 will remain at 85 points. Eligible clinicians and groups who score at least 85 points are eligible to receive an additional positive payment adjustment from a $500 million fund that is not tied to budget neutrality in MIPS.

CMS finalized a retroactive increase in the complex patient bonus from a maximum of 5 points to 10 points for the 2020 performance year due to COVID-19. However, the bonus will return to a maximum of 5 points in 2021.

MIPS Quality Performance Category

Despite AMA concerns with changing category weights in the middle of the COVID PHE, CMS finalized its proposal to lower the weight of the Quality Category performance score from 45 percent to 40 percent of the MIPS final Score for the 2021 performance period. There are a total of 209 quality measures for the 2021 performance period that reflect:

- Substantive changes to 113 existing MIPS quality measures (7 of which had substantive changes that don't allow comparison with historical data).
- Addition and/or removal of measures from specific specialty sets.

- Removal of 10 quality measures from the MIPS program.
- Replacing the administrative claims *All-Cause Hospital Readmission measure* with the *Hospital-Wide 30-day All Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups measure*. However, CMS maintains that the measure will only apply to practices with 16 or more eligible clinicians and must have 200 attributed cases.
- Addition of administrative claims *risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure* with a 3-year (36 consecutive months) performance period, including elective primary total hip/knee arthroplasty procedures performed between October 1, 2018 to September 30, 2021.

Due to COVID-19 and by the urging of the AMA, CMS is delaying the sunsetting of the CMS Web Interface collection type to the 2022 performance period, which was originally proposed to start with the 2021 performance period. In addition, CMS proposed to potentially utilize performance period benchmarks for the 2021 MIPS performance period rather than baseline period historic data to set 2021 benchmarks because of concern that CMS would not receive a sufficient sample of 2019 data due to the 2019 data submission period taking place during the start of the PHE. However, CMS received a sufficient amount of data and is able to calculate historical benchmarks for the 2021 performance period.

MIPS Cost Performance Category

CMS finalized its proposal to increase the cost category weight in eligible clinicians' final score to 20 percent in performance year 2021. By law, the cost category generally must be weighted at 30 percent beginning in 2022. Given the expansion of telehealth during the COVID-19 pandemic, CMS also added the costs of applicable telehealth services to the existing episode-based cost measures and the Total Per Capita Cost measure. Download updated measure specifications here.

MIPS Promoting Interoperability (PI) and Certified Health Information Technology (Health IT)

For the CY 2021 Medicare Promoting Interoperability (PI) Program, CMS finalized the following:

- Maintaining the continuous 90-day period EHR reporting period in CY 2022;
- Maintains the Electronic Prescribing objective's Query of PDMP measure as optional but increasing the bonus points from five to 10 points;
- Adds 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.

- Physicians participating in PI or QPP are 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 2023. The extension of the required adoption date from 2022 to 2023 is a result of AMA advocacy.

MIPS Improvement Activities

For CY 2021, CMS finalized the following changes to the QPP Improvement Activities (IA) category:

- Changes to the Annual Call for Activities: CMS finalized 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. CMS also established 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: CMS established a process to allow it to consider HHS-nominated improvement activities all year long in order to address HHS initiatives in an expedited manner.
- Modifications: As expected, CMS finalized the modification two existing IAs: (1) Engagement of patient through implementation of improvements in patient portal, and (2) Comprehensive Eye Exams.
- Removal: While not proposed in the NPRM, CMS finalized the removal of the existing IA, Partner in Patients Hospital Engagement Network.
- COVID-19 Activities: CMS will provide credit for the following activities related to the COVID-19 PHE and Improvement Activities: (1) clinicians participating in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and who report their findings through a clinical data registry for the duration of their study; and (2) clinicians participating in the care of a patient diagnosed with COVID-19 who simultaneously submits clinical patient data to a clinical data registry for research.

Performance Category Weights

Below are the finalized and statutory performance category weights for 2021 and 2022 for eligible clinicians and groups in MIPS:

Performance Year/Payment Year	Quality	Cost	Improvement Activities	Promoting Interoperability
2021 / 2023	40%	20%	15%	25%
2022 / 2024	30%	30%	15%	25%

MIPS Participation Projections

Table 108 of the final rule provides estimates of the number of clinicians who will be eligible to participate in MIPS during 2021, the number who will be excluded from MIPS by the low-volume threshold, and the number that could potentially be MIPS eligible or could be below the low-volume threshold but eligible to opt-in to MIPS on a voluntary basis. In total, CMS estimates approximately 891,000 clinicians will be MIPS eligible in 2021.

In general, the maximum MIPS penalties and incentive payments is 9 percent in 2023, which is tied to the 2021 performance year. CMS estimates 93 percent of eligible clinicians who submit data will be eligible for a neutral payment adjustment or incentive payment, and 53 percent will be eligible for an additional bonus for exceptional performance. CMS notes these estimates are based on 2019 data and do not account for disruptions due to the COVID-19 PHE.

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, which was originally proposed to begin with the 2020 performance year. Due to AMA advocacy, CMS is also modifying the QCDR measure testing requirement to be a two-step process that first requires face validity testing and eventually full measure testing (beta testing). For existing QCDR measures that were previously approved for the CY 2020 MIPS performance period, are required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 MIPS performance period. QCDR measures that were approved for the 2022 performance period with face validity, are required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2023 MIPS performance period and beyond) in order to be considered for inclusion in the MIPS program. For a new QCDR measure to be approved for the CY 2022 MIPS performance period, a QCDR measure must be face valid; QCDR measures that were approved for the 2022 performance period with face validity, are required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2023 MIPS performance period and beyond) in order to be considered for inclusion in the MIPS program.

APM Performance Pathway (APP) and Medicare Shared Savings Program

CMS finalized its proposal to require Accountable Care Organizations participating in the Shared Savings program and MIPS APM participants to report quality measure data via the APM Performance Pathway (APP), instead of the CMS Web Interface or quality measures that were specific to individual APM programs. However, due to COVID-19, reporting the APP measures will be optional in 2021 and ACOs will still have the option to report quality through the Web Interface in 2021. Starting in 2022, the Web Interface will sunset and ACOs will be required to report quality via the APP measure set. While the AMA asked for a delay, we are disappointed CMS moved forward with the APP measure set because we feel there is a need for additional physician input and discussion to determine the most appropriate measure set that balances physician burden and improves the quality of care.

Under this new approach, ACOs and APM participants would only need to report one set of quality metrics that would meet requirements under both MIPS and MSSP. The APP will have a quality measure set that consists of three eCQM/MIPS CQM/Medicare Part B Claims measures, a CAHPS for MIPS Survey measure, and 2 measures that will be calculated by CMS using administrative claims data. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, CMS would remove such measure from the quality performance category score for such MIPS eligible clinician, group, or APM Entity. In the APP, the Cost performance category will be weighted at zero percent as MIPS APM participants are responsible for resource use in their APMs.

CMS also finalized a modified version of its original proposal to allow for a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. In addition, in response to comments, CMS finalized a modification to retain the pay-for-reporting year for new ACOs only.

Due to the COVID-19 pandemic, CMS finalized its proposal to allow APM Entities to submit an application to reweight MIPS performance categories as a result of extreme and uncontrollable circumstances, such as the public health emergency resulting from the COVID-19 pandemic. This policy will apply beginning with the 2020 performance period. CMS also finalized policies to waive the CAHPS for ACOs reporting requirement and to provide automatic full credit to ACOs for the CAHPS patient experience of care survey for program year 2020.

Advanced Alternative Payment Models (APMs)

CMS finalized a change in the Qualifying APM Participants (QP) threshold methodology to exclude Medicare beneficiaries who have already been attributed to another APM entity to prevent diluting the QP threshold scores. CMS finalized a targeted review process allowing clinicians and APM entities to appeal CMS errors that result in omitting clinicians from a participation list for purposes of QP determinations. Unfortunately, CMS finalized a deadline of November 1 or 60 days after CMS announces initial APM incentive payments have been made for QPs with missing billing information to provide the necessary details to CMS in order to receive their payment. After the cutoff date, payments that cannot be made will be forfeited.

The final rule includes an estimate that between 196,000 and 252,000 eligible clinicians will become QPs in 2021, will be excluded from MIPS, and will receive a five percent incentive payment in 2023.

Appendix A

Table 106: CY 2021 PFS Estimated Impact on Total Allowed Charged by Specialty

		Impact of			
(A) Specialty	(B) Allowed Charges (mil)	(C) Work RVU Changes	(D) PE RVU Changes	(E) MP RVU Changes	(F) Combined Impact
ALLERGY/IMMUNOLOGY	$247	5%	4%	0%	9%
ANESTHESIOLOGY	$2,020	-6%	-1%	0%	-8%
AUDIOLOGIST	$75	-4%	-2%	0%	-6%
CARDIAC SURGERY	$266	-5%	-2%	0%	-8%
CARDIOLOGY	$6,871	1%	0%	0%	1%
CHIROPRACTOR	$765	-7%	-3%	0%	-10%
CLINICAL PSYCHOLOGIST	$832	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	$857	0%	1%	0%	1%
COLON AND RECTAL SURGERY	$168	-4%	-1%	0%	-5%
CRITICAL CARE	$378	-6%	-1%	0%	-7%
DERMATOLOGY	$3,767	-1%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$748	-1%	-2%	0%	-3%
EMERGENCY MEDICINE	$3,077	-5%	-1%	0%	-6%
ENDOCRINOLOGY	$508	10%	5%	1%	16%
FAMILY PRACTICE	$6,020	8%	4%	0%	13%
GASTROENTEROLOGY	$1,757	-3%	-1%	0%	-4%
GENERAL PRACTICE	$412	5%	2%	0%	7%
GENERAL SURGERY	$2,057	-4%	-2%	0%	-6%
GERIATRICS	$192	1%	1%	0%	3%
HAND SURGERY	$246	-2%	-1%	0%	-3%
HEMATOLOGY/ONCOLOGY	$1,707	8%	5%	1%	14%
INDEPENDENT LABORATORY	$645	-3%	-2%	0%	-5%
INFECTIOUS DISEASE	$656	-4%	-1%	0%	-4%
INTERNAL MEDICINE	$10,730	2%	1%	0%	4%
INTERVENTIONAL PAIN MGMT	$936	3%	3%	0%	7%
INTERVENTIONAL RADIOLOGY	$499	-3%	-5%	0%	-8%
MULTISPECIALTY CLINIC/OTHER PHYS	$153	-3%	-1%	0%	-3%
NEPHROLOGY	$2,225	4%	2%	0%	6%
NEUROLOGY	$1,522	3%	2%	0%	6%
NEUROSURGERY	$811	-4%	-2%	-1%	-6%
NUCLEAR MEDICINE	$56	-5%	-3%	0%	-8%
NURSE ANES / ANES ASST	$1,321	-9%	-1%	0%	-10%
NURSE PRACTITIONER	$5,100	5%	3%	0%	7%
OBSTETRICS/GYNECOLOGY	$636	4%	3%	0%	7%
OPHTHALMOLOGY	$5,343	-4%	-2%	0%	-6%
OPTOMETRY	$1,359	-2%	-2%	0%	-4%
ORAL/MAXILLOFACIAL SURGERY	$79	-2%	-2%	0%	-4%

ORTHOPEDIC SURGERY	$3,812	-3%	-1%	0%	-4%
OTHER	$48	-3%	-2%	0%	-5%
OTOLARNGOLOGY	$1,271	4%	3%	0%	7%
PATHOLOGY	$1,265	-5%	-4%	0%	-9%
PEDIATRICS	$67	4%	2%	0%	6%
PHYSICAL MEDICINE	$1,164	-3%	0%	0%	-3%
PHYSICAL/OCCUPATIONAL THERAPY	$4,973	-4%	-4%	0%	-9%
PHYSICIAN ASSISTANT	$2,901	5%	2%	0%	8%
PLASTIC SURGERY	$382	-4%	-3%	0%	-7%
PODIATRY	$2,133	-1%	0%	0%	-1%
PORTABLE X-RAY SUPPLIER	$95	-2%	-4%	0%	-6%
PSYCHIATRY	$1,112	4%	3%	0%	7%
PULMONARY DISEASE	$1,654	0%	0%	0%	1%
RADIATION ONCOLOGY AND RADIATION / THERAPY CENTERS	$1,809	-3%	-3%	0%	-5%
RADIOLOGY	$5,275	-6%	-4%	0%	-10%
RHEUMATOLOGY	$548	10%	5%	1%	15%
THORACIC SURGERY	$352	-5%	-2%	0%	-8%
UROLOGY	$1,810	4%	4%	0%	8%
VASCULAR SURGERY	$1,293	-2%	-4%	0%	-6%
TOTAL	**$97,008**	**0%**	**0%**	**0%**	**0%**

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