

September 5, 2018

Seema Verma, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1693-P P.O. Box 8016 Baltimore, MD 21244-8016

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the proposed rule titled, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program" published by the Centers for Medicare & Medicaid Services (CMS) in the July, 27, 2018, Federal Register.

The AAFP commends your continued leadership and commitment to identifying and implementing policies that improve the Medicare program. We have been pleased to work with you and your team on many of these important initiatives and we look forward to continuing to do so in the future.

Since becoming Administrator, you have prioritized two items that are among the AAFP's top priorities for our members: reducing the administrative burden of modern medical practice and preserving independent physician practices. We share these goals and policy objectives and are committed to helping you and the Administration achieve them.

We are equally committed to assisting you and the Administration to achieve your stated goal of transforming the Medicare program into one that prioritizes the delivery of high-quality, patientcentered, and efficient care. As we have stated, and literature supports, achieving meaningful transformation of our health care system starts with achieving meaningful transformation of primary care and continues with an increased investment in primary care to sustain the transformation.

We appreciate the opportunity to share our official response to the 2019 proposed rule. Our comments are comprehensive and intended to provide constructive recommendations so CMS can implement policies that will be meaningful for beneficiaries, supportive of their family physicians, and improve the financial security of the program. It is our hope that you and the full CMS team find these comments to be supportive and beneficial to your work ahead.

The AAFP is respectfully offering commentary on four high-level items for your consideration prior to engaging in responses to the policies proposed in the rule. The four items are:

1. Alternative Payment Models for Primary Care

President Michael Munger, MD

Speaker

Oregon, WI

President-elect John Cullen, MD Overland Park, KS Valdez, AK

Alan Schwartzstein, MD Russell Kohl, MD

Vice Speaker

Stilwell, KS

Board Chair John Meigs, Jr., MD Brent, AL

Douglas E. Henley, MD

Directors John Bender, MD, Fort Collins, CO Gary LeRoy, MD, Dayton, OH Carl Olden, MD, Yakima, WA Executive Vice President Robert Raspa, MD, Orange Park, FL Leonard Reeves, MD, Rome, GA Ada Stewart, MD, Columbia, SC

STRONG MEDICINE FOR AMERICA

Sterling Ransone, MD, Deltaville, VA Windel Stracener, MD, Richmond, IN Erica Swegler MD, Austin, TX Benjamin F. Simmons, III, MD (New Physician Member), Concord, NC Alexa Mieses, MD (Resident Member), Durham, NC John Heafner, MPH (Student Member), St. Louis, MO

Leawood, KS

- 2. Priority Proposals in the 2019 Medicare Physician Fee Schedule
- 3. Impact on Medicare Beneficiaries
- 4. Impact on Solo and Small Physician Practices

Alternative Payment Models for Primary Care

The AAFP shares your goals for Medicare reform, and we wish to propose an alternative that we view as less complex with fewer unintended consequences. The AAFP has serious reservations as to whether the bold reforms included in the 2019 proposed rule can be practically (or at all) achieved under the legacy fee-for-service system and the regulatory framework of Medicare in general, and Part B specifically.

Feedback we have received is that most family physicians, especially those in independent practices, believe these proposed changes would have a net-negative impact on their practices. While many have expressed appreciation for the concepts of reforms proposed, they are concerned about the policies in as drafted. While comfort with an existing system may play a role, the feedback we have received from family physicians, based on analysis of their practice trends, suggest that the policies would not achieve their stated objectives and would place economic strains on their practices.

The AAFP believes that the pathway to true reform of the Medicare program, especially for primary care, lies in the broader proliferation of Alternative Payment Models (APMs) versus efforts to tweak the legacy fee-for-service system. The authority granted to CMS and the Center for Medicare and Medicaid Innovation (CMMI) under previous laws provides you tremendous flexibility to implement changes in the delivery of care and payment of professional services.

To achieve meaningful transformation of primary care – and the health system more broadly – the AAFP has developed and put forth the Advanced Primary Care Alternative Payment Model (APC-APM). The APC-APM proposal was considered and positively advanced by the PTAC in December 2017. Since that time, we have been actively engaged with CMMI to develop and implement an advanced primary care APM focused on small independent practices.

The APC-APM is consistent with the proposed changes put forth in the 2019 Medicare Physician Fee Schedule proposed rule – as well as the goals outlined in the April 2018 Direct Provider Contracting Request for Information to increase access, reduce administrative burden, and provide predictable revenue streams for providers to deliver patient-centered care. The APC-APM achieves both simplification in coding and documentation. It prioritizes comprehensive, continuous, and coordinated primary care, and it includes an evaluation of performance that is based on both quality and utilization. Additionally, while the APC-APM would require the use of an electronic health record system, the APC-APM would incentivize physicians to focus on using the EHR as a tool to assist them in care delivery, not as a tool focused solely on payment.

The AAFP strongly encourages you to seize upon the authority granted to you to identify and implement APMs, such as the APC-APM, as a means of achieving a greater investment in primary care, among other goals. The implementation of this primary care APM would drive Medicare toward the proven values of primary care - first contact, comprehensive, continuous, and coordinated care. Furthermore, it would be an important step towards achieving the Administration's goal of transforming the Medicare program into one that prioritizes the delivery of high-quality, patient-centered, and efficient care.

Priority Proposals in the 2019 Medicare Physician Fee Schedule

The 2019 Medicare Physician Fee Schedule seeks to improve the Medicare program by creating a practice environment that facilitates high-quality care delivered in the most efficient manner. In the rule, you have proposed four major changes to the Medicare Part B Fee-For-Service program that would have an immediate and measurable impact on family medicine. Those items are:

- 1. simplify payment by adopting a single payment rate for evaluation and management (E/M) codes for new patients (99201-99205) and existing patients (99211-99215);
- 2. reduce documentation burden by allowing physicians to document only at the 99202 or 99212 level;
- 3. establish a new G-code valued at approximately \$5.00 per visit that could be added to the newly established value for existing patient E/M services; and
- 4. reduce by 50% payment for services provided in connection with an E/M code using the modifier -25

In addition to these four items, the proposed rule outlines several other polices that aim to enhance patient care via telemedicine, coverage of other non-face-to-face services, and extended visits for complex patients. Each of these are important policies that we discuss in our comments below.

With respect to the 50 percent reduction in value for services provided at the same visit as an E/M service, using a modifier -25, the AAFP has long-standing policy opposing such a policy or any other policy that seeks the reduction of payment for services provided to patients in connection to E/M services. We believe that the valuation of such services, as established through the RUC process, already accurately accounts for any efficiencies that may exist, and further reductions are not justified. We therefore oppose this proposed policy change.

The proposed rule also contains several changes to the Quality Payment Program (QPP). The AAFP appreciates CMS' commitment to improving the QPP program and there are several revisions in the proposed rule that we strongly support. Again, we comment extensively on these proposed changes in our comments below.

Finally, we also commend your efforts to create neutrality in payments between sites of care proposed in a separate rule. The AAFP strongly supports site-neutral payment policies and encourages CMS to finalize that proposal.

We recommend five major changes that would strengthen the proposed policies included in the 2019 MPFS. Those recommendations are:

- Proceed with the proposed changes in documentation and implement these immediately <u>but</u> <u>without the collapse to a single payment for codes 99202-99205 and 99212-99215.</u> Furthermore, we urge CMS to use its unique position to drive changes in documentation not only in Medicare, but through all public and private health plans.
- 2. Delay implementation of any changes to E/M policies or codes and their descriptors until the AAFP and other medical associations can work with CMS to develop new or revised office visit codes, descriptors, and values that incentivize comprehensive, continuous, and coordinated primary care and not fragmentation and churn.
- 3. Eliminate the proposed primary care add-on code and replace it with a 15% increase in payment for E/M services provided by physicians who list their primary practice designation as family medicine, internal medicine, pediatrics, or geriatrics.

- 4. Eliminate the proposed 50 percent Multiple Procedure Payment Reduction (MPPR) for physicians who list their primary practice designation as family medicine, internal medicine, pediatrics, or geriatrics.
- 5. Work with Congress to eliminate the applicability of deductible and co-insurance requirements for the chronic care management (CCM) codes. Eliminating CCM cost-sharing requirements would facilitate greater utilization of these codes and increase coordination of care for those beneficiaries with the greatest health care needs. Furthermore, the AAFP urges CMS to further reduce excessive CCM documentation requirements.

Impact on Medicare Beneficiaries

The AAFP is concerned that the changes included in the proposed rule may harm the quality and cost of care for Medicare beneficiaries. As noted previously, the value of primary care is achieved when delivery systems are foundational in first contact, comprehensive, continuous, and coordinated primary care. To achieve these four principles, delivery and payment models must be aligned with these goals. We are concerned that the proposed changes would move us further from these principles by incentivizing greater fragmentation in care delivery. Since the proposed rule would place an emphasis on prioritizing their time with a patient, versus focusing on comprehensiveness, it is likely that patients would experience more frequent, shorter duration physician visits. This incentivization of churn is inconsistent with the principles of advanced primary care and could not only be frustrating for patients but could also harm access to care in rural and other health professional shortage areas.

Additionally, since beneficiaries are required to pay 20 percent of most Part B services, it is possible that beneficiary out-of-pocket costs would increase due to more frequent physician or clinician visits. Also, visits paid at a higher rate than was the case before the proposed collapse of payment levels could multiply out-of-pocket costs. Many beneficiaries already face challenges accessing physicians due to logistical and financial challenges. We are very concerned that the proposed rule has the potential to create fragmentation and churn that could exacerbate these challenges.

Again, we believe the implementation of APM models such as the APC-APM, which focus on comprehensive, continuous, and coordinated primary care, are a better approach.

Impact on Solo and Small Physician Practices

Small, independent family medicine (primary care) practices are the foundation of our health care system, yet they face unique challenges that require some accommodation if they are to be successful in the future. The narrow margins of small, independent practices leave little room for variation in revenue. In addition, patient panels for these practices are more populated by Medicare and Medicaid beneficiaries and they tend to have fewer Medicare Advantage patients. These factors cause changes in Medicare fee-for-service to have a disproportionate impact on these practices.

The AAFP has been warned of the proposal's potential harm by numerous independent practices which have outlined in detail the negative impact the proposed changes would have on them. The collapsing of E/M payment, in conjunction with the 50% reduction in payment for multiple services through the modifier -25, are perceived to be an economic death knell by these practices. The AAFP agrees. Most have expressed that the implementation of the changes would result in significant financial strains that would require either a decrease in the number of Medicare beneficiaries they care for or the sale of their practice to a larger organization. The further elimination of independent practices through consolidation is not positive for American communities, Medicare beneficiaries, or

Administrator Verma Page 5 of 80 September 5, 2018

the financial sustainability of the Medicare program. The AAFP, like you, believes we need to protect these independent practices and take steps to ensure their economic viability.

Again, we believe the best way to protect these independent practices and preserve the important role they play in our health care system is to transition them away from fee-for-service towards APMs such as the APC-APM. The volatility fee-for-service causes is inconsistent with the comprehensive, continuous, coordinated primary care practiced by these family physicians. The <u>Commonwealth Fund</u> recently published a study demonstrating the quality and cost value of independent primary care practices. The AAFP stands ready to assist you in creating practice environments that allow these physicians to continue performing at a high level.

Summary

The AAFP applauds your commitment to improving the Medicare program for beneficiaries and the physicians who care for them. The AAFP stands ready to assist you in achieving these goals. We strongly support reducing documentation burden and increasing investment in primary care. These objectives are priorities for the AAFP and our members. However, we believe that these objectives are easier to achieve through the implementation of APMs such as the APC-APM versus through the legacy FFS system.

To this end, we urge you to approve for implementation the APC-APM and work with the AAFP to recruit small, independent physician practices to participate in the model starting in 2019. As previously stated, we strongly believe the best path to accomplishing the goals you have articulated in the 2019 proposed rule is through the APC-APM.

The AAFP's official response to the 2019 proposed rule follows.

e. Updates to Prices for Existing Direct Practice Expense (PE) Inputs Summary

As part of its authority under section 1848(c)(2)(M) of the *Social Security Act*, as added by the *Protecting Access to Medicare Act* (PAMA), CMS initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the Medicare Physician Fee Schedule (MPFS) direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. After reviewing the StrategyGen report, CMS proposes to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. With some exceptions, CMS proposes to phase in its use of the new direct PE input pricing over a four-year period using a 25/75 percent split (CY 2019), 50/50 percent split (CY 2020), 75/25 percent split (CY 2021), and 100/0 percent split (CY 2022) between new and old pricing. This approach is consistent with how CMS has previously incorporated significant new data into the calculation of PE relative value units (RVUs), such as the four-year transition period finalized in the CY 2007 MPFS final rule with comment period when changing to the "bottom-up" PE methodology. Exceptions to the phase-in approach and for which CMS will implement new prices without transition include:

- New supply and equipment codes for which CMS establishes prices during the transition years (CYs 2019, 2020, and 2021) based on the public submission of invoices.
- Existing supply and equipment codes, when CMS establishes prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family.

In conjunction with this proposal, CMS seeks public comment regarding whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the four-year pricing

transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages following the conclusion of the transition for supplies and equipment. These options would avoid other potentially large shifts in PE RVUs during the four-year pricing transition period.

AAFP Response

The AAFP supports CMS using the most current, reliable information to update its payment methodology. The AAFP further supports CMS' proposal to phase-in use of the new pricing data to avoid large swings in relative values from one year to the next.

We agree with CMS that the rates for the clinical labor staff should also be updated along with the updated pricing for supplies and equipment. In the spirit of using the most current, reliable information, we would encourage CMS to proceed to do so during the four-year pricing transition for supplies and equipment rather than waiting until that transition is complete. To the extent CMS is concerned about potentially large shifts in PE RVUs during the four-year pricing transition period, changes in rates of clinical labor staff could also be phased-in over time.

II.D. Modernizing Medicare Physician Payment by Recognizing Communication Technology-based Services

1. Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVCI1) *Summary*

CMS is proposing to pay separately, beginning January 1, 2019, for a newly-defined type of physicians' service using communication technology. This service would be billable when a physician or other qualified health care professional has a brief, non-face-to-face check in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. CMS proposes this service can only be furnished for established patients.

The proposed code would be described as GVCI1 (Brief communication technology-based service, e.g., virtual check in by a physician or other qualified health care professional who can report evaluation and management (E/M) services, provided to an established patient, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). CMS further proposes that in instances when the brief communication technology-based service originates from a related E/M service provided within the previous seven days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable. CMS proposes in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the previous E/M service and would not be separately billable. CMS proposes in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post-visit time of the associated E/M service, and therefore, would not be separately billable.

CMS seeks comment on:

- Proposed definition of the code
- Types of communication technology utilized by physicians or other qualified health care
 professionals in furnishing these services, including whether audio-only telephone interactions
 are sufficient compared to interactions that are enhanced with video or other kinds of data
 transmission

- Whether it would be clinically appropriate to apply a frequency limitation on the use of this code by the same practitioner with the same patient, and on what would be a reasonable frequency limitation
- Timeframes under which this service would be separately billable compared to when it would be bundled and whether CMS should consider broadening the window of time and/or circumstances in which this service should be bundled into the subsequent related visit
- How clinicians could best document the medical necessity of the service
- Whether it should require verbal consent that would be noted in the medical record for each service

CMS proposes pricing this distinct service at a rate lower than existing E/M in-person visits. Details related to valuation of this service (on which CMS is also seeking comment) are in section II.H of the proposed rule, and details on utilization estimates are in section VII.

AAFP Response

The AAFP supports the creation of this code and payment for this service as a stand-alone service that could be separately billed to the extent that there is no resulting E/M office visit and there is no related E/M office visit within the previous seven days of the service being furnished. We support CMS' intent to limit the service to established patients, since an existing patient-physician relationship, as well as available technology capabilities impact whether the standard of care can be achieved. With respect to the other aspects of the proposal on which CMS seeks comment:

- We would encourage CMS to add "or his or her designated representative" after "established patient" in the proposed definition of the code. This would permit the physician to report the code in situations where the patient is uncommunicative, non-competent, etc., but would still benefit from a "check in" as envisioned in the code.
- We imagine that most family physicians would use a telephone, or other *Health Insurance Portability and Accountability Act* (HIPAA) compliant avenues of communication, to provide this service and that a telephone would be sufficient to do so in most instances.
- We believe it would be reasonable to apply a frequency limit of no more than once a day, per patient. Depending on the condition in question, daily check ins may be medically necessary for a period.
- Documentation of the service should reflect the time spent in direct communication and the nature or content of the medical discussion that occurred.
- The 5-10 minutes parameter should not be a "medical discussion," but rather the time spent by the physician and/or other qualified health care professional to furnish the service. Current technology allows for the collection of patient data without a medical discussion. The renderer of the service could spend significant time reviewing and performing medical decision making outside of the time of the direct medical discussion with the patient. Additionally, valuable check ins with patients could be accomplished with non-verbal communication, such as chat. Therefore, the definition of medical discussion should also not be limited to only verbal communication.
- We think it would be reasonable to require verbal consent if the service is initiated by the physician. If the service is initiated by the patient (or his or her designated representative), then no verbal consent should be required, since the patient has, in effect, consented to the service by contacting the physician.

Administrator Verma Page 8 of 80 September 5, 2018

2. Remote Evaluation of Pre-recorded Patient Information (HCPCS code GRAS1) *Summary*

Effective January 1, 2019, CMS is proposing to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. CMS notes that it believes these services involve pre-recorded, patient-generated still or video images.

When the review of the patient-submitted image and/or video results in an in-person E/M office visit with the same physician or qualified health care professional, CMS proposes this remote service would be considered bundled into that office visit, and therefore would not be separately billable. CMS further proposes in instances when the remote service originates from a related E/M service provided within the previous seven days by the same physician or qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable. In summary, CMS proposes this service to be a stand-alone service that could be separately billed to the extent there is no resulting E/M office visit and there is no related E/M office visit within the previous seven days of the remote service being furnished.

The proposed code for this service would be described as GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient [e.g., store and forward], including interpretation with verbal follow up with the patient within 24 business hours, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). CMS is seeking comment on the proposed definition of the code and whether these services should be limited to established patients.

Details related to valuation of this service (on which CMS is also seeking comment) are in section II.H of the proposed rule, and details on utilization estimates are in section VII.

AAFP Response

As discussed in section II.H below, the AAFP opposes the creation of code GRAS1. We note there is an existing CPT code, 99444 (Online evaluation and management service provided by a physician or other qualified health care professional who may report E/M services provided to an established patient or guardian, not originating from a related E/M service provided within the previous seven days, using the internet or similar electronic communications network). The AAFP, along with the American Academy of Pediatrics and American College of Physicians, is presenting a proposal to the CPT Editorial Panel in September to revise the descriptor of this code. If code 99444 needs revision from CMS' perspective, then we encourage it to work with the CPT Editorial Panel to make the necessary changes rather than create a separate HCPCS code.

We would respectfully request that CMS delete the word "verbal" from its description of the code. How the follow up occurs with the patient (e.g., verbal, via secure patient portal, etc.) should be left to the discretion of the physician dependent on what the circumstances require. We think it is enough to require follow up with the patient without dictating how that follow up occurs in every case.

3. Inter-professional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

Summary

CMS proposes separate payment for these services, discussed in section II.H. Valuation of Specific Codes, of this proposed rule. CMS is seeking comment on its assumption these are separately-

Administrator Verma Page 9 of 80 September 5, 2018

identifiable services and the extent to which they can be distinguished from similar services that are nonetheless primarily for the benefit of the practitioner. CMS is seeking comment on how best to minimize potential program integrity issues and is particularly interested in information on whether these types of services are paid separately by private payers and if so, what controls or limitations private payers have put in place to ensure these services are billed appropriately. CMS is proposing to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record, like the conditions of payment associated with the care management services under the MPFS. CMS welcomes comments on this proposal.

AAFP Response

The AAFP supported creation of these codes at CPT, and we support CMS' proposal to make separate payment for them under the MPFS. We share CMS' concern with potential gaming of these codes, particularly as it relates to code 994X0. To minimize potential program integrity issues, we would encourage CMS to specify the service must be pertinent to the patient's condition and establish appropriate limitations on its use, such as the professional originating the consultation has an established relationship with the patient. We do not know whether private payers pay for these types of services and, thus, what, if any, controls or limitations they have put in place to ensure these services are billed appropriately.

However, we are concerned about CMS' proposal to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record (like the conditions of payment associated with the care management services under the MPFS). Such a requirement increases administrative burden and negates the premise of the necessity of the codes. Additionally, we believe it is contrary to the treatment, payment, and operation provisions within the *Health Insurance Portability and Accountability Act* (HIPAA).

4. Medicare Telehealth Services under Section 1834(m) of the Act

Summary

CMS is proposing to add Healthcare Common Procedure Coding System (HCPCS) codes G0513 and G0514 (Prolonged preventive service(s) [beyond the typical service time of the primary procedure], in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes [list separately in addition to code for preventive service] and [Prolonged preventive service(s) [beyond the typical service time of the primary procedure], in the office or other outpatient contact beyond the usual service; each additional 30 minutes [list separately in addition to code G0513 for additional 30 minutes of preventive service]) to the telehealth list for CY 2019.

CMS found that the services described by HCPCS codes G0513 and G0514 are sufficiently like office visits currently on the telehealth list. CMS believes that all the components of this service can be furnished via interactive telecommunications technology. Additionally, CMS believes that adding these services to the telehealth list would make it administratively easier for practitioners who report these services in connection with a preventive service that is furnished via telehealth, as both the base code and the add-on code would be reported with the telehealth place of service.

CMS proposes not to add to the Medicare telehealth services list procedures for chronic care remote physiologic monitoring, interprofessional internet consultation, and initial hospital care; or to change

Administrator Verma Page 10 of 80 September 5, 2018

the requirements for subsequent hospital care or subsequent nursing facility care. CMS notes the procedures for chronic care remote physiologic monitoring and interprofessional internet consultation are inherently non-face-to-face, and therefore not Medicare telehealth services. CMS will instead, pay for them under the MPFS, as described in section II.H (Valuation of Specific Codes) of the proposed rule.

Regarding initial hospital care, CMS believes it is critical the initial hospital visit by the admitting practitioner be conducted in person to ensure the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. CMS notes that Medicare beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list, including those for subsequent hospital care, initial and follow-up telehealth inpatient and emergency department consultations, as well as initial and follow-up critical care telehealth consultations. Therefore, CMS is not proposing to add the initial hospital care services to the list of Medicare telehealth services for CY 2019.

Regarding subsequent hospital care services, they are currently on the list of Medicare telehealth services but can only be billed via telehealth once every three days. A requester asked that CMS remove the frequency limitation. CMS believes most of these visits should be in person to facilitate the comprehensive, coordinated, and personal care that medically-volatile, acutely-ill patients require on an ongoing basis. CMS continues to believe admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Therefore, CMS is not proposing to remove the frequency limitation on these codes.

Regarding the subsequent nursing facility care services, CPT codes 99307-99310 are currently on the list of Medicare telehealth services but can only be billed via telehealth once every 30 days. A requester asked that CMS remove the frequency limitation when these services are provided for psychiatric care. Since these codes are used to report care for patients with a variety of diagnoses, including psychiatric diagnoses, CMS does not think it would be appropriate to remove the frequency limitation only for certain diagnoses. Therefore, CMS is not proposing to remove the frequency limitation for subsequent nursing facility care services in CY 2019.

AAFP Response

The AAFP <u>supports</u> expanded use of telehealth and telemedicine as an appropriate and efficient means of improving health, when conducted within the context of appropriate standards of care. The appropriateness of a telemedicine service should be dictated by the standard of care and not by arbitrary policies. Available technology capabilities, as well as an existing physician-patient relationship impact whether the standard of care can be achieved for a specific patient encounter type.

Telehealth technologies can enhance patient-physician collaborations, increase access to care, improve health outcomes by enabling timely care interventions, and decrease costs when utilized as a component of, and coordinated with, longitudinal care. Responsible care coordination is necessary to ensure patient safety and continuity of care for the immediate condition being treated, and it is necessary for effective longitudinal care (for clarification, forwarding documentation by electronic means, including fax, is not acceptable for coordination of care with the primary care physician or medical home). As such, the treating physician within a telemedicine care encounter should bear the

Administrator Verma Page 11 of 80 September 5, 2018

responsibility for follow up with both the patient <u>and</u> the primary care physician or medical home regarding the telemedicine encounter.

Payment models should support the patient's freedom of choice in the form of service preferred (i.e., copays should not force patients to a specific modality). Additionally, payment models should support the physician's ability to direct the patient toward the appropriate service modality (i.e., provide adequate reimbursement) in accordance with the current standard of care.

Accordingly, the AAFP supports CMS' proposal to add codes G0513 and G0514 to the Medicare telehealth list for 2019. We also support CMS' assessment of the procedures for chronic care remote physiologic monitoring and interprofessional internet consultation and proposal to pay for them under the MPFS, as described in section II.H (Valuation of Specific Codes) of the proposed rule, rather than as Medicare telehealth services.

We support CMS' proposal not to add initial hospital care services to the Medicare telehealth services list. As CMS notes, Medicare beneficiaries who are being treated in the hospital setting can already receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list, including those for initial telehealth inpatient consultations and initial critical care telehealth consultations.

However, we disagree with CMS' proposal to not remove the frequency limitation on subsequent hospital care codes. As noted, telehealth technologies can enhance patient-physician collaborations, increase access to care, improve health outcomes by enabling timely care interventions, and decrease costs when utilized as a component of, and coordinated with, longitudinal care. Appropriate standards of care, not frequency limits, should dictate whether the service is provided in person or via telehealth technology. We also note that not all patients receiving subsequent hospital care are medically volatile and acutely ill. Per CPT, which CMS follows in this regard, patients receiving 99231 are usually stable, recovering, or improving. Likewise, for 99232, the patient is usually responding inadequately to therapy or has developed a minor complication, which hardly equates to medically volatile and acutely ill. That latter description is probably only applicable to patients receiving the highest level of subsequent hospital care (99233), which CPT describes as usually "unstable or has developed a significant complication or a significant new problem." Accordingly, we encourage CMS to reconsider this proposal and, at a minimum, remove the frequency limitation for subsequent hospital care services 99231 and 99232 delivered via telehealth for 2019.

Lastly, we disagree with CMS' proposal to not remove the frequency limitation for subsequent nursing facility care services in CY 2019. We agree with CMS that it would not be appropriate to remove the frequency limitation only for certain diagnoses, since these codes are used to report care for patients with a variety of diagnoses. However, as with subsequent hospital care services, we believe appropriate standards of care, not frequency limits, should dictate whether the service is provided in person or via telehealth technology. Accordingly, we encourage CMS to reconsider this proposal and remove the frequency limitation for subsequent nursing facility care services delivered via telehealth for 2019.

Administrator Verma Page 12 of 80 September 5, 2018

7. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders (SUDs)

Summary

CMS is considering whether it would be appropriate to develop a separate bundled payment for an episode of care for treatment of substance use disorders (SUDs). CMS seeks public comment on whether such a bundled episode-based payment would be beneficial to improve access, quality, and efficiency for SUD treatment. Further, CMS seeks public comment on developing coding and payment for a bundled episode of care for treatment for SUDs that could include overall treatment management, any necessary counseling, and components of a medication-assisted treatment (MAT) program. Specifically, CMS is seeking public comments related to what assumptions it might make about the typical number of counseling sessions, as well as the duration of the service period, which types of practitioners could furnish these services, and what components of MAT could be included in the bundled episode of care. CMS is interested in stakeholder feedback regarding how to define and value this bundle and what conditions of payment should be attached. Additionally, CMS is seeking comment on whether the concept of a global period, like the currently existing global periods for surgical procedures, might be applicable to treatment for SUDs.

CMS also seeks comment on whether the counseling portion and other MAT components could also be provided by qualified practitioners "incident to" the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment, like the structure of the Behavioral Health Integration codes. CMS welcomes comments on potentially creating a bundled episode of care for management and counseling treatment for SUDs, which CMS will consider for future rulemaking.

Additionally, CMS invites public comment and suggestions for regulatory and subregulatory changes to help prevent opioid use disorders (OUDs) and improve access to treatment under the Medicare program. CMS seeks comment on methods for identifying nonopioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these nonopioid alternatives, including barriers related to payment or coverage. CMS is interested in suggestions to improve existing requirements to more effectively address the opioid epidemic.

AAFP Response

Family physicians are the most visited specialty—especially in underserved areas. Family physicians conduct approximately one in five of all office visits in the United States. This represents more than 192 million visits annually. Therefore, family physicians find themselves at the crux of the issue, balancing care for patients with chronic pain and the challenges of managing the appropriate use of opioids, while always mindful of their misuse and abuse. In the face of opioid misuse, family physicians have a unique opportunity to be part of the solution. Effective pain management should be coordinated by a primary care physician who best knows the patient and integrated into continuous, comprehensive whole-patient care. The AAFP stands ready to work with CMS to make changes to the payment and regulatory framework on behalf of all patients coping with SUD.

The Medicare program plays an important role in providing access to health care, behavioral health, and treatment services for millions of Americans who suffer from SUDs. Medicare helps ensure patients with chronic health disease(s) can manage those conditions and prevent them from progressing, and, therefore, reduce the need for pain management that is associated with surgeries and adverse outcomes. The AAFP supports efficient efforts to increase patient engagement and access and is encouraged by efforts to improve best practices in Medicare related to SUDs.

Administrator Verma Page 13 of 80 September 5, 2018

Unfortunately, Medicare has no comprehensive SUD treatment benefit, including reimbursement for services delivered or drugs dispensed by an opioid treatment program. Given the needs of patients served by Medicare, it is critical the program provide comprehensive MAT coverage.

Regarding the potential for a separate bundled payment for an episode of care for treatment of SUD, the AAFP would argue that a bundled payment may not be the most appropriate model for the delivery of comprehensive, coordinated, and longitudinal care for these patients if the bundle is meant to be a one-time payment encompassing the whole of SUD treatment. A SUD is a chronic disease of the brain. From the AAFP's perspective, chronic diseases do not lend themselves well to episodes of care or global periods payable through a one-time bundled payment, because chronic diseases typically involve ongoing treatment without a definitive end point.

Further, unlike procedures (e.g., hip replacement) that do lend themselves well to one-time bundled payments or global periods, SUD cannot generally be treated in isolation of other conditions experienced by the patient. Patients with SUD often have a variety of comorbid, chronic, physical conditions and mental health issues in the context of which SUD is treated. Teasing SUD apart from those other conditions for purposes of establishing a one-time, fixed bundled payment that appropriately compensates physicians for the variable mix of chronic conditions that accompany SUD is not feasible. If CMS pursues developing a separate bundled payment for an episode of care for treatment of SUD, we urge CMS to structure payment in a manner consistent with the ongoing, multivariate nature of SUD as a chronic condition. For instance, CMS may want to consider a risk-adjusted per-patient per-month bundled payment.

We believe there are things CMS could do at a regulatory and sub-regulatory level to help prevent OUDs and improve access to treatment under the Medicare program. For instance, the AAFP supports adding resources to the Medicare handbook and having the annual notice to Medicare beneficiaries include educational resources regarding opioid use, pain management, and alternative pain management treatments. In addition, we support the development and use of effective patient education materials to support physicians in educating patients to help them overcome resistance to nonpharmacologic approaches to pain treatment. Patient education is integral to change or enhance a patient's knowledge, attitude, or skills to maintain or improve health.

Similarly, the AAFP supports proposals that would require prescription drug plans to provide Medicare Part D enrollees with information about the potential adverse effects of opioid use and alternative pain treatments. The Part D plan may elect to send the information to all enrollees or just an "appropriate subset," (e.g., those who have been prescribed an opioid within the last two years).

The AAFP also supports a proposal that would require Medicare Part D plans to provide a prescription and pharmacy lock in for patients who are flagged as at risk of opioid abuse. Currently, Part D Plans are authorized to allow lock ins for certain patients, but they are not required to do so. The AAFP has historically opposed physician lock-in policies, but at this time, we believe that the benefits of the proposed policy may outweigh its restrictions.

With respect to preventing OUDs and improving access to treatment under the Medicare program, the AAFP sees the value of improving care coordination and transitions of care for a broad population of patients to include those with conditions that are also associated with chronic pain, such as those with diabetes, fibromyalgia, and shingles. Left untreated, these conditions may require long-term pain

Administrator Verma Page 14 of 80 September 5, 2018

management, which, in turn, could increase the possibility of addiction. Ensuring patients transition to a primary care physician can help encourage more individuals to find a medical home where their needs can be addressed in a comprehensive and coordinated way. Research shows high-quality care coordination for patients leaving the hospital can improve outcomes for a range of conditions.

Family physicians are prepared to provide transitional care management (TCM) for patients in order to link patients with complex pain management needs back to a primary care physician. Unfortunately, due to a lack of communication between hospitals and other health care facilities with primary care physicians, the transmission or release of discharge information to the primary care physician often does not occur at all or does not occur within the two business days allotted to contact the patient as required by CMS to bill TCM. The AAFP believes CMS can help correct this situation by updating its rules and communications related to hospital discharge planning. The AAFP has previously supported CMS proposals to mandate that hospitals and other facilities better inform primary care physicians about the discharge of their patients in a timely fashion, which would help address the barrier family physicians encounter in attempting to use TCM codes within the two business days of discharge to contact the patient/caregiver.

In addition, in some instances, the primary care physician is not identified or documented at the time of an acute care hospital admission. When this is the case, the primary care physician does not receive discharge information that would improve care transitions and are required for timely contact with the patient under TCM. If the Medicare hospital conditions of participation or other Medicare rules governing hospitals do not address this issue, we ask CMS to make the necessary revisions to ensure these rules require hospitals to document the patient's primary care physician.

Regarding methods for identifying nonopioid alternatives for pain treatment and management and the barriers that may inhibit access to these nonopioid alternatives, we note that the fee-for-service (FFS) reimbursement model continues to undervalue E/M services and fails to reward taking the time and effort necessary to provide the kind of comprehensive, continuous care patients need. In a volume-over-value FFS environment, it is often easier and more economically viable for the physician to write a prescription rather than explore alternative treatment options for chronic pain as outlined by the Centers for Disease Control and Prevention (CDC) guidelines and affirmed by AAFP.

Regrettably, other barriers to nonpharmacologic therapies for chronic pain also exist in public and private health insurance plans. While we commend Congress for permanently repealing the Medicare therapy caps in the recent *Bipartisan Budget Act* of 2018 (now Public Law 115-123,) geographic and other barriers, such as inadequate providers of nonpharmacologic therapy hinder its universal use. Coverage of these therapies is also often lacking. The administrative burden for prescribing or referring patients for nonpharmacologic therapies, like physical therapy, home health, etc., is a barrier to the use of nonpharmacologic treatments. It is currently easier to write a prescription for opioids than to prescribe nonpharmacologic treatment. CMS may wish to consider incentivizing evidence-based, nonpharmacologic therapies by reducing their associated administrative burden, decreasing or removing co-pays for nonpharmacological therapies, and increasing coverage for those services.

One of the most onerous administrative burdens is prior authorization, which tops the list of physician complaints on administrative burden. In coalition with 16 other medical organizations, the AAFP has called for the reform of prior authorization and utilization management requirements that impede patient care in <u>Prior Authorization and Utilization Management Reform Principles</u>. In addition, the AAFP has published, <u>Principles for Administrative Simplification</u>, calling for an immediate reduction in

Administrator Verma Page 15 of 80 September 5, 2018

the regulatory and administrative requirements family physicians and practices must comply with daily.

The process of obtaining prior authorization for services and/or dispensing of medications for an OUD is burdensome and delays treatment to life-saving care. It also reduces patient-focused time to complete required paperwork. Some private insurers—such as Aetna, Anthem, Cigna, and United Health Group—have already lifted prior authorizations for MAT and we encourage CMS to do the same.

As a more effective alternative to prior authorization (including electronic prior authorization), the AAFP supports embedding evidence-based guidelines within the prescribing workflow. To provide accurate, timely prescriber information, evidence-based clinical guidelines should be integrated within the prescribing workflow in an unobtrusive manner. The online guidelines should be unobtrusive, because they are necessarily not personalized to the individual patient.

As noted, Medicare payment incentives could be used to reduce or remove co-pays for screening and treatment for OUD and SUD. Such incentives should also be used to support the appropriate coprescribing of naloxone as outlined by the AAFP and the American Medical Association Opioid Task Force. CMS should also ensure coverage for MAT and other evidence-based treatments for OUD. While the evidence is still evolving on the use of Screening, Brief Intervention, and Referral to Treatment (SBIRT) for opioids, SBIRT is recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA) and others and could be implemented like screening for tobacco and alcohol misuse.

The AAFP recognizes the intertwined public health issues of chronic pain management and the risks of opioid misuse. We understand that high levels of misuse and addiction persist with devastating consequences, despite annual decreases in the number of opioids prescribed in the U.S. since 2010. To promote evidence-based care for patients with chronic pain, while minimizing the risk of OUDs and SUDs, we must recognize that both pain management and dependence therapy require patient-centered, compassionate care as the foundation of treatment. These are attributes that family physicians uniquely bring to their relationships with patients. It is unfortunate that the payment and regulatory framework for physician practices has reduced face-to-face time with patients, making it more difficult for physicians and patients alike. Our current payment models, coupled with a crippling regulatory structure, threaten access for millions of patients to receive evidenced-based pain care and OUD and SUD treatment from primary care physicians.

II.E. Potentially Misvalued Services under the MPFS

3. CY 2019 Identification and Review of Potentially Misvalued Services

a. Public Nominations

Summary

CMS notes that it received one submission that nominated several high-volume codes for review under the potentially misvalued code initiative. The submitter noted a systemic overvaluation of work RVUs in certain procedures and tests based "on a number of Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) reports, media reports regarding time inflation of specific services, and the January 19, 2017 Urban Institute report for CMS." The submitter suggested that the times CMS assumes in estimating work RVUs are inaccurate for procedures, especially due to substantial overestimates of preservice and postservice time, including follow-up inpatient and outpatient visits that do not take place. According to the submitter, the time

estimates for tests and some other procedures are primarily overstated as part of the intraservice time. Furthermore, the submitter stated that previous Relative Value Scale Update Committee (RUC) reviews of these services did not result in reductions in valuation that adequately reflected reductions in surveyed times. The submitter requested that the following codes be prioritized for review under the potentially misvalued code initiative:

TABLE 8—PUBLIC NOMINATIONS DUE
TO OVERVALUATION

CPT code	Short description
27130 27447 43239 45385	Total hip arthroplasty. Total knee arthroplasty. Egd biopsy single/multiple. Colonoscopy w/lesion re- moval.
70450 93000 93306	CT head w/o contrast. Electrocardiogram complete. Tte w/doppler complete.

Another commenter requested that CPT codes 92992 (Atrial septectomy or septostomy; transvenous method, balloon [e.g., Rashkind type; includes cardiac catheterization]) and 92993 (Atrial septectomy or septostomy; blade method [Park septostomy; includes cardiac catheterization]) be reviewed under the potentially misvalued code initiative to establish national RVU values for these services under the MPFS. These codes are currently priced by the Medicare Administrative Contractors (MACs).

AAFP Response

In general, we support CMS' proposal to prioritize the codes in Table 8 (and their respective code families) for review as potentially misvalued. As described in further detail below, we would encourage CMS to expand that list to include other codes identified by the Urban Institute and RAND.

As the submitter in question notes, there is a systemic overvaluation of work RVUs in certain procedures and tests, which has been observed by the GAO, MedPAC, and CMS contractors, including the Urban Institute and RAND. Most recently, in <u>chapter 3 of its June 2018 report to</u> <u>Congress</u>, MedPAC noted that CMS, with input from the American Medical Association/Specialty Society RUC, has reviewed the work RVUs of many potentially mispriced services since 2009. However, CMS' review has not yet addressed services that account for a substantial share of fee schedule spending and is hampered by the lack of current, accurate, and objective data on clinician work time and practice expenses. Consequently, work RVUs for procedures, imaging, and tests are systemically overvalued relative to other services, such as ambulatory evaluation and management (E/M) service.

As we did in response to the proposed rule on the 2018 MPFS, we remind CMS of two of its own efforts to identify and review potentially misvalued services that still warrant action by CMS. First, CMS funded a pilot project by the Urban Institute to develop a validation process for the work RVUs used in the fee schedule for both new and existing services. The project focused on the physician service times used in establishing physician work RVUs and included two distinct elements: developing empirical measures of physician service times and considering the implications of these estimates for physician work RVUs. Table 3 in the final report from the project showed a significant difference in 2016 MPFS intra-service time for some services and the median empirical intra-service time from the study. For most codes, the MPFS intraservice time was greater than the median empirical intraservice time. We would respectfully suggest that any code (and its related code family)

Administrator Verma Page 17 of 80 September 5, 2018

in this table whose 2016 MPFS intraservice time was 10 percent more or less than median empirical intraservice time from the Urban Institute study is worthy of review, unless it has already been reviewed in the interim.

The other effort was a CMS-funded project by RAND to develop a model to validate the physician work values using external data sources. The <u>final report from that study</u> offered findings similar to those of the Urban Institute project referenced above. For instance, the RAND estimates of intraservice time, which are based on data in independent datasets, are typically shorter than the current CMS estimates. As detailed in Chapter 4 of the RAND project report, for 83 percent of the procedures, the RAND time is shorter than the CMS estimates. This difference in time is a critical issue because intraservice time is highly correlated with total work RVUs. Table 4.3 in the RAND report compares CMS and RAND intraservice time estimates for the "Top 20" procedures used by RAND. Again, we respectfully suggest that any code (and its related code family) in this table whose CMS intraservice time was 10 percent more or less than the average intraservice time from the RAND models is worthy of review, unless it has already been reviewed in the interim.

We note that the RAND report is full of other comparisons between its models and what CMS uses to set fees under the MPFS. We suggest the RAND report, which CMS funded, would be a good source for developing additional screens to identify misvalued codes. RAND believes CMS could use the model, the individual components that go into the building-block model, and the overall work RVUs RAND generates in two key ways to validate codes:

- CMS could use the RAND model estimates as another means of identifying potentially misvalued codes.
- CMS could use the RAND model estimates as an independent estimate of the work RVUs to consider when assessing a RUC recommendation.

We think these suggestions are worthy of CMS' consideration.

b. Update on the Global Surgery Data Collection

Summary

As required by section 523 of the *Medicare Access and CHIP Reauthorization Act* (MACRA), CMS is collecting data on the number and level of postoperative visits, so it can use these data to assess the accuracy of global surgical package valuation. In the CY 2017 MPFS final rule, CMS adopted a policy to collect postoperative visit data. Beginning July 1, 2017, CMS required practitioners in groups with 10 or more practitioners in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island) to use the no-pay CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure) to report postoperative visits. Practitioners who are only in practices with fewer than 10 practitioners are exempted from required reporting, but are encouraged to report, if feasible. The 293 procedures for which reporting is required are those furnished by more than 100 practitioners, and either are nationally furnished more than 10,000 times annually or have more than \$10 million in annual allowed charges.

According to the proposed rule, among 10-day global procedures performed from July 1, 2017, through December 31, 2017, where it is possible to clearly match postoperative visits to specific procedures, only four percent had one or more matched visits reported with CPT code 99024. Among all the specialties listed in Table 11 in the proposed rule, the percentage of 10-day global procedures with one or more matched 99024 claims never reaches or exceeds 50 percent.

Among 90-day global procedures performed from July 1, 2017, through December 31, 2017, where it is possible to clearly match postoperative visits to specific procedures, 67 percent had one or more matched visit(s) reported using CPT code 99024. However, this does not address the level of those visits relative to what is assumed in the valuation of 90-day global procedures. To address that aspect, CMS anticipates soon beginning a separate, survey-based data collection effort on the level of postoperative visits, including the time, staff, and activities involved in furnishing postoperative visits and non-face-to-face services. RAND will lead the survey effort. To increase response rates (relative to a pilot survey done by RAND) and collect sufficient data on the level of visits associated with at least some procedures with 10-day and 90-day global periods, CMS has refocused the survey effort to collect information on postoperative visits and non-face-to-face services associated with a small number of high-volume procedure codes. The survey sampling frame includes practitioners who perform above a threshold volume of the selected high-volume procedure codes. Future survey-based data collection may cover post-operative visits and non-face-to-face services associated with a broader range of procedures with 10-day and 90-day global periods.

In the meantime, CMS is soliciting suggestions as to how to encourage reporting of 99024 (where required) to ensure the validity of the data without imposing undue burden. Specifically, CMS is soliciting comments on whether it needs to do more to make practitioners aware of their obligation and whether it should consider implementing an enforcement mechanism. Given the very small number of postoperative visits reported using code 99024 during 10-day global periods, CMS is also seeking comment on whether it might be reasonable to assume that many visits included in the valuation of 10-day global packages are not being furnished, or whether there are alternate explanations for what could be a significant level of underreporting of postoperative visits.

CMS is also soliciting comments on whether it should consider requiring use of the modifiers in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether a transfer of care is formalized.

Lastly, CMS is also seeking comment on the best approach to 10-day global codes, for which the preliminary data suggest that postoperative visits are rarely performed by the practitioner reporting the global code. That is, CMS is seeking comments on whether it should consider changing the global period and reviewing the code valuation.

AAFP Response

As CMS notes in the proposed rule, its findings suggest that postoperative visits following procedures with 10-day global periods are not typically being furnished. Accordingly, we agree that it is reasonable to assume that many visits included in the valuation of 10-day global packages are not being furnished. Thus, we strongly recommend that CMS change all codes with a 10-day global period to zero-day global periods and revalue the codes accordingly.

We do not think CMS needs to do more to make physicians aware of their obligation to report 99024, where required. According to Table 9 in the proposed rule, almost half of all practitioners who could have reported 99024 did so between July 1 and December 31, 2017. Further, among the more procedurally-oriented specialties, this percentage was often in the 80 to 90 percent range, indicating those who should be reporting are aware of their obligation. We believe CMS and the national specialty societies have done an adequate job of communication in this regard. CMS does not need

Administrator Verma Page 19 of 80 September 5, 2018

to do more and does not need to implement an enforcement action if the natural consequence of failure to report is appropriate revaluation of the services in question.

To the question of whether CMS should consider requiring use of modifier 54 (Surgical care only) in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether a transfer of care is formalized, we argue that CMS should not require it, but should allow it. That is, if there are circumstances other than a formal transfer of care (such as the death of the patient) in which a surgeon does not expect to perform the postoperative visits, the surgeon should have an opportunity to report that through use of modifier 54.

In this context, we note that it is not only postoperative visits that surgeons elect not to perform as part of the global surgical package. Many times, surgeons do not perform the assumed preoperative care, such as the "history and physical," instead delegating it to the patient's primary care physician in the form of a "preoperative clearance," for which the primary care physician may not be paid if the payer in question does not consider it medically necessary. In recognition of the fact that surgeons often provide only the surgical care, CPT provides modifier 55 (Postoperative management only) and modifier 56 (Preoperative management only) along with modifier 54. We encourage CMS to be mindful of this aspect of global surgical valuation too. Furthermore, we strongly suggest CMS expeditiously study and reduce payment for procedures with 10-and 90-day global periods and hold providers of global surgical services to the same documentation standards and guidelines as providers who bill evaluation and management (E/M) services. Global surgical packages are inflated in terms of the number and level of post-operative visits assumed to be included and incorporated in the value of the codes in question. The AAFP strongly urges CMS to continue efforts to pay accurately for surgical services.

We look forward to the results of the survey CMS and RAND plan to do regarding the level of postoperative visits including the time, staff, and activities involved in furnishing postoperative visits and non-face-to-face services, particularly as it relates to services with a 90-day global period.

<u>G. Payment Rates under the MPFS for Nonexcepted Items and Services Furnished by Nonexcepted</u> <u>Off-Campus Provider-Based Departments of a Hospita</u>l

Summary

Section 603 of the *Bipartisan Budget Act* of 2015 amended the Medicare statute as it relates to the outpatient prospective payment system (OPPS) by requiring that applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will be paid "under the applicable payment system" under Medicare Part B rather than the OPPS. In the CY 2017 OPPS/ambulatory surgical center (ASC) final rule with comment period, CMS finalized the MPFS as the "applicable payment system" for most nonexcepted items and services furnished by off-campus provider-based departments (PBDs).

Since there is no technological capability, at least in the near term, to allow off-campus PBDs to bill under the MPFS for those nonexcepted items and services, nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a claim line modifier "PN" to indicate that an item or service is a nonexcepted item or service. CMS adjusts the OPPS rate for those items and services to a comparable MPFS rate by applying the "MPFS relativity adjuster." The MPFS relativity Adjuster refers to the percentage of the OPPS payment amount paid under the MPFS for a nonexcepted item or service to the nonexcepted off-campus PBD under this policy. The MPFS relativity adjuster is currently 40 percent (i.e., CMS pays 40 percent of the OPPS payment amount). CMS proposes to continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim using a "PN" modifier until CMS identifies a workable alternative mechanism that would improve payment accuracy. In calculating the proposed MPFS relativity adjuster for CY 2019, CMS employed the same fundamental methodology that it used to calculate the MPFS relativity adjuster for CY 2017 and CY 2018. Its updated analysis supports maintaining a MPFS relativity adjuster of 40 percent. In view of this analysis, CMS proposes to continue applying a MPFS relativity adjuster of 40 percent for CY 2019, and to maintain this MPFS relativity adjuster for future years until updated data or other considerations indicate that an alternative adjuster or a change in approach is warranted, which CMS would then propose through notice and comment rulemaking.

Regarding policies related to supervision, beneficiary cost sharing, and geographic adjustment, in the CY 2018 MPFS final rule, CMS finalized policies related to supervision rules, beneficiary cost sharing, and geographic adjustments. CMS finalized and, is maintaining for 2019, that:

- Supervision rules in nonexcepted off-campus PBDs that furnish nonexcepted items and services are the same as those that apply for hospitals, in general;
- All beneficiary cost-sharing rules that apply under the MPFS continue to apply when payment is made under the MPFS for nonexcepted items and services furnished by nonexcepted offcampus PBDs, regardless of cost-sharing obligations under the OPPS; and
- The same geographic adjustments used under the OPPS apply to nonexcepted items and services furnished in nonexcepted off-campus PBDs.

For CY 2019, CMS proposes to continue to identify the MPFS as the applicable payment system for partial hospitalization program (PHP) services furnished by nonexcepted off-campus PBDs, and CMS proposes to continue to set the MPFS payment rate for these PHP services as the per diem rate that would be paid to a community mental health center in CY 2019. CMS further proposes to maintain these policies for future years until updated data or other considerations indicate that a change in approach is warranted, which CMS would then propose through notice and comment rulemaking.

Finally, in future years, CMS continues to believe the amendments made by section 603 of the *Bipartisan Budget Act* of 2015 were intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for items and services they furnish there. Therefore, CMS continues to believe the payment policy under this provision should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services they furnish. CMS is broadly interested in stakeholder feedback and recommendations for ways in which CMS can improve pricing and transparency concerning the differences in the payment rates across sites of service.

AAFP Response

The AAFP supports CMS efforts to align payment policies for physicians in independent practice with those owned by hospitals. The AAFP continues to encourage CMS also to consider site-of-service payment parity polices from a broader perspective. Namely, CMS should not pay more for the same services in the inpatient, outpatient, or ambulatory surgical center setting than in the physician office setting.

Administrator Verma Page 21 of 80 September 5, 2018

The AAFP encourages CMS to create incentives for services to be performed in the most costeffective location, such as a physician's office. The AAFP considers the artificial distinction between "inpatient," "outpatient," and other sites of service as a product of the equally artificial distinction between Part A and Part B. The AAFP calls for policies that progress beyond this silo mentality and instead pay for health care services in a more consistent and equitable manner.

Like CMS, we believe that the intent of section 603 of the *Bipartisan Budget Act* of 2015 is to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services. The AAFP supported CMS' original proposal, made in 2016, to pay nonexcepted, off-campus PBDs or excepted off-campus PBDs that provide nonexcepted items and services under the MPFS at the non-facility rate for 2017. We continue to believe that this was a reasonable response consistent with section 603 of the *Bipartisan Budget Act*.

Accordingly, we are disappointed that CMS will continue to pay nonexcepted, off-campus PBDs or excepted off-campus PBDs that provide nonexcepted items and services under what, in essence, remains the OPPS, albeit at a discounted rate. Nominally, the payment rates are under the MPFS, but as CMS has noted in the past, these rates are "specific to and can only be reported by hospitals reporting nonexcepted items and services on the institution claim form," which acknowledges explicitly that payments to all hospital outpatient departments—excepted or nonexcepted—will maintain an enhanced status.

The reality that payment rates continue to be based on OPPS rather than the MPFS is evidenced by the fact that CMS applies the geographic adjustments used under the OPPS, rather than those used under the MPFS. The necessity to incorporate the OPPS payment policies for comprehensive ambulatory payment classification (APC), packaged items and services, and the multiple procedure payment reductions is further evidence that the current, ongoing payment methodology is really just a stealth version of OPPS, rather than the MPFS, even though CMS finalized the MPFS as the "applicable payment system" for most nonexcepted items and services furnished by off-campus PBDs.

The payment methodology for 2019 will not assure equal payments for the same service, regardless of site of service. As noted in the proposed rule, the MPFS relativity adjuster reflects the overall relativity of the applicable payment rate for nonexcepted items and services furnished in nonexcepted off-campus PBDs under the MPFS, compared with the rate under the OPPS. The actual relativity for individual items and services may vary. That means hospitals may still be incentivized to buy physician practices based on the mix of services they provide and bill for them as PBDs at Medicare rates higher than would have been paid had the practice not been bought by the hospital, which is contrary to the intent of section 603. Equalizing payments "in the aggregate" still encourages hospitals to make business decisions that run counter to the public interest and the goals of the Medicare program.

Thus, we continue to support an approach like the one that CMS initially proposed for CY 2017. Under this approach, CMS would pay nonexcepted off-campus PBDs for their nonexcepted items and services at a true MPFS-based rate that would reflect the relative resources involved in furnishing the services. For most services, this MPFS-based rate would equal the non-facility payment rate under the MPFS minus the facility payment rate under the MPFS for the service in question. For other services for which CMS does not provide separate payment under the MPFS, if payment is made under OPPS, this MPFS-based rate would equal the MPFS non-facility rate. For still

other services, the technical component rate under the MPFS would serve as the MPFS-based rate. Such an approach would, in fact, equalize payment rates between physician offices and nonexcepted off-campus PBDs on a procedure-by-procedure basis, which is consistent with the AAFP's vision for how Medicare payment should be designed.

H. Valuation of Specific Codes

Proposed Valuation of Specific Codes for CY 2019
 (60) Chronic Care Management Services (CPT code 994X7)

Summary

In February 2017, the CPT Editorial Panel created a new code to describe at least 30 minutes of chronic care management (CCM) services performed personally by the physician or qualified health care professional over one calendar month. The new code (currently identified as 994X7) is described as follows:

Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored

For CPT code 994X7, the RUC recommended a work RVU of 1.45 for 30 minutes of physician time. CMS believes this work RVU overvalues the resource costs associated with the physician performing the same care coordination activities that are performed by clinical staff in the service described by CPT code 99490. Additionally, CMS notes that this valuation of the work is higher than that of CPT code 99487:

Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month)

CMS believes it would create a rank order anomaly within the family of codes if it were to accept the RUC recommended value for 994X7, given the current value of 99487.

CPT code 99490 has a work RVU of 0.61 for 15 minutes of physician time. Therefore, as CPT code 994X7 describes 30 minutes of physician time, CMS proposes a work RVU of 1.22 for 994X7, which is double the work RVU of CPT code 99490 (which has 15 minutes of physician time). CMS is not proposing any direct PE refinements for this code.

AAFP Response

The AAFP, which participated in the RUC survey of code 994X7, appreciates CMS's desire to avoid creating a rank order anomaly in the valuation of this code. However, we believe CMS is making a flawed assumption in proposing to value the work of 994X7 at 1.22, which is twice the value of 99490, based on the fact the physician time of 994X7 is twice that of 99490. Specifically, CMS appears to

Administrator Verma Page 23 of 80 September 5, 2018

assume the intensity of a physician personally performing CCM is equal to the intensity of a physician supervising the performance of CCM by clinical staff.

When a physician personally performs CCM activities for a patient, he or she does so because the patient and the patient's condition(s) requires a level of knowledge and skill that only the physician can provide. Mental effort and judgment and technical skill are all elements of intensity. The value recommended by the RUC recognizes that when a physician's mental effort, judgment, and technical skills are personally brought to bear on behalf of a patient, the intensity of the service is greater than when the physician is simply supervising the efforts of the clinical staff.

There is precedence elsewhere in the MPFS for attributing greater intensity to a service when done personally by a physician rather than clinical staff. For example, code 96101 describes "Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report." It has an intraservice work per unit of time (IWPUT) of 0.0284. In comparison, code 96102 describes "Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, e.g., MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face" and has an IWPUT of 0.0214. CMS has attributed a greater intensity (as reflected in the IWPUT) to 96101, the psychological testing personally administered by the physician or psychologist, than it has to the same testing administered by a technician. The same principle applies in valuing 994X7 relative to 99490.

Far from avoiding a rank order anomaly among the CCM codes, CMS's proposed value of 1.22 for 994X7 would create a rank order anomaly among other E/M codes personally provided by physicians. As noted in the RUC recommendations to CMS, a level 4 established patient office visit 99214 has 25 minutes intraservice time and work RVU of 1.50, which compares very favorably to the 1.45 work RVUs for 30 minutes of physician time recommended for 994X7. The recommended value of 1.22 work RVUs would undervalue the 30 minutes of physician work compared to other E/M codes with 30 minutes of total physician time, including:

- 99283 (level 3 emergency department visit): 1.34 work RVUs
- 99381 (preventive medicine visit, new patient; infant [age younger than one year]): 1.50 work RVUs
- 99392 (preventive medicine visit; established patient; early childhood [age one through four years]): 1.50 work RVUs

For all these reasons, we encourage CMS to accept the RUC recommendation and value 994X7 at 1.45 work RVUs.

(65) Structured Assessment, Brief Intervention, and Referral to Treatment for Substance Use Disorders (HCPCS codes G0396, G0397, and GSBR1) *Summary*

HCPCS codes G0396 (Alcohol and/or substance [other than tobacco] abuse structured assessment [e.g., AUDIT, DAST] and brief intervention, 15 to 30 minutes) and G0397 (Alcohol and/or substance [other than tobacco] abuse structured assessment [e.g., AUDIT, DAST] and intervention greater than

30 minutes) have service-specific <u>documentation requirements</u> as follows: The medical record for covered SBIRT services must:

- Create complete, legible medical records
- Denote start/stop time or total face-to-face time with the patient because some SBIRT HCPCS codes are time-based
- Document the patient's progress, response to changes in treatment, and revision of diagnosis
- Document the rationale for ordering diagnostic and other ancillary services, or ensure it can be easily inferred
- For each patient encounter, document:
 - Assessment, clinical impression, and diagnosis
 - o Date and legible identity of observer/provider
 - o Physical examination findings and prior diagnostic test results
 - o Plan of car
 - o Reason for encounter and relevant history
- Identify appropriate health risk factor
- Include documentation to support all codes reported on the health insurance claim
- Make past and present diagnoses accessible for the treating and/or consulting physician
- Sign all services provided/ordered

For CY 2019, CMS proposes to eliminate the service-specific documentation requirements for HCPCS codes G0397 and G0398.

Additionally, CMS proposes to create a third HCPCS code, GSBR1, with a lower time threshold to accurately account for the resource costs when practitioners furnish these services, but do not meet the requirements of the existing codes. The proposed code descriptor is: Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST), and brief intervention, 5-14 minutes. CMS proposes a work RVU of 0.33, based on the intraservice time ratio between HCPCS codes G0396 and G0397.

AAFP Response

The AAFP supports CMS' proposal to eliminate the service-specific documentation requirements associated with this family of services. As CMS notes in the proposed rule, utilization of these services is relatively low. We agree that low utilization is in part due to the service-specific documentation requirements, and we support removing the additional documentation requirements will also ease the administrative burden on providers. Given the ongoing opioid epidemic and the current needs of the Medicare population that CMS mentions, this proposal is a "win" for both patients and physicians.

For similar reasons, we support CMS' proposal to create a third code as described. We agree that the proposed work RVUs of 0.33 for the new code make sense, given the timeframe of the new code and the work RVUs and associated intraservice times of the existing codes, G0396 and G0397.

(66) Prolonged Services (HCPCS code GPRO1)

Summary

As discussed in section II.I, CMS is proposing HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) [beyond the typical service time of the primary procedure] in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30

Administrator Verma Page 25 of 80 September 5, 2018

minutes [List separately, in addition to code for office or other outpatient evaluation and management or psychotherapy service]), which could be billed with any level of E/M code. CMS notes that it does not propose to make any changes to CPT codes 99354 and 99355, which could still be billed, as needed, when their time thresholds and all other requirements are met. CMS proposes a work RVU of 1.17, which is equal to half of the work RVU assigned to CPT code 99354. Additionally, CMS proposes direct PE inputs for HCPCS code GPRO1 equal to one-half of the values assigned to CPT code 99354.

AAFP Response

As discussed elsewhere in this response to the proposed rule, we believe the existing CPT prolonged services codes are adequate to describe prolonged physician services and support CMS' intent to not make any changes to CPT codes 99354 and 99355, which could still be billed, as needed, when their time thresholds and all other requirements are met. Per CPT, code 99354 can be reported once the prolonged service reaches 30 minutes beyond the typical time of the base code to which it's being added. Medicare follows this same policy; section 30.6.15.1 (Prolonged services with direct face-to-face patient contact service [ZZZ codes]) of chapter 12 of the Medicare Claims Processing Manual states, in part, "Prolonged service of less than 30 minutes total duration on a given date is not separately reported because the work involved is included in the total work of the evaluation and management codes." Accordingly, we do not see a need for CMS to create a new HCPCS code, GPRO1, for prolonged services of 30 minutes, since such services are already reportable using code 99354.

If CMS proceeds in creating the new HCPCS code anyway, then we support its proposal to set the work RVUs equal to 1.17 (i.e., one-half of the work RVUs assigned to 99354), since the physician time of GPRO1 will be half of the time currently assigned to 99354. We also support its proposal to set the direct PE inputs for HCPCS code GPRO1 equal to one-half of the values assigned to CPT code 99354 on the same basis.

(67) Remote pre-recorded services (HCPCS code GRAS1)

Summary

As noted in section II.D of the proposed rule, CMS proposes to make separate payment for a new HCPCS G-code, GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow up with the patient within 24 business hours, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). CMS proposes to value this service by a direct crosswalk to CPT code 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio [INR] test result, patient instructions, dosage adjustment [as needed], and scheduling of additional test(s), when performed). Thus, CMS proposes for code GRAS1 a work RVU of 0.18, preservice time of three minutes, intraservice time of four minutes, and post-service time of two minutes. CMS also proposes to add six minutes of clinical labor (L037D) in the service period.

AAFP Response

The AAFP does not, at the present time, support the creation of code GRAS1. We note there is an existing CPT code, 99444 (Online evaluation and management service provided by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided

within the previous seven days, using the internet or similar electronic communications network) that already describes this service, but which Medicare otherwise does not cover. Creation of a similar HCPCS code, like GRAS1, is potentially confusing and of limited utility. We encourage CMS to cover code 99444. If code 99444 needs revision from CMS' perspective, then we encourage it to work with the CPT Editorial Panel to make the necessary changes rather than create a separate HCPCS code.

Since Medicare does not cover code 99444, it lacks RVUs in the MPFS. On an interim basis only, until code 99444 can be reviewed by the RUC and valued by CMS, we support establishing times and RVUs for 99444 based on a crosswalk to 93793. The description of 99444 is sufficiently comparable to that of 93793. Further, a review of other codes with a comparable global period and the same intraservice time and comparable total time suggests the proposed value of 0.18 is appropriate on a relative value basis.

(68) Brief Communication Technology-based Service, e.g., Virtual Check in (HCPCS code GVCI1) *Summary*

As noted in section II.D of the proposed rule, CMS proposes to make separate payment for a new HCPCS code, GVCI1 (Brief communication technology-based service, e.g., virtual check in, by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion).

CMS proposes to base the code descriptor and valuation for HCPCS code GVCI1 on existing CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion), which is currently not separately payable under the MPFS. As CPT code 99441 only describes telephone calls, CMS proposes to create code GVCI1 to encompass a broader array of communication modalities. However, CMS believes the resource assumptions for CPT code 99441 would accurately account for the costs associated with providing the proposed virtual check-in service, regardless of the technology. Thus, CMS proposes a work RVU of 0.25, based on a direct crosswalk to CPT code 99441. For the direct PE inputs for HCPCS code GVCI1, CMS is also proposing the direct PE inputs assigned to CPT code 99441.

Given the breadth of technologies that could be described as telecommunications, CMS looks forward to receiving public comments and working with the CPT Editorial Panel and the RUC to evaluate whether separate coding and payment is needed to account for differentiation between communication modalities.

AAFP Response

The AAFP supports CMS' proposal to base the valuation of proposed code GVCI1 on the existing code 99441. Given the similarities in description and physician time involved, this crosswalk makes sense to us. We also support CMS' intention to work with the CPT Editorial Panel and the RUC to evaluate whether separate coding and payment is needed to account for differentiation between communication modalities. We are inclined to think separate coding and payment for different communication modalities is unnecessary and potentially confusing. We think revision of codes

Administrator Verma Page 27 of 80 September 5, 2018

99441-99443 (and potentially 99444) to encompass a broader array of communication modalities makes more sense.

(69) Visit Complexity Inherent to Certain Specialist Visits (HCPCS code GCG0X) *Summary*

As discussed in section II.I, CMS proposes to create a HCPCS G-code, GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care [Add-on code, list separately in addition to an evaluation and management visit]). This code is to be reported with an E/M service to describe the additional resource costs for specialties for whom E/M visit codes make up a large percentage of their total allowed charges and who CMS believes primarily bill level 4 and level 5 visits. CMS proposes a valuation for HCPCS code GCG0X based on a crosswalk to 75 percent of the work RVU and time of CPT code 90785 (Interactive complexity), which would result in a proposed work RVU of 0.25 and a physician time of 8.25 minutes for HCPCS code GCG0X. CPT code 90785 has no direct PE inputs.

AAFP Response

As discussed elsewhere in this response to the proposed rule, we have concerns with the proposed definition and valuation of GCG0X. First, it is unclear how CMS determined the specialties listed in the proposed code descriptor. According to the proposed rule, this code is for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches CMS believes are generally reported using the level 4 and level 5 E/M visit codes. These would likely be specialties most likely to experience a negative impact under CMS' proposal to pay a single allowed amount for level 2 through 5 services. However, table 21 in the proposed rule indicates that otolaryngology and OB/GYN would benefit from the singled allowed amount proposal, while cardiology would not, yet all three specialties are covered by the proposed add-on code.

It is also unclear how the value of this proposed code was crosswalked to 75% of the work and time for CPT code 90785 (Interactive complexity). We can understand why an existing add-on code for interactive complexity might serve as a useful reference code for a new add-on code intended to compensate physicians for visit complexity. However, prior to implementing any such change, we ask that CMS provide additional data on the use of 75% of the reference code's time and work make sense, and why this should be more than the visit complexity associated with a primary care E/M service (as discussed below). Because of our concerns, we cannot support the proposed add-on code for visit complexity inherent to certain specialist visits as envisioned and valued by CMS.

(70) Visit Complexity Inherent to Primary Care Services (HCPCS code GPC1X) *Summary*

As discussed in section II.I, CMS proposes to create a HCPCS G-code for primary care services, GPC1X (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 [Add-on code, list separately in addition to an evaluation and management visit]). This code describes furnishing a visit to a new or existing patient and can include aspects of care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. HCPCS code GPC1X would be billed in addition to the E/M visit code when the visit involved primary carefocused services. CMS proposes a work RVU of 0.07 and physician time of 1.75 minutes. According

Administrator Verma Page 28 of 80 September 5, 2018

to CMS, this proposed valuation accounts for the additional work resource costs associated with furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits and maintains work-budget neutrality across the office/outpatient E/M code set. CMS seeks comment on the code descriptor, as well as the proposed valuation for HCPCS code GPC1X.

AAFP Response

As discussed elsewhere in this response to the proposed rule, we cannot support the proposed add-on code for primary care as envisioned and valued by CMS for reasons outlined. We strongly support CMS' objective of providing greater resources to family medicine and primary care, however, it is our opinion that CMS should redefine and revalue the code prior to implanting it in the program.

The AAFP questions whether this proposed add-on code is valued appropriately. We are unclear how CMS arrived at its proposed RVUs for the add-on code. We are unclear how less than two minutes of physician time and \$5.40 (the proposed total RVUs of 0.15 times the 2018 conversion factor) "accounts for the additional resource costs associated with furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits."

This proposed value is even more problematic when one compares it to the value that CMS proposes for the proposed add-on code for complex visits provided by other specialties, discussed above. CMS proposes that the value of the primary care add on would involve less than one-third of the work and less than one-fourth of the time assumed to be involved in the add-on code for complex visits provided by other specialties. We strongly disagree with this assumption. Primary care physicians address many of the same issues as the subspecialties proposed to be covered by the other add-on code for complex visit. Those issues include diabetes (endocrinology), arthritis (rheumatology), neuropathy (neurology), allergies (allergy/immunology), heart disease (cardiology), chronic pain (interventional pain management), etc. Further, primary care physicians typically address various combinations of these multiple issues at a single visit. In fact, as Dr. David Katerndahl and others have demonstrated, family medicine outpatient encounters are more complex than those of cardiology, and family medicine and internal medicine encounters are the most complex overall, especially when duration-of-visit is considered. Accordingly, we cannot support any proposal that values primary care physicians at a lesser value than other specialties with a supposedly high complexity of patient visits. CMS should eliminate the proposed primary care add-on code and replace it with a 15% increase in payment for E/M services provided by physicians who list their primary practice designation as family medicine, internal medicine, pediatrics, or geriatrics. CMS has shown a real commitment to supporting primary care in recent years. The difference in payment levels of the two add-on codes flies in the face of that commitment.

We also have concerns that the primary care add on is available to physicians practicing in nonprimary care specialties. As proposed, code GPC1X is for "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." However, the proposed rule posits no definition for "primary medical care" other than to say it's "partially defined by an ongoing relationship with the patient" and does not extend to visits furnished within the global period of a procedure. Indeed, CMS states that GPC1X "can also be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding."

Administrator Verma Page 29 of 80 September 5, 2018

Our concern is that, as proposed, CMS will not be able to distinguish when the add-on code is being used appropriately, and that any physician specialty will be able to report the primary care add-on code under almost any circumstance for an established patient outside the global period of a procedure. Our concern is exemplified in the following statement from the proposed rule: "While we expect that this code will mostly be utilized by the primary care specialties, such as family [medicine] or pediatrics, we are also aware that, in some instances, certain specialists function as primary care practitioners—for example, an OB/GYN or a cardiologist." If CMS is unable to distinguish OB/GYNs and cardiologists from primary care physicians, we have little confidence that it can ensure proposed code GPC1X is used for its intended purposes.

CMS references the AAFP's <u>definition</u> of primary care in the proposed rule. While we appreciate your desire to use our comprehensive definition of primary care, we would encourage CMS to focus on the key elements of that definition. Primary care is care that is 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. A primary care physician is a specialist in family medicine, internal medicine, or pediatrics who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's comprehensive care. Such a physician must be specifically trained to provide comprehensive primary care services through residency or fellowship training in acute and chronic care settings.

Physicians who are not trained in the primary care specialties of family medicine, general internal medicine, or general pediatrics may sometimes provide patient care services that are usually delivered by primary care physicians. These physicians may focus on specific patient care needs related to prevention, health maintenance, acute care, chronic care, or rehabilitation. These physicians, however, do not offer these services within the context of comprehensive, first contact and continuing care. They are not primary care physicians, and the care they provide is not primary care.

Finally, we are concerned that use of the proposed primary care add-on code may be limited to established patients. In section II.H of the proposed rule, CMS states, "This code describes furnishing a visit to a <u>new</u> or existing patient...." (emphasis added) However, in its discussion of the code in section II.I, CMS says it intends to limit reporting of the code to established patients.

Central to the concept of primary care is the patient. A primary care practice serves as the patient's first point of entry into the health care system and as the continuing focal point for all needed health care services. Primary care practices provide health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment of acute and chronic illnesses 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. None of this excludes new patients.

With these concerns in mind, we recommend CMS redefine code GPC1X before it makes any attempt to implement it. Specifically, we recommend CMS redefine the code as follows:

Visit complexity inherent to evaluation and management associated with primary medical care services provided by **family physicians, general internists, and general pediatricians**, as well as other qualified health care professionals that work with them, who offer comprehensive

Administrator Verma Page 30 of 80 September 5, 2018

> first contact and/or continuing care for the undifferentiated patient not limited by problem origin, organ system, or diagnosis, and who serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to a new or established patient evaluation and management visit)

The code could be used by any physician in one of the designated primary care specialties with any established patient E/M service and with any new patient E/M service if the physician expected to have an ongoing relationship with the patient. The auditable evidence of an ongoing relationship with a new patient would be a subsequent claim for services provided to the patient within the next 12 months. As CMS proposes, the code would not be applicable to any separately identifiable E/M service furnished within the global period of a procedure.

Again, we cannot support any proposal that values primary care physicians at a lesser value than other specialties with a supposedly high complexity of patient visits. CMS should eliminate the proposed primary care add-on code and replace it with a 15% increase in payment for E/M services provided by physicians who list their primary practice designation as family medicine, internal medicine, pediatrics, or geriatrics.

II.I. Evaluation & Management (E/M) Visits

2. CY 2019 Proposed Policies

AAFP Overall Comments

The AAFP appreciates that CMS has recognized the problems with the current E/M documentation guidelines and codes, and we sincerely thank CMS for its desire to address them. The AAFP is committed to—and supports—payment policies that support the delivery of patient-centered primary care that is comprehensive, continuous, coordinated, connected, and accessible. We welcome the opportunity to work with CMS to ensure that all Medicare beneficiaries have access to coordinated, longitudinal care that improves patient outcomes and reduces health care spending.

The AAFP strongly supports reduction in documentation guidelines and administrative burden in all health care programs, public and private. We urge CMS to use its unique influence to drive action by all payers.

We strongly recommend that CMS decouple the documentation and payment proposals, as proposed. This is necessary because, while we believe the proposal to reduce documentation burden is headed in the right direction, it can and must be significantly improved upon. Therefore, we request a phased-in approach with documentation relief in 2019 and any payment revisions until we have a chance to model other payment proposals or evaluate potential changes to the current CPT office visit codes and their descriptors. Further, we would suggest that CMS would be well served by testing any payment revisions on a limited scale via a demonstration project before implementing them nationally. A phased-in approach to E/M documentation and payment reform will allow time for physician education and mitigating the potential negative effects of heterogeneity in payment approaches among payers.

The AAFP is particularly concerned about the effect of the payment proposals on patients and small, independent physician practices. As discussed in more detail below, we are concerned about the financial impact on beneficiaries from potentially increased cost sharing in some cases. We are also concerned that the payment changes as currently proposed would inhibit the delivery of comprehensive, coordinated, and longitudinal care. However, the AAFP would appreciate the

Administrator Verma Page 31 of 80 September 5, 2018

opportunity to work with CMS—and share the experiences of family physicians—to further develop payment changes that can support the delivery of high-quality, patient-centered care.

a. Lifting Restrictions Related to E/M Documentation

(i) Eliminating Extra Documentation Requirements for Home Visits Summary

CMS proposes to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office.

AAFP Response

The AAFP supports this proposal. As noted in the proposed rule, the beneficiary need not be confined to the home to be eligible for such a visit, so the physician should not be required to document the medical necessity of furnishing the visit in the home rather than in the office. If the encounter is medically necessary, where it occurs is immaterial. We urge CMS to finalize this proposal.

(ii) Public Comment Solicitation on Eliminating Prohibition on Billing Same-day Visits by Practitioners of the Same Group and Specialty

Summary

Chapter 12, Section 30.6.7.B, of the Medicare Claims Processing Manual states:

As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on-campus, outpatient hospital setting which could not be provided during the same encounter.

CMS solicits public comment on whether it should eliminate the manual provision, given the changes in the practice of medicine or whether there is concern that eliminating it might have unintended consequences for practitioners and beneficiaries. CMS recognizes that this instruction may be appropriate only in certain clinical situations, so it seeks public comments on whether and how it should consider creating exceptions to, or modify, this manual provision, rather than eliminating it entirely. CMS also requests that the public provide additional examples and situations in which the current instruction is not clinically appropriate.

AAFP Response

The AAFP encourages CMS to eliminate this provision. As CMS notes in the proposed rule, the provision fails to recognize that physicians with the same nominal Medicare enrollment specialty may have different areas of expertise. Under the current provision, if a family physician provides an office visit to a patient and then sends the patient to an orthopedist for an office visit on the same day, Medicare will pay for both visits. However, if the family physician sends the patient to another family physician in the same group who has expertise in sports medicine, Medicare paradoxically only pays for one visit, even if the family physician with sports medicine expertise is doing the same thing as the orthopedist.

As CMS also notes in the proposed rule, the current provision incentivizes physicians to schedule E/M visits on two separate days, which unnecessarily inconveniences the patient. To the extent the separate visit either occurs on a separate date or is provided by a physician of another specialty (inside or outside the group), Accordingly, we urge CMS to proceed with elimination of the provision.

b. Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits
(i) Providing Choices in Documentation – Medical Decision-Making, Time or Current Framework Summary

CMS proposes to allow physicians to choose, as an alternative to the current documentation framework specified under the 1995 or 1997 guidelines, either medical decision making (MDM) or time as a basis to determine the appropriate level of E/M visit.

CMS proposes to allow physicians to rely on MDM in its current form to document their visit and solicits public comment on whether and how guidelines for MDM might be changed in subsequent years.

The proposal to allow physicians the choice of using time to document office/outpatient E/M visits would mean this time-based standard is <u>not</u> limited to E/M visits in which counseling and/or care coordination accounts for more than 50 percent of the face-to-face physician-patient encounter. Rather, the amount of time personally spent by the billing physician on the face-to-face encounter with the patient could be used to document the E/M visit, regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter.

CMS proposes to require the billing physician to document the medical necessity of the visit and show the total amount of face-to-face time with the patient. CMS is soliciting public comment on what the total time should be for payment of the single, new rate for E/M visits levels 2 through 5. The typical time for the proposed new payment for E/M visit levels 2 through 5 is 31 minutes for an established patient and 38 minutes for a new patient.

One alternative is to apply the American Medical Association (AMA) CPT codebook provision that, for timed services, a unit of time is attained when the midpoint is passed. Under this alternative, CMS would require documentation that at least 16 minutes for an established patient (more than half of 31 minutes) and at least 20 minutes for a new patient (more than half of 38 minutes) were spent on face-to-face time by the billing physician with the patient. This would support making payment at the proposed single rate for visit levels 2 through 5 when the physician chooses to document the visit using time.

Another alternative is to require documentation that the typical time for the CPT code that is reported (which is also the typical time listed in the AMA CPT codebook for that code) was spent face-to-face by the billing physician with the patient. In contrast to other proposed documentation approaches discussed above, this approach of requiring documentation of the typical time associated with the CPT visit code reported on the claim would introduce unique payment implications for reporting that code, especially when the time associated with the billed E/M code is the basis for reporting prolonged E/M services. CMS solicits public comments on the use of time as a framework for documentation of office/outpatient E/M visits, and whether it should adopt any of these approaches or specify other requirements with respect to the proposed option for documenting time.

CMS solicits comments for ways in which the time associated with, or required for, the billing of any add-on codes (especially the proposed prolonged E/M visit add-on code(s) described in section II.I.2.d.v) would intersect with the time spent for the base E/M visit, when the physician is documenting the E/M visit using only time. CMS proposes that, when a physician chooses to document using time and reports prolonged E/M services, CMS would require the physician to

document the typical time required for the base or "companion" visit is exceeded by the amount required to report prolonged services.

As a corollary to its proposal to adopt a single payment amount for office/outpatient E/M visit levels 2 through 5 (see section II.I.2.c.), CMS proposes to apply a minimum documentation standard where, for the purposes of MPFS payment for an office/outpatient E/M visit, physicians would only need to meet documentation requirements currently associated with a level 2 visit for history, exam and/or MDM (except when using time to document the service).

CMS solicits public comment on whether Medicare should use or adopt any aspects of other E/M documentation systems that may be in use among physicians, such as the Marshfield Clinic scoring point system. CMS is interested in feedback as to whether the 1995 and 1997 guidelines contain adequate information for physicians to use in documenting visits under CMS' proposals, or whether these versions of the guidelines would need to be supplemented in any way.

CMS is interested in public comments on physicians' ability to avail themselves of these choices with respect to how they would impact clinical workflows, electronic health record (EHR) templates, and other aspects of physician work.

AAFP Response

The AAFP applauds CMS for recognizing the need to review and revise the 1995 and 1997 documentation guidelines for E/M services, and we believe reform should occur as rapidly as possible. We appreciate that CMS proposes to offer physicians flexibility and choices in how to document E/M services. The AAFP supports CMS' proposal to allow physicians to choose, as an alternative to the current documentation framework specified under the 1995 or 1997 guidelines, either MDM or time as a basis to determine the appropriate level of E/M visit.

We believe CMS should adopt this proposal regardless of its adoption of the proposed single payment amount for levels 2 through 5 of the office/outpatient visit codes. We believe providing physicians with a choice about the basis for documenting E/M visits will facilitate E/M documentation that better reflects the current practice of medicine, improve clinical workflows, and alleviate documentation burden. Family physicians' ability to avail themselves of these choices may depend on the ability of their EHRs to accommodate alternative E/M documentation. EHR readiness in this regard is unclear.

For those physicians who choose to document E/M services solely based on MDM, we support CMS' proposal to allow physicians to rely on MDM in its current construct, but recommend CMS make specific changes to the E/M documentation guidelines related to MDM. We continue to believe, as described in CPT, that the complexity of MDM is a function of the following:

- Number of diagnoses or management options
- Amount and/or complexity of data to be reviewed
- Risk of complications and/or morbidity or mortality

However, the 1995 and 1997 versions of the E/M documentation guidelines do not appropriately capture the different levels of MDM in the context of current medical practice. The table of risk is particularly outdated. To remedy this situation, we recommend specific changes to this section of the documentation guidelines, which are provided in Addendum 1 as a mark-up of the 1995 E/M documentation guidelines. That mark-up includes other suggested changes to the guidelines that

Administrator Verma Page 34 of 80 September 5, 2018

would be helpful, regardless of whether CMS finalizes any of its other proposals related to the E/M codes. The MDM documentation guidelines may also be improved by incorporating the Marshfield Clinic scoring point system as it relates to MDM, in order to alleviate potential ambiguity. We believe making these changes to the E/M documentation guidelines would be helpful regardless of what CMS does with its other proposals related to E/M documentation and payment.

Concerning the proposal to allow physicians the choice of using time to document office/outpatient E/M visits, regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter, we support CMS' intent to focus on the amount of time personally spent by the billing physician's face-to-face time with the patient. We also support CMS' proposal to require the physician to document the medical necessity of the visit (which physicians must do in any case) and show the total amount of time spent by the billing physician's face-to-face time with the patient. To the extent physicians find this onerous, they have the option to document using MDM or current documentation guidelines instead.

As to what the total time should be to justify payment of the service, that will depend on whether CMS maintains separate payment for each of the current five levels of service or otherwise collapses payment among the service levels. Currently, per CPT and Medicare, when coding based on time (because counseling and/or coordination of care dominate the encounter), the typical times in E/M code descriptors serve as thresholds. For instance, if a physician spends more than half of a 20-minute established patient office visit in counseling/coordination of care and chooses to code on the basis of time, the physician should select code 99213 (typical time of 15 minutes) rather than 99214 (typical time of 25 minutes), because the total time of the encounter did not reach the threshold of 25 minutes associated with 99214.

If CMS maintains separate payment for each of the current five levels of service and allows physicians the choice of using time to document office/outpatient E/M visits regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter, we believe the typical times in the E/M code descriptors used as thresholds should justify payment for the service. This is the same as they do now when physicians code based on time because counseling and/or coordination of care dominate the encounter. This approach is most consistent with current E/M coding conventions and would therefore pose the least administrative burden for physicians to implement. Further, to the extent use of prolonged E/M service codes is keyed to the typical time in other E/M code descriptors, this approach is most consistent with current conventions related to use of prolonged services codes.

If CMS collapses payment among the service levels, as proposed, then we believe the total time physicians must document to justify payment is either 20 minutes for a new patient or 10 minutes for an established patient. These are the typical times for 99202 and 99212, respectively. This approach is consistent with CMS' proposal to apply a minimum documentation standard where, for the purposes of MPFS payment for an office/outpatient E/M visit, physicians would only need to meet documentation requirements currently associated with a level 2 visit for history, exam, and/or MDM. If CMS intends to pay the same amount for any level of office/outpatient visit among levels 2 through 5, it is only essential that physicians document at least a level 2 visit, and we see no reason to treat visits documented based on time any different from those documented based on history, exam, and/or MDM.

As discussed below, the AAFP cannot support CMS' proposal to adopt a single-payment amount for office/outpatient E/M visit levels 2 through 5. If CMS proceeds with finalizing that proposal, then we support CMS' corollary proposal to apply a minimum documentation standard where, for the purposes of MPFS payment for an office/outpatient E/M visit, physicians would only need to meet documentation requirements currently associated with a level 2 visit. If CMS intends to pay the same amount for any level of office/outpatient visit among levels 2 through 5, it is only essential that physicians document at least a level 2 visit, and documentation at level 2 seems appropriate under those circumstances.

(ii) Removing Redundancy in E/M Visit Documentation Summary

The current E/M documentation guidelines provide some flexibility in documenting the history of an established patient. For example, a review of systems (ROS) and/or a pertinent past, family, and/or social history (PFSH) obtained during an earlier encounter does not need to be rerecorded if there is evidence that the physician reviewed and updated the previous information. Similarly, the ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others.

CMS proposes to expand this policy to further simplify the documentation of history and exam for established patients such that, for both key components, physicians would only be required to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than redocumenting a defined list of required elements. Physicians would not need to rerecord these elements (or parts thereof) if there is evidence that they reviewed and updated the previous information. CMS seeks comment on whether there may be ways to implement a similar provision for any aspects of medical decision making, or for new patients, such as when prior data is available to the billing physician through an interoperable EHR or other data exchange. CMS also proposes that, for both new and established patients, physicians would no longer be required to reenter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary.

These proposed policy changes would be optional. A physician could choose to continue to use the current framework, and the more detailed information could continue to be entered, re-entered, or brought forward in documenting a visit, regardless of the documentation approach selected by the physician.

AAFP Response

The proposed rule includes meaningful reductions in administrative burden and removing redundancy in documentation for E/M codes is welcome. The AAFP supports both of CMS' proposals to remove the redundancy in E/M visit documentation and appreciates that they would be options for physicians. CMS' proposals in this regard are consistent with changes to the E/M documentation guidelines the AAFP recommends, as reflected in the attached mark up of those guidelines contained in Addendum 1. We believe CMS should finalize, and we strongly support, these proposals to reduce administrative burden and remove redundancy in documentation, regardless of whether it finalizes its other proposals related to E/M services.

We also believe these proposals should be equally applicable to new patients. If physicians have access to prior information on a new patient, they should be able to take advantage of the same efficiencies in documentation that CMS otherwise proposes for established patients.

c. Minimizing Documentation Requirements by Simplifying Payment Amounts *Summary*

In conjunction with its proposal to reduce the documentation requirements for E/M visit levels 2 through 5, CMS proposes to simplify the payment for those services by paying a single rate for the level 2 through 5 E/M visits. CMS proposes to develop a single set of relative value units (RVUs) under the MPFS for E/M office-based and outpatient visit levels 2 through 5 for new patients (CPT codes 99202 through 99205) and a single set of RVUs for visit levels 2 through 5 for established patients (CPT codes 99212 through 99215) while maintaining the code set. To set RVUs for the proposed single payment rate for new and established patient office/outpatient E/M visit codes, CMS proposes to develop resource inputs based on the current inputs for the individual E/M codes, generally weighted by the frequency at which they are currently billed, based on the five most recent years of Medicare claims data (CY 2012 through CY 2017). Specifically, CMS proposes a work RVU of 1.90 for CPT codes 99202-99205, a physician time of 37.79 minutes, and direct PE inputs that sum to \$24.98. Similarly, CMS proposes a work RVU of 1.22 for CPT codes 99212-99215, with a physician time of 31.31 minutes, and direct PE inputs that sum to \$20.70. The proposed RVUs are as follows:

Codes	Work RVUs	Non-Facility PE RVUs	Malpractice RVUs	Total RVUs
99202-99205	1.90	1.69	0.14	3.73
99212-99215	1.22	1.25	0.08	2.55

CMS believes it has identified three types of E/M visits that differ from the typical E/M visit and are not appropriately reflected in the current office/outpatient E/M code set and valuation. Per CMS, these three types of E/M visits can be distinguished by the mode of care provided and, as a result, have different resource costs. The three types of E/M visits that differ from the typical E/M service, according to CMS, are:

- Separately identifiable E/M visits furnished in conjunction with a 0-day global procedure;
- Primary care E/M visits for continuous patient care; and
- Certain types of specialist E/M visits, including those with inherent visit complexity.

CMS addresses each of these visit types in subsequent proposals.

CMS is interested in stakeholder input on the best number of E/M visit levels and how to best achieve a balance between number of visit levels and simpler, updated documentation rules. CMS seeks input as to whether these two aspects of its proposals together can reduce burden and ensure accurate payment across the broad range of E/M visits, including those for complex and high-need beneficiaries.

AAFP Response

The AAFP supports payment changes that help family physicians and their practices deliver primary care that meets the needs of each Medicare beneficiary. As CMS has recognized, the current MPFS undervalues the services and care that primary care physicians provide—and we appreciate CMS reexamining payment levels for those services. Administrator Verma Page 37 of 80 September 5, 2018

Despite our strong support for re-evaluating the values of codes primarily used for primary care services, we have concerns with the proposed structure of reducing the levels of E/M codes within both the new patient and established patient office/outpatient visit families. As CMS notes in the proposed rule, most visits are already reported as levels 3 and 4 (76% of new patient visits and 89% of established patient visits in 2016), and the most important distinctions between the kinds of visits furnished to Medicare beneficiaries are not well reflected in the current E/M visit coding.

Although further simplification is critical, we are concerned with and cannot support the structure of CMS' proposal to collapse the payment for levels 2 through 5 office/outpatient E/M codes to a single set of RVUs for new patients and a single set for established patients, at least at the proposed RVUs. We acknowledge, as CMS notes in the proposed rule, that providing for two levels of payment and documentation (setting aside level 1 visits which are primarily visits by clinical staff) relieves administrative burden relative to the current five levels. However, the cost of that burden relief is, in our opinion at the present time, too great.

Physicians may still need to document at a higher level for patient care and medical-legal reasons. Also, unless other payers follow CMS' lead, greater documentation will be required for them.

The proposed payment levels create at least two potential negative consequences for patients. First, Medicare beneficiaries will pay more out of pocket for level 2 and 3 visits than they have in the past, because the allowed amount on which their co-insurance is based will increase. Patient cost sharing will be the same regardless of the length or content of the visit.

Second, the proposed payment structure will penalize physicians who continue to address multiple problems at a given encounter, rather than ask patients to return for additional visits. Family physicians and others who care for patients with multiple problems and the frail elderly will likely be disadvantaged by the most by the current proposal, because they will simply not be able to spend the time needed to care for those patients properly and keep their practices financially solvent. This disruption in continuity and comprehensiveness is the foundation of our concerns. It is our fear, that the payment policy, if implemented, will work contrary to comprehensive, continuous, and coordinated primary care and, instead, incentivize more frequent visits that are shorter in duration and limited in scope. This is bad for beneficiaries and is inconsistent with high performing, efficient primary care.

In short, we worry that CMS' proposal could place an even greater emphasis on episodic care of discrete conditions that creates pressure to stint on care at an office/outpatient visit and churn patients. This scenario is contrary to the tenets of family medicine described above, which emphasize continuous, comprehensive care of patients. Like CMS' proposal to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, CMS' proposal to collapse level 2 through 5 office/outpatient visit codes into a single payment level is "penny wise, but pound foolish." Family physicians tend to manage many and diverse problems at a single visit. If family physicians are pressured to see fewer problems per visit (e.g., by their employers), this will ultimately lead to more expensive care for patients.

Access becomes a potential issue, especially for rural patients and patients of limited means and/or limited mobility (i.e., the complex and high-needs patients about whom CMS is most concerned). CMS' proposal could also inadvertently penalize physicians for treating the sickest patients who

require additional time and resources that will no longer be recognized by Medicare. It may also create an incentive for hospitals and health systems employing physicians to reduce the scheduled time for visits to 5-10 minutes and encourage physicians and other clinicians to address only one medical problem per visit, which could reduce the quality of care, especially for patients with multiple illnesses.

More levels create a greater need for program integrity mechanisms to prevent upcoding than what CMS' proposal would require. However, this proposal is not just about simplifying program integrity. It is also about reducing burden for physicians in a way that is sustainable for their practices and less onerous to their complex and high-need beneficiaries. The AAFP welcomes the opportunity to work with CMS over the next year to revise the proposed structure to simplify E/M payments to achieve the goals of better outcomes for patients, reduced health care costs for CMS and patients, and lower administrative burden for both CMS and physicians.

d. Recognizing the Resource Costs for Different Types of E/M Visits

(i) Accounting for E/M Resource Overlap between Stand-alone Visits and Global Periods *Summary*

CMS proposes that, as part of its proposal to make payment for the E/M levels 2 through 5 at a single MPFS rate, it would reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier -25. CMS estimates, based on CY 2017 Medicare claims data, that applying a 50 percent reduction to E/M visits furnished as separately identifiable services in the same day as a procedure would reduce expenditures under the MPFS by approximately 6.7 million RVUs. CMS proposes to re-allocate this toward the values of the add-on codes that reflect the additional resources associated with E/M visits for primary care and inherent visit complexity, as discussed below.

AAFP Response

The AAFP has long-standing policy opposing the application of this type of policy on primary care physicians in all health care programs, public and private. This policy is inconsistent with our vision of advanced primary care and is places unnecessary strains on patients. We have outlined several concerns with this proposal, and we strongly oppose it and urge CMS to not implement it.

First, we believe the proposed policy does not account for the fact CMS has already set the relative values of the procedures in question. The RUC already accounts for overlap in procedures typically done on the same day as an E/M in its recommendations to CMS. To the extent CMS accepts the RUC's recommendations (which it does most of the time), this overlap has already been accounted for. The proposed reduction double counts that reduction.

Second, we believe this proposed policy does not support the delivery of patient-centered care that meets the unique needs of a beneficiary. It could have the unintended effect of encouraging medical practices to turn patients away for same-day procedures and have patients return another day to have the procedure performed. This potential consequence is especially problematic for rural patients and patients of limited means and/or limited mobility (i.e., the complex and high-needs patients about whom CMS is most concerned).

Third, this proposed policy could hamper progress towards value-based payment models to which CMS is otherwise encouraging family physicians to migrate. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities. However, family physicians are financially dependent on the thin margins associated with the current fee-for-service payments to pay for day-to-day business expenses and the costs associated with transitioning to and success in value-based contracts. As a result, the proposed policy would significantly hamper family physicians' ability to operate a medical practice and transition to value-based care.

Fourth, this proposed policy may cost Medicare more than it saves. CMS expects to reduce expenditures under the MPFS by approximately 6.7 million RVUs under this proposal. We expect primary care physicians will either ask patients to return another day for the procedure or refer patients to higher cost sub-specialists to do the procedure. We believe delayed care or sub-speciality care could cost the agency more money than if it simply continues to pay primary care physicians for providing procedures on the same day as the primary care office visit, where appropriate.

Last, CMS should consider the experience of private payers who have tested a similar policy. For instance, Anthem, Inc. announced plans to implement the same policy, but recently halted the change. In a <u>statement</u> released by Anthem, they stated, "the company believes making a meaningful impact on rising health care costs requires a different dialogue and engagement between payers and providers." The AAFP agrees with this statement and believes physician engagement is key prior to implementing policies that reduce access to affordable quality care.

(ii) Proposed HCPCS G-code Add-ons to Recognize Additional Relative Resources for Certain Kinds of Visits

Summary

CMS believes the proposed value for the single payment rate for the E/M levels 2 through 5 new and established patient visit codes does not reflect the additional resources inherent to primary care visits. To more accurately account for the type and intensity of E/M work performed in primary care-focused visits, CMS proposes to create a HCPCS add-on G-code that may be billed with the generic E/M code set to adjust payment to account for additional costs beyond the typical resources accounted for in the single payment rate for the levels 2 through 5 visits.

CMS proposes to create a HCPCS G-code for primary care services, GPC1X (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 [Add-on code, list separately in addition to an established patient E/M visit)]. Since CMS believes a primary care visit is partially defined by an ongoing relationship with the patient, this code would describe furnishing a visit to an established patient. HCPCS code GPC1X can also be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. CMS believes the additional resources to address inherent complexity in E/M visits associated with primary care services are associated only with stand-alone E/M visits, as opposed to separately identifiable visits furnished within the global period of a procedure.

For HCPCS code GPC1X, CMS proposes a work RVU of 0.07, physician time of 1.75 minutes, a PE RVU of 0.07, and a malpractice RVU of 0.01. According to CMS, this proposed value maintains workbudget neutrality across the office/outpatient E/M code set and would help to mitigate potential payment instability that could result from our adoption of single payment rates that apply for E/M code Administrator Verma Page 40 of 80 September 5, 2018

levels 2 through 5. CMS anticipates that it would be billed with every primary care-focused E/M visit for an established patient.

CMS seeks comment on how best to identify whether a primary care visit was furnished, particularly in cases where a specialist is providing those services. For especially complex patients, CMS also expects that it may be billed alongside the proposed new code for prolonged E/M services described later in this section.

CMS also seeks comment on whether this policy adequately addresses the deficiencies in CPT coding for E/M services in describing current medical practice, and concerns about the impact on payment for primary care and other services under the MPFS. CMS seeks feedback on any unintended consequences of its proposals. CMS also seeks comment on any other concerns related to primary care that it might consider for future rulemaking.

CMS also proposes to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches CMS believes are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding. CMS proposes to create a new HCPCS code GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care [Add-on code, list separately in addition to an evaluation and management visit]). CMS believes these are specialties that apply predominantly non-procedural approaches to complex conditions that are intrinsically diffuse to multi-organ or neurologic diseases. The high complexity of these services is reflected in the large proportion of level 4 and level 5 visits that CMS believes are reported by these specialties, and the extent to which E/M visits are a high proportion of these specialties' total allowed charges.

To establish a value for this add-on service to be applied with a stand-alone E/M visit, CMS proposes a crosswalk to 75 percent of the work and time of CPT code 90785 (Interactive complexity), which results in a work RVU of 0.25, a PE RVU of 0.07, and a malpractice RVU of 0.01, as well as 8.25 minutes of physician time based on the CY 2018 valuation for CPT code 90785. Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more resources due to the complexity of the patient.

CMS believes the additional resources to address inherent complexity in E/M visits are associated with stand-alone E/M visits. CMS proposes that physicians in the specialty of psychiatry would not use either add-on code because psychiatrists may utilize CPT code 90785 to describe work that might otherwise be reported with a level 4 or level 5 E/M visit.

AAFP Response

Primary Care Add-on

The AAFP agrees that the proposed value for the single payment rate for the E/M levels 2 through 5 new and established patient visit codes does not reflect the additional resources inherent to primary care visits. We appreciate CMS' attempt to address this inadequacy in their single-payment rate proposal by also proposing to create an add-on code for primary care services. However, we cannot support the proposed add-on code for primary care as envisioned and valued by CMS and believe the code should be redefined and revalued if CMS intends to implement it.

First, the AAFP recommends CMS ensure the proposed add-on code is valued appropriately. It is unclear how CMS calculated the proposed RVUs for the add-on code. As proposed, it appears that less than two minutes of physician time and \$5.40 (the proposed total RVUs of 0.15 times the 2018 conversion factor) "accounts for the additional resource costs associated with furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits." The value primary care and family medicine bring to Medicare and its beneficiaries is worth significantly more than \$5.40 per encounter.

We are also concerned that the proposal would set the value of the primary care add-on at less than one-third of the work and less than one-fourth of the time assumed to be involved in the add-on code for complex visits provided by other specialties. Primary care physicians address many of the same issues as the sub-specialties proposed to be covered by the other add-on code for complex visit. Those issues include diabetes (endocrinology), arthritis (rheumatology), neuropathy (neurology), allergies (allergy/immunology), heart disease (cardiology), chronic pain (interventional pain management), etc. Further, primary care physicians typically address various combinations of these multiple issues at a single visit. In fact, as Dr. David Katerndahl and others have demonstrated, family medicine outpatient encounters are the most complex overall. Accordingly, we cannot support any proposal that values primary care physicians at a lesser value than other specialties. CMS should eliminate the proposed primary care add-on code and replace it with a 15% increase in payment for E/M services provided by physicians who list their primary practice designation as family medicine, internal medicine, pediatrics, or geriatrics.

The AAFP appreciates that CMS has shown a strong commitment to supporting primary care in recent years—and we look forward to working with CMS to share our data, member experiences, and analyses to ensure appropriate valuation of primary care services.

Second, we have concerns that the primary care add-on is available to physicians practicing in a nonprimary care specialty. As proposed, code GPC1X is for "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." However, the proposed rule posits no definition for "primary medical care" other than to say it is "partially defined by an ongoing relationship with the patient" and does not extend to visits furnished within the global period of a procedure. Indeed, CMS states that GPC1X "can also be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding."

Our concern is that, as proposed, CMS will not be able to distinguish when the add-on code is being used appropriately and that any physician specialty will be able to report the primary care add-on code under almost any circumstance for an established patient outside the global period of a procedure. Our concern is exemplified in the following statement from the proposed rule: "While we expect that this code will mostly be utilized by the primary care specialties, such as family [medicine] or pediatrics, we are also aware that, in some instances, certain specialists function as primary care practitioners—for example, an OB/GYN or a cardiologist." If CMS is unable to distinguish OB/GYNs and cardiologists from primary care physicians, we have little confidence that it can ensure proposed code GPC1X is used for its intended purposes.

Administrator Verma Page 42 of 80 September 5, 2018

We note that "obstetrics/gynecology" and "cardiology" are also part of the descriptor for the proposed HCPCS code for visit complexity inherent to certain E/M services. Consequently, given the statement above, we are unclear how the two add-on codes are to be distinguished and applied appropriately. If CMS finalizes both codes, CMS needs to clarify both the code descriptors and appropriate application of the codes.

We appreciate that CMS references the AAFP's <u>definition</u> of primary care in the proposed rule. However, it is our opinion that the application of that definition should be limited to those 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. A primary care physician is a specialist in Family Medicine, Internal Medicine or Pediatrics who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's comprehensive care. Such a physician must be specifically trained to provide comprehensive primary care services through residency or fellowship training in acute and chronic care settings.

Physicians who are not trained in the primary care specialties of family medicine, general internal medicine, or general pediatrics may, at times, may provide some primary care 'services' that are similar to those usually delivered by primary care physicians – but this does not constitute primary care. These physicians may focus on specific patient care needs related to prevention, health maintenance, acute care, chronic care, or rehabilitation. These physicians, however, do not offer these services within the context of comprehensive, first contact and continuing care.

Third, we are concerned that use of the proposed primary care add-on code is limited to established patients. A primary care practice serves as the patient's first point of entry into the health care system and as the continuing focal point for all needed health care services. Primary care practices provide health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses 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. None of this excludes new patients. Further, in its discussion of this code in section II.H of the proposed rule, CMS states, "This code describes furnishing a visit to a <u>new</u> or existing patient...." (emphasis added)

With these concerns in mind, we recommend CMS redefine code GPC1X. Specifically, we recommend CMS redefine the code as follows:

Visit complexity inherent to evaluation and management associated with primary medical care services provided by family physicians, general internists, and general pediatricians, as well as other qualified health care professionals that work with them, who offer comprehensive first contact and/or continuing care for the undifferentiated patient not limited by problem origin, organ system, or diagnosis, and who serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to a new or established patient evaluation and management visit)

The code could be used by any physician in one of the designated primary care specialties with any established patient E/M service and with any new patient E/M service if the physician expected to

Administrator Verma Page 43 of 80 September 5, 2018

have an ongoing relationship with the patient. As CMS proposes, the code would not be applicable to any separately identifiable E/M service furnished within the global period of a procedure.

To be clear, we view CMS's proposals as an attempt to address the deficiencies in CPT coding for E/M services related to current medical practice and longstanding concerns about the impact on payment for primary care and other services under the MPFS more generally. The proposals are a step in the right direction, but, as proposed, do not achieved the desired ends. We are committed to working with CMS to find a better way forward that addresses E/M coding issues and appropriate payment for primary care.

Visit Complexity Add-on

As suggested by our comments on the proposed primary care add-on, we also have concerns with the proposed definition and valuation of the add-on code for visit complexity in non-primary care specialties.

First, it is unclear how CMS determined the specialties listed in the proposed code descriptor. According to the proposed rule, this code is for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches CMS believes are generally reported using the level 4 and level 5 E/M visit codes. Ostensibly, these would be specialties most likely to experience a negative impact under CMS's proposal to pay a single allowed amount for level 2 through 5 services. However, table 21 in the proposed rule indicates that otolaryngology and OB/GYN would benefit from the singled allowed amount proposal, while cardiology would not, yet all three specialties are covered by the proposed add-on code.

Second, we believe that additional information would be helpful to understand how CMS crosswalked the value of this proposed code to 75% of the work and time for CPT code 90785 (Interactive complexity). We understand why an existing add-on code for interactive complexity might serve as a useful reference code for a new add-on code intended to compensate physicians for visit complexity. However, it is unclear why this should be more than the visit complexity associated with a primary care E/M service.

(iv) Proposed Adjustment to the PE/HR Calculation

Summary

As noted in section II.B. of this proposed rule, CMS generally allocates indirect costs for each code based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other PEs that are not directly attributable to a service for a patient. Generally, the proportion of indirect PE allocated to a service is determined by calculating a PE/hour (HR) based upon the mix of specialties that bill for a service.

According to CMS, establishing a single MPFS rate for new and established patient E/M levels 2 through 5 would have a large and unintended effect on many specialties due to the way that indirect PE is allocated based on the mixture of specialties that furnish a service. The single payment rates proposed for E/M levels 2 through 5 cannot reflect the indirect PE previously allocated differentially across those eight codes.

Due to the magnitude of the proposed coding and payment changes for E/M visits, it is unclear how the distribution of specialties across E/M services would change. CMS is concerned that such

Administrator Verma Page 44 of 80 September 5, 2018

changes could produce anomalous results for indirect PE allocations since CMS does not yet know the extent to which specialties would utilize the proposed simplified E/M codes and proposed G codes.

In the past, when utilization data are not available or do not accurately reflect the expected specialty mix of a new service, CMS has proposed to crosswalk the PE/HR value from another specialty. As such, CMS proposes to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes discussed above) of approximately \$136, based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. CMS believes this proposal is consistent with the methodology used to develop the inputs for the proposed simplified E/M payment for the levels 2 through 5 E/M visit codes, and that, for purposes of consistency, the new PE/HR should be applied across the additional E/M codes. CMS believes a new PE/HR value would more accurately reflect the mix of specialties billing both the generic E/M code set and the add-on codes. If CMS finalizes this proposal, it will consider revisiting the PE/HR after several years of claims data become available.

AAFP Response

The AAFP has serious concerns about the proposed approach to create a new PE/HR value for E/M visits, because if CMS did not make this adjustment, "establishing a single MPFS rate for new and established patient E/M levels 2 through 5 would have a large and unintended effect on many specialties." Despite the apparent magnitude of this impact, there is little detail about the effect on specific groups of physicians due to the proposed solution. For instance, the AAFP believes it is important to examine key questions such as:

- How does this proposed E/M PE/HR value impact specific specialties?
- What would be the consequences of not implementing this proposal?

We recommend CMS provide more detailed and extensive information on the proposal and its alternatives before implementing any changes, and the AAFP is willing to work with CMS on this issue.

(v) Proposed HCPCS G-Code for Prolonged Services

Summary

According to CMS, currently, there is inadequate coding to describe services where the primary resource of a service is physician time. Stakeholders have informed CMS that the "first hour" time threshold in the descriptor for CPT code 99354 (Prolonged evaluation and management or psychotherapy service(s) [beyond the typical service time of the primary procedure] in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour [List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service]) is difficult to meet and is an impediment to billing this code. In response, CMS proposes to create a new HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) [beyond the typical service time of the primary procedure] in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes [List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service(s) [beyond the typical service time of the primary procedure] in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes [List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service]). Given that the physician time of HCPCS code GPRO1 is half of the physician time assigned to CPT code 99354, CMS proposes a work RVU of 1.17, which is half the work RVU of CPT code 99354.

AAFP Response

The AAFP believes there is adequate coding to describe services where the primary resource of a service is physician time. As noted, CPT includes prolonged services codes for both the office/outpatient (99354, 99355) and inpatient/observation (99356, 99357) settings with direct patient contact, as well as prolonged services without direct patient contact (99358, 99359). All these codes are covered and separately payable by Medicare.

We also believe the "first hour" time threshold in the descriptor for CPT code 99354 can be met and is not an impediment to billing this code. Per CPT, code 99354 can be reported once the prolonged service reaches 30 minutes beyond the typical time of the base code to which it is being added. Medicare follows this same policy; section 30.6.15.1 (Prolonged Services With Direct Face-to-Face Patient Contact Service [ZZZ codes]) of chapter 12 of the Medicare Claims Processing Manual states, in part, "Prolonged service of less than 30 minutes total duration on a given date is not separately reported because the work involved is included in the total work of the evaluation and management codes."

In sum, we believe the existing CPT prolonged services codes are adequate to describe prolonged physician services and support their reporting as prescribed by CPT and the Medicare Claims Processing Manual.

(vi) Alternatives Considered

Summary

CMS considered establishing single payment rates for new and established patients for combined E/M visit levels 2 through 4, instead of combined E/M visit levels 2 through 5. Ultimately, CMS believes that providing for two levels of payment and documentation (setting aside level 1 visits which are primarily visits by clinical staff) relieves more burden than three levels, and that two levels, plus the proposed add-on coding more accurately captures the differential resource costs involved in furnishing E/M services to all patients.

CMS notes that if it retained a coding scheme involving three or more levels of E/M visits, it would not be appropriate to apply a minimum documentation requirement as it proposes to do. CMS would need to develop documentation requirements unique to each of the higher-level visits, and there would be a greater need for program integrity mechanisms to prevent upcoding and ensure that practitioners who chose to report the highest-level visit justified their selection of code level. CMS could still simplify the documentation requirements for E/M visits relative to the current framework, but would need a more extensive, differential documentation framework than what it proposes in this rule, to distinguish among visit levels.

CMS is interested in stakeholder input on the best number of E/M visit levels and how to best achieve a balance between number of visit levels and simpler, updated documentation rules. CMS seeks input as to whether these two aspects of its proposals together can reduce burden and ensure accurate payment across the broad range of E/M visits, including those for complex and high-need beneficiaries.

CMS also considered proposing the use of the patient-relationship modifiers it created as required by MACRA to adjust payment for E/M visits and using these modifiers as an alternative to the proposed use of G-codes to reflect visit complexity inherent to E/M in primary care and certain other specialist services. CMS seeks comment on this alternative. CMS is particularly interested in whether the

Administrator Verma Page 46 of 80 September 5, 2018

modifiers would accurately reflect the differences between resources for E/M visits across specialties and would therefore be useful to adjust payment differentially for the different types of E/M visits that CMS previously identified.

AAFP Response

The AAFP agrees with CMS that the alternative of combining E/M visit levels 2 through 4 and maintaining level 5 coding and payment is not preferable. We think CMS can and should simplify the documentation requirements for E/M visits relative to the current framework, even if it left the current framework in place. We encourage CMS to finalize many of its proposed documentation simplifications, regardless of what it does with payment levels among the office/outpatient E/M services.

Regarding the patient-relationship modifiers mandated by MACRA, we note that they were never intended to adjust payment or reflect visit complexity. They are intended solely to denote the relationship between the patient and the physician at a given encounter. In primary care, patient relationships can span a wide range of visit complexity and resource use. We urge CMS to avoid the use of patient-relationship modifiers to either adjust payment or reflect visit complexity.

e. Emergency Department and Other E/M Visit Settings

Summary

CMS is not proposing any changes to the emergency department E/M code set or to the E/M code sets for settings of care other than office-based and outpatient settings at this time. However, CMS is seeking public comment on whether it should make any changes to it in future years, whether by way of documentation, coding, and/or payment and, if so, what the changes should be.

Consistent with public feedback to date, CMS emphasizes that it is taking a step-wise approach and limiting its policy proposals this year to the office/outpatient E/M code set (and the limited proposal regarding documentation of medical necessity for home visits in lieu of office visits). CMS may consider expanding its efforts more broadly to additional sections of the E/M visit code set in future years and seeks public comment broadly on how it might proceed in this regard.

AAFP Response

We support CMS' step-wise approach and intent to limit its policy proposals affecting E/M payment levels to the office/outpatient code set initially. Once payment policy for the office/outpatient code set is settled, CMS and stakeholders can consider the implications for other E/M code families. We think how CMS proceeds in this regard will depend on the ultimate decisions made concerning the office/outpatient code set, so we are withholding comment on how to proceed until then.

f. Proposed Implementation Date

Summary

CMS proposes that these proposed E/M visit policies would be effective January 1, 2019. CMS seeks comment on whether a delayed implementation date, such as January 1, 2020, would be appropriate for its proposals.

AAFP Response

The AAFP concurs with CMS that all the proposals aimed at easing the documentation burden associated with E/M codes should be implemented effective January 1, 2019. Any changes to the payment levels, which as proposed we cannot support, for the office/outpatient E/M code set should

be delayed indefinitely until efforts can be explored to address needed changes to the CPT codes for office visits and their descriptors and definitions. Physicians and other stakeholders will need more than 60 days (the usual time between release of the final rule and start of the new year) to adjust to payment changes in a code set as significant as the office/outpatient visit codes.

We also caution that, to the extent other payers do not change their coding and documentation requirements, implementing the CMS proposal too soon could increase complexity and confusion. We would like to delay the implementation, in part, so we may work toward acceptable changes that all payers will accept and utilize.

CMS will need time to issue clear coding instructions. CMS, specialty societies, health systems, clearinghouses, and EHR vendors will also need sufficient time to educate physicians about any new codes and update systems to accommodate changes of this magnitude. Delaying the payment proposals for a year would allow the necessary education and system changes to support this proposal. We will work with CMS to further develop this proposal and strengthen beneficiary access to primary care.

IIJ. Teaching Physician Documentation Requirements for Evaluation and Management Services Summary

Under federal regulations at 42 CFR §415.172(b), for certain procedural services, the participation of the teaching physician may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. However, for E/M visits, the teaching physician is required to personally document their participation in the medical record.

CMS proposes to amend §415.172(b) to provide that, except for services furnished as set forth in §§415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service is furnished. Additionally, the revised paragraph would specify that the presence of the teaching physician during procedures and (E/M) services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. CMS also proposes to amend §415.174, by deleting paragraph (a)(3)(v), which currently requires the teaching physician to document the extent of their participation in the review and direction of the services furnished to each beneficiary, and adding new paragraph (a)(6), to provide that the medical record must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary, and that the extent of the teaching physician's participation in the review and direction may be demonstrated by the notes in the medical records made by a physician's participation may be demonstrated by the notes in the medical records made by a physician's participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

AAFP Response

The AAFP supports CMS' proposals in this regard. We believe the requirements for documenting an E/M visit in which a teaching physician is involved should be no more stringent than those associated with a procedural service in which a teaching physician is involved. Further, we appreciate CMS extending this administrative relief to E/M services otherwise covered by the "primary care exception" in §415.174.

K. Solicitation of Public Comments on the Low-expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS)

Summary

The *Protecting Access to Medicare Act* of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the CLFS. In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected for the 6-month data collection period and reported to CMS in the 3-month data reporting period and is equal to the weighted median of the private payor rates for the CDLT. In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the MPFS. CMS refers to this component of the applicable laboratory definition as the "majority of Medicare revenues threshold." The definition of applicable laboratory also includes a "low expenditure threshold" component, which requires an entity to receive at least \$12,500 of its Medicare revenues from the CLFS in a data collection period for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs). CMS established \$12,500 as the low expenditure threshold because the agency believed it achieved a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS.

Citing the belief that physician offices are generally not prepared to identify, collect, and report each unique private payer rate from each private payer for each laboratory test code on the CLFS and the volume associated with each unique private payer rate, CMS believes revising the low-expenditure threshold so that more physician office laboratories are required to report applicable information would be a very significant administrative burden on physician's offices. CMS seeks comments on:

- Reducing the low-expenditure threshold by 50 percent, from \$12,500 to \$6,250, in CLFS revenues during a data collection period. Since more physician office laboratories would meet the low-expenditure threshold, CMS would expect such an approach to increase the level of applicable information reported by physician office laboratories and small independent laboratories.
- Regarding the potential administrative burden on physician office laboratories and small independent laboratories that would result from reducing the low-expenditure threshold, an approach that would increase the low-expenditure threshold by 50 percent, from \$12,500 to \$18,750, in CLFS revenues received in a data collection period.
- Whether physician offices and small independent laboratories currently have adequate staff levels to meet the data collection and data reporting requirements.

AAFP Response

Since passage of the PAMA, the AAFP has <u>repeatedly expressed concern</u> to CMS about PAMA's Section 216, which significantly revises the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the CLFS. The AAFP agrees with the CMS commentary that the largest laboratories with the highest test volumes will continue to dominate the weighted median of private payer rates. Unfortunately, those rates do not cover the cost of tests performed in the medical office when the patient is present with the physician. The 2018 CLFS has significant enough cuts that some tests are not fully covered, and the situation will continue to get worse when the next reduction in CLFS is implemented in 2019.

There are approximately 259,000 CLIA-certified labs, and over 71% (184,000) of these labs are waived, physician office labs. Most are not being required to report data under PAMA based on the

Administrator Verma Page 49 of 80 September 5, 2018

way CMS has defined "applicable laboratory." The AAFP is concerned that such a large number of labs are not represented. While the AAFP does not want to increase the administrative burden of data reporting, there is no way to predict the impact of the additional data from more labs reporting due to the lower threshold, unless it occurs. We therefore encourage CMS to collect data from at least a representative sample of all laboratory sizes, including small and rural physician-owned laboratories. Doing so would more accurately account for the cost of providing services paid under the CLFS.

III.A. Clinical Laboratory Fee Schedule

Summary

CMS proposes to revise the way Medicare Advantage (MA) payments are treated, specifically, excluding data from MA plan revenues from the total Medicare revenue, as stated in the definition of applicable laboratory.

AAFP Response

MA plans should be treated as other commercial payers. The result of MA plans being excluded, if the proposal is passed, should increase the numbers of medical offices meeting the "applicable lab" definition, and therefore, be reporting private payer rates. This proposal may help lessen the disparity of the different types of laboratories represented. However, as stated before, the largest reference-type laboratories will continue to dominate the data.

III.C. Payment for Care Management Services and Communication Technology-based Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Summary

CMS proposes to include the new CPT code (994X7) in the calculation of the payment rate for HCPCS code G0511. Beginning in 2019, rural health clinics (RHCs) and federally qualified health centers (FQHCs) would be paid for G0511 based on the national average of the national non-facility MPFS payment rates for CPT codes 99490, 99487, 99484, and 994X7.

AAFP Response

The AAFP supports payment for these services for FQHCs and RHCs.

III.C.3 – Other Options Considered

Summary

CMS considered, but is not proposing to add communication technology-based and remote evaluation services as RHC- or FQHC-standalone services. CMS also considered but is not proposing to allow RHCs and FQHCs to bill HCPCS codes GVCI1 and GRAS1. CMS seeks comment on:

- The appropriateness of payment for communication-based and remote evaluation services in the absence of an RHC or FQHC visit.
- The burden associated with documentation for billing these codes.
- Any potential impact on the per diem nature of the RHC and FQHC billing and payment structure, as a result of payment for these services.
- Whether it would be clinically relevant to apply a frequency limitation on the use of the new virtual communications G code by the same RHC or FQHC with the same patient.
 - What would be a reasonable frequency limitation to ensure this code is appropriately utilized?

AAFP Response

The AAFP supports payment for these services for FQHCs and RHCs. We do not believe there needs to be a frequency limitation on these services. For further comments on these services we refer CMS to our comments on II.D.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Summary

The *Protecting Access to Medicare Act* of 2014 established a program that would deny payment for advanced imaging services unless the physician ordering the service had consulted appropriate use criteria (AUC). CMS had previously delayed implementation of the AUC by including a voluntary reporting period, which started in July 2018 and runs through December 2019. In 2020, the AUC program period will begin with an educational and operations testing period, during which CMS will continue to pay claims, whether or not they correctly include AUC information. CMS proposes to:

- Expand the definition of an applicable setting to include independent diagnostic testing facilities.
- Create significant hardship exceptions from AUC requirements that are specific to the AUC program and independent of other Medicare programs.
- Establish the coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims.
- Allow nonphysicians, under the direction of an ordering professional, to consult with AUC when the consultation is not performed personally by the ordering professional.

CMS clarifies that AUC consultation information must be reported on all claims for an applicable imaging service (e.g., if separate, both the technical and professional claim must include the AUC information). CMS also invites comments on how to identify potential outliers that will be subject to prior authorization in future years.

AAFP Response

The AAFP continues to have ongoing, significant concerns about the disproportionate burden primary care physicians will face when trying to comply with AUC requirements. AUC requirements will place more burdens on primary care physicians than on other clinicians and add an unnecessary level of complexity to the already complex Medicare system that severely overtaxes our members. The AAFP, therefore, strongly urges a delay in implementing this program until the AUC is fully aligned with the Quality Payment Program (QPP). With the passage and implementation of MACRA, which begins to align payment with value, the need for AUC requirements has been supplanted, and those requirements will now likely hinder, rather than improve, effective care.

Regarding the CMS proposals made to the AUC, the AAFP is concerned with expanding the definition to include independent diagnostic testing facilities until CMS and other impacted stakeholders have a better understanding of the program and 3-5 years of experience with it.

We support the concept of significant hardship exemptions from AUC requirements since. As noted, other Medicare programs align payment with value. We urge CMS to exempt all primary care physicians participating in the QPP from AUC requirements.

We are concerned with the proposal to use G-codes and modifiers, since these codes are new and by definition, are not readily understood by physician practices or private payers. As such, the AAFP urges CMS to work with the physician community to create CPT codes for this purpose.

Though we oppose the AUC program in general, we appreciate that CMS proposes to allow nonphysicians, under the direction of an ordering professional, to consult with AUC when the consultation is not performed personally by the ordering professional.

<u>E. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)</u> Summary

CMS intends to align electronic clinical quality measure (eCQM) requirements for Medicaid EPs with the requirements of Medicare quality improvement programs, to the extent practicable. To keep eCQM specifications current and minimize complexity, CMS proposes to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS-eligible clinicians for the CY 2019 performance period. Specifically, CMS proposes that the eCQMs available for Medicaid EPs in 2019 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period.

CMS requests comments on whether the agency should, in future years of the Medicaid promoting interoperability program beyond 2019, include all e-specified measures from the core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (the child core set) and the core set of health care quality measures for adults enrolled in Medicaid (adult core set) (hereinafter together referred to as "core sets") as additional options for Medicaid EPs.

For 2019, CMS proposes that Medicaid EPs would report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. CMS also proposes that for 2019, the Medicaid promoting interoperability program, the agency would adopt the MIPS requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high-priority measure).

CMS requests comments on how high priority measures should be identified for Medicaid EPs. CMS proposes to use all three of the following methods to identify which of the available measures are high-priority measures.

- 1. CMS would use the same set of high-priority measures for EPs participating in the Medicaid promoting interoperability program that the MIPS program has identified for eligible clinicians (ECs).
- For 2019, CMS would also identify as high-priority measures the available eCQMs that are included in the previous year's core sets and that are also included on the MIPS list of eCQMs.
- 3. CMS would also give each state the flexibility to identify which of the available eCQMs selected by CMS are high-priority measures for EPs in that state, with review and approval from CMS, through their State Medicaid HIT Plans (SMHP), similar to the flexibility granted states to modify the definition of meaningful use.

CMS proposes that any eCQMs identified via any of these mechanisms be considered high-priority measures for EPs participating in the Medicaid promoting interoperability program for 2019. CMS also propose that the eCQM reporting period for EPs in the Medicaid promoting interoperability program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category.

AAFP Response

The AAFP supports CMS' efforts to simplify the program through alignment across CMS programs. We support a common core set of clinical quality measures. We support the flexibility in identifying priority measures as provided by an EP using any of the three listed options.

To promote further alignment with other MIPS performance categories, the AAFP encourages CMS to recognize the attributes of a patient-centered medical home (PCMH) by providing full credit in the promoting interoperability category for any PCMH if it is a recognized accredited PCMH, a Medicaid medical home model, or a medical home model. Accredited PCMHs should be recognized if they are accredited by the:

- Accreditation Association for Ambulatory Health Care;
- The National Committee for Quality Assurance (NCQA) PCMH recognition;
- The Joint Commission Designation;
- The Utilization Review Accreditation Commission (URAC); or
- Certification from other payer, state or regional programs if the certifying body has 500 or more certified member practices

3. Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for EPs Participating in the Medicaid Promoting Interoperability Program *Summary*

CMS proposes that the EHR reporting period (and eCQM reporting period) in 2021 for all EPs in the Medicaid promoting interoperability program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid promoting interoperability program payments on or before December 31, 2021.

AAFP Response

The AAFP supports the proposal to have a minimum of any continuous 90-day period in 2021 for all EPs in the Medicaid promoting interoperability program.

4. Proposed Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs

a. Proposed Change to Objective 6 (Coordination of Care through Patient Engagement) [W]e propose to amend §495.24(d)(6)(i) such that the thresholds for Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement) would remain five percent for 2019 and subsequent years.

AAFP Response

We agree with CMS' determination to not increase the threshold for 2019 or subsequent years.

F. Medicare Shared Savings Program Quality Measures

Summary

For performance year 2018, 31 quality measures are used to determine accountable care organization (ACO) quality performance. The measures are submitted to CMS through the CMS Web Interface, calculated by CMS from administrative and claims data, and collected via patient experience of care survey (Consumer Assessment of Healthcare Providers and Systems [CAHPS] for ACO). The CAHPS for ACOs survey includes the core questions contained in the CG-CAHPS, plus additional questions to measure access to and use of specialist care, experience with care

coordination, patient involvement in decision making, experiences with a health care team, health promotion and patient education, patient functional status, and general health. From 2014-2017, ACOs had the option to use a short version of the survey with eight summary survey measures (SSMs) or a longer version (eight SSMs for quality and four SSMs for informational purposes only). In 2018, the CAHPS for ACOs survey incorporated updates from AHRQ to the CG-CAHPS survey and CMS removed all items included in the SSMs, "Helping You Take Medications As Directed and Between Visit Communication." These were optional, and their removal reduced the number of questions from 80 to 58.

CMS proposes to begin scoring the two SSM measures that are currently collected for information only. The two measures added would be ACO-45, CAHPS: Courteous and Helpful Office Staff, and ACO-46: CAHPS: Care Coordination. Both have been core measures in the CG-CAHPS survey. They would be pay-for-reporting for two years, then transition to pay-for-performance beginning in performance year 2021. Inclusion of these measures would place greater emphasis on outcome measures and the voice of the patient and would more align with the Merit-based Incentive Payment System (MIPS) measure set.

CMS seeks comment on the change to the quality measure set.

CMS also seeks comment on potentially converting the health and functional status SSM (ACO-7) to pay-for-performance in the future. They have not scored this measure in the past because it may reflect the underlying health of beneficiaries and not the quality of care provided by the ACO. They could look for a measure of change in health status over time. CMS is seeking comment on this approach, as well.

AAFP Response

The AAFP supports the change in the quality measure set and agrees with the phase-in approach, which begins with pay-for-reporting and transitions to pay-for-performance.

However, the AAFP opposes changing the measure to pay-for-performance and basing payment to clinicians on measures that are outside of their control. We believe such performance measures should be evidence-based, consistent, universal, well-defined, and transparent, and must meet the highest standards for validity, reliability, feasibility, importance, and risk-adjustment to avoid unintended consequences (AAFP Policies: <u>Performance Measures Criteria</u>; <u>Pay-for-Performance</u>). Measures must allow for exceptions for individual patient circumstances, values, and needs. Performance measures should be limited to factors that have the greatest impact on health, health care, and costs, and that are within reasonable control of entities or professionals to which payment adjustments apply.

c. Proposed changes to the CMS Web Interface and Claims-based Quality Measure Sets Summary

CMS acknowledges the work of the meaningful measures initiative and the Core Quality Measure Collaborative (CQMC). CMS proposes to reduce the total number of measures in the Medicare Shared Savings Program (MSSP) quality measure set. CMS proposes to retire three measures which have a high degree of overlap with other measures that would remain in the set. The measures for removal are:

- ACO-35 SNF 30-Day All-Cause Readmission;
- ACO-36 All-Cause Unplanned Admissions for Patients with Diabetes;

• ACO-37 All-Cause Unplanned Admissions for Patients with Heart Failure.

CMS also proposes to retire ACO-44, Use of Imaging Studies for Low Back Pain. This measure is for individuals age 18-50, which results in a low denominator for the MSSP. CMS will continue to provide data on these measures, since they are claims-based, but the measures will not be scored. CMS seeks comment on the removal of these four measures.

CMS also proposes to remove six measures from the CMS Web Interface measure set, although the measures will be retained in MIPS with substantive changes. These measures include:

- ACO-12 (NQF #0097) Medication Reconciliation Post-discharge;
- ACO-13 (NQF #0101) Falls: Screening for Future Fall Risk;
- ACO-15 (NQF #0043) Pneumonia Vaccination Status for Older Adults;
- ACO-16 (NQF #0421) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up;
- ACO-41 (NQF #0055) Diabetes: Eye Exam; and
- ACO-30 (NQF #0068) Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.

CMS also seeks to add one measure to the CMS Web Interface for purposes of the Quality Payment Program: ACO-47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. This measure combines three current measures for a more robust, stratified measure of fall risk and is endorsed by the National Quality Forum (NQF) as one combined measure. MSSP ACOs would be responsible for reporting this measure starting in performance year 2019.

AAFP Response

The AAFP agrees with removal of measures that are redundant, would reduce administrative burden, are not valid due to low numbers, or that are topped out. The AAFP supports the addition of ACO-47 (revised NQF #0101) to the Web Interface/ACO measure set (as a replacement for current measure ACO-13, NQF #0101).

H. CY 2019 Updates to the Quality Payment Program

b. MIPS Determination Period

Summary

Beginning with the 2021 MIPS payment year, CMS proposes to consolidate the low-volume threshold, non-patient facing, small practice, and hospital-based determination periods into a single MIPS determination period. CMS does not propose to include the facility-based or virtual group eligibility determination periods or the rural and health professional shortage area (HPSA) determinations in the MIPS determination period, as they each require a different process or timeline that does not align with the other determination periods, or do not utilize determination periods.

CMS invites comments on the possibility of incorporating these determinations into the MIPS determination period in the future.

AAFP Response

The AAFP appreciates the effort to consolidate multiple determination periods as this simplifies the program for clinicians and for the agency. We also support quarterly snapshots showing preliminary

Administrator Verma Page 55 of 80 September 5, 2018

eligibility status. Moving forward, we would encourage a continued effort to align more determination periods across the program.

3. MIPS Program Details

Summary

CMS seeks comment on their proposal to specify the following:

- MIPS applies to payments for covered professional services by MIPS eligible clinicians (ECs) on or after Jan 1, 2019.
- MIPS ECs do not include partial qualifying Alternative Payment Model (APM) participants that do not elect to report on MIPS measures.
- MIPS adjustment factors do not apply to those who are not MIPS ECs, including those who voluntarily report.

AAFP Response

The AAFP agrees with the proposals as stated.

<u>4. Proposed Additional Low-volume Threshold (LVT) Criterion Based on Number of Covered</u> <u>Professional Services</u>

CMS proposes to add the minimum number of covered professional services provided to Part B enrolled individuals by the clinician to the LVT determination. ECs who meet at least one of the following would not exceed the LVT:

- Allowed charges less than \$90K,
- Provide services to 200 or fewer Part B enrolled individuals, or
- Provide 200 or fewer covered professional services to Part B enrolled individuals.

AAFP Response

The AAFP supports the expanded definition of the low-volume threshold as it allows CMS to offer the opt-in policy. As stated in previous comment letters, the AAFP believes that family physicians should be able to voluntarily participate in the program even if they otherwise qualify for an exemption.

5. LVT Opt-In

Summary

If an EC or group exceeds at least one of the LVT criteria, they may choose to opt in to MIPS. To opt in, ECs would need to elect to participate through the Quality Payment Program (QPP) portal. Once the election is made, it cannot be changed for the performance year. If an EC elects to join a virtual group (VG), they must exceed at least one of the LVT criteria to receive a payment adjustment. The VG election is used in place of the election through the QPP portal. APM entities that are in MIPS APMs, but do not exceed the LVT and want to opt in and participate under the APM scoring standard must elect to do so. Their choice is also irrevocable. Individual clinicians in an APM entity cannot opt in as individuals if their entity chooses not to opt in.

CMS seeks comments on modification of LVT definition and other LVT criteria and supporting justification for the recommended criteria. CMS seeks comment on the proposal that a clinician who is eligible to opt in would be required to make an election to opt in, or be a voluntary reporter, or (by not submitting any data) not report. CMS seeks comment on APM entities only being allowed to opt in as a group.

AAFP Response

The AAFP strongly applauds CMS for operationalizing the MIPS opt in. We believe this will allow many ECs the opportunity to participate in the MIPS program that might otherwise have been excluded, leading to higher program participation, improved quality, and lower costs. The criteria CMS has defined for the LVT criteria is reasonable, consistent with past criteria. Therefore, the AAFP is supportive of the thresholds as described. The AAFP agrees with CMS that an affirmative election to report is necessary to avoid confusion and possible inadvertent claims submissions that might involuntarily opt in a clinician to MIPS. Finally, the AAFP also supports CMS' proposal to only allow APM entities to opt in as a group.

6. Part B Services Subject to MIPS Payment Adjustment

Summary

CMS seeks comment on the *Bipartisan Budget Act* adjustment to MIPS that removed Part B drugs from the MIPS adjustment factor payments.

AAFP Response

The AAFP agrees with your decision to remove Part B drugs from the MIPS adjustment factor payments.

III.H.3.e Group Reporting

Summary

CMS is requesting comment on implementing sub-group level reporting through a separate sub-group sub-identifier in QPP year four and possibly future years of the program. CMS specifically seeks comment on:

- Whether and how a subgroup should be treated as a separate group from the primary group. For example, if there is one subgroup within a group, how to assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the sub-group level;
- Whether all of the subgroup's MIPS performance data should be aggregated with that of the primary group or should be treated as a distinct entity for determining the subgroup's final score, MIPS payment adjustments, and public reporting, and whether eligibility should be determined at the whole group level;
- Possible low-burden solutions for identification of subgroups. For example, whether we should require registration similar to the CMS Web Interface or a similar mechanism to the low-volume threshold opt in; and
- Potential issues or solutions needed for subgroups utilizing submission mechanisms, measures, or activities, such as APM participation, that are different than the primary group.

AAFP Response

The AAFP is supportive of CMS' position to allow for subgroup reporting and appreciates the agency is attempting to offer flexibility in this regard. The AAFP believes it would be both beneficial and logical if those in similar practices that might be part of a larger, multispecialty group could report as a smaller subgroup, specifically for quality reporting. There are a variety of ways a tax identification number (TIN) could split into subgroups, such as by practice site or specialty.

We believe that CMS should be able to operationalize subgroup reporting as it already has a similar infrastructure created for VG reporting. Those wishing to form a subgroup could make an election through the CMS Portal. CMS could assign an identifier to the subgroup and assess the subgroup's performance, scoring, and payment adjustment. ECs within a subgroup would be identified by

TIN/National Provider Identifier (NPI)/subgroup identifier. MIPS final scores should be calculated at the subgroup level and any corresponding payment adjustments applied to NPIs associated with the subgroup. When splitting into a subgroup, the practice would need to account for all eligible NPIs within the TIN (i.e., each NPI would need to be associated with either the primary group or a subgroup). All ECs within a TIN should still be required to report if a TIN has been determined to be above the LVT and the TIN has decided to a group. For example, a TIN should not be able to "carve out" high-performing individuals to form a subgroup and choose not to report on the remaining ECs. This would ensure consistency with the policies established for group reporting. We urge CMS to apply its group policies to subgroups, as it has done with VGs, and not create a separate set of policies.

III.H.3.f(2) – Virtual Group Election Process

Summary

Beginning with the 2022 MIPS payment year, CMS is proposing to update §414.1315(c)(2)(ii) to provide that a VG election would occur in manner specified by CMS. They anticipate a VG representative would make an election on behalf of the group using a web-based system developed by CMS. CMS seeks comment on this proposal.

AAFP Response

The AAFP is supportive of this proposal as it aims to alleviate burden on ECs.

III.H.3.g - MIPS Performance Period

Summary

CMS requests comments on its proposal that the performance period for the quality and cost performance categories would be the full calendar year. CMS also seeks comments on its proposal to establish a 90-day reporting period for the promoting interoperability and improvement activities performance categories. Both proposals would begin with the 2022 MIPS payment year and apply to future years.

AAFP Response

The AAFP is supportive of this proposal.

h. MIPS Performance Category Measures and Activities

b. Collection Types, Submission Types and Submitter Types

Summary

CMS proposes and seeks comments on the following newly-defined terms:

- "Collection type": sets of quality measures (electronic clinical quality measures [eCQMs], MIPS CQMs, qualified clinical data registry [QCDR] measures, claims, Web Interface, CAHPS for MIPS).
- "Submitter type": MIPS EC, group, or third party that submits to MIPS.
- "Submission type": mechanism by which the submitter type submits (direct, log in and upload, log in and attest, claims, Web Interface).

CMS also clarifies how each category may be submitted. CMS seeks comment on the clarification of how each performance category may be submitted.

CMS wants to move away from claims-based reporting in the future since approximately 69 percent of Medicare Part B claims measures are topped out. CMS realizes this would impact a small

Administrator Verma Page 58 of 80 September 5, 2018

practice's ability to participate in MIPS. CMS proposes to allow claims-based reporting for small practices, regardless of whether they report as an individual or as a group. Previously, groups could not report via claims.

CMS has previously allowed Web Interface submissions for groups for the quality, improvement activities, and promoting interoperability categories. CMS is proposing to only allow Web Interface submissions for quality. CMS proposes to allow third-party intermediaries to submit data on behalf of groups to the Web Interface. CMS also solicits comment on expanding the CMS Web Interface submission type to groups consisting of 16 or more ECs.

AAFP Response

The AAFP appreciates that CMS is recognizing the complexity associated with the terms and definitions of the program. However, we caution CMS against the continuous changing of names within the program, as it leads to confusion and frustration for participants.

The AAFP appreciates CMS' acknowledgement of the challenges faced by small practices as they report to the MIPS program. We support the proposal to allow claims-based reporting for small practices reporting as individuals or as a group.

The AAFP supports the expansion of groups allowed to report to the Web Interface to include those with 16 or more ECs. This change would align the criteria more closely with the definition of "large practice," as a small practice is defined as 15 or fewer ECs.

c. Submission Deadlines

Summary

CMS proposes to give the agency the ability to alter submission deadlines as needed due to unforeseen circumstances (e.g., the deadline falls on a weekend, technical difficulties, etc.). Also, CMS proposes to align the CMS Web Interface submission deadlines with all other submission deadlines.

AAFP Response

The AAFP supports the flexibility CMS is proposing and appreciates the agency further aligning deadlines within the program.

2. Quality Performance Category

(ii) Contribution to Final Score

Summary

For 2019 performance year (i.e., payment year 2021), CMS proposes to score quality at 45 percent and cost at 15 percent.

AAFP Response

The AAFP is supportive of the gradual 5 percent increase each year in the cost category percentage and corresponding decrease in the quality category percentage. However, we continue to believe that the current measures within the cost category are flawed (see below). The AAFP remains opposed to the use of Medicare Spending per Beneficiary (MSPB) and Total Per capita Cost. These measures were developed for use at the TIN level, and their validity at the solo/small practice level is questionable. The AAFP offers to work with CMS to ensure that cost measures are Administrator Verma Page 59 of 80 September 5, 2018

applicable—and fair—for primary care physicians participating in diverse practice settings and geographies.

(ii) Topped Out Measures

Summary

According to the 2018 final rule, after a measure has been identified to be topped out for three consecutive years, CMS can propose to remove the measure through notice and rulemaking. CMS is now proposing that once a measure meets extremely topped-out status (98-100th percentile), the agency may propose to remove it in the next rule-making cycle, regardless of where it is in the topped-out lifecycle. If a QCDR measure reaches topped-out status, CMS is proposing it will not be approved for use in the program.

AAFP Response

The AAFP supports the previously finalized policy from CMS regarding topped-out measures. We would discourage any new, overlapping, and on-going measure removal policy. If needed, CMS could remove all measures currently considered extremely topped out in a one-time "MIPS measure fix."

III.H.3.h(3) – Cost Performance Category

Summary

CMS proposes to weight the cost performance category at 15 percent for the 2019 MIPS performance period. They also anticipate increasing the category weight by five percent each year until the category reaches the required 30 percent for the 2024 payment year. CMS seeks comments on this proposal.

AAFP Response

The AAFP is supportive of the gradual 5 percent increase each year in the cost category percentage and corresponding decrease in the quality category percentage. However, we remind CMS that the current measures within the cost category are flawed (see below). The AAFP remains opposed to the use of Medicare Spending per Beneficiary (MSPB) and Total Per capita Cost. These measures were developed for use at the TIN level, and their validity at the solo/small practice level is questionable. The AAFP offers to work with CMS to ensure that cost measures are applicable—and fair—for primary care physicians participating in diverse practice settings and geographies.

II.H.3.h(3)(b) - Cost Criteria

CMS is proposing to add eight episode-based measures for the 2019 MIPS performance period and future performance periods. CMS proposes a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures. Each measure meets CMS' previously finalized reliability threshold of 0.4 using these case minimums. However, the percentage of TIN/NPIs (31.8%) with 20 episodes at this reliability threshold for Simple Pneumonia with Hospitalization is lower than the other measures. CMS considered increasing the case minimum to 30. One hundred percent of TIN/NPIs would meet the reliability threshold with an increased case minimum, but fewer TIN/NPIs and TINs would meet the case minimum.

CMS seeks comment on the alternative case minimum for the Simple Pneumonia with Hospitalization measure. CMS also seeks comment on whether it should expand the performance period for the cost category to two or more years in future rulemaking. Expanding the performance period could allow more ECs to meet the case minimums but could increase the time between the measurement of

Administrator Verma Page 60 of 80 September 5, 2018

performance and the application of the MIPS payment adjustment. It would also take CMS longer to introduce new cost measures.

AAFP Response

The AAFP strongly encourages CMS to maintain a performance period of one year for the cost category. Extending the performance period for one category would only add more complexity to the program. CMS – and participating physicians - need to fully understand how well the cost category can be assessed in the first few years of the program before considering or proposing changes.

The AAFP remains extremely concerned about CMS' low-reliability threshold for cost

measures. We remind CMS that a reliability score of at least 0.8 is generally recognized as good if a measure is to be used for decision making. We are not certain which reference was used by CMS to determine that a reliability score of 0.4 to 0.7 is moderate, as the sources we consulted stated otherwise (see below), and which suggest a reliability coefficient lower than 0.6 should not be considered at all and should definitely not be applicable to the individual level or to small groups. We remain concerned not only of the low reliability of the measure, but also of the impact this has on the validity of the measure.

We point out that a measure may be reliable, but not valid. A measure cannot be valid unless it is reliable. **Reliability is necessary, but not a sufficient condition of validity**. This leads to the conclusion that the cost measures being used by CMS may, in fact, not be valid, particularly for individuals and small groups. We believe that the measures themselves are flawed (wrong or invalid) and new measures are needed to score cost, and that these flawed measures are inappropriately rewarding or penalizing physicians being measured. CMS must determine cost measures that are both reliable and valid before using them to rate and pay physicians.

Evaluation of Reliability Coefficient	
.9 or higher	High reliability. Suitable for making a decision about an examinee based on a single test score.
.8 to .89	Good reliability. Suitable for use in evaluating individual examinees if averaged with a small number of other scores of similar reliability.
.6 to .79	Low/moderate reliability. Suitable for evaluating individuals only if averaged with several other scores of similar reliability.
.40 to .59	Doubtful reliability. Should be used only with caution in the evaluation of individual examinees. May be satisfactory for determining average score differences between groups.
Source: <u>http://ericae.net/ft/pug/reliabil.txt;</u> <u>https://www.nap.edu/read/1862/chapter/8</u> Robert Frary is an expert in reliability, with multiple peer-reviewed articles on the subject	
Robert Frary is an expert in reliability, with multiple peer-reviewed articles on the subject.	

We continue to believe the dearth of episode-based measures across specialties creates an unlevel playing field for clinicians. Clinicians should not be assessed on cost unless they can be reliably measured on at least two reliable and valid cost measures. As measures are developed and implemented, we urge CMS to ensure measures can be reliably assessed at both the individual NPI

and TIN levels. We applaud CMS' efforts to work with stakeholders through the technical expert panels (TEPs) and look forward to continued collaboration with CMS as they develop new measures. We strongly encourage CMS to develop measures that meet a 0.8 reliability threshold at both the TIN and TIN/NPI levels. We also ask CMS to consider establishing a TEP for the review of the total per capita cost measure.

4. Improvement Activities Performance Category

Summary

CMS proposes to change the vocabulary around submission in this category as previously explained. The submission will now be referred to as "direct, login and upload, and login and attest." CMS also proposes to add that submitters must submit a "yes" response for each activity performed for at least a continuous 90 days.

AAFP Response

The AAFP appreciates CMS recognizing the complexity of the program and the variety of names that can cause confusion. However, the AAFP cautions against continuously changing names within the program and asks for stability to reduce confusion and administrative complexity.

(A) Criteria for Nominating New Improvement Activities

Summary

CMS believes it is important to place attention on public health emergencies, such as the opioid epidemic, when considering new improvement activities. Therefore, CMS proposes a new criterion for improvement activities entitled, "Include a public health emergency as described by the Secretary" to the current criteria for nominating a new improvement activity.

AAFP Response

The AAFP agrees that promoting clinicians' addressing public health emergencies, like the opioid crisis, through improvement activities will raise clinician awareness and will promote best practice. We support the new improvement activities criteria for inclusion.

(C) Weighting of Improvement Activities

Summary

CMS weighted improvement activities as high based on the extent to which they supported the patient-centered medical home (PCMH). Activities that required performance of multiple actions, such as the Transforming Clinical Practice Initiative (TCPI), focused on a public health priority, had a high intensity (like travel or working under challenging physical circumstances), and participation in the CMS study were also considered a high-weighted improvement activity.

CMS believes an activity that requires significant investment of time and resources should be a highweighted improvement activity. For example, CAHPS for MIPS survey is considered high weighted. CMS believes medium-weighted improvement activities are simpler to complete and require less time and resources.

CMS is clarifying that an improvement activity is, by default, a medium-weighted improvement activity unless it meets specifications to be high weighted.

CMS seeks comment on potentially applying high weighting for any improvement activity employing certified electronic health record technology (CEHRT), or any other considerations for high or medium weighting.

AAFP Response

The AAFP agrees that, as bonus points are removed from the promoting interoperability category for using CEHRT to complete improvement activities, it would make sense to now have those activities count as high weighted to encourage the continued use of CEHRT.

(D) Timeframe for the Annual Call for Activities

Summary

CMS is proposing to delay the year for which nominations of prospective new and modified improvement activities would apply, and to expand the submission timeframe. CMS proposes six new improvement activities, proposes to modify five improvement activities, and to remove one improvement activity.

AAFP Response

The AAFP agrees with the new improvement activities and agrees with the modifications and removal as proposed.

III.H.3.h(5) – Promoting Interoperability (PI)

Summary

CMS continues to believe it is appropriate to require ECs to use 2015 edition CEHRT beginning with the 2019 performance period. CMS notes that 2014 edition CEHRT criteria includes out-of-date standards and at least 66 percent of ECs have 2015 edition CEHRT available to them.

CMS is proposing to overhaul the scoring methodology for the promoting interoperability performance category. Beginning with the 2019 performance period, ECs will be required to report on a smaller set of objectives and will be scored solely based on performance. The proposed smaller set of objectives include: e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. Clinicians must report on all measures (numerator of at least one or "yes/no" attestation) to receive a promoting interoperability score. Failure to report on the required measures or claim an exclusion will result in a category score of zero. Each individual measure would be scored based on performance. CMS considered an alternative approach where scoring would occur at the objective level and ECs would be required to report on only one measure to earn a score for the objective. Each objective would be weighted, and bonus points awarded for reporting on any additional measures beyond the required four. CMS is seeking comment on their alternative approach and whether other flexibilities should be considered, such as allowing MIPS ECs to select which measures to report within an objective and how those objectives should be weighted, as well as additional scoring approaches or methodologies to be considered.

CMS is also proposing to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. The e-Prescribing measure would be weighted at 10 points. Should an EC claim an exclusion for the measure in 2019, CMS would redistribute the points to measures within the Health Information Exchange objective. The Query of PDMP and Verify Opioid Treatment Agreement measures would be optional in 2019, but ECs may earn up to five bonus points for each measure. The new measures would be required beginning with performance period 2020. CMS will make an exclusion available for the measures in 2020. The five points for the measure would be redistributed to the e-Prescribing measure. All measures within the e-Prescribing objective will be weighted at five points beginning in 2020. If an EC claims an exclusion for all three measures, the 15 points for the objective will be redistributed evenly among measures within the HIE and Provide Patients Electronic Access to their Health Information objectives.

For the health information exchange (HIE) objective, CMS is proposing to change the name of the "Send a Summary of Care" measure to "Support Electronic Referral Loops by Sending Health Information." CMS is also proposing a new measure that combines two existing measures: "Request/Accept Summary of Care" and "Clinical Information Reconciliation." The new measure would be called, "Support Electronic Referral Loops by Receiving and Incorporating Health Information." Both measures would be required and worth 20 points each. An exclusion is available for 2019 for ECs unable to implement "Support Electronic Referral Loops by Receiving and Incorporating Health Information." The 20 points would be redistributed to "Support Electronic Referral Loops by Sending Health Information."

ECs must report "yes" or claim an exclusion for two measures within the Public Health and Clinical Data Exchange objective, worth 10 points total. If an EC claims exclusions for both measures, the 10 points would be reassigned to the "Provide Patients with Electronic Access to their Health Information" measure. Measures for this objective include: Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting. No bonus points are available for reporting more than two measures.

CMS is proposing to no longer score the "Security Risk Analysis" measure, but it would remain part of the requirements of the promoting interoperability category. Clinicians would need to report that they completed the actions included in the measures to receive a promoting interoperability score.

Measure points would be calculated using the following formula: performance rate multiplied by total measure points. For example, an e-Prescribing performance rate of 80 percent would yield eight measure points towards the promoting interoperability category score (80% x 10=8).

CMS is seeking comment on various aspects of its proposed category restructure.

AAFP Response

The AAFP is supportive of the industry's move to 2015 edition CEHRT. Yet, we have concerns with it being mandated for ECs. We must also realize that adopting a 2015 edition CEHRT does not mean that a practice or hospital will be interoperable. Mandates are more beneficial to health information technology (IT) developers than to ECs. Mandates relieve market pressures to lower the cost of upgrades and increase the value of upgraded versions. The cost of EHRs continues to rise, whereas IT in every other industry has decreased in cost. We strongly encourage CMS to not mandate 2015 edition CEHRT, but rather incentivize its adoption through scoring, which benefits 2015 edition CEHRT users.

While the proposed opioid measures are evidence of CMS' dedication to addressing the opioid epidemic, they potentially add burden to physicians due to the fragmented structure of the MIPS program. As discussed later, the AAFP believes CMS should harmonize program requirements across the performance categories. For example, reporting on an opioid-related quality measure or

Administrator Verma Page 64 of 80 September 5, 2018

improvement activity should automatically satisfy any opioid-related promoting interoperability measure. ECs should not need to double report for such measures.

The new structure proposed by CMS maintains an "all or nothing" policy. **The AAFP remains adamantly opposed to such a policy.** Clinicians should only need to attest to performing a subset of measures. CMS could identify high-priority measures and award a set number of points for each measure, so that the total points available is 100. If a clinician does not attest to a measure, they would not receive points for that measure, but could still receive points for any other measures to which they attest. While the AAFP understands CMS' desire to focus on measures that promote interoperability, a clinician's ability to perform on these measures is highly dependent upon their selected EHR's interoperability. Unfortunately, interoperability is either not available or cost prohibitive to physicians. We urge CMS to focus its efforts, along with those of the Office of the National Coordinator for Health Information Technology (ONC), on ensuring all CEHRT is interoperable (at no additional cost to clinicians).

We believe that the time for health IT utilization measures has passed. With CMS' authority to measure cost and quality, we strongly recommend that the health IT utilization measures of promoting interoperability be eliminated. Short of eliminating these measures, CMS should provide the ECs with ample flexibility in selecting measures and eliminate any required single measure.

To promote further alignment with other MIPS performance categories, the AAFP encourages CMS to recognize the attributes of a patient-centered medical home (PCMH) by providing full credit in the promoting interoperability category for any PCMH if it is a recognized accredited PCMH, a Medicaid medical home model, or a medical home model. Accredited PCMHs should be recognized if they are accredited by the:

- Accreditation Association for Ambulatory Health Care;
- The National Committee for Quality Assurance (NCQA) PCMH recognition;
- The Joint Commission Designation;
- The Utilization Review Accreditation Commission (URAC); or
- Certification from other payer, state or regional programs if the certifying body has 500 or more certified member practices.

III.H.3.h(5)(f)(ii) - Measure Proposals for the e-Prescribing Objective

Summary

For the new e-Prescribing measures, CMS proposes to define opioids as Schedule II controlled substances under 21 CFR 1308.12. CEHRT is required to be the sole means of creating the prescription and transmission to the pharmacy.

CMS is seeking comment on what the impact of implementing the measures could have on patients who receive opioids due to medical diagnoses, such as cancer or receiving hospice care, as well as the treatment of patients under a program involving substance abuse education, treatment, or prevention. CMS also seeks comment on the federal and state statutory and regulatory requirements that may impact implementation of these new measures.

AAFP Response

As with any measure, it should be evaluated for unintended consequences. CMS could develop automatic exclusions for prescriptions written for patients with certain diagnoses, such as cancer.

The AAFP would support the policy that opioids should be e-prescribed, but we do not support a required piece of technology, such as CEHRT. It is only very recent that it is even legal to e-prescribe a schedule II drug according to the Drug Enforcement Administration (DEA).

III.H.3.h(5)(f)(ii)(A) - Proposed Measure: Query of PDMP

Summary

CMS proposes that the query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. This measure would include all permissible prescriptions and dispensing of Schedule II opioids, regardless of amount prescribed. ECs who are unable to electronically prescribe Schedule II opioids can claim an exclusion for the measure. While there are no existing certification criteria for the query of a PDMP, CMS believes the use of structured data in the CEHRT can support querying a PDMP through the broader use of health information technology (HIT).

CMS is seeking comment on its proposed query of the PDMP measure.

AAFP Response

The AAFP fully recognizes the intertwined public health issues of chronic pain management and the risks of opioid misuse. We advocate for physicians to use their state PDMP before prescribing any potentially abused pharmaceutical product. However, the success of such efforts depends on state reporting systems that are accessible, timely, and interoperable. Since most PDMPs are not currently integrated into EHRs, this measure could prove administratively burdensome and costly for clinicians. CMS has promoted e-prescribing within EHRs through incentives, penalties, and certification and can leverage that investment to drive the policy goal of improved opioid management. This functionality needs to be part of CEHRT so prescribers do not have to leave the CEHRT to login to multiple PDMPs to retrieve a medication history for opioids for the patient. We would strongly encourage CMS to not push for query of stand-alone PDMPs, but rather set policy that incentivizes integration of these functionalities within the robust e-prescribing ecosystem that it has been pushing. Doing so would better support the delivery of coordinated care across settings.

The AAFP believes the promoting interoperability category should be based on attestation of using CEHRT functionalities and that the MIPS program requirements should be streamlined. This proposed measure overlaps with an existing improvement activity (IA_PSPA_6). An EC should be able to attest to this activity and automatically receive credit in the promoting interoperability category.

III.H.3.h(5)(f)(ii)(B) – Proposed Measure: Verify Opioid Treatment Agreement

Summary

This measure is for MIPS ECs to identify whether there is an existing opioid treatment agreement when they e-prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. CMS proposes that this measure would include all Schedule II opioids prescribed for a patient electronically using CEHRT by the EC during the performance period, as well as any Schedule II opioid prescriptions identified in the patient's medication history request and response transactions during a six-month look-back period, where the total number of days for which a Schedule II opioid was prescribed for at least 30 days. CMS is not proposing to define an opioid treatment agreement as a standardized electronic document; nor are they proposing to define the data elements, content structure, or clinical purpose for a document to be considered a treatment agreement. ECs unable to electronically prescribe Schedule II opioids in accordance with applicable law would be able to claim an exclusion for this measure.

CMS seeks feedback on this proposed measure.

AAFP Response

We believe the intent of this measure overlaps with existing and proposed quality and improvement activities – and that the lack of interoperability would make this measure burdensome. CMS should work to alleviate burden by allowing ECs to report/attest to any related quality measure or improvement activity, and automatically receive credit in the promoting interoperability category.

III.H.3.h(5)(f)(iii) – Measure Proposals for the HIE Objective

Summary

CMS proposes to change the name of the "Send a Summary of Care" measure to "Support Electronic Referral Loops by Sending Health Information." CMS is proposing to allow ECs to use any document template within the Consolidated Clinical Document Architecture (C-CDA) standard for the measures in the HIE objective. For the "Support Electronic Referral Loops by Sending Health Information" measure, CMS proposes to allow ECs to use the templates most appropriate to their workflows.

CMS acknowledges challenges associated with the "Request/Accept Summary of Care" measure. These include the difficulty for machine calculation of the measure, burden associated with workflows, inadequate definition of "incorporate," and inconsistencies and redundancies with the "Clinical Information Reconciliation" measure. CMS proposes to combine these measures to create a new measure called, "Support Electronic Referral Loops by Receiving and Incorporating Health Information." CMS is not proposing to change the actions associated with either measure. ECs with fewer than 100 transitions of care or referrals or fewer than 100 encounters with patients never before encountered would be allowed to claim an exclusion for the measure. CMS proposes to continue their policy for cases in which the EC determines there is no update or modification necessary based on the information received. The EC would be able to count the reconciliation in the numerator without having to complete a redundant update in the record.

If CMS does not finalize the proposed scoring methodology, they would maintain the current promoting interoperability performance category objectives, measures, and reporting requirements.

CMS seeks comment on its proposals for the Health Information Exchange objective.

AAFP Response

The rate limiting step to the incorporation of clinical information within C-CDA documentation into the receiving clinician's EHR is not the clinician. CMS should work with ONC to strengthen the interoperability requirements for CEHRT and eliminate this measure on ECs. This measure only perpetuates the role of physicians being the interoperable component instead of CEHRT.

If CMS chooses to continue using these measures, clinicians should be able to attest to performing these activities using CEHRT. These measures overlap with existing quality measures and improvement activities. Clinicians who report on any related quality measure or improvement activity should automatically receive credit for these measures. Examples of overlapping quality measures and improvement activities include Quality ID 347, Quality ID 046, IA_CC_1, and IA_CC_13.

III.H.3.h(5)(f)(v) – Proposed Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

Summary

CMS is proposing that an EC would be required to submit two of the five measures associated with this objective. They are proposing the measure exclusions previously finalized through the EHR Incentive Programs rulemaking. CMS intends to propose to remove the Public Health and Clinical Data Exchange objective and measures in future rulemaking, but no later than CY 2022.

CMS seeks comment on its proposed changes to this objective.

AAFP Response

The AAFP believes these should be optional measures, as they remain difficult for clinicians due to lack of availability of interoperable public health registries. Additionally, implementation of bilateral exchange of information with public health registries remains expensive and resource intensive for practices.

III.H.3.h(5)(f)(vi) – Request for Comment – Potential New Measures for HIT Across the Care

Summary

CMS is seeking comment on two new potential measures: "Support Electronic Referral Loops by Sending Health Information Across the Care Continuum" and "Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum." These measures would include the exchange of information with providers, such as those in long-term care and post-acute care settings, skilled nursing facilities, and behavioral health settings that have made significant advancements in the adoption and use of HIT.

CMS specifically seeks comment on potential new measures related to HIT across the care continuum.

AAFP Response

The AAFP strongly urges CMS to reduce the complexity of the existing program and category requirements before it considers developing new measures. As we stated earlier, we believe CMS should focus initially on improving and increasing interoperability.

III.H.3.h(5)(g) – Improvement Activities Bonus Score under the Promoting Interoperability Performance Category and Future Reporting Considerations

Summary

Beginning with the 2019 performance period, CMS is proposing to eliminate the bonus for completing certain improvement activities using CEHRT. CMS seeks comments on this proposal.

CMS is considering establishing several sets of multi-category measures that would cut across the different performance categories and allow MIPS ECs to report once for credit in all three performance categories. For example, a combined measure that would bring together elements of the promoting interoperability measure "Support Electronic Referral Loops by Sending Health Information," the improvement activity "Implementation of Use of Specialist Reports Back to the Referring Clinician or Group to Close Referral Loop," and the quality measure "Closing the Referral Loop: Receipt of Specialist Report." CMS is also considering MIPS public health priority sets across

Administrator Verma Page 68 of 80 September 5, 2018

the four performance categories. They intend to develop the first few public health priority sets around: opioids, blood pressure, diabetes, and general health (healthy habits).

CMS is seeking comment on the multi-category measures concept and possible measure and activity suggestions to enhance the link between the three performance categories. CMS seeks input on additional public health priority areas for consideration and whether the sets should be more specialty focused versus condition specific. CMS seeks comment on how they could implement public health priority sets and how they could encourage or incentivize health care providers to consider using the public health priority sets.

AAFP Response

The AAFP is supportive of CMS' desire to allow clinicians to report once for credit in multiple performance categories. We believe a simplified program structure was the part of the original intent of the MACRA legislation. However, the current design of the MIPS pathway has created four siloed categories that have made the program overly complex and burdensome. An updated architecture that would allow clinicians to report once and receive credit in multiple categories could alleviate significant burden from practices and allow them to more easily focus their efforts on relevant initiatives. As we have outlined above, CMS could operationalize this by making the promoting interoperability category based upon attestation.

<u>III.H.3.h(6) – APM Scoring Standard for MIPS ECs Participating in MIPS APMs</u> Summary

CMS is proposing to modify regulation to clarify that a MIPS APM must be designed in such a way that participating APM entities are incentivized to reduce costs, utilization, or both. A MIPS APM could take cost/utilization performance using model design features other than the direct use of cost/utilization measures.

Beginning with the 2019 performance period, if a MSSP ACO fails to report quality measures, CMS will allow a solo practitioner (a MIPS EC who has only on NPI billing through their TIN) to report on any available measures. If an APM entity (i.e., ACO) fails to complete reporting for Web Interface measures, but reports the CAHPS for ACOs survey, CMS will score the CAHPS for ACO survey and apply it towards the APM entity's quality score. The MSSP TIN-level reporting exception would not be triggered and all MIPS ECs within the ACO would receive the APM entity Score. CMS seeks comment on this proposal.

CMS is proposing to allow MIPS ECs who participate in the MSSP to report on the promoting interoperability category at either the individual or group level like all other MIPS ECs under the APM scoring standard. CMS seeks comment on this proposal.

AAFP Response

The AAFP is supportive of this proposal.

III.H.3.i(1)(b)(iii)(B) – Additional Policies for the CAHPS for MIPS Measure Score

Summary

CMS proposes to continue its policy to apply a three-point floor for each quality measure that can be reliably scored against a benchmark based on the baseline period.

Beginning with the 2021 payment year, CMS proposes to reduce the quality performance category denominator by 10 points for groups that register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements. CMS is concerned groups may register for the CAHPS for MIPS survey, even if they know in advance they are unlikely to meet the sampling requirement. As such, CMS seeks comment on whether they should limit this proposed policy to groups for only one MIPS performance period.

AAFP Response

The AAFP supports CMS' proposal to reduce the quality performance category denominator by 10 points when a group has registered to report CAHPS for MIPS survey, but does not meet the beneficiary sampling threshold. We would support limiting this proposal for only one MIPS performance period.

III.H.3.i(1)(b)(iv) – Assigning Measure Achievement Points for Topped-out Measures Summary

Since the CAHPS for MIPS survey was revised in 2018, CMS does not have historical benchmarks to allow them to apply the topped-out policy for the 2019 performance period. CMS is seeking feedback on ways they can score CAHPS for MIPS Summary Survey Measures (SSM). For example, CMS could score all SSMs, which means there would effectively be no topped-out scoring for CAHPS for MIPS SSMs, or they could cap the SSMs that are topped out and score all other SSMs. CMS seeks comment on these approaches and other potential approaches.

AAFP Response

The AAFP would support an approach where CMS caps SSMs considered topped out and scores the remaining SSMs.

III.H.3.i(1)(b)(v) – Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements

Summary

CMS is looking for ways to improve policies, including how to handle measures that do not meet case minimums. CMS seeks comment on ways they can improve their case-minimum policy.

CMS is proposing to maintain the policies finalized for the CY 2018 performance period as it relates to measures that do not meet case-minimums, do not have a benchmark, or do not meet data completeness. CMS proposes to assign zero points for measures that do not meet data completeness. All measures submitted by small practices would continue to receive three points for all future MIPS performance periods, regardless of if the measure meets data completeness criteria.

AAFP Response

The AAFP supports CMS' proposal to continue the policy to assign three points to measures that do not meet case minimums or do not have a benchmark. We applaud CMS' proposal to continue assigning three points to all measures submitted by small practices.

As the program matures, the performance threshold will also increase. We believe the increased performance threshold will discourage clinicians from knowingly reporting on measures that do not meet the case minimum. We encourage CMS to continue to assess if large numbers of small practices are consistently unable to meet the case minimums.

III.H.3.i(1)(b)(ix) – Incentives to Report High-priority Measure

Summary

CMS proposes to discontinue awarding bonus points to CMS Web Interface reporters for reporting high-priority measures.

AAFP Response

We support CMS's proposal to discontinue awarding bonus points for Web Interface reporters. The previous policy essentially gave Web Interface reporters unnecessary automatic bonus points as the Web Interface measure set already includes additional high-priority measures and Web Interface reporters are required to report on all measures.

III.H.3.i(1)(b)(xii) – Future Approaches to Scoring the Quality Performance Category Summary

CMS is seeking comment on the following approaches:

- Option 1: Restructure the quality requirements with a predetermined denominator (e.g., 50 points), but with no specific requirements regarding the number of measures submitted. Measures would be categorized by value. The highest tier would include measures that are considered the "gold" standard, such as outcome, composite, or measures that address agency priorities (opioids). Measures included in the second tier, or "silver," would include process measures directly related to outcomes and have a good gap in performance (i.e., not topped out). Lower value measures, or the "bronze" standard, would have a scoring cap and could include standard of care process measures or topped-out process measures. Gold measures would receive between 15-20 points, silver measures would receive up to 10 points, and bronze measures would receive up to five points.
- Option 2: Maintain the current approach but change the minimum number of measure achievement points available to vary by the measure tier. High-tier measures could qualify for high-priority bonus and/or have a higher potential floor (five points instead of three); low-tier measures could have a lower floor (one point instead of three).

CMS believes removing the validation process to determine if an EC has measures available and applicable would simplify the quality performance category.

CMS has received feedback that ECs are hesitant to report QCDR measures without benchmarks as they are concerned a benchmark may not be able to be established using performance period data. CMS seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data. CMS seeks comment on developing QCDR benchmarks from historical data. CMS welcomes comment on how they can incorporate incentives for the use of electronic clinical quality measurement into the future approaches described in this section, as well as other ways to encourage more efficient technology-enabled measurement approaches.

AAFP Response

The AAFP strongly encourages CMS not to make changes to the quality category requirements until the QPP has been in place for several years. The previously finalized topped-out measures policy will help weed out less meaningful measures that would make a tiered approach unnecessary. Additionally, CMS could do a one-time "measure fix" outside of the topped-out measures cycle to remove all measures that are currently outdated or are not meaningful.

III.H.3.i(2)(b)(ii)(B) – Reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories for Extreme and Uncontrollable Circumstances

Summary

CMS seeks comment on specific circumstances where the extreme and uncontrollable circumstances policy should be made applicable to third-party intermediary issues.

CMS is proposing that, if a MIPS EC submits a reweighting application, but also submits data on the measures and activities for the quality and improvement activities category, the EC would be scored on the submitted data like all other MIPS ECs. CMS proposes to apply the policy finalized for VGs to groups submitting reweighting applications for the quality, cost, or improvement activities categories. CMS will evaluate on case-by-case basis if there were sufficient measures and activities applicable and available. If finalized, this policy would go into effect beginning with the 2018 performance period.

AAFP Response

CMS notes that they do not believe they should extend the extreme and uncontrollable circumstances policy to include third-party intermediaries because a MIPS EC may identify multiple ways to submit data to CMS. While this is true, we encourage CMS to reconsider this policy. Similar to when a MIPS EC encounters issues with their third-party intermediary, identifying an alternative reporting method can be time and resource intensive for a practice. We also note that an extreme and uncontrollable circumstance can occur at any time during the performance period. Should a third-party intermediary face such a circumstance late in the performance period, a MIPS EC may not have time to identify and contract with another party.

III.H.3.i(2)(b)(ii)(D) – Proposed Automatic Extreme and Uncontrollable Circumstances Policy Beginning with the 2020 MIPS Payment Year

Summary

CMS is proposing to apply the previously finalized automatic extreme and uncontrollable circumstances policy with the following changes. CMS proposes to include the cost category in the automatic extreme and uncontrollable circumstances policy beginning with the 2018 performance period.

AAFP Response

We fully support CMS continuing its policy that applies the extreme and uncontrollable circumstance policies for the MIPS performance categories without requiring a MIPS EC to submit an application. The application of the extreme and uncontrollable circumstances policies should be available when CMS determines a triggering event has occurred and the clinician is in an affected area. The AAFP agrees with the agency that doing so will reduce burden for clinicians who have been affected by these catastrophes.

The AAFP also supports that the types of events that could trigger this policy would be events designated as Federal Emergency Management Agency (FEMA) major disasters or a public health emergency declared by the secretary.

III.H.3.i(2)(b)(iii) - Redistributing Performance Category Weights

Summary

CMS proposes to reweight the promoting interoperability category to 45 percent and the improvement activities to 40 percent when the quality category is reweighted to zero percent. CMS has received feedback that their redistribution policies place undue weight on the quality category. CMS seeks

Administrator Verma Page 72 of 80 September 5, 2018

comment on alternative redistribution policies in which they would also redistribute weight to the improvement activities category. CMS also seeks comment on redistributing weight to the cost performance category in future program years.

AAFP Response

The AAFP is supportive of CMS' reweighting policies. The AAFP does not believe it would be appropriate to redistribute weight to the improvement activities category, as most clinicians will not have difficulties performing in this category. Category weights should not be redistributed to the cost category.

The AAFP believes all specialists and subspecialists should be required to meet the same program expectations as other MIPS ECs. This can be accomplished by maintaining cross-cutting measures within the MIPS measures list. Since cross-cutting measures are designed to apply across specialties, a specialist or subspecialist with fewer than six measures that are applicable and available within their specialty set could report on additional cross-cutting measures to reach a total of six quality measures.

In addition, we recommend that CMS not calculate a cost score for clinicians or groups unless at least two cost scores can be calculated. As such, the AAFP asks CMS to revise its policy regarding the reweighting of the cost category to redistribute the category weight for clinicians in small practices, and clinicians and groups that cannot be measured on at least two measures.

III.H.3.i(2)(c) - Final Score Calculation

Summary

CMS is proposing to revise the final score calculation to omit the small practice bonus and seeks comment on this proposal. CMS also seeks comment on approaches to simplify the final score calculation.

AAFP Response

The AAFP urges CMS to continue including the five-point small practice bonus as part of the final score. This allows for program stability and simplicity. We understand that CMS wishes to encourage small practices to submit quality measures. One way to accomplish this and include the small practice bonus in the final score would be to require practices to submit at least one quality measure to qualify for the five points. Small practices face unique challenges in complying with MIPS requirements. They often do not have the same resources to allocate towards data collection and analysis as larger practices. We also note that small practices will have smaller patient panels and fewer patients in their measure denominators. It is important for CMS to continue taking these factors into consideration so that there is a level playing field for all MIPS ECs.

We strongly encourage CMS to maintain the final score calculation until the agency has gained more experience with the program.

i. MIPS Payment Adjustments

(2) Establishing the Performance Threshold

Summary

The Bipartisan Budget Act allowed the Secretary to set the performance threshold for performance years 2019-2021, but the threshold must gradually increase. If CMS used the mean score, the performance threshold for performance year 2019 would have been between 63 and 68 points. If

CMS used the median, the threshold would have been between 77 and 82 points. CMS proposes a performance threshold of 30 points for performance year 2019. CMS estimates that the performance threshold for 2024 would be between 63 and 68 points. CMS seeks comment on whether the agency should use the median instead of the mean when setting the threshold for 2024. CMS also seeks comment on if it would benefit clinicians to know, in advance, what the thresholds will be from now until 2024.

AAFP Response

The AAFP supports the use of the mean final score for the MIPS performance threshold beginning in 2024. We also support the suggestion from CMS to lay out a clear performance threshold path for clinicians from performance year 2019 until 2024. This information would allow clinicians to plan, budget, and develop a long-term strategy for successful participation in MIPS.

(4) Application of MIPS Payment Adjustment Factors

Summary

Due to the *Bipartisan Budget Act*, payment adjustments will apply only to Part B payments for covered professional services and not Part B payments for other items and services.

AAFP Response

The AAFP is supportive of CMS removing Part B drugs from the application of the MIPS payment adjustment.

(c) Waiver of the Requirement to Apply the MIPS Payment Adjustment to Certain Payment Models Tested Under Section 1115A

Summary

CMS proposes to waive payment adjustments for participants in certain models beginning with performance year 2019. These ECs' payment adjustments from 2017 (for payment in 2019) would affect their per member, per month payments in certain models and would alter the effectiveness of the model and the ability to evaluate the model.

AAFP Response

The AAFP agrees with and supports the waiver of payment adjustments to participants of certain APMs and Advanced APMs.

(d) CY 2018 Exclusion of MIPS ECs Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive Demonstration

Summary

CMS designed this demonstration to determine whether excluding MIPS ECs who participate to a sufficient degree in certain Medicare Advantage arrangements from MIPS reporting and adjustments will increase or maintain participation in these arrangements, and therefore change how ECs deliver care. To do this, CMS proposes an exclusion from MIPS. Removing these ECs from the larger MIPS pool might affect the aggregate amount of MIPS payment adjustments.

AAFP Response

The AAFP appreciates CMS' efforts to expand the availability of alternative payment models. We believe that family physicians need more APM options, not less. We continue to engage with the Agency on the development and potential implementation of the AAFP's Advanced Primary Care APM, but we would stress the urgency about our request to make available more APM options for

family physicians. This program is a step towards that goal, but much more needs to be done. In general, we would view the Medicare Advantage demonstration like an AAPM. Participants in AAPMs are also removed from the aggregate MIPS pool, and movement to AAPMs is the direction and intent of MACRA. Therefore, the AAFP supports excluding clinicians in the Medicare Advantage demonstration from MIPS.

(2) Quality

<u>(3) Cost</u>

Summary

CMS will report on all measures in the quality category. CMS originally proposed to not report on measures their first year in the program. However, CMS is now proposing to not report measures for the first two years the measure is in the program.

To mirror the quality section, CMS proposes to not post cost measures until they have been in the program for two years.

AAFP Response

The AAFP is supportive of not publicly reporting a measure until it has been in the MIPS program for a minimum of two years.

(5) Promoting Interoperability

Summary

CMS had previously finalized a policy to put an indicator on Physician Compare for anyone who scored 50 or higher in the promoting interoperability category. They would indicate high performance for those who scored 100 points. CMS is now proposing to remove the "high" designation as it was confusing to consumers and to change to only a designation of "successful." CMS proposes this for 2018 data available for reporting in 2019. CMS seeks comment on this and any electronic health record (EHR) utilization performance information which stakeholders would like to see added to Physician Compare.

AAFP Response

The AAFP supports the move to a designation of "successful" and removal of the "high" designation in the promoting interoperability category.

(6) Achievable Benchmark of Care (ABC[™])

Summary

By year three of the QPP, CMS will use benchmarks from performance data two years prior to the applicable performance period. Benchmarks would be published prior to the performance period. For the 2019 performance period, benchmarks would be taken from 2017 performance. For the 2018 performance period, benchmarks will be established using the most recent available data.

AAFP Response

The AAFP is supportive of the benchmarking proposal.

H.4. Overview of APM Incentive

Summary

CMS proposes to require at least 75 percent of ECs within an APM entity to use CEHRT for the APM to qualify as an AAPM.

AAFP Response

The AAFP is supportive of the increase in the CEHRT requirement to 75 percent.

(3) MIPS Comparable Quality Measures

Summary

CMS explains they are exploring different ways to define what they mean by "comparable" to MIPS quality measures. This would include:

- Limiting comparable measures to those from the MIPS measure list; and
- Including measures that have an evidence-based focus and are found to be reliable through measure testing.

CMS recognizes that this may restrict some APMs. There has been ambiguity about which measures AAPMs can structure their program around, and many models are already in development for 2019. Beginning with the 2020 performance period, CMS proposes a new definition with more clarity. To be considered a MIPS-comparable measure, the measure must be from the finalized list of MIPS measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidence-based, reliable, and valid.

AAFP Response

The AAFP supports the clarification given in this proposed rule. In addition, we believe AAPMs should be required to include more than one of MIPS-comparable measure.

(C) Outcome Measures: Evidence-based, reliable, and valid

Summary

AAPMs are required to include one outcome measure. CMS did not previously specify that this measure must be evidence-based, reliable, and valid, but the agency is now proposing to add this requirement beginning in 2020.

AAFP Response

The AAFP supports this proposal as we believe all measures used for payment should be evidencebased, reliable, and valid.

(4) Bearing Financial Risk For Monetary Loss

Summary

CMS proposes to maintain the revenue-based nominal amount standard at eight percent of average estimated Medicare Parts A and B revenue through performance period 2024. CMS is considering whether to increase this to 10 percent in 2025 and increase the expenditure-based nominal amount to four percent in 2025.

AAFP Response

The AAFP appreciates CMS extending the revenue-based nominal amount standard at eight percent through performance period 2024. In the recent Pathways to Success proposed rule, CMS proposes to create the BASIC track to help clinicians transition to risk. Within the BASIC track, there will be five glide paths, with the final level (Level E) introducing downside risk. CMS proposes to set the risk levels consistent with the generally applicable nominal risk amount standard, so the track meets the criterion to be considered and Advanced APM. If the loss sharing limit based on revenue exceeds the expenditure-based nominal amount standard, CMS will cap the loss sharing limit at one percentage

point higher than the Advanced APM expenditure-based nominal amount standard. As this BASIC track is designed to help clinicians transition to risk, we urge CMS to maintain the eight percent revenue-based nominal amount standard at least through QP Performance Period 2024. We also ask that CMS maintain the three percent expenditure-based nominal amount standard through QP Performance Period 2024. This will provide much-needed consistency in the program and support CMS's efforts to ease clinicians into downside risk.

III.H.4.e - Qualifying APM Participant (QP) and Partial QP Determinations

Summary

CMS is proposing to reduce the claims run out for QP and partial QP determinations to 60 days. This will allow CMS to notify ECs of their QP status more quickly. CMS seeks comment on this proposal.

AAFP Response

The AAFP supports this proposal.

III.H.4.e(3)(b) - Alignment of Partial QP Election Policies

Summary

When an EC determined to be partial QP at the individual level, CMS proposes that the individual EC will make an election whether to report to MIPS. If an EC elects to report to MIPS, they will be subject to MIPS reporting requirements and payment adjustments. ECs that elect not to report to MIPS or do not take any action will not be subject to MIPS reporting requirements and payments. CMS seeks comment on this proposal.

AAFP Response

The AAFP supports this proposal as it will protect ECs from inadvertently being subjected to MIPS requirements when information has been reported on their behalf.

III.H.4.g(2)(c) – Use of CEHRT

Summary

CMS is proposing to change the CEHRT use criterion for Other Payer AAPMs. Beginning in 2020, an other payer arrangement must require at least 75 percent of participating ECs in each APM entity to use CEHRT to be considered an Other Payer AAPM. CMS is also proposing that a payer or EC must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payer arrangement by at least 50 percent of ECs in 2019, and 75 percent in 2020 and beyond. CEHRT use must be explicitly required under the terms of the payment arrangement. CMS seeks comment on these proposals.

AAFP Response

The AAFP is supportive of this proposal.

III.H.4.g(2)(e) - Financial Risk for Monetary Losses

Summary

CMS is proposing to maintain the generally applicable revenue-based nominal-risk standard at 8 percent of the total combined revenues from the payer of provider and services in participating APM entities through the 2024 QP performance period. CMS seeks comment on this proposal.

AAFP Response

The AAFP supports this proposal.

III.H.4.g(3) - Determination of Other Payer Advanced APMs

Summary

CMS is proposing that after the first year, a payer, APM entity, or EC would only need to submit information on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement. For multi-year arrangements, the certifying official for the requester must agree to review the submission at least once annually. A multi-year Other Payer Advanced APM determination would remain in effect until the arrangement is terminated or expires, but in no event longer than five years. CMS seeks comment on this proposal.

CMS aims to align the Payer Initiated process for other payers with the previously finalized process for Medicaid, Medicare Health Plans, and CMS Multi-Payer models. They propose to eliminate the Payer-Initiated process and submission form for the CMS Multi-Payer models. CMS believes they can submit their arrangements through the Payer-Initiated process for remaining Other Payers or through the Medicaid, Medicare health plan submission process.

AAFP Response

The AAFP supports CMS' proposal to only require payers, APM entities, and ECs to submit information on changes to the payment arrangement. We appreciate CMS' efforts to alleviate burden and simplify the process for those submitting other payer arrangements.

IV. Requests for Information

A. Request for Information on Promoting Interoperability and Electronic Health Care Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers *Summary*

CMS is interested in stakeholder feedback on how they could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (conditions of participation [CoPs], conditions for coverage [CfCs], and requirements for participation [RfPs] for long-term care [LTC] facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. CMS could consider revisions to CoPs for hospitals, such as requiring that hospitals transferring medically-necessary information to another facility upon a patient transfer or discharge do so electronically; requiring hospitals to electronically send required discharge information to a community provider.

AAFP Response

We appreciate CMS thinking broadly about how it could promote interoperability and reduce information blocking. The AAFP is uncertain if tying interoperability requirements to participation in Medicare would achieve the desired outcomes. We strongly doubt that it will lead to wide-scale interoperability, and we have strong concerns about the unintended consequences. A probable consequence is that hospitals comply with the letter of the regulations and exchange data, but the data will not be integrated into the patient's record by CEHRT, but rather will place additional administrative burden on physicians and providers. Instead of looking to the rules of participation in Medicare, we would strongly recommend that the Department of Health and Human Services exercise its authority under the 21st Century Cures Act to quickly release regulations around information blocking.

Administrator Verma Page 78 of 80 September 5, 2018

V. Collection of Information Requirements

A. Proposed ICRs

2. ICRs Regarding Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (§414.94 and Section III.D. of this proposed rule)

Summary

For AUC consultations, CMS proposes to revise its regulations to allow the AUC consultation, when not performed personally by the ordering professional, to be performed by auxiliary personnel under the direction of, and incident to, the ordering professional's services. CMS uses "family and general practitioner" from the list of Bureau of Labor Statistics (BLS) occupation titles to calculate physician costs and "registered nurse" (RN) to calculate the auxiliary personnel costs. CMS estimates it takes two minutes to consult with a Clinical Decision Support Mechanism (CDSM). Based on the ratio of new patient office visits to established patient office visits, CMS estimates 10% of CDSM consultations will be done by physicians and 90% will be done by auxiliary personnel. CMS estimates the cost per consultation at \$2.33.

CMS estimates no burden associated with annual reporting (distinct from the consultation process), because the currently-approved data fields, instructions, and burden on Medicare claim forms are not expected to change. Likewise, CMS assumes the significant hardship exception imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, CMS notes that the use of this process is not "information" as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the *Paperwork Reduction Act*.

For recordkeeping related to AUC, CMS estimates that the average time for office clerical activities associated with this storage of information to be 10 minutes (0.167 hour) at \$17.25/hr. for a medical secretary to perform 6,699 recordkeeping actions, since consultation will not take place in the year when a hardship is incurred and 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year of MIPS eligibility and special status file suggests this estimate of those seeking hardship (control number 0938-1314). In aggregate, CMS estimates an annual burden of 1,119 hours (6,699 recordkeeping activities x 0.167 hr.) at a cost of \$19,303 (1,119 hr. x \$17.25/hr.).

AAFP Response

In general, the AAFP finds CMS' estimate of the burden of AUC to be defensible, except for its equation of "auxiliary personnel" with an RN. Most family physicians and general practitioners would not employ an RN for this purpose and instead rely upon a licensed practical nurse or medical assistant. To the extent CMS is using the cost of an RN to estimate costs, it is likely overestimating the costs in question. If CMS anticipates an RN is needed to complete these tasks, such a professional would be cost prohibitive for most family medicine practices.

10. QPP Information Collection Requests (ICRs) Regarding Promoting Interoperability Data (§414.1375)

Summary

For **Promoting Interoperability Reweighting Applications**, table 77 summarizes the burden for clinicians to apply for reweighting the promoting interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or because of a decertification of an EHR. CMS estimates the total number of respondents as 87,211, which is an increase of 46,566 from the number of respondents currently approved by the Office of

Administrator Verma Page 79 of 80 September 5, 2018

Management and Budget (OMB). CMS estimates it would take 0.25 hours to submit the application. This is a reduction from the 0.5 hours estimated in the CY 2018 Quality Payment Program final rule.

For **Submitting Promoting Interoperability Data**, CMS proposes an adjustment to the number of respondents (from 218,215 to 67,622) based on a more accurate estimation of the number of hospital-based MIPS ECs, clinicians in small practices, and the number of group TINs submitting for MIPS APMs; and also accounting for respondents which may submit data via two or more submission or collection types and would thus be double counted otherwise. CMS also proposes a decrease to the per respondent time estimate (from three hours to two hours and 40 minutes) due to our proposed net reduction of three measures. Table 78 shows the estimated number of respondents and table 79 shows the estimated burden for 2019.

AAFP Response

The AAFP doubts it would only take 15 minutes for ECs to complete a reweighting application and urges CMS to instead use 30 minutes to an hour.

12. QPP ICRs Regarding Improvement Activities Submission

Summary

Table 81 shows the estimated number of organizations submitting improvement activities performance category data on behalf of clinicians. CMS proposes to decrease its burden estimates, since the actual submission experience of the user is such that improvement activities data is submitted as part of the process for submitting quality and promoting interoperability data, resulting in less additional required time to submit improvement activities data. For instance, CMS estimates the per response time to be five minutes, rather than the previously estimated one hour. Table 82 shows the estimated burden for 2019.

AAFP Response

The AAFP agrees that it will likely not take an hour to submit the data for improvement activities but believes it will take longer than five minutes. We believe 15-30 minutes is a more accurate estimate.

13. QPP ICRs Regarding the Nomination of Improvement Activities

Summary

CMS proposes to adjust the number of respondents (from 150 to 125) based on more recent data and to adjust its per response time estimate (from 0.5 hours to 2.0 hours). CMS also proposes to adopt one new criteria and remove one existing criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. Table 83 shows the estimated burden for 2019.

AAFP Response

If CMS is referring to how long it would take a practice administrator and clinician to identify and propose an activity, the AAFP believes the estimated time is underrepresented. Practices should assess a need in their practice situation, formulate a creative solution, and determine how they would implement it in their practice. This process would need to be documented and submitted to CMS, as well. The AAFP firmly believes this would take more than a cumulative two hours.

Administrator Verma Page 80 of 80 September 5, 2018

We appreciate the opportunity to make these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or <u>rbennett@aafp.org</u>, with any questions or concerns.

Sincerely,

m

John Meigs, Jr., MD, FAAFP Board Chair

About Family Medicine

Family physicians conduct approximately one in five of the total medical office visits in the United States per year—more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.

Addendum 1

AAFP Recommended Edits to the 1995 Documentation Guidelines for Evaluation and Management (E/M) Services

Anticipating proposals were imminent based on previous Medicare Physician Fee Schedule regulations, the AAFP compiled known issues with E/M Documentation Guidelines. These issues were addressed by staff and changes were presented to the AAFP's Commission on Quality and Payment in June 2018. The subsection, Table of Risk, was presented to the AAFP representatives and liaisons of the RUC and CPT teams for input. The AAFP offers the following document for consideration and submission to CMS to aid in the reduction of documentation redundancy and burden.

I. INTRODUCTION

WHAT IS DOCUMENTATION AND WHY IS IT IMPORTANT? Medical record documentation is required to record pertinent facts, findings, and observations about an individual's health history including past and present illnesses, examinations, tests, treatments, and outcomes. The medical record chronologically documents the care of the patient and is an important element contributing to high quality care. The medical record facilitates:

- the ability of the physician and other healthcare professionals to evaluate and plan the patient's immediate treatment, and to monitor his/her healthcare over time;
- communication and continuity of care among physicians and other healthcare professionals involved in the patient's care;
- collection of data that may be useful for research and education.

An appropriately documented medical record can reduce many of the "hassles" associated with claims processing and may serve as a legal document to verify the care provided, if necessary.

WHAT DO PAYERS WANT AND WHY?

Appropriate claims documentation and records review allows for payers to review claims in a timely manner and process payments to providers accurately and quickly. Proper documentation and claims submission allows for accurate utilization review and applicable quality of care evaluations.

Because payers have a contractual obligation to enrollees, they may require reasonable documentation that services are consistent with the insurance coverage provided. They may request information to validate:

- the site of service;
- the medical necessity and appropriateness of the diagnostic and/or therapeutic services provided; and/or
- that services provided have been accurately reported.

II. GENERAL PRINCIPLES OF MEDICAL RECORD DOCUMENTATION

The principles of documentation listed below are applicable to all types of medical and surgical services in all settings. For Evaluation and Management (E/M) services, the nature and amount of physician work and documentation varies by type of

service, place of service and the patient's status. The general principles listed below may be modified to account for these variable circumstances in providing E/M services.

- 1. The medical record should be complete and legible.
- 2. The documentation of each patient encounter should include:
 - reason for the encounter and relevant history, physical examination findings, and prior diagnostic test results;
 - assessment, clinical impression, or diagnosis; plan for care; and
 - date and legible identity of the individual recording the encounter observer.

3. If not documented, the <u>The</u> rationale for ordering diagnostic and other ancillary services should be easily inferred.

4. Past and present diagnoses should be accessible to the treating and/or consulting physician.

5. Appropriate health risk factors should be identified.

6. The patient's progress, response to and changes in treatment, and revision of diagnosis should be documented.

7. The CPT and ICD-9-CMHIPAA mandated (CPT, HCPCS, and ICD-10) codes reported on the health insurance claim form or billing statement should be supported by the documentation in the medical record.

III. DOCUMENTATION OF E/M SERVICES

This publication provides definitions and documentation guidelines for the three *key* components of E/M services and for visits which consist predominately of counseling or coordination of care. The three key components--history, examination, and medical decision making--appear in the descriptors for office and other outpatient services, hospital observation services, hospital inpatient services, consultations, emergency department services, nursing facility services, domiciliary care services, and home services. While some of the text of CPT has been repeated in this publication, the reader should refer to CPT for the complete descriptors for E/M services and instructions for selecting a level of service. **Documentation guidelines are identified by the symbol • DG.**

The descriptors for the levels of E/M services recognize seven components which are used in defining the levels of E/M services. These components are:

- history;
- examination;
- medical decision making;
- counseling;
- coordination of care;
- nature of presenting problem; and
- time.

The first three of these components (i.e., history, examination and medical decision making) are the *key* components in selecting the level of E/M services. An exception to this rule is the case of visits which consist predominantly of counseling or

coordination of care; for these services time is the key or controlling factor to qualify for a particular level of E/M service.

For certain groups of patients, the recorded information may vary slightly from that described here. Specifically, the medical records of infants, children, adolescents and pregnant women may have additional or modified information recorded in each history and examination area.

As an example, newborn records may include under history of the present illness (HPI) the details of mother's pregnancy and the infant's status at birth; social history will focus on family structure; family history will focus on congenital anomalies and hereditary disorders in the family. In addition, information on growth and development and/or nutrition will be recorded. Although not specifically defined in these documentation guidelines, these patient group variations on history and examination are appropriate.

A. DOCUMENTATION OF HISTORY

The levels of E/M services are based on four types of history (Problem Focused, Expanded Problem Focused, Detailed, and Comprehensive). Each type of history includes some or all of the following elements:

- Chief complaint (CC);
- History of present illness (HPI);
- Review of systems (ROS); and
- Past, family and/or social history (PFSH).

The extent of history of present illness, review of systems, and past, family and/or social history that is obtained and documented is dependent upon clinical judgment and the nature of the presenting problem(s).

The chart below shows the progression of the elements required for each type of history. To qualify for a given type of history, **all three elements in the table must be met.** (A chief complaint is indicated at all levels.)

History of Present Illness (HPI)	Review of Systems (ROS)	Past, Family, and/or Social History (PFSH)	Type of History
Brief	N/A	N/A	Problem Focused
Brief	Problem Pertinent	N/A	Expanded Problem Focused
Extended	Extended	Pertinent	Detailed
Extended	Complete	Complete	Comprehensive

- DG: The CC, ROS and PFSH may be listed as separate elements of history, or they may be included in the description of the history of the present illness.
- DG: A ROS and/or a PFSH obtained during an earlier encounter does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information. This may occur when a physician updates his/her own

record or in an institutional setting or group practice where many physicians use a common record. The review and update may be documented by:

- describing any new ROS and/or PFSH information or noting there has been no change in the information; and
- o noting the date and location of the earlier ROS and/or PFSH.
- DG: The medical record ROS and/or PFSH may be recorded by any ancillary staff involved in the patient's care or on a form completed by the patient, as appropriate. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others. There should be evidence to confirm physician review. Written documentation may include physician initials and date; an electronic record may utilize "footprint" to verify the information.
- DG: If the physician is unable to obtain a history from the patient or other source, the record should describe the patient's condition or other circumstance which precludes obtaining a history.

Definitions and specific documentation guidelines for each of the elements of history are listed below.

CHIEF COMPLAINT (CC)

The CC is a concise statement describing the symptom, problem, condition, diagnosis, physician recommended return, or other factor that is the reason for the encounter.

• DG: The medical record should clearly reflect the chief complaint.

HISTORY OF PRESENT ILLNESS (HPI)

The HPI is a chronological description of the development of the patient's present illness from the first sign and/or symptom or from the previous encounter to the present. It includes the following elements:

- location;
- quality;
- severity;
- duration;
- timing;
- context;
- modifying factors; and
- associated signs and symptoms.

Brief and **extended** HPIs are distinguished by the amount of detail needed to accurately characterize the clinical problem(s).

A *brief* HPI consists of one to three elements of the HPI.

• DG: The medical record should describe one to three elements of the present illness (HPI).

An *extended* HPI consists of four or more elements of the HPI.-or the status of at least three chronic or inactive conditions.

• DG: The medical record should describe <u>at least</u> four or more elements of the present illness (HPI) or associated comorbidities, or the status of at least three chronic or inactive conditions.

REVIEW OF SYSTEMS (ROS)

A ROS is an inventory of body systems obtained through a series of questions seeking to identify signs and/or symptoms which the patient may be experiencing or has experienced.

For purposes of ROS, the following systems are recognized:

- Constitutional symptoms (e.g., fever, weight loss)
- Eyes
- Ears, Nose, Mouth, Throat
- Cardiovascular
- Respiratory
- Gastrointestinal
- Genitourinary
- Musculoskeletal
- Integumentary (skin and/or breast)
- Neurological
- Psychiatric Endocrine
- Hematologic/Lymphatic
- Allergic/Immunologic

A *problem pertinent* ROS inquires about the system directly related to the problem(s) identified in the HPI.

• DG: The patient's positive responses and pertinent negatives for the system related to the problem should be documented.

An *extended* ROS inquires about the system directly related to the problem(s) identified in the HPI and a limited number of additional systems.

• DG: The patient's positive responses and pertinent negatives for two to nine systems should be documented.

A *complete* ROS inquires about the system(s) directly related to the problem(s) identified in the HPI <u>plus</u> all additional body systems.

 DG: At least ten organ systems must be reviewed. Those systems with *Ppositive or pertinent negative responses must be individually documented for affected body systems*. For the remaining systems, a notation indicating all other systems are negative is permissible. In the absence of such a notation, at least ten systems must be individually documented.

PAST, FAMILY, AND/OR SOCIAL HISTORY (PFSH)

The PFSH consists of a review of three areas:

- past history (the patient's past experiences with illnesses, operations, injuries and treatments);
- family history (a review of medical events in the patient's family, including diseases which may be hereditary or place the patient at risk); and

• social history (an age appropriate review of past and current activities).

For the categories of subsequent hospital care, follow-up inpatient consultations and subsequent nursing facility care, CPT requires only an "interval" history. It is not necessary to record information about the PFSH.

A *pertinent* PFSH is a review of the history area(s) directly related to the problem(s) identified in the HPI.

• DG: At least one specific item from any of the three history areas must be documented for a pertinent PFSH.

A *complete* PFSH is a review of at least two or all of the three of the PFSH history areas, depending on the category of the E/M service. A review of all three history areas is required for services that by their nature include a comprehensive assessment or reassessment of the patient. A review of two of the three history areas is sufficient for other services.

- DG: At least one specific item from two of the three history areas must be documented for a complete PFSH. for the following categories of E/M services: office or other outpatient services, established patient; emergency department; subsequent nursing facility care; domiciliary care, established patient; and home care, established patient.
- DG: At least one specific item from each of the three history areas must be documented for a complete PFSH for the following categories of E/M services: office or other outpatient services, new patient; hospital observation services; hospital inpatient services, initial care; consultations; comprehensive nursing facility assessments; domiciliary care, new patient; and homecare, new patient.

B. DOCUMENTATION OF EXAMINATION

The levels of E/M services are based on four types of examination that are defined as follows:

- **Problem Focused** -- a limited examination of the affected body area or organ system. (One body area or organ system.)
- Expanded Problem Focused -- a limited examination of the affected body area or organ system and other symptomatic or related organ system(s). (Two to four body areas or organ systems.)
- **Detailed** -- an extended examination of the affected body area(s) and other symptomatic or related organ system(s). (Five to seven body areas or organ systems.)
- Comprehensive -- a general multi-system examination or complete examination of a single organ system. (Eight or more body areas or organ systems.)

For purposes of examination, the following *body areas* are recognized:

- Head, including the face
- Neck
- Chest, including breasts and axillae
- Abdomen
- Genitalia, groin, buttocks

- Back, including spine
- Each extremity

For purposes of examination, the following organ systems are recognized:

- Constitutional (e.g., vital signs, general appearance)
- Eyes
- Ears, nose, mouth, and throat
- Cardiovascular
- Respiratory
- Gastrointestinal
- Genitourinary
- Musculoskeletal
- Skin
- Neurologic
- Psychiatric
- Hematologic/lymphatic/immunologic

The extent of examinations performed and documented is dependent upon clinical judgment and the nature of the presenting problem(s). They range from limited examinations of single body areas to general multi-system or complete single organ system examinations.

- DG: Specific abnormal and relevant negative findings of the examination of the affected or symptomatic body area(s) or organ system(s) should be documented. A notation of "abnormal" without elaboration is insufficient.
- DG: Abnormal or unexpected findings of the examination of the unaffected or asymptomatic body area(s) or organ system(s) should be described.
- DG: A brief statement or notation indicating "negative" or "normal" is sufficient to document normal findings related to unaffected area(s) or asymptomatic organ system(s).
- DG: The medical record for a general examination should include:
 - Problem-focused-one body area or organ system
 - Expanded problem-focused-two to four body areas or organ systems
 - Detailed-five to seven body areas or organ systems
 - Comprehensive-eight or more of the 12 organ systems.

The medical record for a general multi-system examination should include findings about 8 or more of the 12 organ systems.

C. DOCUMENTATION OF THE COMPLEXITY OF MEDICAL DECISION MAKING

The levels of E/M services recognize four types of medical decision making (straightforward, low complexity, moderate complexity, and high complexity). Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option as measured by:

- the number of possible diagnoses and/or the number of management options that must be considered;
- the amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed; and

• the risk of significant complications, morbidity, and/or mortality, as well as comorbidities associated with the patient's presenting problem(s), the diagnostic procedure(s) and/or the possible management options.

The chart below shows the progression of the elements required for each level of medical decision making. To qualify for a given type of decision making, **two of the three elements in the table must be either met or exceeded.**

Number of diagnoses or management options	Amount and/or complexity of data to be reviewed	Risk of complications and/or morbidity or mortality	Type of decision making
Minimal	Minimal or None	Minimal	Straightforward
Limited	Limited	Low	Low Complexity
Multiple	Moderate	Moderate	Moderate Complexity
Extensive	Extensive	High	High Complexity

Each of the elements of medical decision making is described on the following page.

NUMBER OF DIAGNOSES OR MANAGEMENT OPTIONS

The number of possible diagnoses and/or the number of management options that must be considered is based on the number and types of problems addressed during the encounter, the complexity of establishing a diagnosis and the management decisions that are made by the physician.

Generally, decision making with respect to a diagnosed problem is easier than that for an identified but undiagnosed problem. The number and type of diagnostic tests employed may be an indicator of the number of possible diagnoses. Problems which are improving or resolving are less complex than those which are worsening or failing to change as expected. The need to seek advice from others is another indicator of complexity of diagnostic or management problems.

- DG: For each encounter, an assessment, clinical impression, or diagnosis should be documented. It may <u>must</u> be explicitly stated or implied in documented decisions regarding management plans and/or further evaluation.
 - For a presenting problem with an established diagnosis the record should reflect whether the problem is: a) improved, well controlled, resolving or resolved; or, b) inadequately controlled, worsening, or failing to change as expected.
 - For a presenting problem without an established diagnosis, the assessment or clinical impression may be stated in the form of a differential diagnoses or as "possible," "probable," or "rule out" (R/O) diagnoses, <u>subject to applicable ICD-10-CM coding conventions</u>.
- DG: The initiation of, or changes in, treatment should be documented. Treatment includes a wide range of management options including patient instructions, nursing instructions, therapies, and medications.

• DG: If referrals are made, consultations requested or advice sought, the record should indicate to whom or where the referral or consultation is made or from whom the advice is requested.

AMOUNT AND/OR COMPLEXITY OF DATA TO BE REVIEWED

The amount and complexity of data to be reviewed is based on the types of diagnostic testing ordered or reviewed. A decision to obtain and review old medical records and/or obtain history from sources other than the patient increases the amount and complexity of data to be reviewed.

Discussion of contradictory or unexpected test results with the physician who performed or interpreted the test is an indication of the complexity of data being reviewed. On occasion the physician who ordered a test may personally review the image, tracing or specimen to supplement information from the physician who prepared the test report or interpretation; this is another indication of the complexity of data being reviewed.

- DG: If a diagnostic service (test or procedure) is ordered, planned, scheduled, or performed at the time of the E/M encounter, the type of service, eg, lab or x-ray, should be documented.
- DG: The review of lab, radiology and/or other diagnostic tests should be documented. An entry in a progress note such as "WBC elevated" or "chest x- ray unremarkable" is acceptable. Alternatively, the review may be documented by initialing and dating the report containing the test results.
- DG: A decision to obtain old records or decision to obtain additional history from the family, caretaker or other source to supplement that obtained from the patient should be documented.
- DG: Relevant finding from the review of old records, and/or the receipt of additional history from the family, caretaker or other source should be documented. If there is no relevant information beyond that already obtained, that fact should be documented. A notation of "Old records reviewed" or "additional history obtained from family" without elaboration is insufficient.
- DG: The results of discussion of laboratory, radiology or other diagnostic tests with the physician who performed or interpreted the study should be documented.
- DG: The direct visualization and independent interpretation of an image, tracing, or specimen previously or subsequently interpreted by another physician should be documented.

RISK OF SIGNIFICANT COMPLICATIONS, MORBIDITY, AND/OR MORTALITY

The risk of significant complications, morbidity, and/or mortality is based on the risks associated with the presenting problem(s), the diagnostic procedure(s), and the possible management options.

- DG: Comorbidities/underlying diseases or other factors that increase the complexity of medical decision making by increasing the risk of complications, morbidity, and/or mortality should be documented.
- DG: If a surgical or invasive therapeutic or diagnostic procedure is ordered, planned, or scheduled at the time of the E/M encounter, the type of procedure eg, laparoscopy, should be documented.

- DG: If a surgical or invasive <u>therapeutic</u> or diagnostic procedure is performed at the time of the E/M encounter, the specific procedure should be documented.
- DG: The referral for or decision to perform a surgical or invasive therapeutic or diagnostic procedure on an urgent basis should be documented or implied.

The following table may be used to help determine whether the risk of significant complications, morbidity, and/or mortality is **minimal**, **low**, **moderate**, or **high**. Because the determination of risk is complex and not readily quantifiable, the table includes common clinical examples rather than absolute measures of risk. The assessment of risk of the presenting problem(s) is based on the risk related to the disease process anticipated between the present encounter and the next one. The assessment of risk of selecting diagnostic procedures and management options is based on the risk during and immediately following any procedures or treatment. The highest level of risk in any one category (presenting problem(s), diagnostic procedure(s), or management options) determines the overall risk.

Table of Risk

Level of	Presenting	Diagnostic Procedure(s)	Management Options
Minimal	One self-limited or minor problem, eg, cold, insect bite, tinea corporis	Laboratory tests requiring venipuncture Chest x- rays EKG/EE G	Rest Gargl es Elastic bandages Superficial dressings
Low	Two or more self- limited or minor problems One stable chronic illness, eg, well controlled hypertension, non- insulin dependent diabetes, cataract, BPH Acute uncomplicated illness or injury, eg, cystitis, allergic rhinitis, simple sprain	Physiologic tests not under stress, eg, pulmonary function tests Non-cardiovascular imaging studies with contrast, eg, barium enema Superficial needle biopsies Clinical laboratory tests requiring arterial puncture Skin biopsies	Over-the-counter drugs Minor surgery with no identified-documented risk factors Physical therapy Occupational therapy IV fluids without additives
Moderate	One or more chronic illnesses with mild exacerbation, progression, or side effects of treatment Two or more stable chronic illnesses Undiagnosed new	Physiologic tests under stress, eg, cardiac stress test, fetal contraction stress test Diagnostic endoscopies with no identified <u>documented</u> risk factors Deep needle or incisional	Minor surgery with identified documented risk factors Elective major surgery (open, percutaneous or endoscopic) with no identified documented

	problem with uncertain prognosis, eg, lump in breast Acute illness with systemic symptoms, eg, pyelonephritis, pneumonitis, colitis Acute complicated injury, eg, head injury with brief loss of consciousness	biopsy Cardiovascular imaging studies with contrast and no identified risk factors, eg, arteriogram, cardiac catheterization Obtain fluid from body cavity, eg lumbar puncture, thoracentesis, culdocentesis Clinical laboratory tests requiring arterial puncture Non-cardiovascular imaging studies with contrast, eg, barium enema	risk factors Prescription drug management <u>(new</u> <u>or established</u> <u>prescription) DEA</u> <u>Classsifications III-V</u> Therapeutic nuclear medicine IV fluids with additives Closed treatment of fracture or dislocation without manipulation
High	One or more chronic illnesses with severe exacerbation, progression, or side effects of treatment Acute or chronic illnesses or injuries that pose a threat to life or bodily function, eg, multiple trauma, acute MI, pulmonary embolus, severe respiratory distress, progressive severe rheumatoid arthritis, psychiatric illness with potential threat to self or others, peritonitis, acute renal failure <u>Five or more stable</u> <u>chronic illnesses</u> An abrupt change in neurologic status, eg, seizure, TIA, weakness, sensory loss	Cardiovascular imaging studies with contrast with <u>identified</u> <u>documented</u> risk factors Cardiac electrophysiological tests Diagnostic Endoscopies with <u>identified</u> <u>documented</u> risk factors Discography Deep needle or incisional biopsy Cardiovascular imaging studies with contrast and no documented risk factors, eg, arteriogram, cardiac catheterization Obtain fluid from body cavity, eg lumbar puncture, thoracentesis, culdocentesis	Elective major surgery (open, percutaneous or endoscopic) with identified_documented risk factors Emergency major surgery (open, percutaneous or endoscopic) Parenteral controlled substances Drug therapy requiring intensive monitoring for toxicity Decision not to resuscitate or to de- escalate care because of poor prognosis Prescription drug management (new or established) prescriptions involving DEA Classifications I-II

D. DOCUMENTATION OF AN ENCOUNTER DOMINATED BY COUNSELING OR COORDINATION OF CARE

In the case where counseling and/or coordination of care dominates (more than 50%) of the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.

- DG: If the physician elects to report the level of service based on counseling and/or coordination of care, <u>the documentation should include the following:</u>
 - the total length of time of the encounter (face-to-face or floor time, as appropriate)
 - <u>a description of</u> should be documented and the record should describe the counseling and/or activities to coordinate care.