

Ohio Academy of Family Physicians
4075 N. High Street
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October 2, 2020

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

Dear Administrator Verma:

On behalf of the Ohio Academy of Family Physicians which represents 5,200 family physicians and medical students, I write in response to the proposed rule on CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc. as published by the Centers for Medicare & Medicaid Services (CMS) in the August 17, 2020 *Federal Register*.

We once again commend CMS' leadership and commitment to improving the Medicare program for all beneficiaries—and in improving access to high-quality, comprehensive, and coordinated care. We deeply appreciate your efforts to support family medicine and primary care. We look forward to working with CMS on designing and implementing policies that support these shared goals through both the Medicare Physician Fee Schedule (MPFS) and the Quality Payment Program (QPP).

We offer comments in support of the following issues, in addition to the more detailed responses that follow:

- Implementation of the office/outpatient evaluation and management (E/M) codes as planned in 2021.
- Permanent coverage and reimbursement of audio-only telephone services.
- Automatic application of the extreme and uncontrollable circumstances policy for the Merit-based Incentive Payment System for the 2020 performance period.
- Increased payment for immunization administration codes.

We appreciate the opportunity to offer our comments to the proposed rule, and we look forward to serving as a resource and partner to CMS in refining and implementing policies that improve the health of Medicare beneficiaries and reduce program costs.

2021 Conversion Factor and Budget Neutrality

CMS calculates the annual conversion factor based on service utilization estimations to ensure that budget neutrality is maintained from year to year. The 2021 conversion factor is 32.2605, which is a nearly 11% reduction from the CY 2020 conversion factor. We recognize that the significant reduction in the conversion factor is partially due to the 2021 changes to

office/outpatient E/M services, which we wholeheartedly support and believe should go into effect as planned. These changes are urgently needed to sustain family medicine practices at a time when many are at risk of closing their doors because of continued revenue losses resulting for the COVID-19 pandemic. The 2021 E/M increases are also vital to preserving access to primary care services for the tens of millions of patients who need, and may have delayed, getting preventive care and treatment for their acute and chronic illnesses. However, we are concerned that the significant reductions to the conversion factor will negate the positive impact of these changes and instead further jeopardize the stability of physician practices and patients' access to care. Accordingly, we recommend that the Department of Health and Human Services (HHS) use its 1135 waiver authority provided under the public health emergency to waive budget neutrality requirements for the 2021 office/outpatient E/M changes.

While we are supportive of waiving budget neutrality to mitigate financial instability as a result of the public health emergency, it is critical that waiving budget neutrality not be accompanied by other policy changes that would delay or reduce the E/M RVU increases or the value of GPC1X. Should HHS use its authority to waive budget neutrality, we also recommend that CMS finalize a reinstatement plan for the conversion factor reductions that provides physician practices with ample time to prepare and does not result in a financial cliff. We understand that HHS's authority is limited by the timing of the end of the public health emergency, but we believe that this approach will provide Congress with needed time to enact an accompanying legislative solution.

II.B Practice Expense RVUs

Summary

This section of the proposed rule reviews CMS's practice expense RVU methodology and solicits comments on some technical refinements that do not directly impact family physicians to a significant degree. At the end of this section, CMS provides an update on the work that the RAND Corporation is doing for CMS regarding potential improvements to CMS' practice expense (PE) allocation methodology and the data that underlie it, including RAND's use of a technical expert panel (TEP) convened earlier this year.

Based on the results of the TEP and RAND's other ongoing research, CMS is interested in potentially refining the PE methodology and updating the data used to make payments under the PFS, although CMS is not making any proposals in this regard. CMS believes potential refinements could improve payment accuracy and strengthen Medicare. CMS is thinking through several questions, including how to best incorporate market-based information, which could be like the market research that CMS recently conducted to update supply and equipment pricing used to determine direct PE inputs under the PFS payment methodology. For instance, CMS solicits comment regarding how it might update the clinical labor data. Historically, CMS has used data from the Bureau of Labor Statistics and is seeking comment to determine if this is the best data source or if there is an alternative. CMS plans to host a Town Hall meeting at a date to be determined to provide an open forum for discussion with stakeholders on its ongoing research to potentially update the PE methodology and the underlying inputs. CMS closes by welcoming feedback from all interested parties either as part of their public comments on the proposed rule or the public comment process, via email.

Response

We appreciate CMS's ongoing interest in and attention to improving its practice expense RVU methodology. As noted in the proposed rule, the Physician Practice Information Survey data that forms the basis of much the indirect PE calculations is more than 10 years old 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. We are aware of AMA efforts to potentially update this data and look forward to working with CMS, the AMA, and others to make that happen. We also look forward to the Town Hall meeting CMS plans in this regard.

We were disappointed that CMS made no mention of the impact that the current Public Health Emergency (PHE) is having on the practice expenses of physician practices nor made any proposals to account for those ongoing expenses in the 2021 Medicare physician fee schedule. Physicians and other Qualified Health Care Professionals (QHPs) across the United States have risen to the challenge of caring for their patients throughout the COVID-19 pandemic. As a part of the PHE, practices have incurred significant costs of maintaining safe offices, particularly in implementing specific infection control measures related to screening patients, purchasing personal protective equipment (PPE), and implementing office redesign measures to ensure social distancing. Grants and loans were initially provided to physicians to assist with revenue loss during the initial months of the pandemic and to partially address immediate costs of re-opening. However, new funding and payment is needed to assist physicians and QHPs for ongoing costs during the PHE.

In this context, the AAFP participated in an effort of the RUC to identify additional clinical staff time, added supplies, increased cost of supplies, and other practice expenses associated with patient encounters in the context of the PHE. That effort led the CPT Editorial Panel to consider and approve the new CPT code 99072 (Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease) with an effective date September 8, 2020. Guidelines to accompany the code and its descriptor are on the [AMA website](#).

Per CPT, code 99072 is used to report the additional supplies, materials, and clinical staff time over and above the practice expense(s) included in an office visit or other non-facility service(s) when the office visit or other non-facility service(s) are rendered during a PHE, as defined by law, due to respiratory-transmitted infectious disease. These required additional supplies, materials, and clinical staff time are intended to mitigate the transmission of the respiratory disease for which the PHE was declared. These include, but are not limited to, additional supplies, such as face masks and cleaning supplies, as well as clinical staff time for activities such as pre-visit instructions and office arrival symptom checks that support the safe provision of evaluation, treatment, or procedural service(s) during the respiratory infection-focused PHE.

If it has not already done so before then, we urge CMS to consider implementation of relative values and payment (outside of budget neutrality) for CPT code 99072 as part of the 2021 Medicare physician fee schedule to address the practice expense impact of the PHE. We also urge CMS to consider implementation of related recommendations made by the RUC, including recommendations to review the utilization assumptions for equipment due to decreased practice capacity during the COVID-19 PHE and a recommendation to add N95 masks to the CMS Direct PE Inputs Medical Supplies Listing.

II.C Potentially Misvalued Services Under the PFS

Summary

CMS reviews the process by which it identifies and evaluates potentially misvalued services under the fee schedule. In this proposed rule, CMS is proposing to nominate only one code, 22867 (Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level) as potentially misvalued and subject to comment in this context.

Response

While we have no interest in the relative value of code 22867, we do believe codes G0442 (Annual alcohol misuse screening, 15 minutes) and G0444 (Annual depression screening, 15 minutes) are potentially misvalued, given the manner in which Medicare and its contractors are interpreting the codes as compared to how CMS has valued them. We believe CMS should revise the descriptor for code G0444 to read “Annual depression screening, up to 15 minutes” and the descriptor for code G0442 to read “Annual alcohol misuse screening, up to 15 minutes.” We also believe CMS should clarify to its staff, Medicare administrative contractors (MACs), and audit contractors that the 15 minutes specified in codes G0444 and G0442 is not a threshold or minimum time to report the code but rather the maximum time for a service that would qualify as screening as opposed to a diagnostic and/or management service. Absent such actions, CMS should consider both codes potentially misvalued.

CMS implemented code G0444 in 2012 because of a national coverage determination (NCD) to cover such screenings for adults. We are aware that some MACs consider the 15 minutes referenced in the descriptor of code G0444 to be a threshold, meaning the physician providing the service must provide a full 15 minutes of depression screening to report the service. Email correspondence with CMS staff at the regional and national level indicate they share this interpretation. As discussed below, we believe this interpretation is incorrect and the descriptor and interpretation of code G0444 should be revised accordingly.

As we read the NCD in question, we understand that “up to 15 minutes” is indicative of the brief screening described and that beyond 15 minutes would imply management of depression has been provided in lieu of screening alone. Further, we note section 190.A of chapter 18 of the Medicare Claims Processing Manual states, “Effective October 14, 2011, CMS will cover annual screening **up to 15 minutes** for Medicare beneficiaries in primary care settings that have staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up.” (Emphasis added)

When CMS valued code G0444 in the final rule on the 2013 Medicare physician fee schedule, it stated:

HCPCS code G0444 (Annual Depression Screening, 15 minutes) was created for the reporting and payment of screening for depression in adults. As we explained in the proposed rule, we believe that the screening service described by HCPCS code G0444 requires similar physician work as CPT code 99211. Accordingly, we proposed a work

RVU of 0.18 for HCPCS code G0444 for CY 2013, the same work RVU as CPT code 99211. For physician time, we proposed 15 minutes, which is the amount of time specified in the HCPCS code descriptor for G0444. For malpractice expense, we proposed a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs were reflected in the CY 2013 proposed PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at www.cms.gov/PhysicianFeeSched/. We requested public comment on this CY 2013 proposed value for HCPCS code G0444.

Comment: Commenters supported the proposed payment for HCPCS code G0444 although a commenter suggested that in the future CMS should use the AMA RUC to assist us in valuing new codes. Response: In response to the suggestion that we rely upon AMA RUC input in valuing new codes, we agree with the commenter that the input of the AMA RUC is extremely useful in valuing new codes and in general, we obtain its recommendations in establishing the original values for new codes. However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in 2012 based upon CPT code 99211 and the AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in response to the solicitation for comment on the CY 2013 proposed rule. After consideration of the public comments we received, we are finalizing the proposed a work RVU of 0.18, and a time of 15 minutes for HCPCS G0444 code.

CMS set the time for G0444 at 15 minutes. However, the crosswalk to code 99211, which has a total physician time of 7 minutes and an intra-service time of only 5 minutes, indicates CMS viewed the 15 minutes assigned to G0444 not as a threshold but as a maximum beyond which the physician is no longer screening and instead providing additional services (e.g. counseling) reported with other codes.

Considering the crosswalk to code 99211, the service as anticipated in the NCD, and the explicit language in the Medicare Claims Processing Manual, we recommend that CMS revise its descriptor for G0444 to read “Annual depression screening, up to 15 minutes.” Further, we recommend CMS clarify to its staff, MACs, and audit contractors that the 15 minutes specified in code G0444 is not a threshold or minimum time to report the code but rather an indication that a service of more than 15 minutes exceeds screening and is reported with other codes. Otherwise, code G0444 appears misvalued by crosswalking a 15 minute service to one with less than half the time, suggesting code G0444 should be valued twice what is now.

For much the same reasons, we recommend CMS revise its descriptor for G0442 to read “Annual alcohol misuse screening, up to 15 minutes” and clarify to its staff, MACs, and audit contractors that the 15 minutes specified in code G0442 is not a threshold or minimum time to report the code but rather an indication that a service of more than 15 minutes exceeds screening and is reported with other codes (e.g., G0396 or G0397, Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention, 15 to 30 minutes or greater than 30 minutes, respectively). As with G0444, CMS crosswalked the value of G0442 to code 99211, suggesting similar logic should apply to the understanding of the

15 minutes specified in the descriptor and that, absent such understanding, G0442 is potentially misvalued for the same reason.

II.D Telehealth and Other Services Involving Communications Technology

Summary

CMS proposes to add nine services to the Medicare telehealth list permanently on a Category 1 basis and 13 services to the Medicare telehealth list on a newly created Category 3 temporary basis. CMS also solicits comments on whether additional services added to the Medicare telehealth list during the COVID-19 Public Health Emergency should be made permanent.

CMS states that it lacks the authority to waive the requirement that telehealth services be furnished using interactive audio-video communication technology outside of a Public Health Emergency. Therefore, CMS is not proposing to continue to recognize audio-only evaluation and management services (CPT code 99441-99443) for payment under the Physician Fee Schedule after the conclusion of the COVID-19 Public Health Emergency. CMS solicits feedback on the creation of a new coding and payment mechanism for audio-only visits, similar to a virtual check-in.

CMS proposes to permanently remove the provision of 42 CFR 410.78(a)(3) that specifies that “telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.”

CMS proposes to allow licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists to bill additional communication technology-based services (CTBS). CMS also proposes creating two new G-codes for practitioners who cannot independently bill for evaluation and management services.

CMS solicits feedback on any impediments that contribute to health care provider burden and that may result in practitioners being reluctant to bill for CTBS.

Response

We support the proposal to add 9 codes to the list of Medicare telehealth services, including GPC1X to capture visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services and home visits for the evaluation and management of an established patient (99347, 99348). We suggest that CMS add codes 99349 and 99350 to the telehealth services list on a permanent basis as opposed to temporarily on a Category 3 basis to avert confusion on the part of the physician or patient. Home visits, like office visits, are E/M services provided to patients on an outpatient basis. In many cases, only the site of service is different. CMS includes all levels of office visit on the Medicare telehealth list on a permanent basis. We believe it should do the same with home visits rather than creating an arbitrary distinction between different levels of home visits. We support CMS adding the additional 11 codes to the Medicare telehealth services list on a temporary basis. It is critically important for CMS and other stakeholders to assess the safety and efficacy of services delivered via telehealth before permanently adding them to the telehealth services list. However, we urge CMS to be transparent about all data collected and studies undertaken on these 13 Category 3 services and any additional services being considered. It is important to minimize disruptions caused by

any changes in Medicare telehealth coverage and reimbursement that could occur if CMS does not opt to adopt any Category 3 services on a Category 1 basis at the conclusion of the temporary period. In the end, we believe that physicians should receive payment for services that are reasonable, necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice. The technology used to deliver the services should not be a consideration, only whether the service is medically reasonable and necessary. The appropriateness of a telemedicine service should be dictated by the standard of care and not by arbitrary policies.

In response to the COVID-19 pandemic, CMS took the critical step of establishing separate payment for audio-only evaluation and management services (CPT codes 99441-99443). This change enabled family physicians to quickly pivot from caring for their patients in-person to caring for them remotely, whether or not those patients had interactive audio-visual technology. Audio-only evaluation and management services are especially critical for caring for patients who lack access to high-speed broadband, who lack the technology or technological literacy to utilize audio-video technology, or who are uncomfortable with video visits. According to a May 2020 survey of AAFP members, audio-only was the most popular modality for family physicians to delivery virtual care to their patients. We have received feedback from members that the audio-only codes were invaluable in allowing them to care for their patients, and they are eager for them to continue beyond the COVID-19 public health emergency.

We disagree with CMS' assertion that it lacks the authority to change the definition of "interactive telecommunications system," and encourages CMS to modify the definition to allow for audio-only interactions. The term "interactive telecommunications system" is not defined under section 1834(m) of the Social Security Act as requiring both audio and visual capabilities, but rather it is defined at 42 CFR 410.78 as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner." We request that CMS make an interim final rule with comment to amend the definition of "telecommunications system" in 42 CFR 410.78 to allow for audio-only services. Even if CMS moves to waive the video component of a telehealth visit, without Congressional action amending the originating and geographic site restrictions under section 1834(m) of the Social Security Act, Medicare beneficiaries in non-rural areas will not be able to access these visits once the COVID-19 public health emergency concludes.

Absent legislative action to amend geographic and originating site restrictions, we support the development of coding and payment mechanism, similar to virtual check-ins but with significantly higher value and longer unit of time. CMS should work through the CPT and RUC processes to develop and value a new code to allow all beneficiaries, regardless of geography or location, to access audio-only visits. CMS should consider the following when developing coding and payment for these services:

- The code should be available to patients regardless of location.
- The code should be limited to established patients.
- Payment for the code must be high enough to adequately cover the cost of delivery care. We have heard from our members that audio-only visits require the same level of medical decision making as audio-video and in-person evaluation and management visits. CMS should consider paying these visits similar to in-person visits to account for varying levels of visits complexity and time when valuing codes.

- This code should be permanent and remain in effect following the COVID-19 public health emergency.

We support CMS' amendment to 42 CFR 410.78(a)(3). Throughout the public health emergency and following the HIPAA waiver, family physicians have been using smartphones to successfully facilitate telehealth. Telephones provide an opportunity for more beneficiaries to participate in telehealth visits when a computer may be unavailable. Furthermore, this amended definition is consistent with our recommendation regarding the permanent inclusion of audio-only telehealth visits.

In response to CMS's solicitation of feedback on contributions to physician burden with billing CTBS, we urge CMS to consider two themes, clarity and consistency. Physicians typically interact with multiple payers which can have multiple plans. As each payer and/or plan has even slightly different rules around billing and coding for CTBS, it adds to the administrative burden of physicians. CMS should strive to harmonize the billing and coding rules for CTBS across all of its different offerings and with the private sector payers. This consistency would ease the burden of physicians and practices. Secondly, it is important for physicians to have clarity on those harmonized rules. We saw during the early stages of the public health emergency physicians and practices struggling to understand existing rules for CTBS billing and coding. CMS should provide clear and concise guidance on its requirement around CTBS. Of course, it is always easier to be clear and concise when the rules are the simplest.

II.E Care Management Services and Remote Physiologic Monitoring Services

Summary

CMS proposes code refinements related to remote physiologic monitoring (RPM), transitional care management (TCM), and psychiatric collaborative care model (CoCM) services as follows:

For CY 2021, CMS is clarifying how it reads CPT code descriptors and instructions associated with CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458) and their use to describe remote monitoring of physiologic parameters of a patient's health. Specifically, CMS proposes to clarify its understanding of these codes as follows:

- For code 99454 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days), the medical device or devices that are supplied to the patient and used to collect physiologic data are considered equipment and as such are direct PE inputs for the code.
- The medical device should digitally (that is, automatically) upload patient physiologic data (that is, data are not patient self-recorded and/or self-reported).
- As E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or nonphysician practitioners (NPPs) who are eligible to bill Medicare for E/M services.
- Practitioners may furnish these services to remotely collect and analyze physiologic data from patients with acute conditions, as well as from patients with chronic conditions.
- "Interactive communication" for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission.

- Time in the code descriptor for codes 99457 and 99458 mean the time spent in direct, real-time interactive communication with the patient.

Additionally, CMS proposes to establish as permanent policy two of the changes it made on an interim basis to the requirements for furnishing RPM services in response to the PHE for the COVID-19 pandemic. First, CMS proposes on a permanent basis to allow consent to be obtained at the time that RPM services are furnished. Second, CMS proposes to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

Lastly, with respect to RPM services, CMS seeks comments on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients. For example, CPT codes 99453 and 99454 currently require use of a medical device (as defined by the FDA) that digitally collects and transmits 16 or more days of data every 30 days for the codes to be billed. However, some patients may benefit from continuous short-term monitoring and not require remote monitoring for 16 or more days in a 30-day period. CMS seeks information that would help it understand whether it would be beneficial to consider establishing coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. Specifically, CMS is interested in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. CMS welcomes comments that may provide further clarification on how RPM services are used in clinical practice, and how they might be coded, billed, and valued under the Medicare PFS.

For TCM, CMS proposes to remove 14 additional actively priced (not bundled or non-covered) codes from the list of remaining codes that cannot be billed concurrently with TCM. The codes in question are CPT codes 90951-90969 (end-stage renal disease (ESRD)-related services). CMS believes no overlap exists that would warrant preventing concurrent reporting between TCM and these codes. CMS also proposes to allow chronic care management (CCM) code G2058 to be billed concurrently with TCM when reasonable and necessary. Minutes counted for TCM services would remain uncountable counted towards other services.

For CoCM, CMS proposes to establish a G code, GCOL1 (Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional). Code GCOL1 would have the same required elements as code 99493 (Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional,) as follows:

- Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant;
- Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health practitioners;

- Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;
- Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;
- Monitoring of patient outcomes using validated rating scales; and
- Relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.).

Additionally, CMS proposes that CPT time rules would apply, meaning code GCOL1 could be reported at more than 15 minutes in a month. This code could be used for either the initial or subsequent months.

Since GCOL1 would describe one half of the time described by code 99493, CMS proposes to price GCOL1 based on one half the work and direct PE inputs for CPT code 99493. CMS also proposes that code GCOL1 could be billed during the same month as CCM and TCM services, provided all requirements to report each service are met and time and effort are not counted more than once. The patient consent requirement would apply to each service independently. Code GCOL1 would necessitate only general supervision.

Response

CMS's understanding of the RPM codes is generally consistent with ours. We appreciate CMS's clarification of its interpretation of those codes and, again, find them consistent with our understanding of CPT and how the codes are intended to be used. We support CMS's proposals, on a permanent basis, to allow consent to be obtained at the time that RPM services are furnished and to allow auxiliary personnel to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

In general, we believe the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients and, thus, have not initiated any CPT code change proposals in this regard. If CMS determines that it would be beneficial to establish coding that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods, we encourage the agency to work through the CPT process to achieve those changes.

As CMS contemplates its approach to RPM services, it should be aware that our members report seeing solicitation for outsourced services to coordinate these devices and data onto a software platform. While there is nothing wrong with that approach per se, the marketing involved is aimed more at the financial opportunity involved than what is good for patients based on the evidence. We are concerned that RPM is ripe for fraudulent and abusive activity by commercial entities.

We support CMS's proposal to allow code G2058 to be billed concurrently with TCM when reasonable and necessary. Like CMS, we believe that if the time involved is not double counted, the services do not overlap and should be separately reportable. Family physicians do not typically provide ESRD-related services defined by CPT codes 90951-90969, so we cannot speak to CMS's proposal as it relates to those codes.

We also support the implementation of new code GCOL1 psychiatric collaborative care management of shorter duration than is captured by the existing codes. Family physicians are often the first point of contact for patients' mental health issues. The creation of new code GCOL1 will provide greater flexibility in the payment of psychiatric collaborative care management, which will facilitate its provision in family medicine practices. Given the current value of 99493, we believe the proposed value for GCOL1 is reasonable given the similar requirements of both codes and the relative time involved.

II.F Refinements to Values for Certain Services to Reflect Revisions to Payments for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

Summary

In general, CMS reaffirms its intent to adopt the CPT changes to the office/outpatient visit E/M codes and the RUC-recommended values for those codes, effective January 1, 2021. This includes the new prolonged services code, 99XXX. CMS also reaffirms its intent to implement a related add-on code, GPC1X, to provide payment for "visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition."

Related to these plans, CMS proposes to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215. As CMS notes, the RUC separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the average times associated with the three service periods does not match the RUC-recommended total time, which was the average of the respondents' total time. A simple example illustrates how this might occur:

	Pre-Service Time	Intra-Service Time	Post-Service Time	Total Time
Respondent A	1	2	1	4
Respondent B	2	2	0	4
Respondent C	3	2	1	6
Median	2	2	1	4

CMS remains concerned by the fact that if one adds up the medians of the individual time components (which is 5 (2+2+1) in the illustration above), the total does not equal the median of total time among all respondents (which is 4 in this illustration). Thus, CMS proposes to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

CMS also proposes to revalue certain services that are analogous to or whose current values are explicitly based on the value of the office/outpatient visit codes (e.g. via a crosswalk), including:

- End-Stage Renal Disease Monthly Capitation Payment Services
- Transitional Care Management Services

- Maternity Services
- Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483)
- Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits
- Psychiatric Collaborative Care Management
- Emergency Department Visits
- Therapy Services
- Behavioral Healthcare Services

In addition to these proposals, CMS seeks comment on two other issues. First, CMS asks whether visits/evaluations that are furnished frequently with same-day procedures should be revalued commensurate with increases to the office/outpatient E/M visits, or whether they are substantially different enough to warrant independent valuation. Second, CMS solicits comments providing additional, more specific information regarding what aspects of the definition of add-on code GPC1X are unclear, how CMS might address those concerns, and how CMS might refine its utilization assumptions for the code.

Lastly, for CPT code 99XXX, CMS proposes that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99XXX could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service, which differs from the CPT guidance to report 99XXX when the minimum time for the level 5 office/outpatient E/M visit is exceeded by 15 minutes.

Response

We appreciate and support CMS's intent to adopt the CPT changes to the office/outpatient visit E/M codes and the RUC-recommended values for those codes, as well as add-on codes 99XXX and GPC1X, effective January 1, 2021. For purposes of administrative simplification, it's critical that CMS and CPT are on the same page in this regard. Further, primary care physicians, who have been hit hard on the front lines of the COVID-19 PHE, desperately need the increase in value for the office/outpatient E/M visit codes, which they use most often.

Regarding CMS's proposal related to the total time for the office/outpatient E/M visit codes, we are disappointed that CMS has apparently changed its mind from what it proposed last year. We continue to support adoption of the RUC-recommended times, in which total time reflects the median of total time among all respondents rather than the sum of the medians for the three components of total time. As the RUC noted in its rationale, "total time is the appropriate measurement of time and each individual survey respondent's total time response should be used in determining the median total time." Like the RUC, we think that approach makes the most sense and best honors the robust survey data that CMS acknowledges in the proposed rule.

We understand this approach differs from the way in which CMS usually approaches total time. That said, for these codes, we believe it's important to use, as the RUC did and as CMS proposed to do last year, the median total time among all respondents. We are happy to work with the RUC and CMS to sort out any implications both for valuation of individual codes and for

PFS rate setting in general as well as how CMS should resolve differences between the sum of the components and median total times when they conflict.

In general, we also appreciate and support CMS's proposals to revalue certain services that are analogous to or whose current values are explicitly based on the value of the office/outpatient visit codes (e.g. via a crosswalk), with two exceptions. The first is therapy evaluations. As CMS notes in the proposed rule, these services "do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits." Further, they are distinct from the office/outpatient E/M visits in other ways, including:

- No distinction between new and established patients
- Three levels of complexity rather than four
- "Clinical decision making" defined differently than "medical decision making"

We believe there are enough differences between these services and the office/outpatient E/M services that CMS should not apply a percentage increase, which CMS estimates to be approximately 28 percent, to the work RVUs for the therapy evaluation and psychiatric diagnostic evaluation services codes. Instead, as with the ophthalmological services codes discussed in the proposed rule, we believe CMS should leave the value of the therapy evaluations unchanged. If the specialties that provide these services most commonly want to better align them with the revised office/outpatient E/M visit codes, there is a mechanism for them to do so via CPT, just as there is a mechanism for them to nominate the codes as potentially misvalued, if they believe the changes to values of the office/outpatient E/M visit codes have created rank order anomalies or other problems in the relativity to therapy evaluations. Absent pursuit of either mechanism, we think CMS should not change the current values, just as it proposes to do with the ophthalmological services codes.

The other exception concerns behavioral healthcare services, in particular stand-alone psychotherapy codes 90832, 90834, and 90837. CMS proposes to increase the value of each of these codes to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times. CMS states that its proposal reflects a desire to maintain relativity within this code family. However, we believe its proposal does just the opposite. For example, in 2020, 30 minutes of psychotherapy has the same work (1.50 work RVUs) whether it's done with an E/M service (90833) or independent of an E/M service (90832). Under CMS's proposal, in 2021, 30 minutes of psychotherapy done with an E/M service (90833) would involve less work (1.50 work RVUs) than 30 minutes of psychotherapy done independent of an E/M service (90832, 1.70 work RVUs). Thus, the proposal changes relativity within the family of psychotherapy services.

CMS seems intent on comparing the work of stand-alone psychotherapy to the sum of work involved in psychotherapy and medical evaluation and management done on the same day. We would argue that is the wrong comparison. CMS should compare psychotherapy to psychotherapy, not psychotherapy to psychotherapy plus E/M. Accordingly, we do not support CMS's proposal to increase the values of 90832, 90834, and 90837 to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times.

With respect to whether visits/evaluations that are furnished frequently with same-day procedures should be revalued commensurate with increases to the office/outpatient E/M visits, or whether they are substantially different enough to warrant independent valuation, we understand that CMS believes that visit/evaluation codes furnished the same day as a minor procedure are not closely analogous to stand-alone office/outpatient E/M visits, and therefore should not be revalued commensurate with the increase to stand-alone office/outpatient E/M visits for 2021. CMS continues to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing office/outpatient E/M visits to warrant different payment.

CMS's reasoning in this regard is not clear to us. When a visit or evaluation is done on the same day as a procedure and the visit/evaluation is significant and separately identifiable from the procedure, the visit/evaluation is separately reportable with an appropriate modifier (e.g. modifier 25). The work of the significantly, separately identifiable visit/evaluation is not changed by the subsequent same-day procedure. Further, when a procedure is typically (more than 50% of the time) done on the same day as a visit/evaluation, that is factored into the valuation of the procedure by the RUC and (to the extent it accepts the RUC's recommendations) by CMS. To pay differently for the visit/evaluation would be, at some level, to account for the same day procedure twice: once in the valuation of the procedure and again in the valuation of the visit/evaluation. We fail to understand the logic behind such a potential double-counting.

In sum, to the extent that the value of procedures already accounts for when they are typically performed on the same day as a visit/evaluation, we do not understand why CMS also wants to consider paying differently for the visit/evaluation, too. We welcome greater clarification of CMS's thinking on this subject and more explicit examples in future rulemaking.

Regarding code GPC1X and its definition, like CMS, we believe the typical visit described by the revised office/outpatient visit E/M code set still does not adequately describe or reflect the resources associated with primary care visits. Accordingly, we support CMS's proposal to maintain an add-on G code (GPC1X) that could be reported in conjunction with a primary care office visit, and like CMS, we expect most family physicians will use the add-on code with most E/M services they provide to their Medicare patients.

The AAFP [defines "primary care"](#) as:

Primary care is that care provided by physicians specifically trained for and skilled in comprehensive first contact and continuing care for persons with any undiagnosed sign, symptom, or health concern (the "undifferentiated" patient) not limited by problem origin (biological, behavioral, or social), organ system, or diagnosis.

Primary care includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings (e.g., office, inpatient, critical care, long-term care, home care, day care, etc.). Primary care is performed and managed by a personal physician often collaborating with other health professionals and utilizing consultation or referral as appropriate. Primary care provides patient advocacy in the health care system to accomplish cost-effective care by coordination of health care services. Primary care

promotes effective communication with patients and encourages the role of the patient as a partner in health care.

Given this definition, we would encourage CMS to consider revising its description of GPC1X as follows (language to be deleted is in ~~strike through~~ and language to be added is underlined):

Visit complexity inherent to evaluation and management associated with medical care and counseling services that serve as the first contact and continuing focal point for all needed health care services in coordination with others as needed ~~and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.~~ (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).

The proposed definition includes the continuing and comprehensive (“all needed health care services”) elements of primary care. However, it lacks the “first contact” and “coordination” elements that are otherwise essential in distinguishing primary care visits from other types of office/outpatient E/M visits. The suggested addition of “and counseling” is in recognition of the fact that some E/M visits are dominated by counseling of the patient rather than “care,” per se.

Regardless of how the new add-on code is defined, CMS will need to issue documentation guidance to support its appropriate use. There will be increased administrative burden associated with a primary care add-on, and clear documentation guidance may help ease that burden.

We understand the latter part of the proposed definition, which we recommend CMS delete, is intended to capture the complexity CMS had previously planned to represent with its add-on code GCG0X (Visit complexity inherent to E/M associated with non-procedural specialty care). Unfortunately, this language seems so broad (e.g. what does “serious” mean in this context) as to invite use of the add-on code with every office/outpatient E/M visit except those limited to an acute problem, which defeats the purpose of the add-on code from our perspective.

CMS has not directly outlined its utilization assumptions about GPC1X, in the 2020 proposed fee schedule. However, the Agency appears to assume that the add-on code will be applied to nearly 50% of all E/M claims for Allergy, Cardiology, Endocrinology, Family Medicine, General Practice, Geriatric Medicine, Hematology/Oncology, Internal Medicine, Interventional Pain Management, Neurology, Nurse Practitioner, Obstetrics/Gynecology, Otolaryngology, Pediatric Medicine, Physician Assistant, Psychiatry, Rheumatology, and Urology specialties. We believe this assumption overstates usage of the code in 2021, which negatively contributes to the downward adjustment in the conversion factor to maintain budget neutrality.

Utilization of new codes tends to be much lower than expected in the first year of implementation. Examples include transitional care management and Medicare annual wellness visits, among others. We expect code GPC1X will be similarly underutilized in 2021. Part of that will be due to lack of awareness among many physicians, despite educational efforts on the part of medical specialty organizations such as the AAFP. Part of it will also be due to uncertainty about when it's appropriate to use the code and fear of audits and unintentional overpayments, which amplifies the need for further clarity in the code descriptor and sub-regulatory guidance by CMS. Absent additional information about how CMS is estimating expected utilization of

GPC1X, it's difficult for us to provide a well-reasoned alternative assumption. However, we believe utilization is more likely to be closer to 10-25% than 50% of all E/M claims for the listed specialties. We urge CMS to reconsider its assumption in this regard, lest it unfairly suppress the 2021 conversion factor more than necessary to achieve budget neutrality and penalize physicians who are otherwise struggling to keep their practices open during the ongoing PHE.

In any case, we support CMS's proposal to value code GPC1X at 100 percent of the work and time values for code 90785, which would yield a proposed work RVU of 0.33 and a physician time of 11 minutes.

Lastly, we vehemently disagree with CMS's proposal that when the total time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99XXX could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. The CPT Editorial Panel clearly intended the minimum times to be the decision point for code selection, as evidenced by revisions to 99XXX that were approved by the CPT Executive Committee in May, which are not otherwise reflected in CMS's discussion of 99XXX in the proposed rule. Our understanding is that CPT included time ranges in the descriptors of the office/outpatient visit codes to eliminate the "midpoint" versus "must meet/exceed the typical time" issue that persists with payers and some coders.

In addition to differing from CPT guidance on the use of 99XXX, CMS's proposal effectively changes the range of time used to report 99205 and 99215 from what is in the CPT descriptor to a range that is 14 minutes longer. As alluded earlier, when CMS and CPT have different rules, this creates administrative burden on physicians. To the extent CMS finds the intent of the CPT Editorial Panel unclear because of the use of the terms "total time" and "usual service" in the CPT code descriptor (which we understand the CPT Executive Committee addressed in May), we urge CMS to address that with the Panel, of which CMS is a member, rather than acting unilaterally to alter the rules and add to the administrative burden of physician practices at the same time CMS is, ironically, trying to put "Patients Over Paperwork."

Section II G. Scope of Practice and Related Issues

(1) Teaching Physician and Resident Moonlighting Policies

b. Supervision of Residents in Teaching Settings through Audio/Video Real-Time Communications Technology

Summary

During the COVID-19 PHE, CMS adopted a policy on an interim basis allowing supervision of a resident by a teaching physician either in person or virtually through audio/video real-time communication technology during the key portion of the service. The goal was to ensure beneficiary access to necessary services and maintenance of sufficient workforce capacity to safely furnish services to patients.

This policy generally requires real time observation by the teaching physician through audio video technology (not mere availability) and does not include audio only (e.g., telephone without video). The primary care exception allows the teaching physician to direct the care and review the services furnished by a resident during or immediately after the visit remotely using

audio/video real-time communication technology. Excluded from the policy is surgical, high risk, interventional, endoscopic, or other complex procedures under anesthesia services.

The presence of COVID-19 may continue to persist in some communities after the expiration date of the PHE. Consideration is being given to whether this policy should be extended on a temporary basis, (that is if the PHE ends in 2021, this policy could be extended to December 31, 2021 to allow for a transition period before reverting back to status quo policy) or be made permanent.

Response:

We strongly encourage CMS to make supervision of residents in teaching settings through audio/video real-time communications technology permanent policy. The virtual presence promotes patient access, continuity, convenience, and choice; and it decreases the spread of communicable diseases.

This does not preclude a teaching physician from providing a greater degree of involvement in services furnished with the resident. The teaching physician would still have the discretion to determine the appropriateness of a virtual presence rather than in-person depending on the services being furnished and the experience of the resident. We agree with CMS that surgical, high risk, interventional, endoscopic, or other complex procedures under anesthesia should remain excluded.

c. Virtual Teaching Physician Presence during Medicare Telehealth Services

Summary

Payment for telehealth services outside the circumstances of the PHE requires the patient location at a telehealth originating site, and the teaching physician furnishing the service as the distant site practitioner with the involvement of the resident.

During the PHE, CMS adopted a policy on an interim basis to allow payment of teaching physician services when a resident furnishes a Medicare telehealth service with the virtual presence of the teaching physician through audio/video real-time communication technology. The relaxation of this regulation assisted in the reduction of exposure risk and increased the capacity of teaching settings' response to the PHE.

Outside of the PHE, CMS is concerned the policy to permit virtual presence of the teaching physician may not allow for sufficient full physician control over such services.

The presence of COVID-19 may continue to persist in some communities after the expiration date of the PHE. CMS is considering whether it should extend this policy on a temporary basis until the calendar year in which the PHE ends or make the policy permanent.

Response

We recommend payment for the teaching physician's virtual presence through audio/video real-time communication technology in the resident's telehealth service is made permanent policy.

The teaching physician can review the service with the resident during or immediately after the visit to exercise full and personal control over the service. The virtual presence promotes patient access, continuity, convenience, and choice, and it decreases the spread of communicable diseases.

Additionally, we recommend the option of an established patient audio-only visit be made permanent policy. Medicare beneficiaries may live in an area with limited broadband access or not have a compatible device that supports an audio-visual telehealth visit. The teaching physician and resident may be in separate locations using audio/video real-time communications for purposes of reviewing the visit.

d. Resident Moonlighting in the Inpatient Setting

Summary

To respond to COVID-19 PHE, CMS amended a regulation for resident services that are not related to their approved GME programs. Resident services that are furnished to hospital inpatients where the resident has a training program are separately billable physician services, provided such services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries. The resident must be fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the state in which the services are performed, and the services can be separately identified from services that are required as part of the approved GME program.

COVID-19 may continue to persist in some communities or experience a resurgence after the PHE ends. Therefore, CMS is considering whether this flexibility on an interim basis should be extended on a temporary basis (that is, if the PHE ends in 2021, this policy could be extended to December 31, 2021 to allow for a transition period before reverting back to status quo policy) or be made permanent.

Response

We continue to support the regulation that moonlighting should be provided by fully licensed physicians (including residents) who are furnishing separately billable physician services outside the scope of their approved GME program.

e. Primary Care Exception Policies

Summary

Under the “primary care exception,” Medicare makes PFS payment to teaching physicians in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the presence of a teaching physician. Regulations require that the teaching physician must not direct the care of more than four residents at a time, must direct the care from such proximity as to constitute immediate availability, and must review with each resident (during or immediately after each visit) the beneficiary’s medical history, physical examination, diagnosis, and record of tests and therapies. The teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiary seen by the resident, and ensure the services furnished are appropriate.

In response to PHE for COVID-19, CMS amended regulations to allow all levels of outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. CMS further expanded the list of services included in the primary care exception during the PHE. Additionally, PFS payment was allowed to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were on the list of Medicare telehealth services.

CMS seeks comments whether these policies should be extended on a temporary basis, (that is if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo) or be made permanent. Additionally, CMS is considering whether specific services added under the primary care exception should be extended temporarily or made permanent.

Response

We are appreciative that CMS expanded the list of services subject to the primary care exception to respond to the PHE for remote precepting of residents. This change provides educational training opportunities for applicable medical residents, expands patient access, and improves relational continuity of the patient and primary care physician in teaching centers.

To continue to address the needs of beneficiaries, we strongly recommend permanent policy enacted by CMS to expand the primary care exception to:

- CPT codes 99201-99204 and 99212-99214
- Telehealth CPT codes 99421-99423 both audio visual and audio only
- Transitional care management CPT code 99495

These low/moderate medical decision-making codes do not involve a diagnostic complexity that is beyond the resident physician skill to provide quality care without direct supervision. This does not preclude a teaching physician from providing a greater degree of involvement in services furnished with the resident. The teaching physician would still have the discretion to determine the appropriateness of a virtual presence rather than in-person depending on the services being furnished and the experience of the resident.

We believe it is safe, appropriate, and advantageous for CMS to expand these codes permanently. By expanding the primary care exception, it strengthens the continuity relationship between the beneficiary and primary care physician in teaching centers and the teaching physician has more time to spend with the resident physician on more complex and unstable patients.

(2) Supervision of Diagnostic Tests by Certain NPPs

Summary

CMS is proposing several policies nearly identical to those found in the President's Executive Order 13890 on "Protecting and Improving Medicare for Our Nation's Seniors" to modify supervision and other requirements that limit healthcare professionals from practicing at the top of their license. The proposed policy change, which was first established on an interim basis during the COVID-19 public health emergency, would allow NPs, CNS, PAs, and CNMs to

provide the level of supervision assigned to a diagnostic test to the extent authorized under state law and scope of practice. It would also allow NPs, CNS, PAs, or CNMs to supervise diagnostic psychological and neuropsychological testing services to the extent they are authorized to perform tests under applicable State law and scope of practice.

Response:

We strongly believe that care should be led by a physician. While we believe that health professionals should work collaboratively as clinically integrated teams in the best interest of patients, we oppose any regulation that undermines the physician-led team-based care models that have proven to be most effective in improving quality, efficiency, and most importantly, patient health.

In the NPRM in Section II. G. "Scope of Practice and Related Issue," CMS states, "Physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries... as long as it is not likely to result in fraud, waste or abuse. To the extent practice patterns change, there could be increased utilization that would increase cost, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to a physician." We firmly believe in the importance of cutting waste in health care, yet no patient, especially those in rural and underserved areas, should be relegated to receiving care by clinicians with lesser training by virtue of their zip code just in the interest of cost savings. Instead, efforts should be made to build physician capacity through an increased commitment to funding Teaching Health Centers Graduate Medical Education and other physician workforce development initiatives to train physicians to practice in underserved, including rural, areas.

While all health care professionals share an important role in providing care to patients, their skills are not interchangeable with those of a fully trained physician, and this is especially true in family medicine and primary care. Physicians complete four years of medical school while NPPs, including nurse practitioners and physician assistants, complete anywhere from one to three years of graduate-level training. In addition, physician residency requirements include 12,000 to 16,000 hours of clinical patient care, compared to 500 to 2,000 hours of clinical patient care for NPPs. Physician-led team-based care addresses patients' needs for high quality, accessible health care and reflects the skills, training and abilities of each of the health care team members to the full extent of their state-based licenses.

II.H Valuation of Specific Codes

Summary

CMS proposes refinements to the physician work and direct practice expenses of multiple codes in the fee schedule. Those of interest to family physicians included the following:

Immunization Administration (CPT codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS codes G0008, G0009, and G0010)

CMS notes these services have generally been valued based on a direct crosswalk to CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular). Because CMS finalized reductions in the valuation for that code for 2018 and because the reductions in overall valuation have been subject to the multi-

year phase-in of significant reductions in RVUs, the payment rate for the vaccine administration codes has been concurrently reduced.

CMS proposes to change that for 2021. Specifically, CMS proposes to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000 (Introduction of needle or intracatheter, vein). CPT code 36000 is a service with a nearly identical work RVU (0.18 as compared to 0.17 for CPT codes 90460, 90471, and 90473) and a similar clinical vignette. CMS believes the additional clinical labor, supply, and equipment resources associated with the furnishing of CPT code 36000 more accurately capture the costs associated with these immunization codes. Per CMS, this crosswalk will result in payment rates for vaccine administration services at approximately the same CY 2017 rates that were paid before the revaluation of CPT code 96372.

Regarding the add-on codes associated with these services (CPT codes 90461, 90472, and 90474) CMS notes the previous valuation methodology set their RVUs at approximately half of the valuation for the associated base codes, above. Absent additional information, CMS proposes to maintain that approach by valuing the three add-on codes at half of the RVUs of the crosswalk to CPT code 36000.

Chronic Care Management Services (CPT code 994XX and HCPCS code G2058)

CMS established payment for HCPCS code G2058 (Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month) in the CY 2020 PFS final rule. At the January 2020 RUC meeting, specialty societies (including the AAFP) requested a temporary crosswalk through CY 2021 between the value established by CMS for HCPCS code G2058 and the value of new CPT code 994XX (with a descriptor identical to G2058), pending a resurvey of the Chronic Care Management code family as part of the 2022 RUC review and Medicare fee schedule process. For CY 2021, CMS proposes the RUC-recommended work RVU of 0.54 and the RUC-recommended direct PE inputs for CPT code 994XX.

Bundled Payments under the PFS for Substance Use Disorders (HCPCS codes G2086, G2087, and G2088)

CMS proposes to revise the descriptor of three codes it created for payment of a bundled episode of care for the treatment of Opioid Use Disorder by changing “opioid use disorder” to “substance use disorder” (SUD) in each code descriptor. CMS notes that while these codes would describe treatment for any SUD, information about which specific SUDs are being treated would provide valuable information that can help assess local, state, and national trends and needs. CMS believes it is important that the diagnosis codes listed on the claim form reflect all SUDs being treated, however, they do not wish to create additional burden on practitioners related to claims submission. Thus, CMS seeks information on whether there are sources of data it could explore in order to provide this information. CMS also seeks information on whether there are differences in the resource costs associated with furnishing services for the various SUDs, and accordingly whether there is a need for more stratified coding to describe these services. CMS notes that in some instances, the CPT Editorial Panel has created CPT codes to replace G codes created by CMS, and CMS would welcome such input on these services and whether more granular coding is needed.

Office/Outpatient Visit E/M Services (CPT codes 99202-99215 and 99XXX)

As discussed elsewhere, CMS proposes to refine the total physician time (but not the planned work RVUs) for several of the codes in this family, so the total time in CMS’s database will equal the sum of the pre-, intra-, and post-service times for each code. Additionally, CMS proposes to not include one piece of equipment (desktop computer with monitor (equipment code ED021) in any of the office/outpatient visit E/M codes. CMS considers this equipment to be an Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service. This refinement would reduce the direct cost for these codes by 10 to 40 cents (depending on the code), which equates to 0.01 RVUs or less using the proposed 2021 conversion factor of \$32.26 per RVU.

Response

We appreciate and support the proposed revaluation of the immunization administration base codes (90460, 90471, 90473) through a crosswalk to code 36000, as the current values of 36000 more accurately reflect the relative resource costs associated with immunization administration. As is the nature of crosswalks, the involved codes are disconnected after the initial crosswalk, so changes to the source code no longer affect the crosswalked code(s). We believe this is the best possible situation for a service as essential as immunization administration and that this proposal will prevent further erosion in the relative value of these immunization administration services and return the rates to the level in effect before CMS revalued code 96372.

We request that CMS reconsider its proposal to value the add-on Immunization Administration codes (90461, 90472, 90474) at “half the valuation of the base codes.” CMS proposes this based on the determination that “the previous valuation methodology set their RVUs at approximately half the value of the base codes.” CMS further states that “absent additional information,” it proposes continuing this methodology. We would like to point out that the value of the add-on Immunization Administration codes are not half of the base codes for work or practice expense PE RVUs. The work RVU for the add-on codes is 88% of the value of the base codes, and the PE RVUs are 91% of the value of the base codes:

Current IA Base Codes wRVU (90460, 90471, 90473)	Current Add-On IA Codes wRVU (90461, 90472, 90474)	Current wRVU of add-on codes as percentage of base codes	Current IA Base Codes PE RVU (90460, 90471, 90473)	Current Add-On IA Codes PE RVU (90461, 90472, 90474)	Current PE RVU of add-on codes as percentage of base codes
0.17	0.15	88%	0.22	0.20	91%

Proposed IA Base Codes wRVU (90460, 90471, 90473)	Proposed Add-On IA Codes wRVU (90461, 90472, 90474)	Proposed wRVU Percentage Difference	Proposed IA Base Codes PE RVU (90460, 90471, 90473)	Proposed Add-On IA Codes PE RVU (90461, 90472, 90474)	Proposed PE RVU Percentage Difference

0.18	0.09	50%	0.69	0.35	51%
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We respectfully request that CMS apply the same magnitude relationship between the base and add-on codes as in the previous valuation:

CMS proposed 2021 IA Base Codes wRVU (90460, 90471, 90473)	AAFP recommended 2021 Add-On IA Codes wRVU (90461, 90472, 90474)	2021 wRVU of add-on codes as percentage of base codes	CMS proposed 2021 IA Base Codes PE RVU (90460, 90471, 90473)	AAFP recommended 2021 Add-On IA Codes PE RVU (90461, 90472, 90474)	2021 PE RVU of add-on codes as percentage of base codes
0.18	0.16	88%	0.69	0.63	91%

As CMS notes in the proposed rule, consistent beneficiary access to vaccinations is vital to public health, especially in the context of the current PHE related to the COVID-19 pandemic. There are enough barriers to vaccinations without inadequate or reduced payment rates for vaccine administration services. We appreciate CMS's proposal to support improved immunization rates through better payment for immunization administration.

We likewise appreciate and support CMS's proposals to accept the RUC-recommended work RVU and direct PE inputs for code 994XX in 2021 and to revise the descriptors for the bundled payments for substance use disorders. The latter proposal is welcome as part of CMS' efforts to expand access to additional services and its commitment to reducing administrative burdens for physicians. It may also help better document those with other challenges, such as those with alcoholism. This code update recognizes the complexity of addiction and that many individuals with SUD may be misusing multiple addictive substances, both legal and illicit, such as alcohol, nicotine, and marijuana. Therefore, any effort that may increase early interventions is welcomed.

We are not aware of any means other than the diagnosis code(s) on the claim to identify which specific SUDs are being treated. We note that every service code may have one or more diagnosis codes connected to it on a claim. Thus, a generic substance use disorder treatment code as CMS proposes still permits physicians to append one or more diagnosis codes to it on the claim and thereby specify which specific SUDs were treated and allow CMS to track that information without adding any more administrative burden than physicians already encounter in filing claims. If there is a need for more or more specific diagnosis codes, that can be addressed through future updates to the ICD-10-CM code set. If we discover alternatives, we will share that information with CMS.

We are also not aware that the associated resource costs vary significantly from one SUD to another, such that more stratified service coding is needed. If we become aware of a need for more granular coding in this regard, we are happy to work with CMS and others to bring an appropriate code change proposal forward through the CPT process.

Although its impact on the valuation of the codes is negligible, we respectfully ask that CMS include personal computers in the direct practice expenses of the office/outpatient visit codes. According to the Centers for Disease Control and Prevention, 85.9% of office-based physicians are using any kind of EHR.¹ Medication and problem lists must be accurately maintained by physicians during a visit using their EHRs. Furthermore, with the multiple medications now required by many patients, monitoring for drug-drug interactions becomes an essential component for patient safety and quality care. All of this makes a computer a typical, indispensable part of the medical equipment used during an office visit. Whether it's a desktop computer with monitor or a laptop, some computer is typically being used during an office visit and, contrary to CMS's belief, is allocated to the use of an individual patient for an individual service, just like the exam table in the room, which CMS does recognize.

There is precedent for including a computer as a direct practice expense. There are 52 CPT codes that include equipment item ED021. For office visits the work being performed using the computer is not administrative in nature. Rather, it is used to record, analyze, and communicate to the physician about every element of data that the clinical staff collects from the individual patient for the individual service.

In sum, the computer is dedicated solely to each patient throughout the visit to collect history, share and discuss lab and test results, and document the visit. It is an essential tool in conducting today's office visits, and CMS should recognize it as a direct medical equipment cost. We encourage CMS to accept the RUC's recommendation to include item ED021 (computer, desktop, with monitor) among the direct practice expense inputs for these codes.

II.I Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs (OTPs)

Summary

In the CY 2020 PFS final rule, CMS noted that it had received comments supporting the proposed definition of OUD treatment services but also requesting that CMS include naloxone to treat opioid overdose in that definition as a medication used in treatment of OUD. Although CMS did not finalize including naloxone in the definition of OUD treatment services in that final rule, it indicated that as it continues to work on refining this new Medicare benefit, it would consider including additional drugs in the definition of OUD treatment services under its discretionary authority in section 1861(jjj)(1)(F) of the *Social Security Act* to include other items and services the Secretary determines are appropriate. After further consideration, CMS has determined that it is appropriate to propose to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by FDA under section 505 of the FFDCFA for emergency treatment of opioid overdose.

Response

We support the inclusion of naloxone within the definition of opioid use disorder treatment and the inclusion of family outreach as part of those services. Naloxone has saved the lives of thousands of people who have experienced an opioid overdose, but it can't save anyone if it's not available when an overdose occurs. Although the number of naloxone prescriptions written has increased dramatically in recent years, patients in many areas of the country that need it the most still don't have easy access to it. The CDC's 2016 Guidelines for Prescribing Opioids for

¹ <https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm> Accessed August 12, 2019

Chronic Pain indicate that if every health care professional had followed that guideline recommendation, nearly 9 million naloxone prescriptions could have been dispensed in 2018 rather than the roughly 406,000 that were dispensed. This is also a very important consideration for improving health and mortality outcomes in rural areas, where naloxone access is lower than in metropolitan areas. From 2017 to 2018, the number of naloxone prescriptions more than doubled among primary care physicians and this proposal will further that progress.

III.B Opioid Treatment Program Provider Enrollment Regulation Updates for Institutional Claim Submissions.

Summary

CMS proposes to allow OTPs to bill on an institutional claim form.

Response

We support this proposal as there would be no differences in coverage or payment between services billed on the institutional claim form versus the professional claim form. This change responds to the need for more uniform forms and administrative flexibility.

III.E - Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Summary

CMS is proposing to add the requirements of section 2002 of the SUPPORT Act to our regulations at § 410.15 and 410.16 for the AWV and IPPE, respectively. Section 2002 of the SUPPORT Act requires a review of any current opioid prescriptions as part of the IPPE and AWV. Such review includes a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's severity of pain and current treatment plan, educational information on non-opioid treatment options, and a referral to a specialist, as appropriate. Section 2002 of the SUPPORT Act also requires adding an element to the IPPE and AWV to include screening for potential SUDs. Along with the screening for SUD, a referral for treatment, as appropriate, was added to the AWV.

CMS is proposing to amend 42 CFR 410.15 and 410.16 by: (1) Adding the term "screening for potential substance use disorders"; (2) Adding the term "a review of any current opioid prescriptions" and its definition; and (3) revising the "Initial Preventive Physical Examination," "first annual wellness visit providing personalized prevention plan services," and "subsequent annual wellness visit providing personalized prevention plan services"

Response

We support efforts to address the opioid crisis. We understand that high levels of misuse and addiction persist with devastating consequences despite annual decreases in the number of opioids prescribed in the United States since 2010. Family physicians are often wary of unfunded mandates, but due to the depth of the crisis, we recognize the need for including this new screen in the AWV. Furthermore, the proposal to define social history to include alcohol, tobacco, and illicit drug usage is appropriate. Also, the recommendation to broaden the focus from opioid use disorder to substance use disorder would be consistent with the need to address patients' complexity of substance usage.

III.H - Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

Summary

A new Medicare Part B benefit to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment is effective January 1, 2021. The law requires that, prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan of care must provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy.

CMS understands that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning CY 2021, CMS proposes that physicians are to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records before establishing a home infusion therapy plan of care. CMS is not proposing to create a mandatory form nor otherwise proposing to require a specific manner or frequency of notification of options available for infusion therapy under Part B. CMS believes current practice provides appropriate notification.

Response

We appreciate and support CMS's approach. We agree that physicians already likely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. We believe the current approach meets the intent of the law and that CMS's recognition of such is consistent with its Patients Over Paperwork Initiative.

III.I - Modifications to Quality Reporting Requirements and extreme and uncontrollable circumstances

Summary

(1) Proposed changes to the Consumer Assessment of Healthcare Providers & Systems (CAHPS) for Accountable Care Organizations (ACOs) Reporting Requirements for Performance Year 2020

Under current CMS extreme and uncontrollable circumstances policy, ACOs that qualify will have their quality performance score set equal to the mean quality performance score for all Shared Savings Program ACOs for the relevant performance year. Alternatively, if the ACO completely and accurately reports all quality measures, CMS will use the higher of the ACO's quality performance score or the mean score for all Shared Savings ACOs.

CMS states that the COVID-19 public health emergency applies to the entire country and ACOs may apply to reweight MIPS reporting categories due to extreme and uncontrollable circumstance in performance year 2020.

Due to numerous factors impacting ACOs due to COVID-19 (e.g., use of telehealth, shortage of staff, volume and nature of visits, and safety concerns) CMS is proposing to waive the CAHPS for ACOs reporting requirement for 2020 and give all ACOs automatic full credit for the CAHPS survey. CMS is requesting suggestions for other ways to conduct the survey that would mitigate concerns.

(2) Modification of the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020 (518-523)

CMS believes ACOs should be held responsible for reporting CMS Web Interface measures for performance year 2020, citing that though the PHE was present during the 2019 data submission period (early 2020) 98.7% of ACOs were able to report. CMS believe the current extreme and uncontrollable circumstances policy along with the proposed automatic full credit for CAHPS offer adequate relief for ACOs for performance year 2020.

CMS is seeking comment on an alternative proposal to modify the current extreme and uncontrollable circumstance policy, recognizing that the PHE creates uncertainty regarding performance rates for ACO quality measures for performance year 2020. The alternative proposes that: ACOs in a second or subsequent performance year that completely and accurately report the CMS web interface measures for 2020 would receive the higher of its 2020 score (including the automatic full credit for CAHPS) or their 2019 score; re-entering ACOs would receive the higher of their most recent quality score or the 2020 score; new ACOs that completely report quality data would score 100% for quality (including the automatic full credit for CAHPS and pay-for-reporting measures); ACOs and re-entering ACOs that do not completely report would receive the 2020 ACO mean quality score. CMS believes this modified extreme and uncontrollable circumstance policy would encourage ACOs to completely and accurately report for 2020 because they would be eligible to receive a score that may be higher than the 2020 mean, while offering protections for ACOs whose performance is adversely affected by the PHE.

Response

We agree with CMS proposal and rationale to waive the CAHPS for ACOs reporting requirement in 2020 and give all ACOs automatic full credit for the CAHPS for ACOs survey measures.

We support the alternate proposal to modify the current extreme and uncontrollable circumstances policy allowing ACOs that completely and accurately report for 2020 to receive the higher of their 2020 or their 2019 quality score (or most recent quality score in the case of re-entering ACOs); and assigning the 2020 mean ACO quality score to ACOs that do not completely and accurately report for 2020. We agree this will reward ACOs that have made efforts to improve their quality ratings with the opportunity to score higher than average. We also agree the alternative policy will encourage reporting, which is important to allow analysis of the impact of PHE on quality, while still protecting ACOs from negative consequences if their performance is adversely affected by the PHE.

**III.G - Medicare Shared Savings Program
Quality and Other Reporting Requirements**

CMS is proposing to revise the Shared Savings Program (SSP) quality performance standard beginning with the 2021 performance year. Under the new approach, the Alternative Payment Model (APM) Performance Pathway (APP) would replace the current SSP quality measure set. ACOs would only need to report one set of quality metrics that would satisfy the reporting requirements under both MIPS and the SSP.

Under this approach, the ACO would be scored based on the measures it reports. The ACO would receive zero points for the measures it does not report.

If an ACO does not report any of the three APP measures and does not field a CAHPS for MIPS survey, the ACO would not meet the quality performance standard for the purposes of the SSP and would not be able to share in savings and would owe maximum losses, if applicable.

This proposal does not include a quality “phase in.” All ACOs, regardless of performance year and agreement period would be scored on all the measures in the APP for the purposes of the SSP quality performance standard.

For MIPS, if an ACO fails to report via the APP would receive a zero in the MIPS quality performance category. If an ACO fails to report via the APP on behalf of its ACO participants, the ACO participants could report outside the ACO, on behalf of the MIPS eligible clinicians (ECs) who bill through the Taxpayer Identification Number (TIN) of the ACO participant and receive a MIPS quality performance score calculated at the ACO participant level.

ACOs would be assessed on a smaller measure set. They would be scored on six measures, and actively required to report three measures:

- Quality ID 001: Diabetes Hemoglobin A1c Poor Controls
- Quality ID 134: Preventive Care and Screening: Screening for Depression and Follow-up Plan
- Quality ID 236: Controlling High Blood Pressure

ACOs would report the measures using a submission method of their choice that aligns with the MIPS data submission types for groups. ACOs would receive a score of between three and 10 points for each measure that meets data completeness and case minimum requirements, which would be determined by comparing measure performance to established benchmarks.

Additionally, ACOs would need to field the CAHPS for MIPS survey and would be assessed on two claims-based measures: Hospital-wide, 30-day, All-cause Unplanned Readmission (HWR) Rate for MIPS EC Groups; and the All-cause Unplanned Admissions for Patients with Multiple Chronic Conditions (MCCs).

Response

We believe APM participants that have taken on responsibility for total cost of care should be provided flexibilities that simplify reporting and reduce burden. As noted elsewhere in our comments, we are concerned the APP framework and corresponding elimination of the APM Scoring Standard will have a negative impact on non-ACO MIPS APM participants. While we are supportive of the proposal to ease reporting burden for MSSP participants, we ask CMS to reconsider the elimination of the APM Scoring Standard.

In general, we support the proposed measures, as they represent a shift away from process measures toward more meaningful outcome measures. However, fewer measures provide less room for error – random variation in one measure will have a larger impact when there are fewer measures to absorb the impact. CMS needs to monitor the measures to ensure they are not overly sensitive to minor changes in performance, random variation, or risk adjustment methodologies.

We ask CMS to release additional information regarding how the CAHPS survey will be calculated as one measure as soon as possible.

We encourage CMS to maintain the “phase-in” and allow ACOs in their first year to submit quality measures for pay-for-reporting. This will help practices adjust to the new structure of an ACO and the MSSP.

We are concerned the elimination of the Web Interface will skew MIPS benchmarks for the remaining reporting methods. Additionally, the delayed release of the final rule will not provide ACOs adequate time to identify and implement alternative reporting processes before the start of the 2021 performance period. We ask CMS to delay retiring the Web Interface until CMS identifies a method to safeguard MIPS benchmarks from being skewed by MIPS APM participants and to allow ACOs an appropriate amount of time to implement a new reporting process.

Shared Savings Program Quality Performance Standard

CMS proposes to specify that the quality performance standard is the overall performance standard the ACO must meet to be eligible to receive shared savings. For all ACOs, CMS designates the quality performance standard as the ACO reporting quality data via the APP, according to the method of submission established by CMS and achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. If an ACO does not report any of the three of the measures ACOs are required to report and does not field a CAHPS survey, the ACO would not meet the quality performance standard.

CMS proposes to add a provision applicable to 2021 and subsequent performance years that specifies that ACOs must submit quality data via the APP to satisfactorily report on behalf of the ECs who bill under the TIN of an ACO participant for purposes of the MIPS quality performance category.

CMS seeks comment on this proposal.

Response

We support the transition away from an all-or-nothing reporting structure. The decrease in measures combined with the increased quality performance standard emphasizes the importance of using measures that are reliable and valid. We reiterate our request that CMS monitor the measures to ensure they are not overly sensitive to minor changes in performance, random variation, or risk adjustment methodologies.

Further, we also ask CMS to continue to evaluate the environment and make appropriate adjustments based on the impact of the COVID-19 pandemic. We appreciate CMS’ acknowledgment that quality benchmarks will be skewed. However, establishing benchmarks using performance period data makes it difficult for practices to gauge the impact of their performance, which is particularly troublesome for ACOs that have assumed downside risk.

Use of ACO Quality Performance in Determining Shared Savings and Shared Losses

For all tracks, CMS proposes that an ACO would qualify for shared savings if the ACO meets the minimum savings rate requirements established for the track/level, meets the proposed quality performance standard, and otherwise maintains its eligibility to participate in the SSP under Part 425.

Beginning with performance years on or after January 1, 2021, CMS proposes that an ACO that is otherwise eligible to share in savings meets the proposed quality performance standard, the ACO would share in savings at the maximum sharing rate according to the applicable financial model and up to the performance payment limit. These revisions would apply to all tracks.

If an ACO meets the quality performance standard, CMS would determine the loss rate by:

- Step 1: Calculating the quotient of the MIPS quality performance category points earned divided by the total MIPS quality performance category points available
- Step 2: Calculating the product of the quotient in step 1 and the sharing rate for the relevant track
- Step 3: Calculating the shared loss rate as 1 minus the product determined in step 2

An ACO with a higher quality score would owe a lower amount of losses compared to an ACO with an equivalent amount of losses but a lower quality score, assuming the ACO's quality score results in a shared loss rate within the range between the minimum shared loss rate and the maximum shared loss rate. Should the ACO's quality score result in a shared loss rate outside the limits, the shared loss rate is set to the minimum or maximum rate, as applicable.

An ACO that fails to meet the quality performance standard would be ineligible to share in savings and would owe the maximum amount of shared losses.

Response

We support this proposal as it provides a larger reward to ACOs for meeting CMS' increased quality performance standard. We support that an ACO's shared loss is based on its quality performance such that an ACO with a higher quality score would owe lower shared loss.

Changes to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2021

CMS proposes to update the extreme and uncontrollable circumstances to align with the APP. Beginning with the 2021 performance year, CMS would set the minimum quality performance score for an ACO affected by extreme and uncontrollable circumstances equal to the 40th percentile MIPS quality performance category score. If the ACO can report quality data and meet the data completeness and case minimum requirements, CMS would use the higher of the ACO's MIPS quality performance score or the 40th percentile.

CMS acknowledges that this policy may not offer the same level of protections for ACOs incurring losses that would have received the higher of their ACO quality score or the mean ACO score under the current policy. However, CMS notes that ACOs in downside risk arrangements are provided relief from losses through the application of the extreme and uncontrollable circumstance policy where shared losses are reduced based on the percentage of the year and the percentage of assigned beneficiaries impacted by the circumstance.

As CMS will no longer generate a Web Interface reporting sample for ACOs, CMS is proposing to determine the percentage of beneficiaries affected by the circumstance by using the quarter four list of assigned beneficiaries.

CMS seeks comment on these proposed revisions.

They are also seeking feedback on a potential alternative policy for performance year 2022 and beyond. The policy would adjust the amount of shared savings for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting. In this approach, CMS would not determine whether an ACO is impacted by an extreme and uncontrollable circumstance based on 20 percent of the beneficiaries being impacted. Nor would CMS use the higher of the ACO's own quality score or mean quality score to determine shared savings. Instead, CMS would determine shared savings for the ACO by multiplying the maximum possible shared savings the ACO would be eligible to receive based on its financial performance and track by the percentage of total months in the performance year affected by an extreme and uncontrollable circumstance and the percentage of the ACO's beneficiaries who reside in the affected area.

Revisions to the Definition of Primary Care Services used in SSP Beneficiary Assignment

CMS proposes to revise the definition of primary care services to include the following:

- CPT Codes 99421-99423
- CPT Code 99483
- CPT Code 99491
- HCPCS Code G2058 and its proposed CPT replacement code
- HCPCS Code G2064 and G2065
- HCPCS Code GCOL1

CMS is not proposing to add HCPCS Codes G2010 and G2012 to the list of primary care services but seeks comment on whether they should be included.

CMS did not propose to include CPT Codes 99441-99443 as these are not covered services outside the PHE.

CMS proposes to exclude advance care planning CPT codes 99497 and 99498 when billed in an inpatient care setting from beneficiary assignment. CMS would exclude ACP services when there is an inpatient facility claim with dates of service that overlap with the DOS for CPT 99497 or 99498. CMS seeks input on an alternative approach where it would exclude ACP services billed on claims with a POS code 21.

CMS welcomes comments on other CPT or HCPCS codes they should consider adding to the definition of primary care services.

Response

We support this proposal. We ask that CMS add the Primary Care Add-on HCPCS Code GPC1X and the new Prolonged Services Add-on CPT Code 99417 (when the base code is also a primary care service code) to the list of primary care services.

We do not support adding Principal Care Management (PCM) to the list of primary care services. We believe, like CMS, that these services will primarily be used by specialists. While the scope and description of services for CCM and PCM may be similar, it does not necessarily follow that both services should be considered primary care services.

III.K - Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a Prescription Drug Plan or an MA-PD plan

Summary

CMS provides background on the adoption of E-prescribing for Controlled Substances (EPCS) and the dramatic increase due to COVID-19 social distancing measures. *“Based on a published report of 2019 data reflecting the majority of prescribing activities across the country, 60.97 percent of U.S. pharmacies were capable of processing EPCSs, yet only 49 percent of prescribers were capable of electronically prescribing controlled substances. The same report showed that 38 percent of controlled substance prescriptions were electronically prescribed, while 85 percent of non-controlled substances were electronically prescribed. Pain management specialists appear to be using electronic prescribing more often for opioids than other prescribers, and family practitioners are using electronic prescribing for opioids less often.”*

Section 2003 of the SUPPORT Act requires e-prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D beginning January 1, 2021, subject to any exceptions, which HHS may specify. CMS discusses challenges to implementing EPCS during the public health emergency, such as identity proofing during social distancing mandates, and therefore is proposing to delay the start date by one year to January 1, 2022.

Response

We agree that significant challenges exist, exacerbated by the public health emergency, to implement EPCS by January 1, 2021. We strongly support CMS’s proposal to delay the mandate to January 1, 2022.

III.M Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule

Summary

The Office of the National Coordinator for Health Information Technology (ONC) updated the certified electronic health record (CEHRT) specification to further expand interoperability. Due to the public health emergency, ONC has delayed the enforcement date for EHRs to become certified under the new requirements. In the CMS proposed rule, they are also delaying the requirement for MIPS providers to use CEHRT certified to the new requirements and therefore allowing providers to use CEHRT certified to either the old or new requirements until August 2, 2022.

Response

Despite the importance of interoperability, the AAFP supports the delay in requiring a new requirement for CEHRT certified EHR until August 2022 due to the public health emergency.

III.N - Proposal to Establish New Code Categories

Summary

Currently, there are four existing HCPCS Level II codes for buprenorphine/naloxone products, which describe groupings of products by different strengths as indicated on their FDA labels. The current codes are:

- J0572 Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine
- J0573 Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
- J0574 Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine
- J0575 Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine

CMS proposes to replace these four codes with 15 new code categories to facilitate more accurate coding and more specific reporting of the variety of buprenorphine/naloxone products on the market. The new codes would be for use to report all currently marketed buprenorphine/naloxone products, based on strength as well as therapeutic equivalence as follows:

- JXXX1 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 2mg; 0.5mg
- JXXX2 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 4mg; 1mg
- JXXX3 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 8mg; 2mg
- JXXX4 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 12mg; 3mg
- JXXX5 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 2.1mg; 0.3mg (Bunavail)
- JXXX6 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 4.2mg; 0.7mg (Bunavail)
- JXXX7 Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 6.3mg; 1.0mg (Bunavail)
- JXXX8 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual 2mg; 0.5mg
- JXXX9 Buprenorphine Hydrochloride; Naloxone Hydrochloride; tablet; sublingual 8mg; 2mg
- JXX10 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 0.7mg; 0.18mg (Zubsolv)
- JXX11 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 1.4mg; 0.36mg (Zubsolv)
- JXX12 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 2.9mg; 0.71mg (Zubsolv)
- JXX13 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 5.7mg; 1.4mg (Zubsolv)
- JXX14 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 8.6mg; 2.1mg (Zubsolv)
- JXX15 Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 11.4mg; 2.9mg (Zubsolv)

CMS notes that these coding proposals do not change Medicare coverage or payment policies for oral or sublingual buprenorphine codes. The drug products described by these codes are not separately payable under Medicare Part B.

Response

We support CMS's proposal. As CMS notes, the new code series would permit physicians to more accurately bill insurers for the drug and dose utilized. Hopefully, it would also permit insurers to pay more appropriately for the drug and dose utilized. Since many payers assign a single payment rate to a single code and each of the current four codes represents multiple products, the payment rate assigned to the code may not appropriately compensate physicians and their practices for the actual product used. The expanded code series would also facilitate more specific and meaningful tracking of utilization of buprenorphine/naloxone products within practices.

IV. Quality Payment Program

MIPS Value Pathway (MVP) Development Criteria

CMS believes it is important to clearly identify linkages between the measures and activities within an MVP which will demonstrate the relevancy of measures and activities to the clinicians being captured within the MVP. Additionally, CMS believes it is important to factor in the appropriateness of the measures and activities being included and the comprehensibility of the MVP to clinicians and patients. CMS believes it is important to consider existing criteria for measure and activity inclusion or removal, as established for each performance category. CMS is proposing to develop and select MVPs using criteria related to the following areas:

- Utilization of measures and activities across performance categories
- Intent of measurement
- Measure and activity linkages with the MVP
- Appropriateness
- Comprehensibility
- Incorporation of the patient voice
- Measure and improvement activities considerations: MIPS quality measures
- Measures and improvement activities considerations: cost measures
- Measures and improvement activities considerations: improvement activities
- Measures and improvement activities considerations: Promoting Interoperability measures

CMS seeks comment on the MVP development criteria.

Response

In general, we support CMS' proposed development criteria for MVPs. We encourage CMS to carefully assess whether a proposed MVP reduces administrative burden and eases the transition to APMs. We urge CMS to ensure all MVPs maintain equitable reporting requirements across all specialties. Specialties and sub-specialties that believe they have fewer than six applicable quality measures should be required to report all cross-cutting measures so that all MVPs include six measures.

We remain concerned with the cost category. Relevant episode-based cost measures for primary care are still under development. Until there are episode-based measures relevant to primary care, family physicians will continue to be measured on total per capita cost and Medicare Spending per Beneficiary. As we stated last year, we are concerned with the appropriateness of these measures for small and rural practices as they have less influence on total costs for their patients and their performance may be easily skewed by outliers. We reiterate our request that CMS and the measure development team address this issue.

We believe practices that attest to using 2015 Edition CEHRT or having patient-centered medical home recognition should automatically receive full credit in the promoting interoperability category. We remain steadfastly opposed to health IT utilization measures.

As we note elsewhere in our comments, CMS should also heavily consider whether the MVP was developed collaboratively and included feedback from the specialties most impacted by the candidate MVP. We believe this collaboration should be required prior to the submission of an MVP to CMS. We appreciate that MVPs will be subject to comments through the rulemaking process but believe transparency and upfront collaboration between stakeholders could assist in this process. The submitter of the candidate MVP could attest they consulted with the stakeholders and specialties that are the primary reporters of the quality measures included in the proposal.

Capturing the Patient Voice

CMS is proposing, beginning with the 2022 performance period, to require stakeholders developing MVPs include patients as part of the MVP development process. Involving patients as part of the stakeholder's MVP development would be considered a pre-requisite for CMS to consider the candidate MVP for the upcoming performance period. CMS seeks comment on this proposal.

Response

We strongly support this proposal. Patients and caregivers play a crucial role in the healthcare system and their voice and perspective should be included in the development of MVPs.

Candidate MVP Co-development Solicitation Process and Evaluation

CMS proposes, beginning with the 2022 performance period, that stakeholders would need to formally submit their MVP candidates using a standardized template. CMS and its contractors will review, vet, and evaluate MVP candidates using the MVP development criteria to determine if the MVP is feasible. CMS will vet the quality and cost measures from a technical perspective. CMS intends to reach out to the stakeholder on an as-needed basis should questions arise. Once CMS completes its internal review, they will reach out to select stakeholders whose candidate MVP may be feasible for the upcoming performance period to discuss CMS' feedback and next steps that may include recommended modifications. As MVPs must be established through rulemaking, CMS will not communicate to the stakeholder whether the MVP candidate has been approved, disapproved, or is being considered for a future year.

CMS seeks feedback on this proposed process. CMS also seeks comment on how they could make this process more transparent in future years, for stakeholders that collaborate to develop MVP candidates and other MIPS stakeholders, should CMS consider the utilization of an advisory committee or technical expert panel to review MVP candidates, or the review of MVPs

by an interdisciplinary committee, similar to what is use for MIPS quality measures. CMS seeks feedback on whether stakeholders are concerned with the possibility of delayed MVP implementation if these additional methods of review are implemented. If so, CMS seeks strategies they should consider if they decide to implement additional methods of allowing public commentary on potential MVP candidates.

Response

We believe CMS should require the developer of a candidate MVP to collaborate and seek feedback from the stakeholders that would be most impacted by the MVP *prior* to submitting to CMS. CMS could facilitate this through an advisory committee or panel that includes representatives from all specialties. Those wishing to submit an MVP could solicit input from the committee. Interested specialties could collaborate and offer feedback as the MVP is developed. We believe this could create robust MVPs from the beginning. Public comment through the rulemaking process is critical. However, it provides feedback on a completed product and does not foster collaboration. We are not concerned with the possibility of a delayed implementation of MVPs. Developing relevant and quality MVPs is necessary if CMS expects ECs to adopt and find value in MVPs.

Reporting of MIPS through Third Party Intermediaries

CMS believes allowing third-party intermediaries to support MVPs will offer ECs and groups additional methods to report an MVP. CMS will work to establish a process to allow Qualified Clinical Data Registries and qualified registries to identify and select which MVPs they can support following the publication of the final rule. CMS seeks comment on this proposal.

Response

We support this proposal.

Timeline for MVP Implementation

CMS is delaying the implementation of MVPs and will revisit potential MVP implementation through future rulemaking, possibly beginning with the 2022 performance period.

Response

We appreciate CMS' willingness to delay the implementation of MVPs. The COVID-19 pandemic has disrupted every aspect of the healthcare system. It has also exposed many of the shortcomings of our healthcare infrastructure. It will be crucial to incorporate the lessons we've learned during the PHE as we build a stronger system.

APM Performance Pathway (APP)

CMS is proposing at §414.1367 to establish an APP under MIPS beginning in the 2021 MIPS performance year. APPs are designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation.

Response

As indicated by our comments below, we are supportive of APPs. However, we ask CMS to continue the APM scoring standard. While the APP eliminates burden for SSP ACOs, the elimination of the APM scoring standard shifts that burden to non-ACO MIPS APM participants.

Reporting through the APP

Individual MIPS ECs who are participants in MIPS APMs may report through the APP at the individual level. Groups and APM entities may report through the APP on behalf of their constituent MIPS ECs. The final score earned by the group would be applied only to MIPS ECs who are on the MIPS APM's Participation List or Affiliated Practitioner List on one or more snapshot dates. The final score would be the highest available final score for that TIN/National Provider Identifier (NPI) or a virtual group score.

For MSSP ACOs, MIPS ECs would have the option of reporting outside the APP, or within it at an individual or group level, for the purposes of being scored under MIPS. MIPS APM participants would be able to report through the APP or through any other available MIPS reporting mechanism.

CMS seeks comment on this proposal.

Response

We are supportive of this proposal. However, we ask CMS to continue the APM scoring standard. While the APP eliminates burden for SSP ACOs, it does not alleviate burden for non-ACO MIPS APM participants or ACO ECs wishing to report outside of the APP.

MIPS APMs

CMS is proposing to revise its definition of MIPS APM. CMS is proposing to maintain two existing criteria: (1) an APM Entity participates in the APM under an agreement with CMS or through a law or regulation; and (2) the APM bases payment on quality measures and cost/utilization. As CMS would not depend on the availability of quality measure data reported directly to the APM, they are not proposing to continue requiring that MIPS APMs be in operation and collecting data for the entirety of the performance period. CMS is proposing to expand the definition of MIPS APM to include those APMs in which there is only an Affiliated Practitioner List and that otherwise meet the proposed MIPS APM criteria. CMS seeks comment on this proposal.

Response

We support this proposal.

MIPS Performance Category Scoring in the APP – Quality

Beginning with the 2021 performance period, MIPS ECs scored under the APP would be scored on the quality measure set finalized for such MIPS performance period. For performance year 2021, CMS is proposing the following measures:

- Quality ID 321: CAHPS for MIPS
- Quality ID 001: Diabetes Hemoglobin A1c Poor Control
- Quality ID 134: Preventive Care and Screening: Screening for Depression and Follow-up Plan
- Quality ID 236: Controlling High Blood Pressure
- Measure # TBD: Hospital-wide, 30-day, All-cause Unplanned Readmission Rate for MIPS EC Groups
- Measure # TBD: Risk Standardized, All-cause Unplanned Admissions for Multiple Chronic Conditions for ACOs

If a measure is unavailable due to the size of the available patient population or MIPS ECs, groups, or APM Entities cannot meet the minimum case threshold, CMS is proposing to remove such measure from the quality performance category score for the MIPS EC, group, or APM Entity.

CMS is proposing to not apply the quality measure scoring cap at §414.1380(b)(1)(iv) if a measure in the APP measure set is topped out. CMS would consider amending the APP quality measure set through future rulemaking, if appropriate.

CMS intends to take the revised version of the Multiple Chronic Conditions measure through the National Quality Forum endorsement process in 2020. As the revisions would make the ACO MCC measure more aligned with the MIPS version, CMS proposes to include the revised All-Cause Unplanned Admissions for Patients with MCC measure in the APP measure set to be reported by any Medicare ACO.

CMS seeks comment on this proposal.

Response

We appreciate CMS' desire to reduce administrative burden for APM participants. However, we encourage CMS to ensure the APP design is applicable to all types of MIPS APM participants, not just those in ACOs.

A Partial Qualifying APM Participant (QP) in Primary Care First (PCF) who elects to report to MIPS through the APP would have to report an additional measure, as Quality ID 134: Preventive Care and Screening: Screening for Depression and Follow-up is not on the list of PCF quality measures. This could cause confusion and add complexity.

Additionally, PCF meets the financial risk requirements to be an Advanced APM (AAPM) under the Medical Home Model standards. As such, many PCF practices may be larger than 50 ECs and would not qualify as a QP or Partial QP and would be required to report to MIPS. These practices that report through the APP and would be required to report the additional measure (Quality ID 134). However, if they were to participate in traditional MIPS, they would need to identify three additional measures to satisfy the quality performance category requirements. Additionally, they would be held accountable for cost in both the PCF program and in MIPS, should CMS eliminate the APM Scoring Standard. Practices currently participating in the Comprehensive Primary Care Plus (CPC+) program would also be subject to the increased quality reporting and would be held doubly accountable for cost. The increased burden these entities would face far outweighs the benefits they receive by participating in an APM.

We strongly urge CMS to ensure the All-Cause Hospital Unplanned Readmission Rate for MIPS EC Groups and the revised All-Cause Unplanned Admissions for patients with Multiple Chronic Conditions are valid and reliable for small groups. We also note that PCF assesses practices on Inpatient Hospital Utilization. While there is no reporting burden for these measures as they are administrative-claims measures, the assessment of PCF practices would be more stringent compared to some other MIPS APMs.

We ask CMS to monitor the impact of this proposal on benchmarks. The CMS Web Interface was the highest used submission mechanism for the 2018 QPP performance period, with most

of those users being MIPS APM participants (42 percent). MIPS APM participants and Web Interface users tend to have higher quality scores than ECs that report through other mechanisms. The high performance rate of these participants could skew the benchmarks for the other reporting mechanisms. This would create a wider discrepancy between MIPS APM participants and groups and individuals. As a result, accurate assessment of an EC's performance, particularly an individual, would be difficult. We note that MIPS APMs already have significantly higher median and mean final scores compared to individual ECs.

We are aware that individuals make up a smaller portion of ECs. We also acknowledge CMS' desire to move more ECs toward APMs. We support this goal as we've seen the COVID-19 pandemic lay bare the extreme short-comings of the fee-for-service system. However, we are concerned the inequalities in MIPS assessment would have the opposite effect. A low performance and negative payment adjustment in MIPS would only worsen the financial situation of practices at a crucial time. MIPS could be a stepping-stone to APMs for many practices – but practices need to be fairly assessed to succeed in MIPS and ultimately APMs.

We ask that CMS clarify the submitter types in Table 41: APM Performance Pathway Quality Measure Set. The table only lists the APM Entity or Third-Party Intermediary as submitter types. We are unclear why individuals, groups, and virtual groups are not included as submitter types.

MIPS Performance Category Scoring in the APP – Cost

CMS is proposing to continue to waive the cost performance categories for MIPS APMs. CMS believes that because of an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population under the APM, it is necessary to give the APM Entity the ability to identify a single beneficiary population to prioritize in its cost-saving efforts so that the goals and evaluation associated with the APM are as clear and free of compounding factors as possible. CMS believes this would allow an APM Entity participating through the APP would be able to indicate their intent to focus their resources on the beneficiary population and services identified by the terms of the APM rather than the population and services they would have been responsible for under the MIPS cost performance category. CMS seeks comment on this proposal.

Response

We support this proposal but would point out that MIPS ECs participating in traditional MIPS are held accountable for total per capita cost and often have even more finite resources than APM Entities.

We urge CMS to maintain the APM Scoring Standard for MIPS APM ECs that do not report through the APP. Without it, those MIPS APM ECs would be held accountable for cost through their MIPS APM and through MIPS.

MIPS Performance Category Scoring in the APP – Improvement Activities (IA)

CMS is proposing to assign a score for the IA category for each MIPS APM and that score will be applied to participant MIPS ECs reporting through the APP. CMS will assign a baseline score for each MIPS APM based on the IA requirements of the MIPS APM. CMS will compare the requirements of the APM with the list of IAs and score those activities they would otherwise be scored according to §414.1380(b)(3). If a MIPS APM participant does not actually perform an activity for which IA credit would be assigned, the MIPS APM participant would not receive

credit for the associated IA. CMS will publish scores for each MIPS APM on the CMS website prior to each performance period. If the assigned score does not represent the maximum IA score, the MIPS ECs reporting through the APP would be able to report additional IAs that would count toward their scores. CMS seeks comment on this proposal.

Response

We support this proposal.

MIPS Performance Category Scoring in the APP – Promoting Interoperability

CMS proposes that the PI performance category would be reported and calculated the same as described in §414.1375. CMS seeks comment on this proposal.

Response

We believe practices that attest to using 2015 Edition Certified EHR Technology (CEHRT) or having patient-centered medical home recognition should automatically receive full credit in the promoting interoperability category. We remain steadfastly opposed to health IT utilization measures.

APP Performance Category Weights

CMS is proposing to reweight the performance categories for APM participants reporting through the APP to:

- Quality: 50%
- Cost: 0%
- PI: 30%
- IA: 20%

CMS seeks comment on this proposal.

Response

We support this proposal. Additionally, we urge CMS to maintain the APM Scoring Standard. The APP primarily benefits participants in MSSP ACOs. Non-ACO participants would face increased burden, regardless of if they report through the APP or through traditional MIPS. Maintaining the APM Scoring Standard would alleviate the burden of reporting to two programs and rewards those participants for transitioning to value-based payment.

Reweight a Performance Category

Should it become necessary to reweight the PI performance category to zero percent, CMS proposes to reweight the quality performance category to 75 percent and the IA performance category to 25 percent. Should the quality performance category be reweighted to zero percent, CMS proposes to reweight the PI performance category to 75 percent and the IA performance category to 25 percent. CMS seeks comment on this proposal.

Response

We support this proposal.

MIPS Performance Category Measures and Activities – Quality

CMS is proposing to establish the weight of the quality performance category for the 2023 and 2024 MIPS payment years. For the 2023 MIPS payment year, the quality category would comprise 40 percent of a MIPS EC's final score. For the 2024 MIPS payment year, the quality category would comprise 30 percent of a MIPS EC's final score. CMS seeks comment on this proposal.

Response

We encourage CMS to continue evaluating the environment as it determines category weights for future performance years. The COVID-19 pandemic has forced many practices to shift to survival mode. Burdensome quality reporting programs are not and should not be the priority right now. As such, once the pandemic subsides, CMS should not assume practices will be able to progress at the same rate as pre-pandemic. There will be a recovery phase where practices reassess their operations and adjust to a new normal. Furthermore, quality and cost performance measurement will need to adjust to accommodate the impact of the COVID-19 pandemic. Adjustments to measures, benchmarks, and methodologies, while warranted, will introduce even more change to practices. Expecting practices to adjust to everything at once is not realistic. Increasing the weight of the cost category when the long-reaching impacts of the COVID-19 pandemic are unknown may further disadvantage practices working to rebuild in the years to come.

We understand that the increase to category weights are statutory. We encourage CMS to work with Congress, so they have additional flexibility to adjust the category weights and the implementation timeline of weight increases.

Establishing Separate Performance Periods for Administrative Claims Measures under the Quality Performance Category Beginning with the 2023 MIPS Payment Year

CMS is proposing to modify the definition of the performance period for the quality and cost categories to the following: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year that occurs two years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in §414.1330(a)(1). CMS seeks comment on this proposal.

Response

In general, we do not have concerns with this proposal. We encourage CMS to monitor the implementation and validity of measures that include extended performance periods.

MIPS Performance Category Measures and Activities – Cost

CMS proposes to establish the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year. CMS proposes the weight of the cost performance category to be 30 percent of the MIPS final score for the 2024 MIPS payment year.

CMS seeks comment on this proposal. CMS is interested in any additional options they should consider, such as a 22.5 percent weight for the 2023 MIPS payment year and 30 percent weight for the 2024 MIPS payment year (a 7.5 percent increase for each year).

Response

We encourage CMS to continue evaluating the environment as it determines category weights for future performance years. The COVID-19 pandemic has forced many practices to shift to survival mode. Burdensome quality reporting programs are not and should not be the priority right now. As such, once the pandemic subsides, CMS should not assume practices will be able to progress at the same rate as pre-pandemic. There will be a recovery phase where practices reassess their operations and adjust to a new normal. Furthermore, quality and cost performance measurement will need to adjust to accommodate the impact of the COVID-19 pandemic. Adjustments to measures, benchmarks, and methodologies, while warranted, will introduce even more change to practices. Expecting practices to adjust to everything at once is not realistic. Increasing the weight of the cost category when the long-reaching impacts of the COVID-19 pandemic are unknown may further disadvantage practices working to rebuild in the years to come.

Additionally, we remain concerned about the cost category in general. We continue to question the appropriateness of the total per capita cost and Medicare Spending per Beneficiary measures for small and rural practices.

We understand that the increase to category weights are statutory. We encourage CMS to work with Congress, so they have additional flexibility to adjust the category weights and the implementation timeline of weight increases.

Addition of Telehealth Services to Previously Established Measures for the Cost Performance Category Beginning with the 2021 Performance Period

Beginning with the 2021 performance period, CMS proposes to add costs associated with telehealth services to the previously established cost measures. Many telehealth services are already captured as they are billed using the same code as when the service is furnished in-person. CMS is proposing to add codes that were newly included on the Medicare telehealth services list through the March 31st COVID-19 IFC. The codes CMS proposes to add represent service categories already captured in the measures. CMS does not consider their addition to alter the intent of the measures or capture a new category of costs. CMS seeks comment on this proposal.

Response

We support this proposal. We ask that CMS release updated measure specifications as soon as possible.

MIPS Performance Category Measures and Activities – Promoting Interoperability

Beginning with the 2024 MIPS payment year and each subsequent MIPS payment year, CMS is proposing to establish a performance period for the PI category of a minimum of a continuous 90-day period within the calendar year that occurs two years prior to the applicable MIPS payment year, up to and including the full calendar year. CMS requests comment on this proposal.

Response

We support this proposal. However, we believe practices that attest to using 2015 Edition Certified EHR Technology (CEHRT) or having patient-centered medical home recognition should automatically receive full credit in the promoting interoperability category. We remain steadfastly opposed to health IT utilization measures.

APM Entity Groups and APM Scoring Standard for MIPS ECs Participating in MIPS APMs
Effective January 1, 2021, CMS is proposing to terminate the APM Scoring Standard. CMS proposes to establish a MIPS APM Performance Pathway and scoring rules that would be available to report to MIPS for MIPS ECs in MIPS APMs. CMS seeks comment on this proposal.

Response

We do not support this proposal. CMS states in the Regulatory Impact Analysis that it assumed non-ACO APM Entities would participate in MIPS rather than the APP. Should a non-ACO APM Entity participate in MIPS, the administrative burden would be double. A practice participating in the PCF initiative is required to report three measures. However, if they were to participate in traditional MIPS, they would need to identify three additional measures to satisfy the quality performance category requirements. Additionally, they would be held accountable for cost in both the PCF program and in MIPS should CMS eliminate the APM Scoring Standard. Practices currently participating in the CPC+ program would also be subject to the increased quality reporting and would be held doubly accountable for cost. The increased burden these entities would face far outweighs the benefits they receive by participating in an APM.

We ask CMS to continue the APM Scoring Standard for non-ACO APM Entities. Entities could choose whether to report via the APP or via the reporting requirements of their APM. CMS seems to have changed the reporting requirements for the SSP and dropped those changes into MIPS and called it the APP. We are supportive of reducing the burden and providing additional flexibilities for APM participants who have taken on responsibility for total cost of care. Rather than modifying MIPS to a one-size-fits-all that primarily impacts SSP ACOs, CMS could move forward with the APP as proposed, but also maintain the APM Scoring Standard to provide burden reduction and additional flexibilities to non-ACO APM Entities.

APM Entity Group Scoring

CMS is proposing that the MIPS final score for the APM Entity would be applied to each MIPS EC in the APM Entity group. The MIPS payment adjustment would be applied at the TIN/NPI level.

CMS is proposing that in cases where an APM Entity reports to MIPS, but a performance category's data submission cannot be made at the APM Entity level, each MIPS EC in the APM Entity group would be assigned the highest available score for that performance category (either at the individual or TIN-level), and the scores for all MIPS ECs in the APM Entity group would be averaged to calculate the APM Entity level performance category score. If a MIPS EC in the APM Entity receives an exception, the EC would receive a null score when CMS calculates the APM Entity's performance category score.

CMS is proposing to calculate an improvement score for each performance category for which a previous year's total performance category score is available.

CMS seeks comments on these proposals.

Response

We support this proposal.

Reweighting based on Extreme and Uncontrollable Circumstances for APM Entity Groups

CMS is proposing to allow an APM Entity to submit an extreme and uncontrollable circumstances application that would apply for all four performance categories and all MIPS ECs in the APM Entity group. If approved, the MIPS ECs within the APM Entity would receive a final score equal to the performance threshold. Requests would be approved or denied in their entirety. CMS proposes to begin this policy with the 2020 performance period.

CMS is proposing that an APM Entity must demonstrate that greater than 75 percent of its MIPS ECs would be eligible for reweighting the PI category for the applicable performance period.

If an APM Entity's reweighting application is approved and MIPS data is submitted, all four categories would still be reweighted. The data submission would not void the request for reweighting and its approval. Reporting done by a MIPS EC or group would result in a score for only that MIPS EC or group.

CMS seeks comments on these proposals.

Response

We support this proposal but encourage CMS to consider a lower threshold for granting the exception. Even if 50 percent of the MIPS ECs are eligible for reweighting, the APM Entity would still face a significant hardship. The threshold of 75 percent may be appropriate for determine reweighting for hospital-based ECs. However, ECs in that situation are not also impacted by an extreme or uncontrollable circumstance.

Quality Measure Benchmarks

CMS believes the flexibilities for the 2019 performance period may result in skewed benchmarks. CMS considered two benchmarking options for the 2021 performance period. CMS intends to use performance period benchmarks for the 2021 performance period. CMS acknowledges that this method would not allow physicians to know benchmarks prior to the start of the performance period, but believes using current information could provide more accurate results for benchmarking purposes for the 2021 performance period and could capture changes that may have occurred because of the COVID-19 PHE.

CMS is seeking feedback on this proposal. CMS considered an alternative approach where they would use historical benchmarks from the 2020 MIPS performance period for the 2021 performance period. The benchmarks used for the 2020 performance period are based on data from the 2018 performance period. CMS is concerned this approach could result in distributions of scores used for benchmarks that no longer reflect the standard of care. CMS seeks comment on this alternative approach.

Response

We are supportive of this proposal. However, we strongly urge CMS to continue to monitor the situation and potentially reassess its policy as more information becomes available. The long-term impact of the PHE on quality performance and benchmarking may not be known for several years.

While not addressed in this proposed rule, we ask CMS to re-evaluate its policies for the 2020 performance period. We believe CMS should automatically apply the extreme and

uncontrollable circumstances exception for the 2020 performance period. In previous rules, CMS noted that events such as a public health emergency could trigger the automatic extreme and uncontrollable circumstances policy. However, in the 2020 Quality Payment Program Exception Applications Fact Sheet, CMS states that no qualifying events had been identified for the 2020 performance period. We respectfully suggest that a global pandemic and twice declared national public health emergency should qualify for such an exemption. Family physicians have responded to the pandemic emergency with flexibility and creativity, often using personal financial resources and risking their lives to care for their communities. Four times as many family physicians have died from COVID-19 than any other medical specialty, a testament to the courage of family physicians as well as lack of PPE for primary care.

The COVID-19 pandemic has had varying impacts on communities across the United States. But there are very few, if any, communities that have not been impacted at all. The automatic extreme and uncontrollable circumstances policy does not prevent or prohibit practices from submitting data and receiving a MIPS final score and payment adjustment. The automatic policy merely protects those who are unable to report and reduces the unnecessary burden of submitting an application. Without the automatic application of the policy, practices that were severely impacted but failed to submit an application would receive the maximum negative payment adjustment. This could be a significant, if not fatal, financial hit to many practices. We implore CMS to provide automatic relief to practices. We ask that CMS make this determination and announcement as soon as possible since practices will soon be facing increased stressors as the flu season begins.

Complex Patient Bonus

CMS acknowledges that there are direct effects of COVID-19 for patients who have the disease as well as indirect effects for patients who postponed care or experienced other disruptions to receiving care. To account for the increased complexity of patients during the PHE, CMS is proposing to multiply an EC's complex patient bonus by two, with a maximum of 10 bonus points available. For example, if an EC were to receive four bonus points, CMS would double that, and the EC would receive eight complex patient bonus points. CMS is proposing this policy for the 2020 performance period.

CMS seeks comment on this proposal and other approaches they should consider.

Response

We support this proposal and encourage CMS to continue monitoring the situation and making additional adjustments as appropriate. We also ask that CMS extend this policy to the 2021 performance period, and possibly beyond.

Final Score Performance Category Weights

For the 2021 performance year, CMS will use similar redistribution policies as previously finalized, but with minor adjustments to account for the increased weight of the cost category. CMS would only redistribute weight to the cost category when the cost and IA categories are the only categories scored. Each performance category would be weighted at 50 percent.

For the 2022 performance year, CMS proposes to only redistribute weight to the cost category when the cost and IA categories are the only categories scored. CMS will revisit its other reweighting policies in future rulemaking.

Response

We request that CMS refrain from redistributing weights to the cost category until that category has more relevant and applicable measures available for all specialties.

Establishing the Performance Threshold

In light of the COVID-19 pandemic, CMS is revisiting the previously finalized performance threshold for the 2021 performance period. CMS is proposing to establish a performance threshold of 50 points for the 2021 performance period. CMS is not proposing to change the exceptional performance threshold that was finalized last year.

CMS proposes to revisit the estimated performance threshold for the 2022 performance period, which is 74.01 points. CMS may update the performance threshold for the 2021 performance period if they receive data that supports updating the estimate for the 2022 performance period.

CMS seeks comment on the proposed performance threshold.

Response

We ask CMS to consider maintaining the 2020 performance threshold for the 2021 performance year. As noted elsewhere in our comments, ECs will be dealing with the COVID-19 pandemic and its residual impact for the foreseeable future. Expecting them to be able to progress as they would have pre-PHE is not reasonable. A five-point increase from 2020 to 2021 may not seem high, but the increase will be higher for practices that received an exception for the 2019 and 2020 performance periods.

APM Incentive Payment

CMS is clarifying that the APM Incentive Payment amount is calculated based on the paid amount of applicable claims for professional services that are subsequently aggregated to calculate the estimated aggregate payments. CMS does not believe it would be appropriate to calculate the APM Incentive payment based on amounts that were allowed, but not actually paid, as the Act specifies the incentive payment is equal to five percent of the estimated aggregate payments for covered professional services.

CMS seeks comment on this proposal.

Response

We agree with this proposal.

APM Incentive Payment Recipient

CMS is proposing to establish a revised approach to identify the TIN(s) to which they make the APM Incentive Payment. The revised approach includes looking at the QP's relationship with their TIN(s) over time, as well as considering the relationship the TIN(s) have with the APM Entity or Entities through which the EC earned QP status, or other APM Entities the QP may have joined in the interim.

CMS is proposing a cutoff date of November 1 of each payment year, or 60 days from the day on which they make the initial round of APM Incentive Payments, whichever is later, as a point

after which CMS will no longer accept new Help Desk requests from QPs or their representatives who have not received their payments.

CMS is proposing a hierarchy to identify the TIN(s) to which they would make the APM Incentive Payment. CMS will progress through the hierarchy until it identifies a TIN(s) to which the QP is currently affiliated. If CMS identifies more than one TIN at a step, they would divide the payment proportionally between the TINs based on the relative paid amount for Part B covered professional services that are billed through each TIN. If CMS is unable to identify any TIN for the QP, they will attempt to contact the QP via a public notice to request their Medicare payment information. The QP must then notify CMS of their claim by November 1 or 60 days after CMS announces that initial payments have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such a payment year. CMS seeks comment on these proposals.

Response

We agree with this proposal. We ask that CMS consider including an appeal process for split incentive payments to allow payments rendered to incorrect TIN(s) to be reconciled retrospectively as QPs may not be aware of being assigned to two or more TIN(s).

Qualifying APM Participant and Partial QP Determinations

Under CMS' current methodology for calculating Threshold Scores includes attribution-eligible beneficiaries in the denominator of the calculation for some APM Entities for whom those same beneficiaries could never be included in the numerator. This may happen when a beneficiary is prospectively attributed to an APM Entity and is precluded by the applicable rules for one or more APMs from attribution to other APM Entities in certain other APMs.

CMS is proposing to amend its regulation to specify that beneficiaries who have been prospectively attributed to an APM Entity for QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

CMS seeks comment on this proposal.

Response

We agree with and support this proposal.

Targeted Review of QP Determinations

CMS is proposing to establish a targeted review process for limited circumstances surrounding QP determinations.

Targeted reviews include instances where the EC believes CMS made a clerical error in their QP determination, such as omission of the EC from the Participation List used for QP determinations. If CMS determines they made an error, they would award the QP the most favorable QP status that was determined at the APM Entity level on any of the snapshot dates on which the EC participated in the APM Entity. CMS would not revisit prior QP determinations as it conducts its review.

CMS is not proposing to conduct targeted reviews of Affiliated Practitioner Lists. Additionally, CMS would not accept targeted review requests to correct omissions from Participation Lists of Other Payer AAPMs.

CMS proposes to align the QP targeted review process with the MIPS targeted review process. Either an EC or an APM Entity could submit a request. Requests must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes MIPS payment adjustment factors available for the applicable payment year.

If a request is denied, CMS will not change the QP or partial QP determination. CMS will respond to each request and determine whether a review is warranted. Should CMS request additional information, it must be provided to CMS within 30 days of CMS' request.

If CMS notices a pattern of CMS error that impacts ECs beyond those who submitted a review request, CMS would correct any additional errors regardless of whether a targeted review request was submitted for the other ECs affected.

Targeted review requests would be final and not subject to further administrative review, appeal, or judicial review.

CMS seeks comment on this policy.

Response

We appreciate CMS' willingness to review QP determinations when the EC believes there has been a clerical error. We support CMS' proposal to automatically correct determinations if a trend or pattern appears. We also appreciate that CMS will not retract any QP determinations as it conducts its review.

We urge CMS to work with Congress to modify the QP thresholds included in the Medicare Access and CHIP Reauthorization Act (MACRA) law. Beginning in 2021, MACRA requires the Medicare payment threshold to increase to 75 percent. This represents a 25-point increase from the previous year. The steep increase may jeopardize the QP status for many APM participants. It is crucial that we maintain and strengthen the momentum to shift away from fee-for-service. We encourage CMS to work with Congress to address this cliff. The Secretary could also use their authority to adjust the patient threshold.

Partial QP Election to Report to MIPS

CMS is requesting comment on whether to allow an APM Entity to make the Partial QP election on behalf of all the individual ECs associated with the APM Entity. CMS is interested in comments, feedback, and recommendations for how to address: (1) conflicting responses either from an APM Entity and an individual or from two or more different APM Entities; and (2) situations where the EC is participating in more than one APM Entity and CMS does not receive elections from all parties. CMS seeks comment on how to handle instances when multiple APM Entities make elections that are not in agreement and the individual EC has not made an election.

Response

We suggest CMS maintain its current policy where elections are made by the ECs themselves.

Appendix 1: Table B.11

CMS proposes to add NQF 0576 “Follow-up After Hospitalization for Mental Illness (FUH)” to the Family Medicine Specialty set. CMS gives the following rationale, “Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Family Medicine specialty set.”

Response

We oppose the addition of this measure to the Family Medicine Specialty set, and note that the measure specifications require a visit with a mental health professional to satisfy the measure (i.e., a visit with a family physician does not satisfy the measure); therefore application to family medicine is inappropriate.

V. Planned 30-day Delayed Effective Date for the Final Rule

Summary

Citing the priority of its efforts in support of containing and combatting the COVID-19 PHE and the significant resources it’s devoting to that end, CMS expects it will determine the PFS final rule will be effective 30 days after publication. Consequently, CMS expects to provide a 30-day delay in the effective date of the final rule (rather than the usual 60-day delay) from the date of its public availability in the *Federal Register*.

Response

We understand that CMS is essentially advising the public that the final rule on the 2021 Medicare physician fee schedule will still be effective January 1, 2021, but won’t be available until December 1, 2020, rather than November 1, 2020, which would normally be the case. We understand the need to for CMS to prioritize the COVID-19 PHE, just as our members have done. While a 30-day period between availability of the final rule and its effective date on January 1, 2021 is not ideal, it is preferable to delaying both the availability of the rule and its effective date to maintain the usual 60-day period. We ask only that CMS be mindful of the administrative burden a shorter implementation period puts on physicians and exercise a modicum of grace in enforcing provisions that require action on the part of physicians effective January 1, 2021.

In conclusion, we appreciate the opportunity to provide these comments. Please contact Ann Spicer at 614/267-7867 with any questions.

Sincerely,



Mike Sevilla, MD, FAAFP
President



Sarah Sams, MD
Public Policy Committee Chair

