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Regulatory Update: CMS Proposed Rule – Revisions to Payment Policies under the Medicare Physician Fee Schedule (PFS) and Other Revisions to Part B for Calendar Year (CY) 2019; Medicare Shared Savings Program (MSSP) Requirements; Quality Payment Program (QPP); and Medicaid Promoting Interoperability (PI) Program

July 25, 2018

On Thursday, July 12, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the calendar year (CY) 2019 Medicare payment and policies for the physician fee schedule (PFS). The rule also proposes changes to the Quality Payment Program (QPP). Comments are due September 10, 2018, and Vizient looks forward to working with members to help inform our letter to the Agency.

Background & Summary

This proposed rule revises payment polices under the Medicare PFS and makes other policy changes – including proposals to implement certain provisions of the Bipartisan Budget Act of 2018[1] (BiBA) related to Medicare Part B payment, applicable to services furnished in CY 2019. CMS is proposing to update PFS rates by 0.13 percent for CY 2019, which includes an increase of 0.25 percent as required under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). After this update and the budget-neutrality adjustment required by law, the proposed 2019 PFS conversion factor is $36.05 (a slight increase from the 2018 conversion factor of $35.99).

Additionally, this proposed rule includes discussions and proposals regarding nonexcepted off-campus provider-based departments of a hospital, Medicare Shared Savings Program (MSSP) quality measures, a Request for Information (RFI) on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers, and an RFI on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information.

Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014[2] (PAMA) gives broad authority to the Department of Health and Human Services (HHS) Secretary to collect information, directly or indirectly, from "any eligible professional or any other source" on the resources related to furnishing services for which payment is made under the PFS. This information can be used to determine relative value units (RVUs) – which account for relative resources typically used in furnishing a service under the PFS (including but not limited to time involved in furnishing services, overhead costs, and any other elements that would improve the valuation of services).

Per the agency's authority under PAMA, CMS engaged StrategyGen to conduct an in-depth market research study to update the PFS direct practice expense (PE) inputs (DPEI) for supply and equipment pricing for CY 2019. StrategyGen submitted a report to CMS with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website. The proposed rule notes that these supply and equipment prices were last systematically developed in 2004-2005.

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology

[1] Pub. L. 115-123, enacted on February 9, 2018.
[2] Protecting Access to Medicare Act of 2014. Pub. L. No. 113–93.

based on rules (laid out in the proposal) considering both data representativeness and reliability. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey);
- Physician panel validation of market research results, prioritized by total spending (Physician Panel);
- The General Services Administration system (GSA);
- An aggregate health system buyers database with discounted prices (Buyers);
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors); and
- *Federal Register*, current DPEI data, historical proposed and final rules prior to FY 2018, and other resources; that is, AMA RUC reports (References).

CMS states that they believe it is important to utilize the most current information available for supply and equipment pricing rather than rely on information that is more than ten years old. Thus, CMS is proposing to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. Because of the potentially significant changes in payment that will occur – both for services and more broadly at the specialty level – CMS is proposing to phase in use of the new direct PE input pricing over a four-year period. The split between new and old pricing is proposed at 25/75 percent (CY 2019); 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022). CMS states that the “transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.”

The proposed transition from the current to the fully-implemented new pricing is provided in the table below.

Example of Direct PE Pricing Transition		
Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 difference between $150 and $200
Final (CY 2022) Price	$200	

While there were no statistically significant differences in pricing at the aggregate level, CMS states that medical specialties will experience increases or decreases in their Medicare payments if the agency finalizes the pricing updates recommended by StrategyGen. Additionally, “at the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing”, although “codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs”, as required by PAMA. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

For new supply and equipment codes for which CMS establishes prices based on the public submission of invoices, the agency is proposing to fully implement those prices with no transition during CYs 2019, 2020 and 2021, given there are no current prices for these supply and equipment items.

CMS is proposing that for existing supply and equipment codes, when the agency establishes prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a Healthcare Common Procedure Coding System (HCPCS) code includes a review of pricing of the supplies and equipment included in the code. When CMS finds that the price on the submitted invoice is “typical for the item in question”, the agency believes it would be appropriate to finalize the new pricing immediately along with any other revisions adopted for the code valuation.

Additionally, CMS is proposing to phase in any updated pricing the agency establishes during the 4-year transition period “for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family.” CMS will implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period.

CMS routinely accepts public submission of invoices as part of their process for developing payment rates for new, revised, and potentially misvalued codes. Invoices are often submitted in conjunction with the Relative Value Scale Update Committee (RUC) recommended values for the codes. CMS notes that for CY 2019, stakeholders submitted invoices after the February 10th deadline established for code valuation recommendations. Typically, to be included in a given year's proposed rule, CMS must receive invoices by the February deadline for consideration of RUC recommendations. However, for CY 2019, CMS will consider invoices submitted as public comments during the comment period of this proposed rule, and will consider any invoices received after February 10 or outside of the public comment process as part of their established annual process for requests to update supply and equipment prices.

CMS believes that the rates for the clinical labor staff should also be updated along with the updated pricing for supplies and equipment, in order to "maintain relativity between the clinical labor, supplies, and equipment portions of the PE methodology." The agency is seeking comment regarding "whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the 4-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition for supplies and equipment, for example, to avoid other potentially large shifts in PE RVUs during the 4-year pricing transition period."

CMS is seeking comment from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration. The full report from the contractor, including the updated supply and equipment pricing as it is proposed to be implemented over the proposed 4-year transition period, will be made available as a public use file displayed on the CMS website (under downloads for the CY 2019 PFS proposed rule).

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

The term "telehealth" is used broadly by health care stakeholders to refer to medical services furnished via communication technology (more detail provided below). While many kinds of services are referred to as "telehealth" by patients, payers, and providers – CMS generally uses the term "Medicare telehealth services" to refer to the subset of services defined in section 1834(m) of the Affordable Care Act (ACA). Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. Several laws have amended §1834 of the ACA to provide for an expansion of Medicare payment and to add certain entities as originating sites for payment of telehealth services.

In this proposed rule, CMS notes that the agency has "come to believe that section 1834(m) [of the ACA] does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology." Rather, CMS believes that it "applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional." Therefore, for CY 2019, CMS intends to increase Medicare beneficiary's access to physicians' services that are "routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology." CMS is proposing to modernize Medicare physician payment for these "communication technology-based services", which would not be subject to limitations on Medicare telehealth services in section 1834(m) of the ACA because CMS does not consider them to be Medicare telehealth services. Like other physicians' services, they would be paid under the PFS.

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

CMS is proposing to pay separately, beginning January 1, 2019, for a newly defined type of physicians' service furnished using communication technology. CMS is proposing a new code to encompass a variety of "communication modalities" - 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 7 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 is proposing a work RVU of 0.25 to facilitate payment for these brief communication technology-based services. "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." As "communication technologies" have evolved over time, the agency is seeking comment on "what types of communication technology are 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.” CMS is also seeking comment on the proposed definition and valuation of this code.

Remote Evaluation of Pre-Recorded Patient Information (HCPCS code GRAS1)

For CY 2019, CMS is proposing to make a “separate payment for remote services when a physician uses pre-recorded video and/or images submitted by a patient in order to evaluate a patient’s condition through new HCPCS G-code GRAS1” (Remote evaluation of recorded video and/or images submitted by the patient, e.g., store and forward). This would include interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment. CMS is proposing a work RVU of 0.18, preservice time of 3 minutes, intraservice time of 4 minutes, and post service time of 2 minutes. Additionally, they are proposing to add 6 minutes of clinical labor (L037D) in the service period. CMS is seeking comment on the code descriptor and valuation for HCPCS code GRAS1. CMS believes the valuation of these services would reflect the resource costs associated with furnishing services utilizing communication technology. CMS is seeking comment on both the proposed definition and valuation of the code.

Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

Recognizing the shift and proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, CMS is proposing to make a separate payment for interprofessional internet consultations. The agency notes that proposing payment for these consultations performed via communications technology is consistent with ongoing efforts to recognize medical practice trends in primary care and patient-centered care management.

CMS is proposing to adopt the CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449 for payment under the PFS. The six codes “describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient’s treating physician or other qualified health care professional requests the opinion and/or treatment advice of a consulting physician or qualified health care professional with specific specialty expertise to assist with the diagnosis and/or management of the patient’s problem without the need for the patient’s face-to-face contact with the consulting physician or qualified health care professional.” Because these codes describe services that are “inherently non-face-to-face”, CMS does not consider them as Medicare telehealth services under section 1834(m) of the ACA and is not proposing to add them to the list of Medicare telehealth services for CY 2019.

CMS notes that they are proposing to make separate payments for these services because they reflect resource costs directly associated with seeking a consultation for the benefit of the beneficiary. However, the agency does have concerns about how these types of services can be distinguished from activities for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education. Furthermore, CMS has program integrity concerns around its or its contractors’ ability to properly evaluate the reasonableness and necessity of these types of interprofessional consultations. CMS is seeking comment on how to best minimize potential program integrity issues.

Because these codes describe services that are furnished without the beneficiary being present, 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 – similar to the conditions of payment associated with the care management services under the PFS. Additionally, the agency notes that any advanced consent must include patient awareness of potential cost sharing. CMS is seeking comments on their proposals regarding policies to modernize Medicare physician payment by recognizing communication technology-based services.

Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period, CMS established the process for adding services to or deleting services from the list of Medicare telehealth services in accordance with statute. CMS notes that this process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by the agency. The current list of telehealth services, including the proposed additions described in this rule, can be viewed in the Downloads section of this proposed rule on the CMS website.

CMS is proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2019 on a category 1 basis:

- HCPCS code G0513 (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).
- HCPCS code 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; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service).

Currently, any requests to add services to the list of Medicare telehealth services must be submitted to and received by CMS no later than December 31 of each calendar year for consideration in the next rulemaking cycle. CMS is proposing that, for CY 2019 and onward, they will accept requests to add services through February 10, consistent with the deadline for receipt of code valuation recommendations from the RUC. In other words, to be considered during PFS rulemaking for CY 2020, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2019.

Expanding the Use of Telehealth under the Bipartisan Budget Act of 2018

Sections 50302 and 50325 of the Bipartisan Budget Act of 2018 (BiBA) modified or removed the limitations relating to geography and patient setting for certain telehealth services – including for certain home dialysis end-stage renal disease-related services and acute stroke-related services, respectively.

Expanding Access to Home Dialysis Therapy under the Bipartisan Budget Act of 2018

Section 50302 of the BiBA expanded access to home dialysis therapy for end-stage renal disease patients. CMS is proposing, that beginning on January 1, 2019, individuals with end-stage renal disease (ESRD) receiving home dialysis will have the option to receive monthly assessments through telehealth. However, these individuals will need to receive an in-person visit at least once a month for the first three months, and then once every three months thereafter. Section 50302 of the BiBA modifies current statute to include a renal dialysis facility and an individual’s home as telehealth originating sites. However, they are only included as a telehealth originating site for the monthly virtual ESRD clinical assessments. Further, beginning on January 1, 2019, geographic requirements for telehealth services will not apply to the monthly virtual ESRD clinical assessments “where the originating site is a hospital-based or critical access hospital-based renal dialysis center, a renal dialysis facility, or the home of an individual.” Lastly, the BiBA required that there will be no originating site facility fee if the originating site is the patient’s home.

Expanding the Use of Telehealth for Individuals with Stroke under the Bipartisan Budget Act of 2018

Section 50325 of the BiBA removed restrictions on “the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished”, beginning on January 1, 2019. The section specified that these services will be able to be conducted in any hospital, critical access hospital (CAH), mobile stroke unit, or any other site the Secretary deems appropriate. To carry out these changes, CMS is proposing to create a new modifier “that would be used to identify acute stroke telehealth services.” The practitioner and, in some cases, the originating site would add this modifier to the HCPCS code when billing for an acute stroke telehealth service. Section 50325 does not waive or change current limits to the scope of telehealth services to those on the Medicare telehealth list. Practitioners would be responsible for assessing whether it would be clinically appropriate to use the new modifier with codes from the Medicare telehealth list. By billing with this modifier, practitioners are indicating that the “codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke.” CMS believes the adoption of a service level modifier is the least administratively burdensome way to implement this provision for practitioners – while allowing the agency to track and analyze utilization.

CMS is proposing to add mobile stroke unit as a permissible originating site for acute stroke telehealth services – defined as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and are seeking comment on this definition, as well as additional information on how these units are used in current medical practice. In other words, CMS is proposing that mobile stroke units and the current eligible telehealth originating sites, which include hospitals and CAHs, would be permissible originating sites for acute stroke telehealth services. Additionally, the agency is seeking comment on other possible appropriate originating sites for telehealth services furnished for the diagnosis, evaluation, or treatment of symptoms of an acute stroke; any additional sites would be adopted through future rulemaking.

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

There is evidence that routine counseling, either associated with medication assisted treatment (MAT) or on its own, can increase the effectiveness of treatment for substance use disorders (SUDs). Current federal guidelines for opioid treatment programs describe that MAT and wrap-around psychosocial and support services can include the following services: physical exam and assessment; psychosocial assessment; treatment planning; counseling; medication management; drug administration; comprehensive care management and supportive services; care coordination; management of care transitions; individual and family support services; and health promotion.

CMS believes that creating a separate payment for a bundled episode of care for components of MAT, such as management and counseling treatment for SUDs, treatment planning, and medication management or observing drug dosing for treatment of SUDs under the PFS could provide opportunities to better leverage services furnished with communication technology, while expanding access to treatment. Furthermore, CMS also believes that this proposal could be effective in preventing the need for more acute services. CMS notes that separate payments would support access to management and counseling services that could help prevent hospital admissions and other acute care events – including opioid-related hospital stays.

CMS is seeking comment on developing coding and payment for a bundled episode of care for treatment for SUDs that could include the components of MAT. CMS is also seeking comments on a number of different aspects of this issue, including suggestions for regulatory and sub-regulatory changes to help prevent opioid use disorder and improve access to treatment under Medicare, which methods are effective in identifying non-opioid alternatives for pain management and treatment, and identifying barriers to access to non-opioid alternatives.

Update on the Global Surgery Data Collection

Currently, CMS bundles payment for postoperative care within 10 or 90 days after many surgical procedures. The agency had not historically collected data on how many postoperative visits are actually performed during the global period. However, Section 523 of the Medicare Access and CHIP Reauthorization Act of 2015[3] (MACRA) required CMS to implement a process to collect data on the number and level of postoperative visits, and use data collected to assess the accuracy of global surgical package valuation. CMS adopted the policy in the CY 2017 PFS final rule. Beginning July 1, 2017, CMS required practitioners in groups with 10 or more practitioners in nine states to use the no-pay CPT code 99024 to report postoperative visits. The 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." The list of procedures for which reporting is required is updated annually to reflect any coding changes and is posted on the CMS website.

The share of practitioners who reported CPT code 99024 on any claims varied widely by specialty and by state. CMS notes that one possible explanation for these findings is that many practitioners are not consistently reporting postoperative visits using CPT code 99024. The agency is soliciting suggestions as to how to encourage reporting without imposing undue burden. Specifically, CMS is seeking comments on whether they "need to do more to make practitioners aware of their obligation" and whether they should consider some kind of enforcement mechanism.

Due to the small number of postoperative visits reported using CPT code 99024 during 10-day global periods, CMS is seeking comment on "whether or not 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 alternative explanations for what could be a significant level of underreporting of postoperative visits." The agency cites possible examples for comment – including whether it is more likely that in many cases the practitioner reporting the procedure code is not performing the postoperative visit, or if the postoperative visit is being furnished by a different practitioner. CMS is also seeking comment on whether it is "possible that some or all of the postoperative visits are occurring after the global period ends and are, therefore, reported and paid separately."

[3] The Medicare Access and CHIP Reauthorization Act of 2015. Pub. L. No. 114-10.

Under current policy, in cases where practitioners agree on the transfer of care for the postoperative portion of the global period, the surgeon bills only for the surgical care using modifier 54 “for surgical care only” and the practitioner who furnishes the postoperative care bills using modifier 55 “postoperative management only” – the payment for global surgery is then split between the two practitioners. Practitioners are not required to report these modifiers unless there is a formal transfer of postoperative care; thus, CMS is also seeking comment on if they should consider “requiring use of the modifiers in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether or not the transfer of care is formalized.” Furthermore, CMS is 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. In other words, the agency is requesting feedback if they should consider changing the global period and reviewing the code valuation.

CMS notes that claims-based data collection using CPT code 99024 is to gather information on the *number* of post-operative visits, and not the *level* of post-operative visits. CMS anticipates “beginning, in the near future, a separate survey-based data collection effort on the level of post-operative visits including the time, staff, and activities involved in furnishing post-operative visits and non-face-to-face services.” The agency states that the survey component is intended to address concerns from the physician community that “information on the number of visits alone cannot capture differences between specialties, specific procedure codes, and setting in terms of the time and effort spent on post-operative visits and non-face-to-face services included in global periods.” Additionally, the agency asserts that “practitioner participation in the survey-based data collection effort is important to ensure that CMS collects useful and representative data to understand the range of activities, staff, and time involved in furnishing post-operative visits.” Future survey-based data collection could 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.

Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

Section 603 of the Bipartisan Budget Act (BBA) of 2015[4] requires that certain items and services – with the exception of dedicated emergency department services – furnished in off-campus provider-based departments (PBDs) that began billing under the Outpatient Prospective Payment System (OPPS) on or after November 2, 2015 are no longer to be paid under the OPPS, but under another “applicable payment system”. In the CY 2017 OPPS/ASC final rule with comment period[5], CMS finalized the PFS as the “applicable payment system” for most non-excepted items and services furnished by off-campus PBDs on or after January 1, 2017. On December 13, 2016, the 21st Century Cures Act was enacted into law, amending Section 603 of the BBA, and providing additional criteria about which off-campus PBDs will be “excepted” from this reduced payment under the law.

In prior rulemaking, CMS established a new set of site-specific payment rates under the PFS to reflect the relative resource cost of furnishing the technical component (TC) of services furnished in nonexcepted off-campus PBDs. “For the majority of HCPCS codes, these rates are based on either 1) the difference between the PFS nonfacility payment rate and the PFS facility rate; 2) the technical component; or 3) in instances where payment would have been made only to the facility or to the physician, the full nonfacility rate.” The PFS Relativity Adjuster is the percentage of the OPPS payment amount paid under the PFS for a nonexcepted item or service to the nonexcepted off-campus PBD.

To “operationalize the PFS Relativity Adjuster” when paying for nonexcepted items and services furnished by nonexcepted off-campus PBDs, CMS also adopted the packaging payment rates and multiple procedure payment reduction (MPPR) percentage that apply under the OPPS. The agency also incorporated the claims processing logic that is used for payments under the OPPS for comprehensive ambulatory payment classifications (C–APCs), conditionally and unconditionally packaged items and services, and major procedures.

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[4] Bipartisan Budget Act of 2015, Pub. L. No. 114-74.
[5] 81 Fed. Reg. 79713, 79720 through 79729 (Nov. 14, 2016)

In the CY 2017 interim final rule, CMS determined that a broad range of non-excepted items and services furnished by non-excepted off-campus PBDs would be paid under the PFS at 50 percent of the OPPS payment amount (i.e., the PFS Relativity Adjuster was 50 percent). In the CY 2018 final rule, CMS revised the PFS Relativity Adjuster for non-excepted items and services furnished by non-excepted off-campus PBDs to be 40 percent of the OPPS payment rate. CMS is not proposing to change this Relativity Adjuster for CY 2019 but is changing the methodology by which they determine this number.

Proposed Payment Policies for CY 2019

CMS proposed and finalized a policy for CY 2017 and CY 2018 in which nonexcepted off-campus PBDs continued to bill for nonexcepted items and services on the institutional claim utilizing a new claim line modifier “PN” to indicate that an item or service is a nonexcepted item or service. For CY 2019, CMS is proposing to continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim using the “PN” modifier until the agency identifies a “workable alternative mechanism that would improve payment accuracy.”

CMS made several adjustments to the methodology for calculating the PFS Relativity Adjuster for CY 2019. The agency had access to a full year of claims data from CY 2017 for services submitted with the “PN” modifier, and was able to incorporate these data to improve the accuracy of the PFS Relativity Adjuster. CMS states that this enabled them to account for the specific mix of nonexcepted items and services furnished in nonexcepted off-campus PBDs. CMS states the CY 2017 claims data reinforced the agency’s previous observation that the most frequently reported service furnished in nonexcepted off-campus PBDs is HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient). They found that nearly half (49 percent) of all claim lines for separately payable or conditionally packaged services included HCPCS code G0463, representing 30 percent of total Medicare payments for these services. In addition, the top 30 HCPCS/Status Indicator (SI) combinations accounted for 80 percent of all claim lines and approximately 60 percent of Medicare payments for services that are separately billable. In contrast with prior analyses, CMS also looked at claims units, which reflects HCPCS/SI combinations that are billed more than once on a claim line.

To calculate the PFS Relativity Adjuster using the full range of claims data submitted with a “PN” modifier in CY 2017, CMS established site-specific rates under the PFS that reflect the technical component (TC) of items and services furnished by nonexcepted off-campus PBDs in CY 2017. CMS states that these “HCPCS-level rates reflect best current estimates of the amount that would have been paid for the service in the office setting under the PFS for practice expenses not associated with the professional component of the service.” For most of the remainder of services that do not have a separately payable TC under the PFS, CMS estimated the site-specific rate as 1) the difference between the PFS non-facility rate and the PFS facility rate, or 2) in instances where payment would have been made only to the facility or only to the physician, the full non-facility rate. As with the PFS rates that previously developed when calculating the PFS Relativity Adjuster for CY 2017 and CY 2018, CMS found that there were large code-level differences between the applicable PFS rate and the OPPS rate.

CMS compared the weighted sum of the site-specific PFS rate with the weighted sum of the OPPS rate for items and services reported in CY 2017. CMS states that the updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent. Thus, for CY 2019, CMS is proposing to continue applying a PFS Relativity Adjuster of 40 percent. CMS indicates that they will maintain this Relatively Adjuster for future years until new data or other considerations suggest that an alternative adjuster or approach is needed (in which case CMS would propose it via formal notice and comment rulemaking). This approach continues to adopt packaging rules and MPPR rules that apply under the OPPS. In the CY 2018 PFS final rule, CMS finalized policies related to supervision rules, beneficiary cost sharing, and geographic adjustments; the agency is maintaining these policies as previously finalized.

For CY 2019, CMS is proposing to continue to use the PFS as the applicable payment system for partial hospitalization program (PHP) services furnished by nonexcepted off-campus PBDs. CMS is also proposing, for CY 2019, to continue to set the PFS payment rate for these PHP services as the per diem rate that would be paid to a community mental health center (CMHC). Once again, CMS proposes to maintain these policies into future years until/unless new data or other considerations would warrant a change in approach.

Future Years

CMS continues to believe that the goal of section 603 of BBA was to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the higher OPPS rate for items and services they furnish there. Thus, the agency asserts that 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.” However, the agency notes that they continue to explore alternative options related to the requirements to implement provisions of Section 603 of the BBA.

CMS recognizes that “for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician office.” CMS intends to continue to examine the claims data in order to assess whether a different PFS Relativity Adjuster is warranted, as well as to consider whether additional adjustments to the methodology are appropriate.

CMS is, in particular, monitoring claims for shifts in the mix of services furnished in nonexcepted off campus PBDs that may affect the relativity between the PFS and OPPS. For example, if, over time, an increase in the share of nonexcepted items and services with lower technical component rates under the PFS compared with APC rates under the OPPS could result in a lower PFS Relativity Adjuster. CMS intends to carefully assess the annual payment policy updates to the PFS and OPPS fee schedule rules to “identify changes in overall relativity resulting from any new or modified policies such as expanded packaging under the OPPS or an increase in the number of HCPCS codes with global periods under the PFS.” CMS is also analyzing PFS claims data in order to identify patterns of service furnished together on the same day. The agency anticipates that this will ultimately allow them to make “refinements to the PFS Relativity Adjuster to better account for the more extensive packaging of services under the OPPS and the potential underreporting of services that are not separately payable under the OPPS but are paid separately under the PFS.” An additional ongoing effort by CMS is the “development and refinement of a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of items and services furnished in nonexcepted off campus PBDs.”

Although CMS maintains that currently, site-specific HCPCS-level rates reflect the best available estimate of the amount that would have been paid for the service in the office setting under the PFS for practice expenses not associated with the professional component of the service – the agency acknowledges that, for the majority of HCPCS codes, there is “no established methodology for separately valuing the resource costs incurred by a provider while furnishing a service from those incurred exclusively by the facility in which the service is furnished.” CMS continues to explore alternatives to current estimates that would more accurately reflect the technical component of services furnished in non-excepted off campus PBDs. The agency is “broadly interested” in feedback and recommendations for ways in which they can improve pricing and transparency with regard to the differences in the payment rates across sites of service. Of particular note, CMS expects that their continued analyses of claims data, along with the ongoing exploration of systems changes that are needed to allow non-excepted off campus PBDs to bill directly for the TC portion of non-excepted items and services, may lead the agency to “consider a different approach for implementing section 603 of the Bipartisan Budget Act of 2015.”

Valuation of Specific Codes

CMS continues to welcome feedback from all interested parties regarding the process of valuing new, revised, and potentially misvalued codes for consideration through the rulemaking process. The proposed work RVUs, work time and other payment information for all proposed CY 2019 payable codes are available on the CMS website under downloads for the CY 2019 PFS proposed rule. The proposed direct PE inputs for CY 2019 are displayed in the CY 2019 direct PE input database are also available on the CMS website. CMS reminds stakeholders that “due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services.”

Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

Public use files for the PFS proposed and final rules for each year display both the services subject to the Multiple Procedure Payment Reduction (MPPR) lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. CMS include a list of procedures that meet the definition of imaging under current statute, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2019 are available on the CMS website under downloads for the CY 2019 PFS proposed rule.

Streamlining Evaluation and Management (E/M) Payment and Reducing Clinician Burden

Under the PFS, physicians and other practitioners bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) – which distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. According to CMS, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services. Within these percentages, there is significant variation among specialties.

Potential misvaluation of E/M codes is an issue that CMS has been considering for several years. In recent proposed and final PFS rules, CMS has discussed at length their views that the E/M visit code set is "outdated and needs to be revised and revalued." This code set represents a high proportion of PFS expenditures, and CMS has been engaged in an "ongoing, incremental effort to identify gaps in appropriate coding and payment." Most recently, in the CY 2018 PFS rulemaking, CMS requested stakeholder feedback on potential changes to the E/M documentation rules – but deferred making any changes to the E/M coding itself in order to focus more immediately on the revision of E/M guidelines to "reduce unnecessary administrative burden." In response to commenters' request that CMS provide additional venues for stakeholder input, the agency held a listening session on March 18, 2018 (transcript and materials are available on the CMS website).

CY 2019 Proposed Policies

After considering stakeholder feedback, CMS is proposing several changes to E/M visit documentation and payment. The proposed changes would only apply to office/outpatient visit codes (CPT codes 99201 through 99215), except where specified otherwise. CMS agrees with commenters that the agency "should take a step-wise approach to these issues, and therefore, is limiting initial changes to the office/outpatient E/M code set. However, CMS notes they "understand from commenters that there are more unique issues to consider for the E/M code sets used in other settings such as inpatient hospital or emergency department care, such as unique clinical and legal issues and the potential intersection with hospital Conditions of Participation (CoPs)." The agency may consider expanding their efforts more broadly to address sections of the E/M code set beyond the office/outpatient codes in future years.

CMS is proposing to change the documentation requirements for E/M levels such that practitioners have the choice to use the 1995 guidelines[6], 1997 guidelines[7], time, or Medical Decision-Making (MDM) to determine the E/M level. CMS believes that these proposed changes will better reflect the current practice of medicine and represent significant reductions in burdens associated with documenting visits using the current set of E/M codes. CMS emphasizes that the proposals regarding E/M documentation require notice and comment rulemaking due to the magnitude of the proposed changes, as well as the intrinsically associated payment policy changes. Furthermore, the agency notes that they are proposing a relatively broad outline of changes, and anticipates that many details related to program integrity and ongoing refinement would need to be developed over time through subregulatory guidance. This gives CMS flexibility and enables the agency "to more nimbly and quickly make ongoing clarifications, changes and refinements in response to continued practitioner experience moving forward."

CMS proposes that these E/M visit policies would be effective January 1, 2019. However, CMS is aware of stakeholder suggestions that they should consider a "multi-year process and proceed cautiously, allowing adequate time to educate practitioners and their staff; and to transition clinical workflows, EHR templates, institutional processes and policies (such as those for provider-based practitioners), and other aspects of practitioner work that would be impacted by these policy changes." CMS notes that the proposed documentation changes for office/outpatient E/M visits would be optional, and practitioners could choose to continue to document these visits using the current framework and rules – which could reduce the need for a delayed implementation. However, CMS acknowledges that practitioners who choose a new documentation framework may need time to deploy it. The agency notes that a later implementation date for the documentation proposals would also allow the American Medical Association (AMA) time to develop changes to the CPT coding definitions and guidance prior to implementation (e.g., changes to MDM or code definitions that the agency could then consider for adoption). Furthermore, it would also allow other payers

[6] CMS 1995 Documentation Guidelines for Evaluation and Management Services.
[7] CMS 1997 Documentation Guidelines for Evaluation and Management Services.

time to react and potentially adjust their policies. Therefore, CMS is seeking "comment on whether a delayed implementation date, such as January 1, 2020, would be appropriate" for these proposals.

Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty

CMS states that "given that the number and granularity of practitioner specialties recognized for purposes of Medicare enrollment continue to increase over time, the value to the Medicare program of the prohibition on same-day E/M visits billed by physicians in the same group and medical specialty may be diminishing." It is becoming more common for practitioners to have multiple specialty affiliations, but have only one primary Medicare enrollment specialty. Therefore, CMS believes that eliminating this policy "may better recognize the changing practice of medicine while reducing administrative burden." The agency acknowledges the impact of this proposal on program expenditures and beneficiary cost sharing is unclear. Given that many of these services are simply scheduled and furnished on different days in response to the prohibition – eliminating this provision may not significantly "increase utilization, Medicare spending and beneficiary cost sharing."

Therefore, CMS is seeking comment on whether they should eliminate this provision due to 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", and is seeking comment on whether and how the agency should consider creating exceptions to, or modifying the provision rather than eliminating it entirely. Additionally, CMS is requesting that stakeholders provide additional examples and situations in which the current instruction is not clinically appropriate.

Removing Redundancy in E/M Visit Documentation – Documentation Guidelines "DG"

The review of systems (ROS) and/or pertinent past, family, and/or social history (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 is proposing to expand this policy to "further simplify the documentation of history and exam for established patients such that, for both of these key components, practitioners 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 re-documenting a defined list of required elements such as review of a specified number of systems and family/social history." Additionally, CMS is proposing that for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. That is, practitioners could simply "indicate in the medical record that they reviewed and verified this information." These proposed policy changes would be optional; practitioners could continue to use the current framework if they so choose. CMS states that the goal is to "allow practitioners more flexibility to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient."

Lifting Restrictions Related to E/M Documentation

CMS believes "that allowing practitioners to choose the most appropriate basis for distinguishing among the levels of E/M visits and applying a minimum documentation requirement, together with reducing the payment variation among E/M visit levels, would significantly reduce administrative burden for practitioners, and would avoid the current need to make coding and documentation decisions based on codes and documentation guidelines that are not a good fit with current medical practice." The practitioner could choose to use MDM, time or the current documentation framework, and could also apply the proposed policies regarding redundancy and who can document information in the medical record.

Providing Choices in Documentation – Medical Decision-Making, Time or Current Framework

Per stakeholder feedback, and as part of the agency's efforts to simplify documentation for the purposes of coding E/M visit levels, CMS is proposing to "allow practitioners to choose, as an alternative to the current 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 states that this proposal would "allow different practitioners in different specialties to choose to document the factor(s) that matter most given the nature of their clinical practice." As part of this proposal, practitioners could use MDM, or time, or they could continue to use the current framework to document an E/M visit.

In other words, CMS is offering practitioners the choice to continue to use the current framework by applying the 1995 or 1997 Documentation Guidelines for all three key components. However, the proposals on payment for office-based/outpatient E/M visits described would apply to all practitioners, regardless of their

selected documentation approach. All practitioners (even those choosing to retain the current documentation framework), would be paid at the proposed new payment rate described in this proposed rule (one rate for new patients and another for established patients), and could also report applicable G-codes that are proposed. CMS wishes to be clear that they are proposing to retain the current CPT coding structure for E/M visits (along with creating new replacement codes for podiatry office/outpatient E/M visits). Practitioners would report on the professional claim whatever level of visit (1 through 5) they believe they furnished using CPT codes 99201-99215.

CMS is proposing to create a single rate under the PFS that would be paid for services billed using the current CPT codes for level 2 through 5 E/M visits. Thus, “it would not be material to Medicare’s payment decision which CPT code (of levels 2 through 5) is reported on the claim, except to justify billing a level 2 or higher visit in comparison to a level 1 visit (provided the visit itself was reasonable and necessary).” CMS expects for record keeping purposes or to meet requirements of other payers, many practitioners would continue to choose and report the level of E/M visit they believe to be appropriate under the CPT coding structure.

Although there would be no payment differential for E/M visits level 2 through 5, CMS states that simplifying and changing documentation requirements will eliminate unnecessary aspects of the current documentation framework. Thus, subsequent to the proposal to adopt a single payment amount for office/outpatient E/M visit levels 2 through 5 – CMS is proposing to “apply a minimum documentation standard where, for the purposes of PFS payment for an office/outpatient E/M visit, practitioners 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 anticipates that practitioners will (and could) choose to document more information for clinical, legal, operational or other purposes, and would continue generally to seek to document medical record information that is consistent with the level of care furnished. However, CMS is proposing that for purposes of the agency’s medical review, for practitioners using current documentation framework or the proposed MDM alternative, “Medicare would only require documentation to support the medical necessity of the visit and the documentation that is associated with the current level 2 CPT visit code.” CMS is proposing to allow practitioners to rely on MDM in its current form to document their visit, and are seeking comment on whether and how guidelines for MDM might be changed in subsequent years.

CMS currently allows time or duration of visit to be used as the “governing factor in selecting the appropriate E/M visit level only when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time).” CMS’s proposal to allow practitioners the choice of using time to document office/outpatient E/M visits means that the time-based standard would not be limited to E/M visits in which counseling and/or care coordination accounts for more than 50 percent of the face-to-face practitioner/patient encounter. Instead, the amount of time “personally spent by the billing practitioner face-to-face 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.” If CMS finalizes this proposal, they will monitor the results for any program integrity issues, administrative burden or other issues.

If a practitioner chooses to support their coding and payment for an E/M visit by documenting the amount of time spent with the patient, CMS is proposing to require the practitioner to document the medical necessity of the visit, and show the total amount of time spent by the billing practitioner face-to-face with the patient. CMS is seeking comment on what the total time should be for payment of the single, new rate for E/M visits levels 2 through 5. CMS notes that 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 – and that they could use these times (which are weighted averages of the intra-service times across the current E/M visit utilization).

Additionally, CMS is considering two alternative proposals regarding time documentation. The first would apply the “AMA’s CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed, such that we 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 face-to-face by the billing practitioner with the patient, to support making payment at the proposed single rate for visit levels 2 through 5 when the practitioner chooses to document the visit using time.” The second alternative proposal CMS is considering 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’s CPT codebook for that code) was spent face-to-face by the billing practitioner with the patient.” However, CMS notes that under this possible

approach, the total amount of time spent by the billing practitioner face-to-face with the patient would inform the level of E/M visit (of levels 2 through 5) coded by the billing practitioner. This time documentation proposal is in contrast to the other proposed approaches in that "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 is seeking comments on the use of time as a framework for documentation of office/outpatient E/M visits, and whether the agency should adopt these approaches, or specify other requirements with respect to the proposed option for documentation using time.

CMS received feedback from stakeholders on the CY 2018 PFS proposed rule that "some practitioners rely on unofficial Marshfield clinic or other criteria to help them document E/M visit levels." CMS states that the comments "conveyed that the Marshfield 'point system' is commonly used to supplement the E/M Documentation Guidelines, because of a lack of concrete criteria for certain elements of medical decision making in the 1995 and 1997 Guidelines or in CPT guidance." Thus, CMS is seeking comment on "whether Medicare should use or adopt any aspects of other E/M documentation systems that may be in use among practitioners, such as the Marshfield tool." The agency is specifically interested in feedback as to whether the 1995 and 1997 guidelines contain adequate information for practitioners to use in documenting visits under the agency's new proposals, or whether these versions of the guidelines would need to be supplemented in any way.

CMS is seeking comment on all of their proposals to simplify documentation for the purposes of coding E/M visit levels and to alleviate documentation burden. CMS is also interested in comments on "practitioners' ability to avail themselves of these choices with respect to how they would impact clinical workflows, EHR templates, and other aspects of practitioner work."

Minimizing Documentation Requirements by Simplifying Payment Amounts

The visit level of the E/M service is tied to the documentation requirements in the 1995 and 1997 Documentation Guidelines for E/M Services, which CMS believes are not reflective of changes in care delivery – including technology. CMS notes that based on stakeholder feedback, the burdens associated with documenting the selection of the level of E/M service are not only a result of the documentation guidelines – but also from the coding structure itself. Similarly to documentation guidelines, distinctions between visit levels "reflect a reasonable assessment of variations in care, effort, and resource costs as identified and articulated several decades ago." CMS now believes that the distinctions between the kinds of visits furnished to Medicare beneficiaries are not best reflected by the current E/M visit coding. CMS further states that current payment for E/M visit levels "are increasingly outdated in the context of changing models of care and information technologies." Additionally, stakeholders have expressed that current E/M coding does not reflect important distinctions in services and differences in resources.

CMS believes that "the current set of 10 CPT codes for new and established office-based and outpatient E/M visits and their respective payment rates no longer appropriately reflect the complete range of services and resource costs associated with furnishing E/M services to all patients across the different physician specialties, and that documenting these services using the current guidelines has become burdensome and out of step with the current practice of medicine." To "alleviate the effects and mitigate the burden" associated with continued use of the outdated CPT code set – CMS is proposing to simplify the office-based and outpatient E/M payment rates and documentation requirements, and create new add-on codes to better capture the differential resources involved in furnishing certain types of E/M visits.

In alignment with the proposed documentation changes, CMS is proposing to develop a single set of RVUs under the PFS 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). In other words, CMS is proposing to simplify the payment for services by paying a single rate for the level 2 through 5 E/M visit levels. If CMS finalizes their proposals to simplify the documentation requirements and the proposal to pay a single PFS rate for new and established patient E/M visit levels 2 through 5, practitioners would still bill the CPT code for whichever level of E/M service they furnished – and they would be paid at the single PFS rate. CMS notes that eliminating the distinction in payment between visit levels 2 through 5 also eliminates the need to audit against the visit levels, thus providing "immediate relief from the burden of documentation." Additionally, CMS believes that "a single payment rate will also eliminate the increasingly outdated distinction between the kinds of visits that are reflected in the current CPT code levels in both the coding and the associated documentation rules."

To set RVUs for the proposed single payment rate for new and established patient office/outpatient E/M visit codes, CMS is proposing 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 5 most recent years of Medicare claims data (CY 2012 through CY 2017). CMS is proposing 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, each based on an average of the current inputs for the individual codes weighted by 5 years of accumulated utilization data. Similarly, CMS is proposing 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. These inputs are based on an average of the inputs for the individual codes, weighted by volume based on utilization data from the past 5 years (CY 2012 through CY 2017).

The tables below reflect the payment rates in dollars that would result from the proposed approach, were it to have been implemented for CY 2018. In other words, the dollar amounts reflect how the proposed changes for CY 2019 would have impacted payment rates for CY 2018.

Preliminary Comparison of Payment Rates for Office Visits – New Patients

<table>
<tr><th>HCPCS Code</th><th>CY 2018 Non-facility Payment Rate</th><th>CY 2018 Non-facility Payment Rate under the Proposed Methodology</th></tr>
<tr><td>99201</td><td>$45</td><td>$44</td></tr>
<tr><td>99202</td><td>$76</td><td rowspan="4">$135</td></tr>
<tr><td>99203</td><td>$110</td></tr>
<tr><td>99204</td><td>$167</td></tr>
<tr><td>99205</td><td>$211</td></tr>
</table>

Preliminary Comparison of Payment Rates for Office Visits – Established Patients

<table>
<tr><th>HCPCS Code</th><th>Current Non-facility Payment Rate</th><th>Proposed Non-facility Payment Rate</th></tr>
<tr><td>99211</td><td>$22</td><td>$24</td></tr>
<tr><td>99212</td><td>$45</td><td rowspan="4">$93</td></tr>
<tr><td>99213</td><td>$74</td></tr>
<tr><td>99214</td><td>$109</td></tr>
<tr><td>99215</td><td>$148</td></tr>
</table>

Proposed RVUs for CY 2019 appear in addendum B of this proposed rule, available on the CMS website.

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

CMS 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; that is, they can be distinguished by the mode of care provided, and therefore have different resource costs. The three types of E/M visits that differ from the typical E/M service are: 1) separately identifiable E/M visits furnished in conjunction with a 0-day global procedure; 2) primary care E/M visits for continuous patient care; and 3) certain types of specialist E/M visits, including those with inherent visit complexity. CMS addresses each of these distinguishable visit types in specific proposals.

For these three types of E/M visits, CMS is making additional proposals for payment policy and rate setting adjustments to account for differential resources costs and reduce burden. CMS notes that these supplemental proposals better reflect important distinctions between the kinds of visits furnished to Medicare beneficiaries, and eliminate complex and burdensome billing and documentation rules to effectuate payment. Thus, CMS is proposing the following adjustments to "better capture the variety of resource costs associated with different types of care provided in E/M visits":

1) An E/M multiple procedure payment adjustment to account for duplicative resource costs when E/M visits and procedures with global periods are furnished together;
2) HCPCS G-code add-ons to ● recognize additional relative resources for primary care visits; and ● inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits;
3) HCPCS G-codes to describe podiatric E/M visits;
4) An additional prolonged face-to-face services add-on G code; and
5) A technical modification to the PE methodology to stabilize the allocation of indirect PE for visit services.

Accounting for E/M Resource Overlap between Stand-Alone Visits and Global Periods

CMS is proposing, using the surgical MPPR as a template, 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 – currently identified on the claim by an appended modifier -25.

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

CMS acknowledges that the proposed value for the single payment rate for E/M levels 2 through 5 new and established patient visit codes does not appropriately reflect the additional resources intrinsic to primary care visits which frequently require additional time for communicating with the patient. These visits are generally reported using level 4 E/M codes. Thus, CMS is proposing 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." The HCPCS add-on code proposed is "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 evaluation and management visit))." CMS expects that this add-on code (GPC1X) may be billed alongside the proposed new code for prolonged E/M services for especially complex patients.

Although CMS expects that this G-code will largely be utilized by primary care specialties (e.g., family practice or pediatrics), the agency is aware that some specialists also serve as primary care practitioners (e.g., an OB/GYN or cardiologist). CMS is seeking comment on how best to identify whether or not a primary care visit was furnished – in particular, for cases where a specialist is providing these services. Given the broad scope of proposals related to E/M services, CMS is seeking feedback on any unintended consequences of the proposals. The agency is also seeking comment on any other concerns related to primary care for consideration in future rulemaking.

CMS is also proposing 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 are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding." CMS is proposing 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))." Although some of these specialties are surgical in nature, CMS believes these surgical specialties are providing increased non-procedural approaches to care for complex conditions in the Medicare population. CMS states that, when "billed in conjunction with standalone office/outpatient E/M visits for new and established patients, the combined valuation more accurately accounts for the intensity associated with higher level E/M visits." CMS is seeking comment on all of these proposals.

HCPCS G-Code for Prolonged Services

CMS states that "currently there is inadequate coding to describe services where the primary resource of a service is physician time." In response to stakeholder feedback and as part of the proposal to implement a single payment rate for E/M visit levels 2 through 5 while maintaining payment accuracy across the specialties, CMS is proposing "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))."

Proposed Adjustment to the PE/HR Calculation

This proposal significantly alters the practice expense per hour (PE/HR) allocation for the office/outpatient E/M codes. Generally, the proportion of indirect PE allocated to a service is determined by calculating a PE/HR based upon the mix of specialties that bill for a service. “Establishing a single PFS 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.” CMS acknowledges that “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.” The agency also notes concerns that these changes would “produce anomalous results for indirect PE allocations” because they do not yet know the extent to which specialties would utilize the proposed simplified E/M codes and proposed G-codes.

CMS is proposing to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes) 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. This methodology is similar to that used to develop inputs for the proposed simplified E/M payment, and for purposes of consistency – the new PE/HR would be applied across the additional E/M codes. CMS believes that 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 this proposal is finalized, CMS will consider revising the PE/HR after several years of claims data become available. CMS is seeking comment on these proposals.

Analysis Regarding Potential Specialty-Level Impacts

In order to estimate the potential impact of the proposed changes, CMS modeled the results of several options and examined the estimated resulting impacts in overall Medicare allowed charges by physician specialty. CMS believes these estimates illustrate the magnitude of potential changes for certain physician specialties. “However, because the modeling did not account for the full range of technical changes in the input data used in PFS rate setting, the potential impacts for these isolated policies are relatively imprecise, especially compared to the specialty-level impacts.” CMS is making additional data available to the public on their website to inform their modeling on the agency’s E/M coding and payment proposals. Tables 21, 22, and 23 in the proposed rule show the estimated changes, for certain physician specialties, and isolated from other proposed changes, in expenditures for PFS services based on potential changes for E/M coding and payment.

Alternatives Considered

CMS is seeking comment on the best number of E/M visit levels and how to achieve a balance between number of visit levels and simpler, updated documentation rules. CMS is seeking feedback on whether their proposals would reduce burden and ensure accurate payment across the broad range of E/M visits, including those for complex and high need beneficiaries.”

As an alternative, CMS considered proposing the use of the patient relationship codes (Level II HCPCS Modifiers) to “adjust payment for E/M visits to the extent that these codes are indicative of differentiated resources provided in E/M visits.” CMS also considered using these codes as an “alternative to the proposed use of G-codes to reflect visit complexity inherent to evaluation and management in primary care and certain other specialist services, as a way to more accurately reflect the resource costs associated with furnishing different kinds of E/M visits.” CMS is seeking comment on this alternative – and is interested “in whether the 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 [they] previously identified.”

Emergency Department and Other E/M Visit Settings

The E/M visit code set is comprised of “individual subsets of codes that are specific to various clinical settings including office/outpatient, observation, hospital inpatient, emergency department, critical care, nursing facility, domiciliary or rest home, and home services.” CMS notes that recent comments “have asserted that some E/M code subsets intersect more heavily than others with hospital conditions of participation (CoP).” CMS has received recent feedback through their coordinated efforts with the Office of the National Coordinator for Health Information Technology (ONC) this year, emphasizing that emergency department visits (CPT codes 99281-99285) may benefit from a coding or payment compression into fewer levels of codes, or that documentation rules may need to be reduced or altered. CMS states that per public comments to the CY 2018 PFS proposed rule, there are several issues unique to the emergency department setting – and therefore requires further consideration. CMS makes note of the range of comments received.

Additionally, CMS notes that although the RUC is in the process of revaluing this code set, they have received comment that the main issue is not that the emergency department visit codes themselves are undervalued. Rather, a greater percentage of emergency department visits are at a higher acuity level, yet payers often do not pay at a higher level of care – and the visit is often inappropriately down-coded based on retrospective review. These commenters believed that the "documentation needed to support a higher level of care is too burdensome or subjective."

CMS states that "it seems that policy proposals regarding emergency department visits billed by physicians might best be coordinated with parallel changes to payment policy for facility billing of these codes, which would require more time and analyses." Accordingly, 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 comment on whether they "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." Although CMS is limiting policy proposals this year to the office/outpatient E/M code set, the agency may consider expanding efforts more broadly to additional sections of the E/M visit code set in future years, and are seeking comment broadly on how they might proceed in this regard.

Teaching Physician Documentation Requirements for E/M Services

Medicare Part B makes payment under the PFS for teaching physician services when certain conditions are met, including that the medical record documentation must reflect the teaching physician's participation in the review and direction of services performed by residents in teaching settings. CMS is proposing to revise existing regulations to "eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or other members of the medical team." Further, CMS notes that the proposed changes are intended to "align and simplify teaching physician E/M service documentation requirements" – and that they will reduce burden and duplication of effort for teaching physicians.

The revised regulations 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 is also proposing to revise the current regulations 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 may be demonstrated by the notes in the medical records made by a physician, resident, or nurse."

GPCI Comment Solicitation

CMS is required by statute to review, and if necessary adjust, the Geographic Price Index Costs (GPCIs) at least every 3 years. The last GPCI update was implemented in CY 2017; thus, CMS is reviewing revisions to the GPCIs for CY 2020. CMS is aware of some stakeholder concern regarding data sources used in developing the indices for PFS geographic adjustment purposes – in particular, the use of residential rent data as a proxy for commercial rent in the rent index component of the PE GPCI (i.e., the data that are used to develop the office rent component of the PE GPCI.) CMS will continue efforts to identify a nationally representative commercial rent data source that could be made available to the agency. CMS is seeking comments regarding potential sources of commercial rent data for potential use in the next GPCI update for CY 2020.

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Consistent with statute[8], current Medicare Fee For Service (FFS) payments for separately payable drugs and biologicals furnished by providers and suppliers include an add-on of 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the "6 percent add-on"). Although the statute does not specifically state what the 6 percent add-on represents, "it is widely

[8] Section 1847A of the Social Security Act (SSA), as established in the Medicare Modernization Act of 2003 (MMA)

believed to include services associated with drug acquisition that are not separately paid for, such as handling, and storage, as well as additional mark-ups in drug distribution channels."

CMS is proposing that effective January 1, 2019, in the case of a drug or biological during an initial sales period in which data on the prices for sales (ASP) is not yet available from the manufacturer, WAC-based payments for Part B drugs will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. CMS usually has sufficient data to calculate and reimburse an ASP for new drugs and biologicals beginning in the third quarter (6 months after launch). Once the ASP information is available, the standard Part B reimbursement rate of ASP plus 6 percent will become effective. CMS is proposing a 3 percent add-on because this percentage is consistent with The Medicare Payment Advisory Commission's (MedPAC) analysis and recommendations, and cited in their June 2017 Report to the Congress.

Although other approaches for modifying the add-on amount, such as a flat fee, or percentages that vary with the cost of a drug, are possible, CMS is proposing a fixed percentage in order to be consistent with other provisions in current statute, which specify fixed add-on percentages of 6 percent[9] or 3 percent[10]. CMS notes that a fixed percentage is "administratively simple to implement and administer, is predictable, and is easy for manufacturers, providers and the public to understand."

If CMS finalizes this proposal, the agency would also change the policy articulated in the Claims Processing Manual that describes the application of the 6 percent add-on to payment determinations made by Medicare Administrative Contractors (MACs) for new drugs and biologicals. CMS would change the policy to permit MACs to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs. This proposal would preserve consistency with the agency's "proposed national pricing policy and would apply when MACs perform pricing determinations, for example during the period when Average Sales Prices (ASPs) have not been reported." This proposed policy would not alter OPPS payment limits. CMS also notes these proposals do not include WAC-based payments for single source drugs where the statute currently specifies that the payment limit is 106 percent of the lesser of ASP or WAC.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

CMS is proposing for Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) practitioners billing under the PFS, separate payment for certain communication technology-based services in CY 2019. CMS is proposing to include what is referred to as "Brief Communication Technology-based Service" for a "virtual check-in", and a separate payment for remote evaluation of recorded video and/or images. RHCs are paid an all-inclusive rate (AIR) for medically-necessary, face-to-face visits with an RHC practitioner. When communication-based technology services are furnished in association with an RHC or FQHC billable visit, the costs of these services are included in the RHC AIR or the FQHC PPS and are not separately billable. However, if as a result of the communication it is determined that a visit is not necessary, there would not be a RHC or FQHC billable visit and there would be no payment. Thus, CMS is proposing that "effective January 1, 2019, RHCs and FQHCs receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC AIR or the FQHC PPS payment when the requirements for these services are met."

The "virtual check-in" visit would be billable when a physician or non-physician practitioner has a brief (5 to 10 minutes), non-face-to-face check-in with a patient via communication technology to assess whether the patient's condition necessitates an office visit. CMS is also proposing payment for practitioners billing under the PFS for remote evaluation services. This payment would be for the remote evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology, including interpretation with verbal follow-up with the patient within 24 business hours.

CMS is proposing that RHCs and FQHCs receive payment when at least 5 minutes of communications-based technology or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient that has been seen in the RHC or FQHC within the previous year. These services may only be billed when the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service

[9] SSA § (1847A(b))
[10] SSA § 1847A(d)(3)(C)

provided within the previous 7 days, and does not lead to an RHC or FQHC service within the next 24 hours or at the soonest available appointment (because in those situations, the services are already paid as part of the RHC or FQHC per-visit payment).

CMS is proposing to create a new Virtual Communications G code for use by RHCs and FQHCs only, with a payment rate set at the average of the PFS national non-facility payment rates for HCPCS code GVCI1 for communication technology-based services, and HCPCS code GRAS1 for remote evaluation services. RHCs and FQHCs would be able to bill the Virtual Communications G-code either alone or with other payable services. The payment rate for the Virtual Communications G-code would be updated annually based on the PFS amounts. CMS is also proposing to waive the RHC and FQHC face-to-face requirements when these services are furnished to an RHC or FQHC patient.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. CMS is proposing modifications to the AUC program largely in response to comments and recommendations received and because the agency believes they will minimize burden of the AUC program on ordering professionals, furnishing professionals, and facilities. In the CY 2018 PFS final rule CMS established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services. For services ordered on and after that date, ordering professionals must consult specified applicable AUC using a qualified Clinical Decision Support Mechanism (CDSM) when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. CMS also specified that the AUC program will begin on January 1, 2020 with a year-long educational and operations testing period; during this time, claims will not be denied for failure to include proper AUC consultation information. Additionally, CMS established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals, and furnishing professionals who are ready to do so may report AUC consultation information on the claim.

CMS is proposing additions to the definition of applicable setting, clarification around who may perform the required AUC consultation using a qualified Clinical Decision Support Mechanism (CDSM), clarification that reporting is required across claim types and by both the furnishing professional and furnishing facility, changes to the policy for significant hardship exceptions for ordering professionals, mechanisms for claims-based reporting, and a solicitation of feedback regarding the methodology to identify outlier ordering professionals.

CMS is also proposing to add independent diagnostic testing facilities (IDTFs) to the definition of applicable settings under the Medicare AUC program. CMS is also proposing that the "consultation with AUC through a qualified CDSM may be performed by clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law, when the consultation is not performed personally by the ordering professional whose National Provider Identifier (NPI) will be listed on the order for an advanced imaging service." CMS notes that the ordering professional is "ultimately responsible for the consultation" given that their NPI is reported on the claim for the imaging service – and that the ordering professional could be identified as an outlier ordering professional and become subject to prior authorization based on their ordering pattern. CMS is proposing to "clarify that AUC consultation information must be reported on all claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system."

In order for the program to be implemented by January 1, 2020, CMS is proposing to use established coding methods, to include G-codes and modifiers, for reporting the required AUC information on Medicare claims. CMS will consider future opportunities to use a unique consultation identifier (UCI) is seeking continued engagement with and feedback from stakeholders. CMS is proposing new significant hardship exceptions, such that "an ordering professional experiencing any of the following when ordering an advanced diagnostic imaging service would not be required to consult AUC using a qualified CDSM, and the claim for the applicable imaging service would not be required to include AUC consultation information." The proposed criteria for significant hardship exceptions are 1) insufficient internet access; 2) EHR or CDSM vendor issues; or 3) extreme and uncontrollable circumstances. CMS expects these situations will be irregular and unusual.

CMS is beginning to seek stakeholder feedback on ideas for a possible methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering

advanced diagnostic imaging services. CMS is seeking specific comments on the data elements and thresholds that CMS should consider when identifying outliers. The agency notes that existing prior authorization programs generally do not specifically focus on outliers; thus, CMS is interested in feedback on how outliers could be determined for the AUC program. CMS will evaluate claims data to inform the methodology, and expects to address outlier identification and prior authorization more fully in CY 2022 or 2023 rulemaking.

Medicare Shared Savings Program (Shared Savings Program)

In October 2017, the agency launched the Meaningful Measures Initiative to reduce the regulatory burden on the health care industry. The goals of this initiative are to foster operational efficiencies and reduce costs while producing quality measures that are easier to collect and report and are more focused on meaningful outcomes. CMS has identified a list of measure priority areas, and is using them to review measures in its quality and value programs. As part of the Meaningful Measures Initiative, CMS is proposing to reduce the total number of measures in the Shared Savings Program quality measure set from 31 to 24, and focusing the measure set on more outcome based measures – including patient experience of care. The proposed measure changes are consistent with the proposed changes to Merit-based Incentive Payment System (MIPS). CMS is seeking public on their proposals to retire these measures from the quality measure set.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule, CMS indicated that they intend to continue to review and post relevant charge data in a consumer-friendly way, as they do by posting hospital and physician charge information on the CMS website. Additionally, in the same proposed rule, CMS specified that effective January 1, 2019, current guidelines will be updated to "require hospitals to make available a list of their current standard charges via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate." The agency also issued a Request for Information (RFI) on price transparency.

In this proposed rule, CMS states that in general, they "encourage all providers and suppliers to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services." CMS encourages providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges. Similar to the IPPS RFI, CMS is considering potential actions to "further their objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including services that could be offered in more than one setting", and is seeking comment on a list of specific questions regarding price transparency in various provider and supplier settings (on page 920 of the proposed rule).

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

Multiple initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act[11] requires "HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum." CMS is requesting information to obtain stakeholder feedback on ways to better achieve interoperability between providers. With the increased adoption of EHRs and availability of health information exchange infrastructure among hospitals, CMS is seeking feedback from stakeholders 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 (that is, the Conditions of

[11] Pub. L. 114-255, 2016

Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers."

CMS states that they might consider revisions to the current CMS CoPs for hospitals that include: "requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested."

Additionally, CMS is seeking specific feedback on a list of specific questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information (on page 915 of the proposed rule).

CMS would also like to directly address the issue of communication between hospitals (in addition to other providers and suppliers across the continuum of care) and their patients and caregivers. The agency notes that "MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records." CMS states: "To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS is seeking ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients." CMS is interested in identifying barriers to interoperability and health information exchange, including those that prevent patients from accessing and controlling their medical records. The agency is also seeking "ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers."

CY 2019 Updates to the Quality Payment Program (QPP) – Year 3

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the QPP for eligible clinicians. Under the QPP, eligible clinicians can participate via one of two tracks – the default Merit-based Incentive Payment System (MIPS), or the Advanced Alternative Payment Models (Advanced APMs). CMS began implementing the QPP through rulemaking for CY 2017, known as the transition year. This rule provides proposed updates for the third and future years of the Program. The proposals will affect eligible clinicians' payment during the QPP's 2019 performance period, which will affect PFS payments in CY 2021. You can find the CMS Fact Sheet on the QPP proposals here.

CMS has placed regulatory reform and reducing regulatory burden as top priorities. In October 2017, the agency launched the Meaningful Measures Initiative to reduce the regulatory burden on the health care industry. The goals of this initiative are to foster operational efficiencies and reduce costs while producing quality measures that are easier to collect and report and are more focused on meaningful outcomes. CMS has identified a list of measure priority areas, and is using them to review measures in in the QPP; proposals for CY 2019 reflect these efforts. Additionally, CMS's Patients over Paperwork initiative establishes an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience.

As the QPP moves into its third year, CMS wants to ensure that there is meaningful measurement and the opportunity for improved patient outcomes while minimizing burden. CMS is also reshaping their focus of interoperability about process-based measures, and is continuing to move towards the development and use of more outcome measures by removing process measures that are topped out, and funding new quality measure development. Additionally, CMS is developing new episode-based cost measures for potential inclusion in the cost performance category beginning in 2019. CMS is proposing the following updates for the 2019 MIPS performance period: 1) adding 10 new MIPS quality measures that include 4 patient reported outcome measures, 7 high priority measures, 1 measure that replaces an existing measure, and 2 other measures on important clinical topics in the Meaningful Measures framework; and 2) removing 34 quality measures

Implementing the Bipartisan Budget Act of 2018

The Bipartisan Budget Act of 2018 (BiBA) provided additional authority to continue the gradual transition in MIPS for three more years. Although BiBA was enacted after publication of the CY 2018 QPP final rule, CMS has already implemented adjustments to the low-volume threshold calculations for Year 2 of the program. In this proposed rule, CMS is proposing to continue using this authority to help further reduce clinician burden.

Key changes to implement the Bipartisan Budget Act of 2018 include:

- Changing the application of MIPS payment adjustments, so that the adjustments will not apply to all items and services under Medicare Part B, but will now apply only to covered professional services paid under or based on the PFS beginning with 2019, which is the first payment year of the program.
- Changing the way MIPS eligibility is determined with respect to the low-volume threshold. The low-volume threshold calculations had been based on all Medicare Part B allowed charges and Part B services furnished to patients. Beginning with performance periods in 2018, this calculation will now be based on allowed charges for covered professional services and the number of covered professional services furnished to patients (rather than items and services covered under Part B). This proposal may affect the previously finalized calculation for the low-volume threshold for certain clinicians because payment for items, such as Part B drugs, which were previously considered in the low-volume determination, are now excluded. In other words, the proposed low-volume threshold criteria for CY 2019 are 1) dollar amount ($90,000); 2) number of beneficiaries (200); and 3) number of covered professional services (200).
- Providing flexibility in the weighting of the Cost performance category in the final score for three additional years. Instead of requiring this performance category to have a weight of 30% in Year 3 of the program (performance period 2019) the weight is required to be not less than 10 percent and not more than 30 percent for the third, fourth and fifth years of the QPP.
- Allowing flexibility in establishing the performance threshold for three additional years (program years 3, 4, and 5) to ensure a gradual and incremental transition to the estimated performance threshold for the sixth year of the program based on the mean or median of final scores from a prior period. For 2019, the proposed performance threshold is 30 points, up from 15 points in 2018.

Merit-based Incentive Payment System (MIPS) – Proposals

As required by the MACRA, eligible clinicians will receive positive or negative payment adjustments of 7 percent in CY 2021, rising to a maximum of 9 percent in CY 2022 and beyond. CMS estimates that 650,000 clinicians would be MIPS eligible clinicians in the 2019 MIPS performance period. This number will depend on a number of factors, including the number of eligible clinicians excluded from MIPS based on their status as Qualifying APM Participants (QPs) or Partial QPs, the number that report as groups, and the number that elect to opt-in to MIPS. MIPS payment adjustments will be equally distributed between negative MIPS payment adjustments ($372 million) and positive MIPS payment adjustments ($372 million) to eligible clinicians, as required by the MACRA statute to ensure budget neutrality. Positive MIPS payment adjustments will also include additional payments for exceptional performance to MIPS eligible clinicians whose final score meets or exceeds the proposed additional performance threshold of 80 points. CMS is proposing to increase the MIPS performance threshold for avoiding a penalty to 30 points, up from 15 points in 2018 – and the exceptional performance threshold to 80 points, up from 70 points in 2018. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2021 MIPS payment year and the distribution of final scores under the program. CMS intends to explore additional approaches to account for patient risk factors through adjustments to the performance category scores or the final score. CMS believes it is appropriate to maintain the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. CMS is maintaining consistent policies (as finalized in the CY 18 QPP rule) for the complex patient bonus until the agency has sufficient evidence and new data sources that support an updated approach to account for patient risk factors

CMS is proposing to expand the definition of MIPS-eligible clinicians to include new clinician types – physical therapists, occupational therapists, qualified speech-language pathologists, certified nurse-midwives, qualified audiologists, clinical social workers, clinical psychologists, registered dieticians or nutrition professionals – with stipulations. Because CMS is proposing to remove several MIPS quality measures in the quality performance category, if those measures are finalized for removal, we anticipate that qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals would each have fewer than 6 MIPS quality measures applicable and available to them. However, if the quality measures are not finalized for removal, CMS will reassess whether these eligible clinicians would have an adequate amount of MIPS quality measures available to them. If CMS finds

that these additional clinicians have at least 6 MIPS quality measures available to them, they propose to include them in the MIPS eligible clinician definition.

Within MIPS, CMS assesses eligible clinicians on four performance categories – Quality, clinical practice improvement activities (referred to as "Improvement Activities"), meaningful use of CEHRT (referred to as "Promoting Interoperability"), and resource use (referred to as "Cost"). CMS has renamed the performance category "Advancing Care Information" to "Promoting Interoperability" in order to align with the new Promoting Interoperability Program requirements for hospitals.

Each category is weighted, and CMS takes the combined score across the categories to calculate the MIPS "final score". Based on their final score, eligible clinicians receive a performance-based payment adjustment under the Medicare Physician Fee Schedule (PFS). For the QPP's 2019 performance year (MIPS payment year 2021), the composite score will be weighted as follows:

Finalized and Proposed Weights by MIPS Performance Category and MIPS Payment Year

Performance Category	Transition Year (Previously Finalized)	2020 MIPS Payment Year (Previously Finalized)	2021 MIPS Payment Year (Proposed)
Quality	60%	50%	45%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%
Cost	0%	10%	15%

- **Quality (45 percent)**
  CMS is proposing to specify, for a MIPS payment year, to use the following quality measures, as applicable, to assess performance in the quality performance category: measures included in the MIPS final list of quality measures established by us through rulemaking; QCDR measures approved by CMS under current statute; facility-based measures as described under current statute; and MIPS APM measures as described under current statute. CMS is making this proposal to account for facility-based measurement and the APM scoring standard. Table 31 in the proposed rule (pg. 554) contains the summary of data completeness requirements and performance period by collection type for the 2020 and 2021 MIPS payment years. Table 32 in the proposed rule (pg. 555) contains a summary of the proposed quality data submission criteria for MIPS payment year 2021 for individual clinicians and groups.

  CMS is proposing, beginning with CY 2019, to define a high priority measure to mean "an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures would include intermediate-outcome and patient-reported outcome measures."

  The new MIPS quality measures proposed for inclusion in MIPS for the 2019 performance period and future years are found in Table A of Appendix 1: Proposed MIPS Quality Measures of this proposed rule. The proposed new and modified quality measure specialty sets can be found in Table B of Appendix 1: Proposed MIPS Quality Measures of this proposed rule, and include new proposed measures, previously finalized measures with proposed modifications, and previously finalized measures with no proposed modifications.

  The 2018 MIPS Quality Benchmarks' file, located on the Quality Payment Program resource library, can be used to determine which measure benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file (which will be available in late 2018 when the 2019 MIPS Quality Benchmarks' file is released).

  CMS notes that for the removal of quality measures, removing all non-high priority process measures would impact nearly 94 percent of specialty sets. Thus, CMS will incrementally remove non-high priority process measures through notice and comment rulemaking. CMS is proposing, beginning

with the 2019 performance period, to incrementally remove process measures where, prior to removal, consideration will be given, but not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty;
- Whether the measure addresses a priority area highlighted in the Measure Development Plan;
- Whether the measure promotes positive outcomes in patients;
- Considerations and evaluation of the measure's performance data;
- Whether the measure is designated as high priority or not; and
- Whether the measure has reached a topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, as described in the proposal in the above topped out measures section.

In outlining the various types of MIPS quality and QCDR measures available for reporting in the quality performance category, such as outcome, high-priority, composite, and process measures, CMS acknowledges that not all measures are created equal. Thus, CMS is seeking comment on "implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure."

- **Improvement Activities (15 percent)**
  CMS believes it is important to place attention on public health emergencies, such as the opioid epidemic, when considering improvement activities for inclusion in the Inventory. Their inclusion raises awareness for clinicians about urgent situations, and promotes clinician adoption of best practices to combat public health emergencies (a list of public health declarations is available here). Beginning with the CY 2019 performance period and future years, CMS is proposing to adopt an additional criterion entitled "Include a public health emergency as determined by the Secretary" to the criteria for nominating new improvement activities.

  Under the Promoting Interoperability performance category, CMS is proposing a "new approach for scoring that moves away from the base, performance, and bonus score methodology currently established." Beginning with the CY 2019 performance period and future years, this new approach would remove the availability of a bonus score for attesting to completing one or more specified improvement activities using CEHRT. If CMS finalizes this policy, the criterion for selecting improvement activities for inclusion in the program entitled "Activities that may be considered for an advancing care information bonus" remains relevant. Thus, CMS is proposing to remove the criterion for selecting improvement activities for inclusion in the program entitled "Activities that may be considered for an advancing care information bonus" (beginning in the CY 2019 performance period and future years). CMS notes that this proposal is "being made in alignment with and contingent upon" those in the Promoting Interoperability performance category. If those proposals are not finalized, this proposal would also not be finalized. In next year's rulemaking, CMS intends to more thoroughly revisit their improvement activity weighting policies. CMS is seeking comment on the need for additional transparency and guidance on the weighting of improvement activities as CMS works to refine the Annual Call for Activities process for future years. CMS does recognize the need to continue incentives for CEHRT. Thus, for future consideration, the agency is seeking comment on "potentially applying high-weighting for any improvement activity employing CEHRT" – as well as any other additional considerations for high- or medium-weighting.

  For CY 2019 performance period and future years, CMS is proposing 6 new improvement activities, to modify 5 existing activities, and remove 1 existing activity. The Improvement Activities Inventory in Tables A and B of Appendix 2 of the proposed rule contain further details. While maintaining the previously required minimum number of measures, CMS is proposing that for the CY 2019 performance period and future years, "participants must submit data and workflows for a minimum of three MIPS quality measures for which they have baseline data." Rather than requiring one outcome measure and one patient experience measure (as previously finalized), CMS is proposing at least one of the minimum of three measures must be a high priority measure.

- **Promoting Interoperability (25 percent)**
  For the Promoting Interoperability (PI) Performance Category (formerly ACI), CMS is proposing to require the use of 2015 Edition Certified EHR Technology (CEHRT) beginning in CY 2019. CMS

previously finalized that the performance period for the PI performance category is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (Jan. 1, 2019 through Dec. 31, 2019). CMS is proposing that beginning in CY 2020, the performance period for the PI performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. In other words, the performance period for the PI performance category would be a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (Jan. 1, 2020 through Dec. 31, 2020).

CMS is also proposing a new scoring methodology aligned with the scoring methodology proposed for the interoperability program in the FY 2019 hospital IPPS proposed rule. CMS is proposing that, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing PI performance category measures, broken into a smaller set of four objectives and scored based on performance. CMS notes that "this is an overhaul of the existing program requirements as it eliminates the concept of base and performance scores." The smaller set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. "Under the proposed scoring methodology, MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level." Tables 36, 37, and 38 in the proposed rule illustrate CMS's proposal for the new scoring methodology and an example of application of the proposed scoring methodology (pgs. 621-623).Table 39 in the proposed rule contains a summary of proposals for the promoting interoperability performance category objectives and measure for the MIPS performance period in 2019 (pg. 635). CMS proposes to continue the complex patient bonus for the 2021 MIPS payment year, proposes a modification to the final score calculation for the 2021 MIPS payment year, and propose refinements to reweighting policies.

CMS is proposing to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. These measures would be optional for the MIPS performance period in 2019. Although not required, MIPS eligible clinicians may choose to report them and earn up to 5 bonus points for each measure. CMS is proposing to require these measures beginning with the MIPS performance period in 2020, and is seeking comment on this proposal. Due to varying state requirements, not all MIPS eligible clinicians would be able to e-prescribe controlled substances, and these measures would not be available. Thus, CMS is proposing an exclusion for these two measures that would provide for any MIPS eligible clinician "who is unable to report the measure in accordance with applicable law would be excluded from reporting the measure, and the 5 points assigned to that measure would be redistributed to the e-Prescribing measure."

- **Cost (15 percent)**
  As permitted by the Bipartisan Budget Act of 2018 (BiBA), CMS proposes to gradually increase the weight of the MIPS cost category by 5 percent each year until it reaches 30 percent in CY 2022. Thus, the proposed weight would be 15 percent in CY 2019. CMS is proposing this modest increase to the weight of the cost performance category because cost measures are still relatively early in the process of development. Furthermore, clinicians currently do not yet have the appropriate level of familiarity or understanding of cost measures.

  CMS is proposing to add 8 episode-based measures to the cost performance category beginning with the 2019 MIPS performance period. CMS will continue to work on developing additional episode-based measures that may be proposed for the cost performance category in future years. CMS notes that introducing more cost measures would allow for more clinicians to be measured in this performance category. CMS considered maintaining the weight of the cost performance category at 10 percent for the 2019 MIPS performance period – recognizing that clinicians are still learning about the cost performance category and being introduced to new measures. Thus, CMS is seeking comment on if the agency should consider an alternative weight (e.g. maintaining 10 percent weight).

  CMS will continue to evaluate whether sufficient cost measures are ready for adoption under the cost performance category as they move towards increasing the weight to 30 percent of the final score. In order to provide for a "smooth transition", CMS is seeking comment on this proposed approach to the weight of the cost performance category, specifically considering flexibility in setting the weight between 10 percent and 30 percent of the final score, the availability of cost measures, and ensuring a smooth transition to the final 30 percent weight.

Section 51003 of the BiBA requires that information on cost measures in use under MIPS, cost measures under development and the time-frame for development, potential future cost measure topics, a description of stakeholder engagement, and the percent of expenditures under Medicare Part A and Part B that are covered by cost measures be posted to the CMS website. This information is required to be posted no later than December 31 of each year beginning with 2018. CMS expects that this posting – in addition to the required information – will further summarize the timeline for measure development, including the “stakeholder engagement activities undertaken, which may include a Technical Expert Panel, clinical subcommittees, field testing, and education and outreach activities, such as national provider calls and listening sessions.” The posting will also provide an overview of potential future topics in cost measure development, including clinical areas in which measures may be developed in the future.

“Episode-based measures differ from the total per capita cost measure and Medicare Spending Per-Beneficiary (MSPB) measure because episode-based measure specifications only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given timeframe.” Table 33 in the proposed rule (pg. 574) contains the episode-based measures proposed for the 2019 MIPS performance period and future performance periods. For these measures, CMS is proposing a case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures beginning with the 2019 MIPS performance period. CMS notes that some clinicians or smaller groups might not ever see enough patients in a single year to meet the case minimum for a specific episode-based measure. Thus, CMS is seeking comment on if, in future rulemaking, the agency should consider expanding the performance period for the cost performance category measures from a single year to 2 or more years. CMS notes that this would allow them to more reliably measure a larger number of clinicians. However, they note concerns that expanding the performance period would increase the time between the measurement of performance and the application of the MIPS payment adjustment. Furthermore, it would take longer for CMS to introduce new cost measures, as they would adopt them through rulemaking prior to the beginning of the performance period. CMS is proposing to, for procedural episode groups specified beginning in the 2019 MIPS performance period, attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes (these trigger services are identified in the measure specifications). The measure score for an individual clinician Tax Identification Number (TIN)/(NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN’s measure score. CMS believes this approach best identifies the clinician(s) responsible for the patient’s care.

MIPS Performance Category Measures and Reporting

CMS is proposing to revise existing and define additional terminology to more “precisely reflect the experience users have when submitting data” to the QPP. As technology continues to evolve, CMS will continue to look for new ways that the agency can offer further technical flexibilities on submitting data to the QPP. CMS is seeking comment on these proposals – and to assist commenters in providing “pertinent comments”, the agency has developed a website that uses wireframe (schematic) drawings to illustrate a subset of the different submission types available for MIPS participation. “Specifically, the wireframe drawings describe the direct, login and attest, and login and upload submission types.” Also, the website “provides specific matrices illustrating potential stakeholder experiences when choosing to submit data under MIPS.”

CMS previously finalized that groups may submit their MIPS data using the CMS Web Interface (for groups consisting of 25 or more eligible clinicians) for the quality, improvement activities, and promoting interoperability performance categories. CMS is proposing that the CMS Web Interface submission type would no longer be available for groups to use to submit data for the improvement activities and promoting interoperability performance categories. “The CMS Web Interface has been designed based on user feedback as a method for quality submissions only; however, groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct, log in and attest or log in and upload submission types.” However, CMS recognizes that certain groups that have elected to use the CMS Web Interface may prefer to have their data submitted on their behalf by a third party intermediary. They recognize the benefit and burden reduction in such a flexibility and propose to allow third party intermediaries to submit data to the CMS Web Interface in addition to, and on behalf of, groups. The

agency is seeking comment on expanding the CMS Web Interface submission type to groups consisting of 16 or more eligible clinicians to inform future rulemaking. The tables below summarize the proposed data submission types for individual MIPS eligible clinicians, and the data submission types for groups, respectively. CMS is seeking comments on these proposals.

Data Submission Types for MIPS Eligible Clinicians Reporting as Individuals

Performance Category/Submission Combinations Accepted	Submission Type	Submitter Type	Collection Type
Quality	Direct Log in and upload Medicare Part B claims (small practices)*	Individual or Third Party Intermediary** Individual	eCQMs MIPS CQMs QCDR measures Medicare Part B claims measures (small practices)
Cost	No data submission required**	Individual	-
Promoting Interoperability	Direct Log in and upload Log in and attest	Individual or Third Party Intermediary	-
Improvement Activities	Direct Login and upload Log in and attest	Individual or Third Party Intermediary	-

*Third party intermediary does not apply to Medicare Part B claims submission type.
** Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. NOTE: As used in this proposed rule, the term "Medicare Part B claims" differs from "administrative claims" in that "Medicare Part B claims" require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

Data Submission Types for MIPS Eligible Clinicians Reporting as Groups

Performance Category/Submission Combinations Accepted	Submission Type	Submitter Type	Collection Type
Quality	Direct Log in and upload CMS Web Interface (groups of 25 or more eligible clinicians) Medicare Part B claims (small practices)*	Individual or Third Party Intermediary** Individual	eCQMs MIPS CQMs QCDR measures CMS Web Interface measures Medicare Part B claims measures (small practices) CMS approved survey vendor measure Administrative claims measures
Cost	No data submission required**	Individual	-
Promoting Interoperability	Direct Log in and upload Log in and attest	Individual or Third Party Intermediary	-
Improvement Activities	Direct Login and upload Log in and attest	Individual or Third Party Intermediary	-

*Third party intermediary does not apply to Medicare Part B claims submission type.
** Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. NOTE: As used in this proposed rule, the term "Medicare Part B claims" differs from "administrative claims" in that "Medicare Part B claims" require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories

In the CY 2018 QPP final rule, CMS established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. CMS does not propose to add additional facility types for facility-based measurement in this proposed rule, but are interested in potentially expanding to other settings in future rulemaking.

CMS is proposing to modify their determination of a facility-based individual clinician in four ways. First, CMS proposes to add on-campus outpatient hospital (Place of Service [POS] code 22) to the other sites of service used to determine whether a clinician is facility-based. Second, CMS is proposing that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room to be eligible for facility-based measurement. While CMS generally believes that clinicians who provide services in the outpatient hospital can impact the quality of care for inpatients, CMS notes that this proposal is required because they believe "that a clinician who is to be measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting." CMS also recognizes "this requirement of one service with the inpatient or emergency department POS may not demonstrate a significant presence in a particular facility", and is therefore seeking comment on "whether a better threshold could be used to identify those who are contributing to the quality of care for patients in the inpatient setting without creating barriers to eligibility for facility-based measurement." Third, CMS is proposing that to be eligible for facility-based measurement, the agency must be able to attribute a clinician to a particular facility that has a Value Based Purchasing (VBP) score. For facility-based measurement to be applicable, CMS must be able to attribute a clinician to a facility with a VBP score. Fourth, CMS proposes to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed in the proposed rule. To align with other determination periods, CMS is proposing to "use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-day claims run out in determining eligibility for facility-based measurement." CMS believes that these four proposals will further expand the opportunity for facility-based measurement and eliminate issues associated with the provision of observation services – while making sure only those clinicians who work in an inpatient setting are eligible.

Although CMS did not specifically address the issue of how facility-based groups would be assigned to a facility (for purposes of attributing facility performance to the group) in the CY 2018 QPP rule, the agency did apply the same standard to individuals and groups. In considering the issue of facility attribution for a facility-based group, CMS believes that a change to facility-based attribution is appropriate to better align the policy with the determination of a facility-based group. A facility-based group is one in which 75 percent or more of the eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals. Additionally, under the current regulation, the VBP score for the highest scoring facility would be used in the case of a tie among the number of facilities at which the group provided services to Medicare beneficiaries. CMS proposes to differentiate how a facility-based clinician or group receives a score based on whether they participate as a clinician or a group. Under the proposal, CMS retains the rule for facility attribution for an individual MIPS eligible clinician as finalized in the CY 2018 QPP final rule.

CMS is also proposing to provide that a facility-based group receives a score under the facility-based measurement scoring standard derived from the VBP score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined if the clinicians had been scored under facility-based measurement as individuals.

CMS considered both the advantages and disadvantages of an opt-in or an opt-out process, and is proposing a modified policy that does not require an election process. Instead, CMS proposes to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score. In other words, if the MIPS eligible clinician or group is eligible for facility-based measurement, CMS would calculate a combined quality and cost performance category score. CMS proposes to use the facility-based score to determine the MIPS quality and cost performance category scores, unless the agency receives another submission of quality data for or on behalf of that clinician or

group and the combined quality and cost performance category score for the other submission results in a higher combined score. If the other submission has a higher combined score, CMS would not apply the facility-based performance scores for either the quality or cost performance categories. "The combined score for the quality and cost performance categories would determine the scores to be used for both categories, for both individual clinicians and for groups."

In MIPS, CMS scores clinicians as individuals unless they submit data as a group. CMS believes this policy should also apply to facility-based measurement, even though there are no submission requirements for the quality performance category for individuals under facility-based measurement. CMS is proposing that there will be no submission requirements for individual clinicians in facility-based measurement – but a group must submit data in the improvement activities or PI performance categories in order to be measured as a group under facility-based measurement. CMS is proposing that if a group does not submit improvement activities or PI measures, then CMS would apply facility-based measurement to the individual clinicians and such clinicians would not be scored as a group. In the case of virtual groups, MIPS eligible clinicians would have formed virtual groups prior to the MIPS performance period. As a result, virtual groups eligible for facility-based measurement would always be measured as a virtual group. CMS notes that "submission of data on the improvement activities or Promoting Interoperability measures indicates an intent and desire to be scored as a group." Thus, CMS "believes that using the choice to submit data as a group to identify a group in the context of facility-based scoring will preserve choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. " CMS is seeking comment on this proposal, specifically – "and other means to achieve the same ends."

Beginning with the 2019 MIPS performance period, CMS is proposing for facility-based measurement to adopt the measure set that the agency finalizes for the FY Hospital VBP program for which payment begins during the applicable MIPS performance period. For example, for the 2019 MIPS performance period, which runs on the 2019 calendar year, CMS proposes to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019. Furthermore, CMS believes it is appropriate to adopt the performance periods for the measures, which generally are consistent with the dates that are used to determine eligibility for facility-based measurement. CMS is proposing for the 2019 MIPS performance period (the 2021 MIPS payment year), the Total Performance Score (TPS) methodology for 2019 would apply for facility-based scoring. In other words, for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2019 Hospital VBP program along with the associated benchmarks and performance periods. CMS notes "that this approach of adopting all the measures in the Hospital VBP program can be applied to other VBP programs in the future, should [they] decide to expand facility-based measurement to settings other than hospitals in the future." CMS is particularly interested in the opportunity to expand facility-based measurement into post-acute care (PAC) and the end-stage renal disease (ESRD) settings and seek comments on how to do so.

Low-Volume Threshold

CMS is proposing to provide an "opt-in" policy for clinicians beginning in CY 2019 (with the 2021 MIPS payment year). CMS proposes that if an eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold determinations, including as defined by dollar amount (less than or equal to $90,000) or number of beneficiaries (200 or fewer), or number of covered professional services (200 or fewer), then the eligible individual or group may choose to opt-in to MIPS. For individual eligible clinicians and groups to make an election to opt-in or voluntarily report to MIPS, they would make an election via the QPP portal by logging into their account and selecting either the option to opt-in (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). Conversely, this policy would not apply to individual eligible clinicians and groups who exceed all of the low-volume threshold criteria and are required to participate in MIPS. Additionally, this policy would not apply to individual eligible clinicians and groups who do not exceed any of the low-volume threshold criteria, who would be excluded from MIPS participation and do not have the ability to opt-in to MIPS. Table 28 in the proposed rule displays low-volume threshold opt-in scenarios (pg. 522).

Beginning in CY 2019, CMS is proposing that a virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. As a result of the virtual group election, any such solo practitioner or group would be treated as a MIPS eligible clinician for the applicable MIPS payment year.

CMS further notes that for APM Entities in MIPS APMs, which meet one or two, but not all, of the low-volume threshold elements to opt-in and are interested in participating in MIPS under the APM scoring standard, they would be required to make a definitive choice at the APM Entity level to opt-in to participate in MIPS.

For APM Entities to make an election to opt-in to MIPS, they would make an election to opt-in via a similar process to the one individual eligible clinicians and groups will use. "Once the APM Entity has elected to participate in MIPS, the decision to opt-in to MIPS is irrevocable and cannot be changed for the performance period in which the data was submitted. Eligible clinicians in APM Entities in MIPS APMs that opt-in would be subject to the MIPS payment adjustment factor."

Advanced Alternative Payment Models (APMs) – Proposals

For the 2021 MIPS payment year, and based on Advanced APM participation during the 2019 MIPS performance period, CMS estimates that between 160,000 and 215,000 clinicians will become Qualifying APM Participants (QPs). As a QP, an eligible clinician is exempt from the MIPS reporting requirements and payment adjustment, and qualifies for a lump sum incentive payment based on 5 percent of their aggregate payment amounts for covered professional services for the prior year. CMS estimates that the total lump sum APM incentive payments will be approximately $600-800 million for the 2021 Quality Payment Program payment year (2019 performance year). The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician.

Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The following APMs are expected to be Advanced APMs in performance year 2019: "the Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model, Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement), Vermont All-Payer ACO Model, Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), Oncology Care Model (Two-Sided Risk Arrangement), Medicare ACO Track 1+ Model, Bundled Payment for Care Improvement Advanced, Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program), and the Shared Savings Program Tracks 2 and 3."

What's Next?

CMS publishes the final PFS/QPP regulation in early November, 2018 and the changes are effective at the beginning of the following calendar year (Jan. 1, 2019). The 60-day comment period closes on September 10, 2018. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

It is possible there will be substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for more information from our office when the final rule is released in November.

Additional Resources

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.