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Medicare Physician Fee Schedule Final Rule for 2019
Summary Part I

Payment Policies under the Physician Fee Schedule; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program; and Expanding Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorders Preventions that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

[CMS-1693-F, CMS-1693-IFC, CMS-5522-F3, and CMS-1701-F]

On November 1, 2018, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2019[1] the Quality Payment Program (QPP) and other policies. It is scheduled to be published in the November 23, 2018 issue of the *Federal Register*. Unless otherwise noted, the policies in the final rule take effect on January 1, 2019.[2]

Due to the length of this final rule, HPA is providing a summary in three parts. Part I covers sections I through III.H of the final rule, including payment policies under the PFS, Medicare Shared Savings Program requirements, the Medicaid Promoting Interoperability Program, and expanding use of telehealth services for treatment of opioid use disorder under the SUPPORT Act. Part II will primarily cover the QPP and Part III will cover the Provisions from the Medicare Shared Savings Program – AccountableCare Organizations – Pathways to Success.

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.
[2] For items finalized with comment, the 60-day comment period ends at the close of business on December 31, 2018.

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I. Introduction and Background

The final rule updates the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities. This final rule includes policies related to office/outpatient Evaluation & Management (E/M) codes, CMS finalizes alternatives for documenting the appropriate level of E/M visit, and delays implementation of E/M coding and payment changes until 2021. CMS finalizes separate payment for two newly defined physicians' services using communication technologies. In addition, CMS finalizes updates to the prices of over 1,300 supplies and 750 equipment items used in the calculation of practice expense.

Prior to 2015, the annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the update for calendar years 2015 through 2025. For 2019, the specified update is 0.5 percent before applying additional adjustments. Section 53106 of the Bipartisan Budget Act (BBA) of 2018 requires for 2019 an update of 0.25 percent before applying any other adjustments. In addition to the update factor, the CF for 2019 takes into account a Relative Value Unit (RVU) budget neutrality adjustment.

The final CF for 2019 is $36.0391, which reflects the 0.25 percent update adjustment factor specified under BBA of 2018 and a budget neutrality adjustment of -0.14 percent (2018 conversion factor is $35.9996*1.0025*0.9986. The 2019 anesthesia conversion factor is $22.2730, which reflects the same adjustments and an additional adjustment due

to an update to the malpractice risk factor for the anesthesia specialty. Table 92 from the final rule, is reproduced below.

TABLE 92: Calculation of the Final 2019 PFS Conversion Factor

Conversion Factor in effect in 2018		**$35.9996**
Statutory Update Factor	0.25 percent (1.0025)	
2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
2019 Conversion Factor		**$36.0391**

The most widespread specialty impacts of the final RVU changes are generally related to changes for specific services resulting from the Misvalued Code Initiatives. This includes the establishment of RVUs for new and revised codes. CMS notes that the estimated impacts for many specialties differ significantly from the proposed rule. This is due in large to part to CMS not finalizing its proposal to establish a single E/M payment rate and a single payment rate for established E/M visit levels 2 to 5 as well as other adjustments.

On a specialty-specific basis, CMS estimates that the combined impact of the final rule policies range from an increase of 3 percent in payments for clinical psychologists, increase of 2 percent for clinical social worker, interventional radiology, podiatry and vascular surgery to a decrease of 5 percent for diagnostic testing facility, and a decrease of 2 percent for independent laboratory and pathology.

The final rule also establishes updates to the Quality Payment Program (QPP) for 2019, Year 3. The QPP is composed of 2 tracks: (1) The Merit-based Incentive Payment System (MIPS) and (2) Advanced Alternative Payment Models (APMs). These provisions will be included in Part II of the HPA summary of this final rule.

CMS estimates that approximately 54 percent of the nearly 1.5 million clinicians billing to Part B (797,990) will be assigned a MIPS score for 2021 payment; others will be ineligible for or excluded from MIPS. About $310 million will be redistributed in MIPS payment adjustments on a budget neutral basis. The vast majority (91.2 percent) of eligible clinicians will have a positive or neutral payment adjustment. CMS estimates that approximately 160,000 to 215,000 clinicians with become Qualifying APM Participants (QPs) and an estimated $600 to $800 million in incentive payments will be made for the 2021 payment year.

The addenda to the final rule along with other supporting documents are only available online at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

II. Provisions of the Final Rule for PFS

A. Determinations of Practice Expense (PE) Relative Value Units (RVUs)

1. Practice Expense Methodology

CMS summarizes the history of the development of PE RVUs, the steps involved in calculating direct and indirect cost PE RVUs, and other related matters.

For 2019, CMS made note of several issues in the proposed rule.

CMS incorporated the available utilization data for two new specialties: hospitalists and advanced health failure and transplant cardiology.[3] CMS finalized its proposal to use proxy practice expense per hour (PE/HR) values for these new specialties by crosswalking the PE/HR from specialties that furnish similar services in the Medicare claims data. Hospitalists will use PE/HR data from emergency medicine, and advanced heart failure and transplant cardiology will use PE/HR data from cardiology. This relevant PE/HR data can be found in the 2019 PFS Final Rule PE/HR file published on CMS' website.[4]

For 2019, CMS proposed to add 28 codes that it has identified as low volume services to the list of codes for which it assigns the expected specialty. CMS finalizes these additions, with modifications based on comments received. CMS adds CPT codes 32654 and 33251 with an expected specialty of thoracic surgery. CMS also changes the expected specialty of CPT code 33251 from cardiac surgery to thoracic surgery. CMS notes that for each of these codes, only the professional component is nationally priced, and that the global and technical components are priced by the Medicare Administrative Contractors (MACs). These new additions to the expected specialty list for low volume services can found in Table 1 of the final rule, and the complete list (2,083 codes) can found on CMS' website.[5] CMS followed its approach finalized in 2018. Under this approach, CMS uses the most recent year of claims data to determine which codes are low-volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). Instead of assigning specialty mix based on the specialties reporting the services in the claims data, CMS assigns an expected specialty based on input from the RUC and other stakeholders. Services for which the specialty is automatically assigned based on previous policies (such as "always therapy" services) are unaffected by the list of expected specialty assignments. These service-level overrides also apply for both PE and MP calculations.

With respect to the formula for calculating equipment cost per minute, CMS notes that it currently uses an equipment utilization rate assumption of 50 percent for most equipment

[3] These became recognized Medicare specialties in 2017.
[4] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-FR-PEHR.zip
[5] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-FR-Specialty-Assignment.zip

(90 percent for expensive diagnostic imaging equipment as required by statute). Stakeholders have suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce this rate. As it has stated in the past, CMS continues to believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate.

CMS received numerous comments on issues related to direct and indicate practice expense methodological issues. With respect to direct practice expense, several commenters requested that CMS include pharmacists as active qualified health care providers for purposes of calculating physician PE direct costs. CMS states that it would welcome more detailed information regarding the typical clinical labor costs, including pharmacists, for particular PFS services.

Several commenters recommended that it was time to consider a new nationwide all specialty PE/HR survey, given that the practice of medicine has substantially evolved in the past decade since the last update. CMS states that it continues to believe that the Physician Practice Expense Information Survey (PPIS) data are the best currently available. It has engaged the RAND Corporation, to explore the feasibility of updating the data used in the development of PE RVUs.

CMS received many comments on its proposed changes to the indirect practice cost indices at the specialty level. Commenters expressed serious concerns that the creation of a separate PE/HR rate for the E/M visits results in a large unintended effect on certain specialties given the way indirect PE is allocated. One commenter expressed concern that there was insufficient information to model how the proposed changes in the office/outpatient E/M visit codes affected the indirect practice cost indices for all other services. In response, CMS notes that the proposed changes in the indirect practice cost indices were not finalized as it delayed the implementation of its E/M policy to pay a single rate for E/M office/outpatient visit levels 2 through 4 until 2021. CMS agreed with the commenter about the importance of transparency, but did not agree that the level of detail provided was insufficient for public comment.

2. Changes to Direct PE Inputs for Specific Services

a. Standardization of Clinical Labor Tasks

CMS states that it continues to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. CMS believes that by doing so, this will increase the transparency of the information used to set PE RVUs, facilitate the identification of exceptions to the usual values, provide greater consistency among codes that share the same clinical labor tasks, and improve relativity of values among codes. In addition, CMS notes the advantage that as medical practice and technologies change over

time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the proposed rule, CMS proposed to maintain the 3 minutes of clinical labor time for the "prepare room, equipment and supplies" activity and remove the clinical labor time for the "confirm order, protocol exam" activity wherever it observes this pattern in the RUC- recommended direct PE inputs. For some codes, these activities have been split into two and CMS is combining them into one activity. CMS note that there would be no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being used in the calculation of PE RVUs.

In response to comments, CMS finalizes its proposal with modifications. Specifically, CMS finalizes its proposal for CPT Codes 27369, 38792, 76870, 77012, 77021, 92273, and 92274. For CPT codes 76978, 76981, and 76982, CMS finalizes the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code. This change was necessary because of how the old clinical labor tasks translated into the new activity codes. As discussed in the proposed rule, beginning in 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code.

b. Equipment Recommendations for Scope Systems

CMS states that during its routine reviews of direct PE input recommendations, it has regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. For example, some of the scopes include video systems bundled into the equipment item, while others include scope accessories as part of their price. To address this issue, CMS finalized in 2017 a structure that separates the scope and the associated video system as distinct equipment items for each code, and finalized a price of the endoscopy video system. These changes applied to reviewed codes for 2017 that made use of scopes, but CMS did not apply these policies to codes with inputs reviewed prior to 2017. CMS did not make further changes to existing scope equipment in 2017 in order to allow the RUC's PE Subcommittee the opportunity to provide feedback, but CMS believed there was miscommunication as the RUC's subcommittee believed no further action was required.

In 2018, CMS made additional proposals, to create a single scope equipment code for each of the five categories detailed in this proposed rule: (1) a rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. CMS stated its belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions within a category, and that creating and pricing a single scope equipment code for each category would help provide additional clarity.
After review of comments, CMS did not finalize its proposal and instead is continuing to seek detailed recommendations from expert stakeholders on an approach (as

suggested by a commenter) that would create scope equipment codes on a per-specialty basis for six categories of scopes (including multi-channeled flexible video scopes).

For 2019, CMS delays any further changes to scope equipment until 2020, so that it can incorporate feedback from a RUC workgroup: the Scope Equipment Reorganization Workgroup. CMS, however, finalizes two proposals:

- Updates the price of the scope video system (ES031) from its current price of $33,391 to a price of $36,306 to reflect the addition of the LED light and miscellaneous small equipment associated with the system.

- Updates the name of the ES031 equipment item from "video system, endoscopy (processor, digital capture, monitor, printer, cart)" to "scope video system (monitor, processor, digital capture, cart, printer, LED light)". CMS believes that this would clarify that the use of the ES031 scope video system is not limited to endoscopy procedures.

c. Balloon Sinus Surgery Kit (SA106) Comment Solicitation

As discussed in the proposed rule, several stakeholders had contacted CMS and advised that the price of the balloon sinus surgery kit (SA106) has decreased significantly since it was priced through rulemaking in 2011 (currently $2,599.86) This kit is used in three CPT codes (31295, 31296, and 31297) related to sinus treatments. In addition, these commenters noted that the same catheter could be used to treat multiple sinuses rather than being a disposable onetime use supply. These commenters wanted CMS to examine this issue as marketing firms and sales representatives have been advertising these CPT codes as a way to generate additional profits (given that payments exceed typical resources needed).

CMS solicited comments on two aspects of the use of the balloon sinus surgery kit (SA106) supply: the supply quantity and the price. With respect to the supply quantity, CMS asked whether the 0.5 supply quantity of the balloon sinus surgery kit in CPT codes 31295-31297 would be typical for these procedures. CMS was concerned that even the 0.5 supply quantity may be overstating the resources typically needed to furnish each service. CMS also solicited comments on the pricing of the balloon sinus surgery kit or its individual components (Table 5 in the proposed and final rule lists the supply components that comprise the kit and the current prices for each).

Several commenters stated that the variability inherent in the underlying patient makes it extremely difficult to reliably assign a fixed number of sinuses that can be dilated per balloon or establish a supply quantity that would constitute the typical case. Commenters also suggested that CMS consider a shift away from the current supply methodology and instead create a separate HCPCS code for the balloon sinus surgery kit which would be billable based on the number of balloons used per patient. Another commenter provided extensive information regarding the pricing and composition of the

balloon sinus surgery kit and that the total cost of the balloon sinus surgery kit varies by sinus dilated, whether navigation is used, and by manufacturer.

In response, CMS notes that creating a separate HCPCS code for the balloon sinus surgery kit would pose a series of potential problems in pricing high cost disposable supply items (refers readers to the 2011 PFS final rule with comment period, 75 FR 73251). CMS stated it was particularly interested in the feedback suggesting that there may be multiple types of balloon sinus surgery kits that have different prices. CMS does not finalize any changes to the balloon sinus surgery kit supply for 2019, outside of the market-based supply and equipment pricing update to the supply cost.

d. Technical Corrections to Direct PE Input Database and Supporting Files

For 2019, CMS proposed to correct several clerical inconsistencies and make some technical corrections to the direct PE input database:

- The RUC alerted CMS that 165 CPT codes billed with an office E/M code have more minimum multi-specialty visit supply packs (SA048) than post-operative visits included in the code's global period. CMS proposed to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in these codes. CMS showed its proposed refinements for the 165 CPT codes in Table 6 of the final rule. For example, CPT code 27780 (treatment of fibula fracture) assumes 3.5 post-op office visits, but 4.5 visit supply packs. CMS proposed 3.5 visit supply packs for this code to align with the number of post-op office visits. CMS did not propose any refinements for the three CPT codes being deleted or the 8 codes being reviewed by the RUC this year.

  After consideration of comments, CMS finalized its proposal to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in these CPT codes listed in Table 6, with the exception of CPT code 43200.

- CMS finalized its proposal to revise the direct PE inputs for CPT code 11311 (shave skin lesion 0.6-1.0 cm) to correct a data entry error. The direct inputs will be revised to reflect the values established through rulemaking in 2013.

- CMS notes in 2018 it assigned too many minutes of clinical labor time for the "Obtain vital signs" task to three therapy codes (CPT codes 97124, 97750, and 97755), as these codes are typically billed in multiple units and in conjunction with other therapy codes for the same patient on the same day. It wouldn't be typical for clinical staff to obtain vital signs each time these codes are reported. CMS finalizes its proposal to refine the "Obtain vital signs" clinical labor task for these three codes back to their previous times of 1 minute for CPT codes 97124 and 97750 and to 3 minutes for CPT code 97755. CMS also finalizes its proposal to refine the equipment time for the table, mat, hi-lo, 6 x 8 platform (EF028) for CPT code 97124 to reflect the change in the clinical labor time.

- CMS finalizes its proposal to add the endoscope disinfector (ES005) to CPT code 52000, and to add 22 minutes of equipment time for that item to match the equipment time of the other non-scope items included in this code.

- CMS also made some additional technical corrections based on comments received.
    - Finalized an immediate postservice work time of 25 minutes for CPT code 22558.
    - Finalized the removal of CPT code 43760 from the work time file (code being deleted for 2019)
    - Finalized a technical correction to the intraservice work times of CPT codes 93281, 93284, and 93286.
    - Finalized the removal of CPT code 96X11 from the work time file (code is not being created for 2019)
    - Finalized the replacement of the 9 minutes of equipment time for the portable X-ray machine (EF041) with 9 minutes of equipment time for a basic radiology room (EL012) for CPT code 71045.

e. Updates to Prices for Existing Direct PE Inputs

For 2019, CMS finalized its proposal to update the prices of four supplies and one equipment item in response to public submission of invoices. These items include the kit, transurethral microwave thermotherapy (SA036); kit, transurethral needle ablation (SA037); stain, Wright's Pack (per slide), (SL140); neurobehavioral status forms, average (SK050); and Breast MRI computer aided detection and biopsy guidance software (EQ370). See Table 15 in the final rule for details on the updated prices, CPT codes affected, and number of services impacted.

CMS notes that to be included in a given year's proposed rule, it generally needs to receive invoices by February (February 10th deadline in 2019). CMS notes it will, of course, consider invoices submitted during the comment period following the publication of the proposed rule or during other times as part of its annual process.

For 2019, CMS also discussed two additional issues in this proposed rule in this section: market-based supply and equipment pricing update, and breast biopsy software.

(1) Market-Based Supply and Equipment Pricing Update

CMS states that as part of its authority under section 1848(c)(2)(M) of the Act, as added by the PAMA, it initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for 2019. CMS notes that these supply and equipment prices were last systematically developed in 2004-2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750

equipment items currently used as direct PE inputs. CMS provided the list of supplies and equipment for the contractor to examine.

CMS discussed the approach StrategyGen took to obtain updated price data and the criteria it used to determine its recommended price for a given item. To obtain prices, for example, StrategyGen examined data sources of commercial prices (e.g. health system provider databases, Amazon Business, Cardinal Health), the General Services Administration (GSA) schedule, and a market research survey of vendors, among other sources. CMS noted that the preliminary data indicated that in the aggregate there were no statistically significant differences between the estimated commercial prices and the current CMS prices for both equipment and supplies. At the service level, however, CMS noted there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing.

CMS proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, CMS proposed to phase in its use of the new direct PE input pricing over a 4-year period. CMS noted that this approach is consistent with how it has previously incorporated significant new data into the calculation of PE RVUs, such as changing to the "bottom-up" PE methodology.

With respect to the phase-in, CMS proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price is implemented for 2019, one third of the difference between the 2019 price and the final price is implemented for 2020, and one half of the difference between the 2020 price and the final price is implemented for 2021, with the new direct PE prices fully implemented for 2022. An example of the proposed transition from the current to the fully-implemented new pricing is provided in Table 7 in the proposed rule (reproduced below).

Table 7: Example of Direct PE Pricing Transition		
Current Price	$100	
Final Price	$200	
Year 1 (2019) Price	$125	1/4 difference between $100 and $200
Year 2 (2020) Price	$150	1/3 difference between $125 and $200
Year 3 (2021) Price	$175	1/2 difference between $150 and $200
Final (2022) Price	$200	

CMS highlighted two instances where it proposed to fully implement those prices with no transition. This includes (1) new supply and equipment codes for which it establishes prices during the transition years (2019, 2020 and 2021) based on the public submission of invoices, and (2) existing supply and equipment codes, when it established prices based on invoices that were submitted as part of a revaluation or comprehensive review of a code or code family

CMS highlighted two other instances where it proposed to phase-in any new or updated pricing over the remaining years of the proposed 4-year transition period. This includes (1) existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which its establishes prices based on invoices submitted by the public, and (2) any updated pricing on 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.

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, and the public use file showing the updated pricing is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-NPRM-Market-Based-Supply.zip

CMS invited comments from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration. CMS also sought public 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.

CMS finalizes its proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. CMS also finalizes implementing the proposed updated prices with a 4-year phase-in. In response to comments and initial feedback provided by the commenters, CMS finalizes changes to the proposed pricing of approximately 60 supply and equipment codes as detailed in Table 9. CMS notes that it continues to welcome feedback from stakeholders, including the submission of additional invoices for consideration.

CMS addressed several issues in response to comments. Many commenters were concerned with the transparency of the data used to calculate medical equipment and supply prices, and, in particular, that small practices are not well represented in the benchmark database. CMS emphasizes in its remarks that the proprietary database of buyer reported pricing is one of the few sources of typical discounted price data available. It also cites the databases' advantages, which is that it represents discounted pricing, larger sample size, and variety with respect to the purchaser's geographic location, purchasing method, procedure volume, and other purchasing arrangements. CMS clarifies that it did not use GSA data to calculated recommended prices because it concluded that its prices were not typically representative of commercially available pricing. As to whether the proposed pricing is representative of prices available to small physician practice and non-facility practitioners generally, CMS indicates that the vendor research conducted indicated that other factors beyond "size and timing" influence discounted pricing, such as service agreements and bundled purchases.

Other commenters had significant concerns with the use of market research to supplement the current AMA/Specialty Society RVS Update Committee (RUC) process. CMS notes that many of the prices in the 2018 direct practice expense inputs are over a decade old, and a significant number date back to research conducted 15 years ago. CMS states that the comprehensive market research plan was designed to supplement the AMA RUC process, not replace it, and notes that the current RUC process does provided for comprehensive pricing updates.

Other commenters wanted CMS to delay implementation of the proposal until there could be a more thorough and adequate review of the inputs and give medical societies more time to examine the data. CMS disagreed with the commenters that more time was needed to obtain more accurate pricing. CMS also emphasized that the 4-year transition allows many opportunities for public comment and the submission of additional, applicable data.

Many commenters addressed the proper pricing of some multi-component items, including supply kits, packs, and trays as well as some items of equipment. Several commenters also requested that certain CMS codes be reviewed again to ensure proper pricing. In response, CMS noted that using the information provided by commenters, StrategyGen contractors re-examined the pricing of the multi-component supply and equipment items. CMS made corrections to the prices when appropriate. Table 9 includes the approximately 60 supply and equipment items with price changes based on feedback from the commenters and the resulting additional research into pricing.

With respect to updating the clinical labor wages, most commenters were supportive of the idea of updating the clinical labor wages during the 4-year pricing transition for supplies and equipment. Many also favored continuing to use the Bureau of Labor Statistics wage data for updating the pricing, subject to public comment. CMS stated that it would take this information into account for future rulemaking.

(2) Breast Biopsy software (EQ370)

As discussed in the proposed rule, CMS received a request that it update the price for the Breast Biopsy software (EQ370) equipment, and that it be included in six CPT codes (19085, 19086, 19287, 19288, 77048, and 77049). This equipment item currently lacks a price in the direct PE database, and CMS decided when an invoice was first submitted (2014 PFS rule) that this item served clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment package (EL008) included in the same CPT codes under review. The stakeholder supplied an invoice with a purchase price of $52,275 for the equipment.

After its review of the use of this software in these codes, CMS is not proposing to update the price or add the software to these procedures for the same reasons as cited previously. CMS plans to update the name of the EQ370 equipment item from “Breast

Biopsy software" to the requested "Breast MRI computer aided detection and biopsy guidance software" to help better describe the equipment in question.

In response to a comment, CMS clarified that the MR room contain a 1.5T MR Scanner as well as coils, NV array, torso array, shoulder, wrist, extremity, dual array, power injector, and a computer workstation. After consideration of all comments, CMS finalizes its proposal to not update the price of the Breast Biopsy software (EQ370). CMS also finalizes the inclusion of CAD Software equipment (ED058) in CPT codes 77048 and 77049 and an update in the price of the CAD Software to $43,308 (average of submitted invoices and data from the StrategyGen contractor). CMS finalizes the replacement of the time assigned to EQ370 Breast Biopsy software in CPT codes 19085, 19086, 19287, and 19288 equal to the time assigned in CPT codes 19085, 19086, 19287, and 19288. CMS deletes the EQ370 equipment item given its redundancy with the new ED058 equipment code.

3. Adjustment to Allocation of Indirect PE for Some Office-Based Services

As background, CMS allocates indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other expenses. For most services, the direct PE input costs are higher in the nonfacility setting than in the facility setting, and thus indirect PE RVUs allocated to these services are higher in the nonfacility setting than in the facility setting. In cases where direct PE inputs for a service are very low, however, the allocation of indirect PE RVUs is almost exclusively based on work RVUs, which results in a very small (or no) site of service differential between the total PE RVUs in the facility and nonfacility setting.

In 2018, CMS finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services (mostly behavioral health services). CMS refers readers to the 2018 PFS final rule (FR 52999 through 53000) for a discussion of this revised methodology. CMS first began implementing this modification in 2018, the first year of a 4-year transition.

For 2019, CMS finalizes its proposal to continue with the second year of the transition of this adjustment to the standard process for allocating indirect PE. There are 29 codes affected by this policy, and the list is available on CMS' website.[6]

B. Determination of Malpractice Relative Value Units (MP RVUs)

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and MP expense. By way of background, the resource-based formula to determine the MP for a given service is comprised of three major components: (1) specialty's risk factor, (2) specialty weight—or the mix of practitioners

[6] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-FR-Alt-Methodology-Indirect-PE.zip

providing the service—compared to all other specialties, and (3) work value for the service. In 2015, CMS implemented the third comprehensive five-year review and update of MP RVUs, which updated each specialty's risk factor based upon updated insurance premium data. In 2016, CMS finalized a policy to conduct annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data) and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). CMS also finalized a policy to modify the specialty mix assignment methodology to use an average of the 3 most recent years instead of the most recent year of data.

In 2017, CMS finalized the eighth geographic practice cost indices (GPCI) update, which reflected updated MP premium data. With respect to updating specialty specific risk factors, CMS noted that the 2017 GPCI update reflects updated MP premium data, collected for the purpose of proposing updates to the MP GPCIs. CMS noted at the time that while it could have used the updated MP premium data to propose updates to the specialty risk factors, this would not be consistent with its current policy (updating as part of the 5-year review in 2020).

In 2018, CMS proposed to use the MP premium data (collected as part of the GPCI update) to update the specialty risk factors used in the calculation of MP RVUs prior to the next 5-year update (2020). After consideration of comments and differences it observed in raw rate filings and how those data were categorized to conform to the specialty risk factors, CMS did not finalize its proposal.

CMS sought additional comments regarding the next MP RVU update which must occur by 2020. CMS states that it received a few comments in response to its solicitation and will consider them for future rulemaking.

C. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services and Interim Final Rule Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders Under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

CMS has generally used the term "Medicare telehealth services" to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. CMS states that it has come to believe section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, CMS believes this section 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.

For CY 2019, CMS aims to increase access for Medicare beneficiaries 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 had several proposals for communication technology-based services, that it believed would not be subject to the limitations on Medicare telehealth services in section 1834(m) of the Act.

1. Brief Communication Technology-based Service, e.g., Virtual Check-in (HCPCS code G2012)[7]

CMS notes that historically, it has considered any routine non-face-to-face communication that takes place before or after an in-person visit to be bundled into the payment for the visit itself. CMS states that it recognizes that advances in communication technology have changed patients' and practitioners' expectations regarding the quantity and quality of information that can be conveyed via communication technology. CMS states that a broader range of services can be furnished by health care professionals via communication technology compared to 20 years ago.

CMS believes that among these services are the kinds of brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted. When these kinds of check-in services are furnished prior to an office visit, then CMS would currently consider them to be bundled into the payment for the resulting visit, such as through an evaluation and management (E/M) visit code. However, in cases where the check-in service does not lead to an office visit, then there is no office visit with which the check-in service can be bundled. CMS believes that check-in visits could be effective in mitigating the need for potentially unnecessary office visits, but there is little incentive for providers to provide these types of services given that they are not billable.

After consideration of comments, CMS finalizes its proposal to pay separately, beginning January 1, 2019, for a newly defined type of physician service furnished using communication technology. This service will be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. CMS sought 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.

The code will be described as G2012 (Brief communication technology based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management 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 noted that that this service could be used as

[7] In the proposed rule, CMS referred to this service as HCPCS code GVCI1, which was a placeholder code.

part of a treatment regimen for opioid use disorders and other substance use disorders. CMS finalized the following specific proposals.

- CMS finalizes its proposal that if the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable. This is consistent with code descriptor language for CPT code 99441 on which this service is partially modeled.

- CMS finalizes its proposal that in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service will be considered bundled into the pre- or post- visit time of the associated E/M service, and therefore, will not be separately billable.

- CMS finalizes it proposal to price this distinct service at a rate lower than existing E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology.

- CMS finalizes its proposal that this service can only be furnished for established patients because it believes that the practitioner needs to have an existing relationship with the patient, and therefore, basic knowledge of the patient's medical condition and needs, in order to perform this service

- CMS is finalizing requiring verbal consent from beneficiaries that is noted in the record for each service.

- CMS is not implementing a frequency limit on the use of this code by the same practitioner with the same patient for 2019, but plans to monitor utilization with the intention of determining whether such a limitation is warranted.

CMS expects that these services would be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. Patients' consent to receiving these services will be necessary.

CMS sought comments on a number of specific issues related to this brief communication technology-based service, including on verbal consent, application of a frequency limitation, timeframes under which this service would be separately bundled, and how best to document this service in the medical record.

Many commenters supported the proposal to pay for these kinds of services, and offered specific suggestions regarding the service definitions and associated billing rules. Commenters suggested that CMS not be overly prescriptive regarding the types of communication technology with some suggesting that it permit the use of email and EHR

patient portals to qualify. In response, CMS was persuaded by commenters not to be overly prescriptive and is finalizing allowing audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission. CMS notes, however, that telephone calls that involve only clinical staff could not be billed using HCPCS code G2012 since the code requires direct interaction between the patient and the billing practitioner. In response to commenters that were concerned that it would be burdensome to obtain consent from the patient prior to each occurrence of this service, CMS notes that obtaining and documenting verbal consent in the medical record is the approach CMS currently uses with care management services. Thus, it does not believe it would impose significant burden. Many commenters were supportive of limiting this service to established patients and were opposed to creating a frequency limitation suggesting that CMS wait and monitor utilization. CMS agrees with commenters, but noted that it plans to monitor utilization to determine whether such a limit is warranted. A few commenters suggested that other clinical staff, such as licensed physical therapists and registered nurses, be allowed to furnish and bill these services. CMS replies that it is maintaining this code as part of the set of codes that is only reportable by those that can furnish E/M services, which is appropriate since this service helps assess whether an office visit is warranted.

2. Remote Evaluation of Pre-Recorded Patient Information (HCPCS code G2010)[8]

Stakeholders have requested that CMS make separate Medicare payment when a physician uses recorded video and/or images captured by a patient in order to evaluate a patient's condition. These services involve what is referred to under section 1834(m) of the Act as "store and-forward" communication technology that provides for the "asynchronous transmission of health care information." Under section 1834(m) of the Act, payment for telehealth services furnished using such store-and forward technology is permitted only under Federal telemedicine demonstration programs conducted in Alaska or Hawaii, and these telehealth services remain subject to the other statutory restrictions governing Medicare telehealth services.

Effective January 1, 2019, CMS finalizes its proposal to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. These services are intended to determine whether or not an office visit or other service is warranted. CMS finalized that this service will be a stand-alone service that could be separately billed to the extent that there is no resulting E/M office visit and there is no related E/M office visit within the previous 7 days of the remote service being furnished. CMS stated that because these services are not meant to substitute for an in-person service currently separately payable under the PFS, these services are distinct from the telehealth services described under section 1834(m) of the Act.

The code for this service is described as G2010 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related

[8] In the proposed rule, CMS referred to this service as HCPCS code GRAS1.

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 noted that this service is distinct from the brief communication technology-based service described above in that this service involves the practitioner's evaluation of a patient-generated still or video image, and the subsequent communication of the resulting response to the patient, while the brief communication technology-based service describes a service that occurs in real time and does not involve the transmission of any recorded image.

CMS sought comment as to whether these services should be limited to established patients; or whether there are certain cases, like dermatological or ophthalmological services, where it might be appropriate for a new patient to receive these services.

Commenters were generally supportive of its proposal to pay for these kinds of services. Of particular note, commenters were mixed on whether CMS should allow this service to be furnished to new patients. Many commenters argued that an established relationship is not required for the practitioner to remotely evaluate an image or video to consider whether an office visit or other service is warranted, particularly in dermatology and ophthalmology. On the other hand, the AMA and others urged CMS to limit these services to established patients. In response, CMS was persuaded by comments limiting payment for these services only for established patients, and thus finalizes the reporting and billing of HCPCS code G2010 only for established patients. A few commenters requested that CMS clarify what mode of communication would count as "verbal follow-up". CMS finalizes that the follow-up could take place visa phone call, audio/video communication, secure text messaging, email, or patient portal communication and notes that it does not intend to include the "verbal" in the code descriptor. CMS finalizes the valuation for HCPCS code G2010 as proposed, and notes that it will monitor utilization of this code and consider any potential adjustments to billing rules or valuation of this service through future rulemaking.

3. Interprofessional Internet Consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449).

As part of its standard rulemaking process, CMS received recommendations from the RUC over a period of 5 plus years to assist in establishing values for six CPT codes that relate to interprofessional telephone/Internet assessment and management service provided by a consultative physician:

- 99446 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review),

- 99447 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review),

- 99448 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review),

- 99449 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review).

- 99452 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified healthcare professional, 30 minutes)

- 99451 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

CMS finalizes, as proposed, separate payment for these services, discussed in section II.H. Valuation of Specific Codes. Currently, the resource costs associated with seeking or providing such a consultation are considered bundled, which provides an incentive for the specialist to schedule a separate visit for the patient when phone or internet-based interaction with the consulting practitioner would have sufficed.

Since these codes describe services that are furnished without the beneficiary being present, CMS finalizes its proposal to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record, similar to the conditions of paymentassociated with the care management services under the PFS. Obtaining advance consent includes ensuring that the patient is aware of any applicable cost sharing.

CMS had concerns about how these services can be distinguished from activities undertaken for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education. CMS highlighted potential program integrity concerns around making separate payment for these interprofessional consultation services, and how to evaluate whether such interactions is reasonable and necessary.

Almost all commenters were supportive of CMS proposing separate payment for these services. Commenters argued that making separate payment for these services would result in accurate payment for both the treating and consulting physician in a consultative scenario. CMS appreciates the suggestions from commenter and agree with many commenters who pointed out that adding many additional billing requirements may inhibit uptake for these services. CMS notes that it is requiring documentation of verbal patient consent in the medical record for each interprofessional consultation service to

receive these services, and are adopting existing CPT prefatory language – consistent with CMS' longstanding practice. Cost sharing will apply for these services, and that these services may only be billed by practitioners that can bill Medicare independently for E/M services.

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

In the 2003 PFS final rule (67 FR 79988), CMS established a process for adding or deleting services from the Medicare telehealth list. CMS assigns requests to two categories: Category 1 and Category 2. Category 1 services are similar to services that are currently on the telehealth list. Category 2 services are not similar to services on the telehealth list and CMS requires evidence demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part. Requests to add services must be submitted and received no later than December 31 of each year to be considered for the next rulemaking cycle. Additional information for submitting a request is available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

In response to requests received in 2017, CMS finalizes its proposal to add two codes because it believes these services are sufficiently similar to services currently on the telehealth services list (this is known as qualifying on a category 1 basis):

- HCPCS codes G0513 and G0514: Prolonged preventive services that is beyond the typical service time of the primary procedure. HCPCS code G0513 is the first 30 minutes, and G0514 is each additional 30 minutes. These are reported in addition to the code for the preventive service. CMS considers this service similar to office visits, and that all components of this service can be furnished via interactive telecommunications technology.

CMS did not propose to add or modify the following services for the reasons noted:

- Chronic Care Remote Physiological Monitoring (CPT codes 99453, 99454, and 99457).
    - CMS states that because these codes describe services that are inherently non face-to-face, it does not consider them Medicare telehealth services under section 1834(m) of the Act.
- Interprofessional Internet Consultation (CPT codes 99451 and 99452)
    - CMS believes these codes describe services that are inherently non face-to-face and CMS does not consider them as Medicare telehealth services. CMS notes, however, that it is proposing to adopt these codes (as described above) for payment under the PFS as these are distinct services furnished via communication technology.
- Initial Hospital Care Services (CPT codes 99221, 99222, and 99223)
    - CMS notes that it has previously considered requests to add these codes to the telehealth list. Based on the description of these services, CMS believes it is critical that the initial hospital visit by the admitting practitioner be conducted in person. Consistent with prior rulemaking, it

does not believe these services should be added on a category 1 basis and that there is not sufficient evidence to add them on a category 2 basis.

- Subsequent Hospital Care Services (CPT codes 99231, 99232, and 99233).
    - These codes are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 3 days. CMS received a request to remove the frequency limitation. CMS continues to believe that the majority of these subsequent hospital care services should be in person to facilitate comprehensive, coordinated, and personal care. Thus, CMS is not proposing to remove the frequency limitation on these codes.
- Subsequent Nursing Facility Care Services (CPT codes 99307, 99308, 99309, and 99310).
    - These codes are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 30 days. A commenter requested that CMS remove the frequency limitation when these services are provided for psychiatric care. CMS states that it does not believe that it would be appropriate to remove the frequency limitation only for certain diagnoses. CMS also cites concerns regarding the potential acuity and complexity of SNF patients.

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

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

Section 50302 of the BBA of 2018 expanded access to home dialysis therapy by providing telehealth options to individuals with end-stage renal disease (ESRD) receiving home dialysis.[9] This allows an individual with end-stage renal disease receiving home dialysis to choose to receive certain monthly end-stage renal disease-related (ESRD-related) clinical assessments via telehealth on or after January 1, 2019. The statute requires that such an individual must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

The statute also does not provide flexibility on the originating site or the location of an eligible Medicare beneficiary at the time the service furnished. Renal dialysis facility and the home of an individual were added as telehealth originating sites but only for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth. Moreover, the statute provides that the geographic requirements for telehealth services (i.e., patient must be at an originating site in a non-MSA or rural area) do not apply to telehealth services furnished on or after January 1, 2019 for purposes of the monthly ESRD-related clinical assessments where the originating site is a hospital-based or critical access hospital-based renal dialysis

[9] Requirements under Section 50302 of the BBA of 2018 amended sections 1881(b)(3) and 1834(m) of the Act

center, a renal dialysis facility, or the home of an individual. As defined in statute, there is no originating site facility fee to be paid if the home of the individual is the originating site.

To conform its regulations with the statute, CMS made several proposals related to telehealth requirements related to home dialysis therapy. CMS proposed to revise its regulation at §410.78(b)(3) to add a renal dialysis facility and the home of an individual as Medicare telehealth originating sites, but only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act. CMS proposed to amend §414.65(b)(3) to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid a when the originating site for these services is the patient's home. Additionally, CMS proposed to add new §410.78(b)(4)(iv)(A), to reflect the provision in section 1834(m)(5) of the Act, added by section 50302 of the BBA of 2018, specifying that the geographic requirements described in section 1834(m)(4)(C)(i) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, in originating sites that are hospital based or critical access hospital-based renal dialysis centers, renal dialysis facilities, or the patient's home, respectively under sections 1834(m)(4)(C)(ii)(VI), (IX) and (X) of the Act, for purposes of section 1881(b)(3)(B) of the Act.

Commenters supported the CMS proposals, and CMS finalizes these regulation text changes, as proposed.

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

Section 50325 of the BBA of 2018 expanded the use of telehealth for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services) for beneficiaries. Specifically, the statute removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. It specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. It also limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions (as defined under section 1834(m)(4)(C) of the Act).

To implement these requirements, CMS finalizes its proposal to create a new modifier that will be used to identify acute stroke telehealth services. This modifier (appended to the HCPCS code) will be used by practitioner and, as appropriate, the originating site, will append this modifier when billing for an acute stroke telehealth service or an originating site facility fee, respectively. By billing with this modifier, practitioners will be indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke. CMS notes its belief that the adoption of a service level modifier is the least administratively burdensome means of

implementing this provision for practitioners, while also allowing CMS to easily track and analyze utilization of these services.

CMS also finalizes its proposal to revise §410.78(b)(3) of its regulations to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. This includes hospitals and critical access hospitals, but excludes renal dialysis facilities and patient homes because they are originating sites only for purposes of home dialysis monthly ESRD-related clinical assessments. CMS also finalizes its proposal to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke. In response to comments from the AMA that suggested that CMS specify in the definition that a mobile stroke unit must include certain equipment (e.g., CT scanner), CMS notes that clinicians are in the best position to make decisions about what supplies and equipment are needed. CMS notes that any additional sites would be adopted through future rulemaking and the originating site facility fee would not apply in instances where the originating site does not meet the originating site type and geographic requirements under section 1834(m)(4)(C) of the Act.

CMS also finalized its proposal to add §410.78 (b)(4)(iv)(B) to specify that the geographic requirements in section 1834(m)(4)(C) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

6. Requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act—Interim Final Rule with Comment Period

Section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, October 24, 2018) (the SUPPORT Act)) makes several revisions to section 1834(m) of the Act. It removes the originating site geographic requirements, adds the home of an individual as a permissible originating site, and removes the originating site facility fee when the individual's home is the originating site for telehealth services furnished on or after July 1, 2019 for the purpose of treating individuals diagnosed with a substance use disorder or a co-occurring mental health disorder. Section 2001(b) of the SUPPORT for Patients and Communities Actgrants the Secretary specific authority to implement the amendments made by section 2001(a) through an interim final rule.

CMS makes the following revisions. CMS adds §410.78(b)(4)(iv)(C) on an interim final basis to specify that the geographic requirements in section 1834(m)(4)(C)(i) of the Act do not apply for telehealth services furnished on or after July 1, 2019, to individuals with a substance use disorder diagnosis for purposes of treatment of a substance use disorder or a co-occurring mental health disorder at an originating site other than a renal dialysis facility. CMS revises §410.78(b)(3) on an interim final basis, by adding §410.78(b)(3)(xii), which adds the home of an individual as a permissible originating site for telehealth services furnished on or after July 1, 2019 to individuals with a substance use disorder diagnosis for purposes of treatment of a

substance use disorder or a co-occurring mental health disorder. CMS amends §414.65(b)(3) on an interim final basis to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid when the originating site for these services is the individual's home.

CMS notes that section 2001 of the SUPPORT for Patients and Communities Act did not amend section 1834(m)(4(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. Practitioners would be responsible for assessing whether individuals have a substance use disorder diagnosis and whether it would be clinically appropriate to furnish telehealth services for the treatment of the individual's substance use disorder or a co-occurring mental health disorder. CMS notes that it may issue additional subregulatory guidance in the future for billing these telehealth services.

CMS invites comment on its policies to implement section 2001 of the SUPPORT for Patients and Communities Act. The comment period ends at the close of business on December 31, 2018.

7. Modifying §414.65 Regarding List of Telehealth Services

CMS finalizes its proposed technical revision to delete the description of individual services and exceptions for Medicare payment for telehealth services in §414.65, by amending §414.65(a) to note that Medicare payment for telehealth services is addressed in §410.78 and by deleting §414.65(a)(1).

8. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

CMS believes making separate payment for a bundled episode of care for management and counseling for substance use disorder (SUDs) could be effective in preventing the need for more acute services. CMS states that creating separate payment for a bundled episode of care for components of Medication Assisted Therapy (MAT) such as management and counseling treatment for SUDs, including opioid use disorder, 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 for SUDs. CMS cites several studies that support such an approach.[10]

[10] See Van L. King, Robert K. Brooner, Jessica M. Peirce, Ken Kolodner, Michael S. Kidorf, "A randomized trial of Web based videoconferencing for substance abuse counseling," *Journal of Substance Abuse Treatment,* Volume 46, Issue 1, 2014, Pages 36-42, http://www.sciencedirect.com/science/article/pii/S0740547213001876; and Pamela L. Owens, Ph.D., Marguerite L. Barrett, M.S., Audrey J. Weiss, Ph.D., Raynard E. Washington, Ph.D., and Richard Kronick, Ph.D. "Hospital Inpatient Utilization Related to Opioid Overuse Among Adults 1993-2012,"
Statistical Brief #177. Healthcare Cost and Utilization Project (HCUP). July 2014. Agency for Healthcare Research

CMS sought comment on whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment. This includes the following issues:

- Developing coding and payment, assumptions about the typical number and duration of counseling sessions, which types of practitioners could furnish these services, and what components of MAT could be included in the bundled episode of care.
- How to define and value this bundle, what conditions of payment should be attached, and whether the concept of a global period might be applicable.
- Whether the counseling portion and other MAT components could also be provided by qualified practitioners "incident to" the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment.[11]

CMS also welcomed comments on potentially creating a bundled episode of care for management and counseling treatment for SUDs for future rulemaking consideration. Additionally, CMS invited comment and suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. This included methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these nonopioid alternatives including barriers related to payment or coverage.

Commenters provided detailed information on this topic. Some commenters expressed concern that the format of a bundled episode of care may fail to take into account the wide variability in patient needs for treatment of SUDs given its chronic nature. They were also concerned that the global period would not lend itself to the treatment of SUD, because the treatment is not an acute intervention like surgery. In response, CMS acknowledges and agrees with commenters that there is wide variability in patient needs for treatment of SUDs, but does not believe the characteristics of these patients precludes payment bundles and/or global periods.

CMS requests additional information from stakeholders and the public that it might consider for future rulemaking regarding payment structure and amounts for SUD treatment. These comments can be included in the 60-day comment period CMS is providing to the public to comment on the interim final telehealth policies and revisions to its regulations. The 60-day comment periods ends at the close of business on December 31, 2018.

[11] CMS states that this approach is similar to similar to the structure of the Behavioral Health Integration codes which include services provided by other members of the care team under the direction of the billing practitioner on an "incident to" basis (81 FR 80231).

D. Potentially Misvalued Services Under the Physician Fee Schedule

1. CY 2019 Identification and Review of Potentially Misvalued Services

a. Public Nominations

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the RVUs for these services.

In the 2012 PFS final rule (76 FR 73058), CMS finalized a process for the public to nominate potentially misvalued codes. The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10 of each year. CMS reviews the information and in the following year's PFS proposed rule, publishes a list of nominated codes and indicates whether it is proposing the code as a potentially misvalued code. CMS finalizes its list of potentially misvalued codes in the final rule.

CMS received one submission that nominated several high-volume codes for review under the potentially misvalued code initiative. In its submission, the commenter noted a systematic overvaluation of work RVUs citing GAO, MedPAC, and other sources. The requester requested that the codes listed in Table 8 (reproduced below) be prioritized for review,

Table 8: Public Nominations Due to Overvaluation	
CPT Code	**Short Description**
27130	Total hip arthroplasty
27447	Total knee arthroplasty
43239	Egd biopsy single/multiple
45385	Colonoscopy w/lesion removal
70450	CT head w/o contrast
93000	Electrocardiogram complete
93306	Tte w/doppler complete

Another commenter requested that CPT code 92992 (Revision of heart chamber) be reviewed in order to establish national RVU values for these services under the PFS (currently priced by the MACs).

Several commenters, including the RUC, expressed concern that the source of the nomination of the seven high-volume codes and its entire nomination letter was not made available. Other commenters noted that CPT codes 27130 and 27447 should not be considered potentially misvalued because the current valuation of these codes was recently established by the RUC and CMS in 2013. Commenters stated that subjecting

these codes so frequently calls into question the validity of the RUC process in the first place. In response, CMS believes that it summarized the contents of the public nomination letter and provided the rational in the 2019 proposed rule with enough detail for commenters to comment substantively. CMS also does not agree that recent review of a code should preclude it from being considered as misvalued. CMS notes that in the future, public nominations that CMS receives by the February 10th deadline will be made available in the form of a public use file with the proposed rule. Thus, CMS adds CPT codes 27130, 27447, 43239, 45385, 70450, 93000, and 93306 to the list of potentially misvalued codes and anticipates reviewing recommendations from the RUC and other stakeholders. CMS reminds readers that the list is intended to prioritize codes to be reviewed and does not necessarily mean that a particular code is misvalued.

b. Update on the Global Surgery Data Collection

CMS provided an update on its effort to collect data on how many postoperative visits are performed during the global period (within 10 or 90 days) for many surgeries. Section 523 of MACRA required CMS to use notice and comment rulemaking to implement a process to collect data on the number and level of postoperative visits and use these data to assess the accuracy of global surgical package valuation.[12] In the CY 2017 PFS final rule, CMS adopted a policy to collect postoperative visit data.

This data collection effort began July 1, 2017 and was required for practitioners in groups with 10 or more in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island). Practitioners were required to use the no-pay CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure) to report postoperative visits.[13]

CMS found that in these nine states over a 6-month period (July 1, 2017 through December 31, 2017), there were 990,581 postoperative visits reported using CPT code 99024. Only 45 percent of participating practitioners reported one or more visits using CPT code 99024 during this 6-month period[14] The share of practitioners who reported any CPT 99024 claims varied widely by specialty. Most of the surgical specialties had high response rates (above 80 percent), including general surgery, orthopedic surgery, vascular surgery, colorectal surgery, hand surgery, and thoracic surgery. Primary care specialties had much lower response rates, including internal medicine (11%), family practice (18%), physician assistant (28%), and nurse practitioner (20%). Emergency

[12]MACRA added a new section 1848(c)(8) to the Act, which includes section 1848(c)(8)(B).
[13]The 293 procedures for which reporting is required are those furnished by more than 100 practitioners, and either are nationally furnished more than 10,000 times annually or have more than $10 million in annual allowed charges. A list of the procedures for which reporting is required is updated annually to reflect any coding changes and is posted on the CMS web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/GlobalSurgery-Data-Collection-.html.
[14]There were 32,573 practitioners who furnished at least one of the 293 procedures for which reporting is required.

medicine (one of the larger specialties reporting a global code), had a response rate of 4 percent.

CMS then examined by specialty what share of procedures had matched post-operative visits (reported with CPT code 99024). Among 10-day global procedures performed during this six-month period, only 4 percent overall had one or more matched visit reported with CPT code 99024. Table 11 in the proposed rule (extract of Table 11 reproduced below) shows that for many specialties less than 5 percent of the 10-day global procedures performed had a matched visit using CPT code 99024. General surgery had the highest share (17%) of those specialties performing more than 10,000 procedures during this period. Among all specialties, hand surgeons had the highest share of procedures with a matched post-operative visit of 44 percent.

Extract of Table 11: Share of Procedures with Matched Post-Operative Visits (those with > 10,000 10-day global procedures)

Provider Specialty	Number of 10-day Global Procedures*	Number of 10-day Global Procedures with 1 or More Matched 99024 Claims**	Percentage of 10-day Global Procedures with 1 or More Matched 99024 Claims**
ALL	436,063	16,802	4%
Dermatology	205,594	6,920	3%
Physician Assistant	57,749	908	2%
Nurse Practitioner	31,937	509	2%
Family practice	16,770	629	4%
Ophthalmology	16,087	1,239	8%
Podiatry	12,639	547	4%
General surgery	12,113	2,095	17%
Diagnostic radiology	11,650	298	3%

*Limited to the 293 procedures where postoperative visit reporting is required and to those performed by practitioners who work in practices with 10 or more practitioners. Because matching may be unclear in these circumstances, multiple procedures performed on a single day and procedures with overlapping global periods were excluded.

**Matching was based on patient, service dates, and global period duration.

Among 90-day global procedures, the percentage of practitioners reporting a post-operative visit with CPT code 99024 was much higher. During this six-month period (July 1, 2017 through December 1, 2017), 67 percent had one or more matched visits reported using CPT code 99024. Table 12 in the proposed rule (extract reproduced below) shows the variation in rates by specialty. For example, among 90-day global procedures performed by orthopedic surgery, 76 percent of these procedures performed had a matched visit using CPT code 99024.

Extract of Table 12: Share of Procedures with Matched Post-Operative Visits, for Procedure Codes with 90-Day Global Periods (those with > 10,000 90-day global procedures)			
Provider Specialty	**Number of 90-day Global Procedures***	**Number of 90-day Global Procedures with 1 or More Matched 99024 Claims****	**Percentage of 90-day Global Procedures with 1 or More Matched 99024 Claims****
ALL	232,235	156,727	67%
Orthopedic surgery	71,991	54,876	76%
Ophthalmology	63,333	41,700	66%
General surgery	25,593	17,559	69%
Pathologic anatomy, clinical pathology	10,149	4,371	43%

*Limited to the 293 procedures where post-operative visit reporting is required and to those performed by practitioners who work in practices with 10 or more practitioners. Because matching may be unclear in these circumstances, multiple procedures performed on a single day and procedures with overlapping global periods were excluded.

**Matching was based on patient, service dates, and global period duration.

CMS recognized that a potential explanation for these findings could be that many practitioners are not consistently reporting postoperative visits using CPT code 99024. To examine this issue, CMS performed a subanalysis of "robust reporters;" these are practitioners who appear to be regularly reporting post-operative visits using CPT code 99024.[15] CMS found that 87 percent of procedures with 90-day global periods had one or more associated post-operative visits. However, CMS found that only 16 percent of procedures with a 10-day global period had an associated postoperative visit reported using CPT code 99024. CMS concludes that these findings suggest that post-operative visits following procedures with 10-day global periods are not typically being furnished rather than not being reported.

CMS also provides an update on its effort to conduct a separate survey-based data collection that would augment its effort on collecting data on number of visits with the level of post-operative visits. This would include detailed information 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. CMS notes that RAND developed a survey and approach (as described in the 2017 PFS final rule) that would have collected data on post-operative visits related to a full range of procedures with 10-day and 90-day global periods. RAND piloted this post-operative visit survey and had a very low response rate raising concerns that this approach would not provide useful or representative information. As a result, CMS has refocused its effort to collect information on post-operative visits and non-face-to-face services associated with a small number of high-

[15]Robust reporters were defined as practitioners who (a) furnished 10 or more procedures with 90-day global periods where it is possible for CMS to match specific procedures to reported postoperative visits without ambiguity, and (b) reported a post-operative visit using CPT code 99024 for at least half of these 90-day global procedures.

volume procedure codes. CMS stresses that it needs practitioner participation to get representative data and that future efforts may cover a broader range of services.

CMS sought comments on its findings and how best to encourage practitioners to consistently report postoperative visits using CPT code 99024. In addition, CMS sought comments 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, and in particular, on whether it should consider changing the global period and reviewing the code valuation. On a related issue, CMS also sought comments on whether it should consider requiring use of the modifiers in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether or not the transfer of care is formalized.

The majority of commenters, including the RUC, believed that physicians needed more time to become aware of reporting and prepare for reporting. In addition, commenters noted that improved reporting was essential if these data were to be used to improve the accuracy of existing codes. Commenters opposed implementing an enforcement mechanism. MedPAC, which supports converting all 10-and 90-day global codes to 0-day global codes and revaluing them as 0-day codes, suggested that these findings are consistent with the OIG's three studies that show that post-operative visits were not occurring at the rate included in the valuation of the global code. In response, CMS states that it will evaluate the public comments received and consider whether to propose action at a future date. To improve awareness, CMS states that it has already sent a letter describing the requirement to practitioners who are required to report in the 9 affected states and plans to send another such letter to these practitioners.

E. Radiologist Assistants

CMS assigns a physician supervision level of general, direct or personal supervision for the technical component of all diagnostic tests.[16] In response to the Request for Information on CMS Flexibilities and Efficiencies in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), many commenters recommended revising the physician supervision requirement for diagnostic tests typically furnished by a radiologist assistant (RA) from personal to direct. In addition to increasing efficiency, stakeholders suggested that the current supervision requirements for certain diagnostic imaging services unduly restrict RAs from conducting tests consistent with their education and training and that they may do under current law in many states.

For diagnostic tests requiring personal supervision, CMS proposed to only require direct supervision when permitted by state law and state scope of practice regulations and performed by:

[16] "General supervision" means the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. "Direct supervision" means that the physician must be immediately available (although not in the room or within any physical boundary of the property) to furnish assistance and direction throughout the performance of the procedure. "Personal" supervision means a physician must be in attendance in the room during the performance of the procedure. (42 CFR §410.32(b)(3)).

- A registered radiologist assistant certified by the American Registry of Radiologic Technologists; and
- A radiology practitioner assistant certified by the Certification Board for Radiology Practitioner Assistants.

Many commenters supported the proposed changes. In response to comments, CMS notes that it did not propose to change the level of physician supervision for diagnostic imaging test requiring a general level of physician supervision and it will modify the regulations to clarify this requirement. CMS disagrees with commenters requesting a new supervision indicator that would be applied to specific codes and would indicate that the procedure may be performed under the direct supervision of a radiologist when performed by a RA appropriately certified. CMS believes this is not necessary and would be burdensome.

After consideration of comments, CMS finalizes with refinements for further clarity, the proposed revisions to §410.32, by adding a new paragraph (b)(4) that states that diagnostic tests performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (3), may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

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

CMS provides a detailed background on sections 1833(t)(1)(B)(v) and (t)(21) of the Act that preclude new office-campus provider-based departments (PBD) opened after November 2, 2015 (with certain exceptions) from being paid under the outpatient prospective payment system (OPPS). Effective January 1, 2017, these new off-campus departments were paid under a special PFS where payment was equal to 50 percent of the OPPS payment amount. Effective January 1, 2018, CMS changed the 50 percent adjustor to 40 percent. To identify services paid under this special PFS, new off-campus PBDs include the modifier "PN" on their claims. CMS adopted the same ancillary payment policies (packaging, multiple procedure payment reduction, C-APCs, etc.) for the special PFS that apply to new off-campus departments as apply under the OPPS.

As this provision was first implemented on January 1, 2017, the 2019 rate-setting cycle is the first one under which CMS will have claims data under the provision. CMS made several technical adjustments to the prior analysis it used to develop the 50 and 40 percent adjustors. CMS describes the detailed analysis it used to determine whether it would change the current 40 percent adjustor. Using new data, CMS proposed to leave the 40 percent adjustor unchanged. The proposed rule further indicated that CMS would maintain the same policies as 2018 related to supervision, beneficiary cost sharing, geographic payment adjustments and partial hospitalization services.

In response to comments expressing disappointment that the proposed rule did not provide the same level of detail about the data and methodology used in calculating the PFS Relativity Adjuster for 2019 as had been provided in prior rulemaking, CMS provides additional details on the analysis used to calculate the 2019 PFS Relativity Adjuster. In addition, CMS is providing a public use file (PUF), available on the CMS website under the "downloads" section of this final rule that contains the 2017 PFS technical-equivalent payment rates for all HCPCS codes reported on an institutional claim with the "PN" modifier, the OPPS payment rate, and the number of claims by OPPS status indicator (available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched). In addition, to increase the precision of its analysis, CMS discusses how it imputed payment rates under the PFS for certain HCPCS codes for which payment is based on rates other than national PFS pricing. The imputed values that were used, both from contractor priced codes and other fee schedules, are also included in the data file posted with this final rule (available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html). In response to a comment, CMS clarifies that for services not priced in the nonfacility setting, it incorporated the OPPS rate as the technical equivalent rate under the PFS. CMS acknowledges a certain level of imprecision inherent in its analysis, but it believes the margin of error is relatively small and would likely affect the PFS and OPPS amounts similarly.

In response to comments about the appropriate comparison for PFS technical-equivalent rates, CMS discusses its methodology for allocating direct and indirect costs as part of the PFS ratesetting process. CMS agrees with commenters that nonexcepted off-campus PBDs incur indirect costs, but it believes the calculations used for the technical-equivalent PFS rates includes the relative resource costs of indirect expenses involved in furnishing these services. CMS notes that if it used the full nonfacility PE RVUs as the basis for comparing PFS rates to OPPS rates, it would effectively be paying twice for a portion of indirect costs, once under the PFS for the PC component of services and again through the PFS Relativity Adjusted payment under the OPPS to off-campus PBDs for the facility part of the same service. CMS acknowledges that the process of allocating indirect costs under the PFS may not reflect situations where physicians and other professionals are paid under salaried arrangements by institutions such as a hospital. The current PFS payment methodology assumes that the indirect costs associated with professional services furnished in institutions like hospital PBDs are incurred by the individual practitioners and not by the institutions; CMS may consider this issue for future rulemaking.

CMS disagrees with commenters suggesting that a 65 percent or higher PFS Relativity Adjuster would be more appropriate. CMS notes it has no reason to believe that the 2017 claims data is not robust and it believes its analysis that a PFS Relativity Adjuster of 40 percent is appropriate.

CMS discusses comments expressing disappointment that CMS did not propose broader changes to implement site-neutrality including additional scaling factors instead of a

single overall scaling factor. Commenters stated that payment for nonexcepted items and services is still fundamentally based on OPPS payment rates. In response, CMS notes it does not currently develop as part of the PFS ratesetting process separate payment rates for the technical aspects of the full range of nonexcepted items and services furnished in nonexcepted off-campus PBDs, especially for services without separate PCs and TCs. Without this information, CMS states it does not have a consistent way for nonexcepted off-campus PBDs and the professionals who furnish services in these settings to bill for the respective portions of the services for which they incurred costs. CMS notes it continues to explore options that would allow hospitals to report nonexcepted items and services on an institutional claim form but receive payments that more directly reflect the technical aspect of services under the PFS.

CMS again acknowledges commenters concerns about the need to respond to two separate rules for policies associated with payment for nonexcepted items and services furnished in nonexcepted off-campus PBDs. It will consider these concerns for future rulemaking.

CMS intends to continue to examine the claims data to assess whether a different PFS Relativity Adjuster is needed and whether additional adjustments to the methodology are appropriate. CMS notes that it is 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, an increase in the share of nonexcepted items and services with lower technical-equivalent rates under the PFS compared with APC rates might result in a lower PFS Relativity Adjuster. It is also analyzing PFS claims data to identify patterns of services furnished together on the same day 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. CMS is also continuing to explore alternatives to the current methodology that would better reflect the TC of services furnished in nonexcepted off-campus PBDs.

CMS finalizes its proposals and maintains the PFS Relativity Adjuster at 40 percent for 2019 and beyond, until there is an appropriate reason and process for implementing an alternative to the current policy. For 2019, CMS also maintains the same policies as 2018 related to supervision rules, beneficiary cost sharing, geographic payment adjustments and partial hospitalization services.

G. Valuation of Specific Codes

The finalized work RVUs, work time and other payment information for all 2019 payable codes are available on the CMS website under downloads for the PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the final rule provide additional details:

- Table 13: 2019 Work RVUs for New, Revised, and Potentially Misvalued Codes;
- Table 14: 2019 Direct PE Refinements;

- Table 15: 2019 Invoices Received for Existing Direct PE Inputs;
- Table 16: 2019 New Invoices; and
- Table 17: 2019 No PE Refinements.

1. Methodology for Establishing Work RVUs

CMS reviews its methodology for proposing work RVUs, including potential information sources and specific approaches.[17] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values. [18] CMS concerns about RUC rationales and their underlying practitioner survey data have increased in recent years, most often centering on the incorporation of service times and time changes into specific work RVU proposals.

CMS discusses the methodology it uses for adjusting work RVU and/or time, including the methodology used when it believes there is overlap between a service typically furnished on the same day as an E/M service. The work RVU for a service is the product of the time involved with furnishing the service multiplied by the work intensity. CMS notes that the pre-service and post-service time have a long-established intensity of work per unit time (IWPUT) of 0.0224; thus, 1 minute of pre-service or post-service time equates to 0.0224 of a work RVU. Using this information, when CMS is concerned about overlap between a service and an E/M service, it generally removes 2 minutes of pre-service time and 2 minutes of post-service time from the procedure which results in removing a work RVU of 0.09 (4minutes x 0.0224 IWPUT).

In response to comments requesting clarification of the terms "reference services", "key reference services" and "crosswalks", CMS notes these are terms created by the specialty societies and the RUC and it did not agree to employ these terms in the identical fashion. In the interest of minimizing confusion, CMS will seek to limit the use of the term "crosswalk" to those cases where it makes a comparison to a CPT code with the identical work RVU.

2. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes. CMS specifically evaluates the methodology, data, and decision-making rationales

[17] Sources include the RUC (and RUC practitioner survey data), the HCPAC, other public commenters, medical literature, comparative databases, PFS code comparisons, Medicare claims data, and input from CMS and other federal government health care professionals. Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.

[18] Time is parsed into pre-service, intra-service, and post-service components, summing to the total time for each service. To assist in the development of pre-service time recommendations, the RUC created standardized pre-service time packages. There are pre-service time packages for services typically furnished in the facility setting and pre-service packages for services typically furnished in the nonfacility setting.

that accompany RUC recommendations, and it determines whether establishing facility or non-facility (or both) direct PE inputs are appropriate.

Table 14 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. CMS notes that, on average, in any case where the impact on the direct cost for a particular refinement is $0.30 or less, the refinement has no impact on the PE RVUs. CMS notes that nearly half of the refinements result in changes under the $0.30 threshold and are unlikely to result in a change to the RVUs.

Common CMS refinements to RUC recommendations are related to or triggered by the following:

- Changes in work component times (e.g., intra-service time, postoperative visit levels);
- Changes in equipment time (e.g., pre-service clinical task is performed outside of highly technical equipment rooms and is excluded from equipment time);
- Clinical labor task times that are inconsistent with standard times in the CMS direct PE input database or overlap with associated E/M visit clinical labor time;
- Recommended items that are not direct PE inputs (e.g. items that are not clinical labor, disposable supplies or medical equipment or cannot be allocated to individual services or patients);
- New supply or equipment items (e.g., when invoices lack sufficient information)[19];
- Clinical labor time in the facility minutes (i.e., facility payment is separate); and
- Application of the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap on imaging services.

CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations).

3. Valuation for Specific Codes

This section of the rule discusses finalized RVUs for 73 code groups. Highlights of CMS' discussion are summarized below; the numbering is consistent with the preamble format.

For many codes, CMS disagrees with the RUC-recommended work RVUs because of the decrease in physician time to perform the service. CMS does not believe that decreases in survey times equate to a one-to-one linear decrease in the valuation of work RVUs, but since the two components of work are time and intensity, significant decreases in time should be incorporated in decreases to the work RVUs. CMS also disagrees with commenters that all of the efficiencies gained in work time associated with improved

[19] CMS may add an item to the direct PE input database as a zero-price item to serve as a placeholder that is readily updated once accurate pricing information becomes available.

technology would be offset by higher intensity due to greater cognitive work by the practitioner. CMS notes that the incorporation of new technology can sometimes make services more complex and difficult to perform, but it can also have the opposite effect of making the service less dependent on manual skill and technique.

CMS also assigned an active status to the Category III code 0509T and finalized work RVU and direct PE inputs. CMS notes that it typically assigns contractor pricing for Category III codes since they are temporary codes. When there is an unusually high volume of services performed under a Category III code, however, CMS has assigned an active status to the procedure and developed RVUs before a formal CPT code is created. CMS believes the code should go through the regular vetting process that other new codes typically follows and will evaluate recommendations for work and PE inputs in the future.

The reader is referred to the final rule for more specific details.

1. Fine Needle Aspiration Codes: CPT codes 10021, 10004 - 10012, 76492, 77002, and 77021

In response to comments, CMS discusses concerns that the recommended work pool for these codes is increasing by approximately 20 percent, while the recommended work time pool for these codes is only increasing by about 2 percent. CMS believes that in general, the recoding of a family of services should maintain the same total work pool, as the services are not changing, only the coding structure for reporting is changing. CMS finalizes as proposed the work RVU and direct PE inputs for all of these codes.

2. Biopsy of Nail: CPT code 11755

In response to comments about the different specialties performing this service, CMS notes that it does not pay differentially for services on the basis of specialty and that a change in the dominant specialty does not impact interpretation of work time and work RVUs. After reviewing comments providing additional information about the risks inherent in the service, CMS finalizes the RUC-recommended work RVU and finalizes the proposed direct PE inputs for this code.

3. Skin Biopsy: CPT codes 11102 - 11107

In February 2017, the CPT Editorial Panel deleted codes 11100 and 11101 and created six new codes. After reviewing comments providing additional information about the work for this family of codes, CMS finalizes the RUC-recommended work RVUs for all the codes in the Skin Biopsy family. CMS finalizes the direct PE inputs as proposed except for the supplies from the three add-on procedures (CPT codes 11103, 11105, and 11107). In response to comments, CMS adds supplies to these add-on procedures.

4. Injection Tendon Origin-Insertion: CPT code 20551

CMS finalizes its proposal to maintain the current work RVU for this code. CMS does agree with comments that clinical staff time needs some refinement and finalizes the direct PE inputs to reflect these changes.

5. Structural Allograft: CPT codes 20932 – 20934

These three new add-on codes describe allografts that were revised to more accurately describe the structural allograft procedures. These codes are all facility-only procedures with no direct PE inputs. CMS finalizes the proposed work RVUs for these codes.

6. Knee Arthrography Injection: CPT code 27369

The CPT Editorial Panel deleted CPT code 27370 and replaced it with a new code, 27369, to report injection procedures for knee arthrography or enhanced CT/MRI knee arthrography. CMS finalizes the proposed work RVU and direct PE inputs.

7. Application of Long Arm Splint: CPT code 29105
8. Strapping of Lower Extremity: CPT codes 29540 and 29550
9. Bronchoscopy: CPT codes 31623 and 31624

CMS finalizes the proposed work RVUs and direct PE inputs for these codes.

10. Pulmonary Wireless Pressure Sensor Services: CPT codes 332X and 93XX1

The CPT Editorial Panel created a code to describe pulmonary wireless sensor implantation and another code for remote monitoring of patients with an implantable, wireless pulmonary artery pressure sensor monitor. CMS finalizes the proposed RUC-recommended work RVUs.

11. Cardiac Event Recorder Procedures: CPT codes 33285 and 33286

The CPT Editorial Panel created two new codes replacing cardiac event recorder codes to reflect new technology. CMS finalizes the proposed RUC-recommended work RVUs and direct PE inputs for these codes.

12. Aortoventriculoplastry with Pulmonary Autograft: CPT code 33440

The CPT Editorial Panel created one new code to combine the efforts of aortic valve and root replacement with subvalvular left ventricular outflow tract enlargement to allow for an unobstructed left ventricular outflow tract. CMS finalizes the proposed RUC-recommended work RVU and the proposed direct PE inputs for this code.

13. Hemi-Aortic Arch Replacement: CPT code 33866

The CPT Editorial Panel created one new add-on code to report hemi-aortic arch graft replacement. For 2019, CMS proposed the RUC-recommended work RVU of 19.74 for this code. In comments, the RUC noted that at the April 2018 RUC meeting, the specialty societies determined that the family of services encompassing CPT code 33866 should be submitted to the CPT Editorial Panel for revisions. Following that meeting, the RUC rescinded its interim value recommendation to CMS and recommended CMS consider the work RVU of 19.74 as an interim value. In response to this comment, CMS recognizes that the RUC rescinded its work RVU recommendation but notes that it longer establishes interim values on a routine basis and it is not convinced that an interim value for the code is necessary. CMS will review any new coding and recommendations provided for future rulemaking. CMS finalizes the proposed work RVU of 19.74.

14. Leadless Pacemaker Procedures: CPT codes 33274 and 33275

The CPT Editorial Panel replaced the five leadless pacemaker services Category III codes with the addition of two new CPT codes to report transcatheter leadless pacemaker procedures and revised five codes to include evaluation and interrogation services of leadless pacemaker systems. CMS disagrees with commenters that the proposed work RVUs were too low. CMS disagrees with a commenter that the newness of a procedure would provide a sufficient rationale for finalizing the RUC-recommended work RVUS for a new CPT code without any further consideration. CMS disagrees with commenters that it provided no qualitative or quantitative rationale to support its choice of a crosswalk to CPT code 33207. It agrees we commenters that CPT code 33274 is a more intense procedure, but is does not believe it should be valued almost a full RVU higher than the reference code given the fewer visits in the global period and the lower surveyed work time. CMS finalizes the proposed work RVUs and direct PE input for these codes.

15. PICC Line Procedures: CPT codes 36568, 36569, 36572, 36573, and 36584

This is another example where CMS is concerned that recoding of a family of services should not significantly increase the related RUC-recommended work pool. For these codes, the RUC-recommended work pool is increasing by approximately 68 percent for the PICC Line Procedures family as a whole, while the RUC-recommended work time pool for the same codes is only increasing by about 22 percent. CMS finalizes its proposal to maintain the current work RVU for this family of codes. After considering the additional information provided by commenters, CMS does not finalize its proposed direct PE refinements and instead finalizes the RUC-recommended direct PE inputs for all five codes.

16. Biopsy or Excision of Inguinofemoral Node(s): CPT code 38531

The CPT Editorial Panel created a new code to describe biopsy or excision of inguinofemoral node(s). This service was previously reported with unlisted codes. After consideration of comments, CMS finalizes its proposed RUC recommended work RVU for this code. CMS also finalizes its proposal to change the global status of this code from a 10-day global to a 90-day global.

17. Radioactive Tracer: CPT code 38792

CMS finalizes the proposed work RVU and direct PE inputs.

18. Percutaneous Change of G-Tube: CPT code 43760

Because this code will be deleted, CMS did not propose work or direct PE values.

19. Gastrostomy Tube Replacement: CPT codes 43762 and 43763

The CPT Editorial Panel created two new codes that describe replacement of gastrostomy tube, with and without revision of gastrostomy tract, respectively. CMS finalizes the proposed work RVUs and direct PE inputs for these codes.

20. Diagnostic Proctosigmoidoscopy- Rigid: CPT code 45300

CMS finalizes the proposed work RVU and direct PE inputs.

21. Hemorrhoid Injection: CPT code 46500

CMS finalizes the proposed work RVU. Based on the additional information provided by commenters about the clinical staff activities, CMS finalizes the RUC-recommended direct PE inputs for this code, with the exception of its refinement to the CA035 clinical labor activity and standard equipment time refinements.

22. Removal of Intraperitoneal Catheter: CPT code 49422

After consideration of comments, CMS finalizes the RUC-recommended work RVU.

23. Dilation of Urinary Tract: CPT codes 50436, 50437, 52334, and 74485

After consideration of comments, CMS finalizes its proposed work RVUs and direct PE inputs for these codes. CMS also finalizes its proposal to exempt CPT code 52334 from the phase-in list for codes with significant PE RVU reductions. Section 1848(c)(7) of the Act, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE and MP RVUs shall be phased in over a 2-year period. Since significant coding revisions within a family of codes can change the relationship among codes, CMS excludes codes from the phase-in when there are significant revisions to the code family to help maintain the appropriate rank order among codes in the family (80 FR 70927 through 70929).

24. Transurethral Destruction of Prostate Tissue: CPT codes 53850, 53852, and 53854

The CPT Editorial Panel created a new code to report transurethral destruction of prostate tissue by radiofrequency-generated water vapor thermotherapy. The family of codes was reviewed. After consideration of comments, CMS finalizes the RUC-recommended work RVUs and direct PE inputs for these three codes.

25. Vaginal Treatments: CPT codes 57150 and 57160
26. Biopsy of Uterus Lining: CPT codes 58100 and 58110
27. Injection Greater Occipital Nerve: CPT code 64405
28. Injection Digital Nerves: CPT code 64455

CMS finalizes the proposed work RVU and direct PE inputs for these codes.

29. Removal of Foreign Body – Eye: CPT codes 65205 and 65210

CMS disagrees with commenters that CMS should not use intraservice time ratios for work evaluation and reiterates that it is required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. CMS also disagrees with commenters that think it should not compare proposed to existing values for determining the integrity of the relative value system. CMS notes that if it were to operate under the assumption that previously recommended work times had been routinely underestimated, this would undermine the entire relativity of the work RVUs. CMS reiterates its belief that it would be irresponsible to ignore changes in time based on the best data available. CMS finalizes the proposed work RVUs and direct PE inputs for these codes.

30. Injection-Eye: CPT codes 67500, 67505, and 67515

CMS finalizes the proposed work RVUs for CPT codes 67500 and 67505. CMS finalizes the RUC-recommended work RVU for CPT code 67515. CMS finalizes the proposed direct PE inputs for all codes.

31. X-Ray Spine: CPT codes 72020, 72040, 72050, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120

With approval from the RUC Research Subcommittee, the specialty societies responsible for reviewing these codes did not conduct surveys but employed a "crosswalk methodology". For these codes CMS proposed an alternative approach to the valuation of work RVUs. CMS maintains the 2018 work RVUs for these codes. CMS finalizes the proposed direct PE inputs for these codes.

32. X-ray Sacrum: CPT codes 72200, 72202, and 72220
33. X-ray Elbow-Forearm: CPT codes 73030, 73080, and 73090
34. X-ray Heel: CPT code 73650

CMS maintains the 2018 work RVUs for this code. CMS finalizes the proposed direct PE inputs.

35. X-ray Toe: CPT code 73660

CMS maintains the 2018 work RVU for this code. CMS finalizes the proposed direct PE inputs with the exception of the patient gown (SB026) supply that was identified by commenters as not a typical supply.

36. X-ray Esophagus: CPT codes 74210, 74220, and 74230
37. X-ray Urinary Tract: CPT code 74420
38. Fluoroscopy: CPT code 76000

CMS finalizes it proposed work RVU and direct PE inputs for these codes.

39. Echo Exam of Eye Thickness: CPT code 76514

CMS disagrees with commenters that this code requires more intensive cognitive work by the practitioner. CMS notes that while the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. For CPT code 76514, CMS believes the technician is now performing the work previously performed by the practitioner. CMS finalizes it proposed work RVU and direct PE inputs.

40. Ultrasound Elastography: CPT codes 76981 – 76983

The CPT Editorial Panel created three new codes describing the use of ultrasound elastography to assess organ parenchyma and focal lesions. The most common use of this code set will be preparing patients with diseases of solid organs or lesions within solid organs. CMS finalizes the proposed work RVUs for these codes. CMS does not finalize its proposed direct PE inputs and instead finalizes the RUC-recommended direct PE inputs for these codes.

41. Ultrasound Exam – Scrotum: CPT code 76870

CMS finalizes it proposed work RVU and direct PE inputs.

42. Contrast-Enhanced Ultrasound: CPT codes 76978 and 76979

The CPT Editorial Panel created two new CPT codes describing the use of intravenous microbubble agents to evaluate suspicious lesions by ultrasound. CMS states it was persuaded by commenters that this new technology involved higher technical skill and time than other established ultrasounds. Instead of finalizing the proposed work RVUs for these codes, CMS finalizes the RUC-recommended work RVUs. CMS also finalizes the RUC-recommended direct PE inputs, with the exception of the refinement to the phosphate buffered saline (SL180) supply.

43. Magnetic Resonance Elastography: CPT code 76391

The CPT Editorial Panel created a new stand-alone code describing the use of magnetic resonance elastography for the evaluation of organ parenchymal pathology. This code will most often be used to evaluate patients with diseases of solid organs (e.g., liver cirrhosis) within solid organs that manifest with increasing fibrosis or scarring. After consideration of comments, CMS finalizes it proposed work RVU and direct PE inputs.

44. Computed Tomography (CT) Scan for Needle Biopsy: CPT code 77012

CMS finalizes it proposed work RVU and direct PE inputs.

45. Dual-Energy X-Ray Absorptiometry: CPT code 77081

CMS finalizes it proposed RUC-recommended work RVU.

46. Breast MRI with Computer-Aided Detection: CPT codes 77046 -77049

CPT codes 77058 and 77059 were identified as potentially misvalued in 2016 using a high expenditure services screen across specialties with Medicare allowed charges of $10 million or more. As a result, the CPT Editorial Panel examined this family of codes. When preparing to survey these codes, the specialties noted that the clinical indications had changed for these codes. Subsequently, the CPT Editorial Panel deleted the original codes and created four new CPT codes to report breast MRI with and without contrast (including computer-aided detection).

This code family included five new equipment items. CMS did not receive any invoices for these items and proposed to use crosswalks to similar equipment items as proxies for three of these items:

- CAD software (ED058) is crosswalked to flow cytometry analytics software (EQ380);
- Breast coli (EQ388) is crosswalked to breast biopsy device (coil) (EQ371); and
- CAD Workstation (CPU + Color Monitor) (ED056 is crosswalked to Professional PACS workstation (ED053),

CMS welcomed submission of invoices with pricing information for these three new equipment items to replace the use of proxies.

For the other two equipment items (CAD Server (ED057) and CAD-Software- Additional User License (ED059)), CMS did not propose prices because it believes these items would be included in the indirect PE methodology. CMS acknowledged that the use of software and other forms of digital tools is complex and believes these items are indirect costs, similar to office rent or administrative expenses. CMS believes that advances in technology have occurred but this does not change the statutory requirement to assign indirect PE on the basis of costs that must be individually allocable to a particular patient for a particular service.

CMS appreciates the submission of additional invoices. After consideration of public comments, CMS finalizes the RUC-recommended work RVUs for these codes. CMS finalizes the direct PE inputs as proposed, with the updates to the pricing of the new equipment based on the additional invoices.

47. Blood Smear Interpretation: CPT code 85060
48. Bone Marrow Interpretation: CPT code 85097

CMS finalizes the proposed work RVU and direct PE inputs for these codes.

49. Fibrinolysins Screen: CPT code 85390

CMS finalizes its proposal to accept the RUC-recommended work RVU for this code.

50. Electroretinography: CPT codes 92X71, 92X73, and 0509T

The specialty society noted that the code was being inappropriately used for a less intensive version of the test and that CPT changes were necessary to ensure appropriate utilization of the code. The CPT Editorial Panel deleted the code and created two new codes to describe electroretinography full field and multi focal. A category III code was retained for pattern electroretinography. CMS proposed pricing for the Category III code.

In response to comments, CMS notes that it typically assigns contractor pricing for Category III codes since they are temporary codes. When there is an unusually high volume of services performed under a Category III code, CMS has assigned an active status to the procedure and developed RVUs before a formal CPT code is created. The information provided by the RUC indicates that approximately 80 percent of the services currently reported using CPT code 92275 (estimated 100,000 services for 2019) would be reported under the new Category III code. Therefore, CMS assigned an active status to Category III code 0509T. CMS agrees that the code should go through the regular vetting process that other new codes typically follows and will evaluate recommendations for work and PE inputs in the future. After consideration of comments, CMS finalizes the proposed work RVUS for these codes. CMS also finalizes the proposed direct PE inputs, with the exception of the addition of one minute of CA011 clinical labor activity.

51. Cardiac Output Measurement: CPT codes 93561 and 93652

After consideration of comments, instead of finalizing the proposed work RVUs for these codes CMS finalizes the RUC-recommended work RVUs.

52. Coronary Flow Reserve Measurement: CPT codes 93571 and 93572

After consideration of comments, CMS finalizes its proposed work RVUs for these codes.

53. Peripheral Artery Disease (PAD) Rehabilitation: CPT code 93668

Before CMS issued a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy for the treatment of PAD, this CPT code was assigned a noncovered status under the PFS. This code now has an active status. CMS used the most recent RUC-recommended work and direct PE inputs for this code and requested the RUC to review these values. CMS finalizes its proposed RUC-recommended work RVUs and direct PE inputs for this code. CMS notes that if commenters believe an additional RUC review is appropriate, it would consider this information or recommendations from other stakeholders for future rulemaking.

54. Home Sleep Apnea Testing: CPT codes 95800, 95801, and 95806

Because of rapid group in service, the CPT Editorial Panel flagged these codes and the RUC recommended that these services should be reviewed. CMS disagrees with commenters that the incorporation of new technology making these services more complex and difficult to perform, offsets all the efficiencies associated with the new technology. CMS finalizes the proposed work RVUs and direct PE input for these codes.

55. Neurostimulator Services: CPT codes 95970, 95976, 95977, 95983, and 95984

In 2014, the RUC recommended that CPT codes 95971, 95972 and 95974 be referred to the CPT Editorial Panel to address the time referenced in the CPT code descriptors for the entire family of codes. The CPT Editorial Panel revised and deleted codes and created four new codes. As part of this review, the CPT Editorial Panel differentiated between simple and complex programming: simple programming of a neurostimulator pulse generator/transmitter is the adjustment of one to three parameter(s) and complex programming is the adjustment of more than three parameters. CMS finalizes the proposed work RVUs and direct PE input for these codes.

56. Psychological and Neuropsychological Testing: CPT codes 96105, 96110, 96116, 96125, 96127, 96112, 96113, 96121, 96130 – 96133, 96136 – 96139, and 96146

Because of changes in testing practices and technologic advances there was confusion about how to report these codes and the entire family of codes was referred for revision to the CPT Editorial Panel. CMS finalizes the proposed work RVUS for these codes. CMS also finalizes the proposed direct PE inputs, with the exception of refinement to the CA021 clinical labor for CPT codes 96136 and 96137 (the addition of ten minutes of CA011 clinical labor activity).

57. Electrocorticography: CPT code 95836)

CPT code 95829 is used for the electrocorticogram performed at the time of surgery. A new code was needed to account for the non-face-to-face service for a review of a month's worth or more of stored data. Several commenters stated that although the

specialty society did not submit any direct PE inputs, the code could be performed in both the nonfacility and facility setting. Commenters understood there would be no direct staffing, equipment or supply costs associated with this service and that indirect costs would be similar regardless of the setting. CMS finalizes the proposed RUC-recommended work RVU for this code. CMS does not finalize any direct PE inputs, but in response to comments, it will value the code in both the facility and nonfacility settings.

58. Chronic Care Remote Physiologic Monitoring: CPT codes 99453, 99454, and 99457

In the 2018 PFS final rule, CMS indicated that there would be new coding describing remote monitoring from the CPT Editorial Panel and the RUC. For 2019, there are three new codes to describe remote physiologic monitoring and management.

Several commenters disagreed with the proposal to remove the "Monthly cellular and licensing fee" supply from CPT code 99454. Commenters stated the fee was a direct PE input because the fee is not a license for the entire practice but it is an individual allocable fee for the period the patient is monitored. Commenters stated that reliance upon a patient's cellular connectivity or WIFI, which may or may not be operating, based on patient technology capabilities, was not reliable for medical purposes. CMS disagrees and continues to believe that these data costs are appropriately captured in the indirect PE methodology. CMS also notes that other services that require around-the-clock monitoring, such as the home PT/INR monitoring described in HCPCS code G0249 does not include additional direct PE inputs for data costs.

In response to commenters requesting clarify about the kinds of technology covered under these CPT codes, CMS notes it plans to issue guidance to help practitioners and stakeholders on these issues. CMS finalizes the proposed RUC-recommended work RVU for CPT code 99457 and the direct PE inputs as proposed.

59. Interprofessional Internet Consultant: CPT codes 99451, 99452, and 99446 - 99449

In 2017, the CPT Editorial Panel revised four codes and created two codes to describe interprofessional telephone/internet/electronic medical record consultation services. These CPT codes are currently assigned a procedure code status of B (bundled) and are not separately payable under Medicare. The CPT Editorial Panel revised these codes to include electronic health record consultations, and the RUC reaffirmed the work RVUs for these codes. With changes in medical practice and technology, CMS proposed to change the procedure status for CPT codes 99446 – 99449 from B (bundled) to A (active) and proposed the RUC work recommendations for these codes.

The CPT Editorial Panel also created two new codes for interprofessional internet consultation. CMS proposed the RUC-recommended work RVU for CPT code 99452 but proposed a work RVU of 0.50 for CPT code 99451. There were no recommended direct PE inputs for this family of codes (discussed in section II.A of this summary). CMS

finalizes the RUC-recommended work RVUs for this family of codes. CMS notes that these codes are payable in both facility and non-facility services.

60. Chronic Care Management Services: CPT code 99491

The CPT Editorial Panel created CPT code 99491 to describe situations when the billing practitioner is doing the care coordination work that is attributed to clinical staff in CPT code 99490 (Chronic care management services). CMS does not finalize its proposal and instead finalizes the RUC-recommended work RVU. CMS notes that this code is for use when the billing practitioner personally performs care management services and cannot be furnished incident to a practitioner.

61. Diabetes Management Training: HCPCS codes G0108 and G0109
62. External Counterpulsation: HCPCS code G0166
63. Wound Closure by Adhesive: HCPCS code G0168
64. Removal of Impacted Cerumen: HCPCS code G0268

CMS finalizes the proposed work RVU and direct PE inputs for these codes.

65. Structured Assessment, Brief Intervention, and Referral To Treatment for Substance Use Disorders: HCPCS codes G0396, G0397, and G2011

In the 2008 PFS final rule (72 FR 66371), CMS created two G-codes (G0396 and G0397) to allow for Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services, but are performed in the context of the diagnosis or treatment of illness or injury. Medicare contractors were instructed to pay for these codes only when the services were considered reasonable and necessary.

CMS was concerned that the relatively low utilization of these services is due, in part, to the service-specific documentation requirements for these codes.[20] CMS believes that removing the additional documentation requirements will ease the administrative burden. CMS welcomed comments on its proposal to eliminate the service-specific documentation requirements for HCPCS codes G0397 and G0398. CMS finalizes its proposal to eliminate the service specific documentation requirements for these codes.

CMS also finalizes its proposal to create a third HCPCS code GSBR1, with a lower time threshold in order to accurately account for the resource costs when practitioners furnish these services, but do not meet the requirements of the existing code. CMS finalizes the code descriptor as: "(Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST), and brief intervention, 5-14 minutes)".

66. Prolonged Services: HCPCS code GPRO1

In response to stakeholders concerns that the time thresholds for CPT codes for prolonged service are too long and as part of CMS' proposal to implement a single PFS rate for E/M visits 2-5, CMS proposed HCPCS code GPRO1: Prolonged E/M or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other

[20] The current requirements can be found at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf.

outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient E/M or psychotherapy service). This code could be billed with any level of E/M code.

CMS notes that as almost all commenters did not support the overall E/M coding and payment proposals, it did not receive many comments with specific suggestions on this code. For 2021, it finalizes this proposed code and the proposed valuation. CMS will consider, through rulemaking, this code and its valuation in the context of any potential changes to CPT codes and recommendations as part of the annual process for valuing PFS services.

67. Remote Pre-recorded Services: HCPCS code GRAS1

CMS finalizes its proposal for HCPCS code GRAS1: Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment. CMS also finalizes its proposal to value this service by a direct crosswalk to CPT code 93793 (Anticoagulation management for patient taking warfarin).

68. Brief Communication Technology-based Service (e.g. Virtual Check-in): HCPCS code GVC11

CMS finalizes its proposal for HCPCS code GVC11: Brief communication technology based service, e.g. virtual check-in, by a physician or other qualified health care professional who may report E/M 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 also finalizes its proposal to value this service based on CPT code 99411 (Telephone E/M services), which is currently not separately payable under the PFS.

69. Visit Complexity Inherent to Certain Specialist Visits: HCPCS code GCG0X

CMS proposed HCPCS code GCG0X: Visit complexity inherent to E/M associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an E/M visit). CMS proposed crosswalking this code to 75 percent of the work RVU and time of CPT code 90785 (Interactive complexity), an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient.

CMS notes that as almost all commenters did not support the overall E/M coding and payment proposals, it did not receive many comments with specific suggestions on this code. For 2021, it finalizes this proposed code and the proposed valuation. CMS will consider, through rulemaking, this code and its valuation in the context of any potential

changes to CPT codes and recommendations as part of the annual process for valuing PFS services.

70. Visit Complexity Inherent to Primary Care Services: HCPCS code GPC1X
CMS proposed HCPCS code GCG1X: Visit complexity inherent to E/M associatedwith 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 E/M visit).

CMS agrees with commenters' suggestion that CMS equalize the value for the primary care add-and the add-on code for specialty visits. For 2021, CMS finalizes the add-on visit for this code using the inputs for HCPCS code GCG0X. CMS will consider, through rulemaking, this code and its valuation in the context of any potential changes to CPT codes and recommendations as part of the annual process for valuing PFS services.

71. Podiatric E/M Services: HCPCS codes GPD0X and GPD1X
CMS proposed HCPCS code GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) and HCPCS code GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient). CMS is not finalizing its proposal to create podiatric E/M services.

72. Comment Solicitation on Superficial Radiation Treatment Planning and Management
CMS discussed the concerns that stakeholders have raised associated with the coding and reimbursement associated with superficial radiation treatment (SRT) delivery. In the 2018 PFS proposed rule, CMS proposed to make separate payments for the professional planning and management associated with SRT using HCPCS code GRRR1. Many commenters did not support this proposal and were concerned it would represent a significant payment reduction. CMS did not finalize this proposal and solicited further comments about this issue.

CMS continues to believe that there are potential coding gaps for SRT-professional services. CMS acknowledges that deferring to the CPT process to address potential coding gaps is generally preferable and that its previous attempt at designing a coding solution did not gain stakeholder consensus.

For 2019, CMS is not proposing any coding or payment policies for SRT-related professional codes. CMS requested comments on the following related issues:

- Creating multiple G-codes specific to services associated with SRT, including codes to separately report services including SRT planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management, and medical physics consultation;
- Creating separate G codes to separate report services to mirror the coding ofother types of radiation treatment delivery; and

- Creating separate codes for professional services associated with SRT in a coding structure parallel to radiation treatment delivery service such as HCPCS code G6003.

CMS was also interested in whether codes should be included in the 2019 PFS and whether these codes should be contractor priced for 2019. CMS notes this proposal would be an interim approach until the CPT Editorial Panel and the RUC could develop a coding solution that could be addressed in future rulemaking.

Many commenters urged CMS to make appropriate payment for SRT-related services and that the coding should recognize new generation Image Guided Superficial Radiation (IGSRT). Some commenters recommended implementation of G-codes for SRT-related professional services and submitted alternative G-codes. A commenter stated that any codes using SRT delivery should require a qualified medical physicist perform the physics work. Commenters disagreed on whether or not CMS should adopt contractor-priced G codes. Many commenters urged CMS not to change coding for 2019.

After consideration of comments, CMS is not making any changes to payment policy for SRT. CMS will take these comments into consideration for future rulemaking. CMS reiterates its belief that multi-specialty input through the CPT and the RUC is the ideal way to develop coding specificity and evaluation. CMS refers readers to CPT guidance that states that CPT code 77401 may be reported with appropriate E/M codes, and this is the appropriate way to currently report professional work associated with SRT. CMS states it will attempt to determine whether MACs are inappropriately denying billing of E/M codes with CPT code 77401 and will instruct MACS accordingly.

73. Adaptive Behavior Analysis Services: CPT codes 97151 – 95158

These codes are formerly contractor priced Category III CPT codes that were converted to Category I for 2019. CMS assigned these codes to a contractor price status in Addendum B. CMS inadvertently excluded these codes in the Addendum B file of the proposed rule and updated the Addendum B file for this final rule.

H. Evaluation & Management (E/M) Visits

1. Background: E/M Visit Codes and Documentation Guidelines

Physicians (and nonphysician practitioners) of nearly all specialties and disciplines have encounters with patients for the purposes of evaluation and management. E/M services account for a very high proportion of PFS allowed charges: 40 percent for all E/M services and 20 percent for office/outpatient E/M services only. E/M visits are reported to Medicare and other payers using CPT codes that reflect site of service, extent of physician effort, and patient complexity but that are not specialty-specific. E/M services share three key components irrespective of service site -- History of Present Illness (History), Physical Examination (Exam), and Medical Decision Making (MDM) – but the number of visit code levels varies across sites (e.g., five levels for office visits and three levels for hospital inpatient visits). Within each site-specific code subset, higher visit levels are associated with increasing physician effort, patient complexity, and/or

encounter time as well as with higher provider payments. E/M coding patterns vary substantially across practitioner specialties and practice settings.

Medical record documentation for each visit must indicate the medical necessity for the encounter and include information consistent with the site and level of visit of the billed CPT code. Medicare's documentation expectations by visit level based on the three key components are described in the 1995 and 1997 E/M Documentation Guidelines (DGs) and incorporate terminology from the E/M CPT code descriptors (e.g. problem-focused history).[21] The DGs also provide for visit level selection based on time (instead of key components), when counseling and/or coordination of care account for more than 50 percent of the encounter.

CMS repeatedly has expressed reservations about E/M service payment accuracy and whether existing E/M code descriptors and DGs capture changes in clinical practice (e.g., team-based care), care delivery processes (e.g., electronic health records) and beneficiary disease burden (e.g., multiple chronic conditions). CMS has been particularly concerned that current E/M codes, DGs, and payments disproportionately undervalue primary care and thereby seriously impede Medicare's transition to value-based care. CMS has sought input in multiple venues and has heard consistently from numerous stakeholders that the codes and DGs are outdated and that the primary care payments are inadequate. Stakeholders also have become increasingly frustrated with regulatory burden imposed upon practitioners to comply with DGs developed two decades ago (e.g., requirements for extensive history-taking or physical examination that now add little to information obtained through readily available advanced imaging). However, having participated in several failed E/M service reform projects, CMS has been mindful of the wide-ranging impacts and possible unintended consequences of extensive E/M service changes.[22] Recent CMS efforts have been more narrowly focused on identifying and fixing coding and payment gaps most commonly encountered in modern primary care such as transitional care services, chronic care management, and behavioral health integration.

2. CY 2019 E/M Proposals, Responses, and Final Actions

a. General Considerations

CMS proposed to continue a stepwise approach to E/M service reform for 2019, emphasizing burden reduction through changes to the DGs rather than to the existing codes and primarily addressing only the Office/Other Outpatient family of services (CPT codes 99201-99205 for new patient visits and CPT codes 99211-99215 for established

[21] See https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf ; https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf; and the Evaluation and Management Services guide at https://www.cms.gov/Outreach-and-Education/Medicare-Learning- Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf .

[22] Factors contributing to failure of prior DG revision attempts have included lack of stakeholder consensus and differing perspectives on whether code revaluation would be necessary as a result of revising the guidelines.

patient visits). Substantive reductions in required documentation for office visits and increased flexibility in visit level selection were linked, however, to significant payment changes. Proposed payment changes included setting a uniform office visit base payment regardless of visit level and to which several new add-on codes could be appended, and applying a multiple procedure payment reduction (MPPR) when an office visit is billed with one or more minor procedures performed by the same physician on a single day. CMS also proposed reducing home visit documentation and solicited comments on allowing separate same-day office visit billing by two physicians of the same specialty.

CMS notes that several thousand commenters responded to the E/M change proposals, with most expressing appreciation for efforts intended to reduce burden and to modernize payment for E/M services. Several proposals (e.g., reducing duplicative medical record documentation) received broad support, but objections were widespread to most of the payment changes (e.g., setting a single payment rate for office visit levels 2 through 5) and the 2019 implementation timeline. Many commenters urged CMS to defer finalizing payment changes while working with the medical community and other stakeholders to develop alternative proposals.

b. Specific Proposals and Final Actions

Home visit justification. CMS proposed to eliminate the Medicare Claims Processing Manual requirement for specific documentation of the medical necessity for furnishing a visit in the home rather than in the office. CMS and commenters agreed that choosing the optimal site of service is a physician judgment that should not trigger additional documentation rules. CMS finalizes removing the requirement for home visit justification as proposed effective January 1, 2019.

Same-Day visit billing prohibition. CMS did not propose changes but did solicit comments about future modification or elimination of the Medicare Claims Processing Manual provision prohibiting two separately-paid office visits on a single day by the same physician or by two physicians of the same specialty in a single group practice. Medical necessity for such same day visits was thought to be rare. More recently, stakeholders have provided CMS with some clinically appropriate examples that typically arise because of increasing physician subspecialization that is not captured through Medicare's physician enrollment specialty list. CMS notes receiving many comments that will be considered during future rulemaking.

Decreasing redundant documentation. Both the 1995 and 1997 DG versions permit a physician furnishing an office visit to review, update, and acknowledge entries for Review of Systems (ROS) and Past, Family and/or Social History (PFSH) already documented and available in the medical record, rather than requiring re-recording of such information. CMS proposed to similarly permit simplified physician documentation (review, update, and acknowledge rather than re-recording) of the remaining history and exam elements for office visits furnished to established patients. Commenters strongly supported this proposal and recommended its rapid implementation. CMS finalizes the simplified documentation of history and exam for established patients as proposed

effective January 1, 2019. CMS also proposed that simplified documentation requirements be applied to record entries already made about the chief complaint and other history elements by ancillary staff or the beneficiary for both new and established office visits. Commenters were very supportive of rapid adoption of this change, and CMS finalizes the change as proposed effective January 1, 2019. CMS adds that simplified documentation will be optional, noting that physicians may choose to continue their current recording processes to allow time to update their record templates and clinical workflows. Finally, CMS indicates that responses received about the potential for simplified MDM documentation were limited but will be incorporated into future discussions on this topic.

Podiatry Visit Codes. In conjunction with office visit payment change proposals (discussed further below), CMS proposed that podiatrists would report their visits using new, more specific G-codes (GPD0X and GPD1X for new and established patients, respectively) in lieu of current, more generic CPT visit codes. The proposed documentation changes and visit level selection options for CPT office visit codes also would be applied to the new podiatric G-codes wherever applicable. CMS received no comments on documentation of the services described by the G-codes. CMS concludes that the absence of comments reflects the general lack of support for creating these codes and for their associated proposed payment changes. CMS is not finalizing creation of podiatric visit G-codes nor any rules for documenting such services. Finally, CMS is not finalizing the proposed valuations for the podiatric visit G-codes.

Flexible Approaches to Visit Level Selection and Documentation. Stakeholders have repeatedly voiced concerns about requiring office visit level selection based upon DGs that are increasingly outdated, not aligned with current healthcare delivery systems, and for which compliant documentation is extremely burdensome. CMS proposed to allow flexibility by allowing physicians to choose 1) the current framework (1995 or 1997 DGs); 2) MDM alone, using relevant criteria from the existing DGs (e.g., number and nature of presenting problems); or 3) time alone (total face-to-face physician-patient encounter time), as a basis for accurately determining levels for their office visits. The use of time would no longer be limited to those office visits wherein counseling and/or coordination of care accounts for more than 50 percent of the total face-to-face time. CMS believed that the proposed flexibility would 1) allow physicians to appropriately tailor their documentation and visit level selection to their specialties and their individual practice circumstances, and 2) reduce Medicare's impact on the standardized recording of history, exam and MDM data in medical records. Physicians would be free to choose their preferred approach for each office visit furnished. The proposed associated payment changes for E/M office services (discussed further below) would be applicable regardless of the approach to level selection chosen. In conjunction with those payment changes, CMS proposed to set the minimum documentation audit standard at that of a level 2 office visit (for a new or established patient, as applicable); the same level 2 standard would be used when auditing levels 2 through 5 office visits regardless of the level reported on the claim. The level 2 documentation requirements for auditing a visit would be based upon the visit level selection approach chosen for that visit (i.e., current framework key components, MDM criteria only, or total face-to-face time alone). CMS

proposed to implement the proposals for flexibility in level selection and documentation and the minimum level 2 audit standard beginning January 1, 2019.

Flexibility to choose level selection and documentation approaches were supported by some but not all commenters. Several worried about degrading the utility of the medical record by introducing too much variation in medical record format and content. Many commenters found the proposals for billing based solely on either MDM or time insufficiently detailed to permit confident, reliable coding, particularly when adding prolonged services codes to office visit codes. Other commenters were concerned about potential abuse of time-based coding, while some supported time as a useful coding guide for their specialties. Many commenters opposed the minimum level 2 audit standard, citing CMS overestimation of burden reduction, operational challenges and costs (e.g., updating EHRs), and introducing disparities between Medicare's standards and those of other payers. Notably, commenters concerned about diverging standards included some payers and payer associations.

Additionally, commenters overwhelmingly opposed the proposed payment policy changes to which the flexibility and minimum audit proposals are linked, and CMS will defer implementing finalized but modified payment changes (discussed below) until January 1, 2021. As a result, CMS is finalizing the proposals providing flexible office visit level selection and documentation with modifications and clarifications. For 2019 and 2020, the framework associated with the current DGs will continue to dictate visit level selection and audit standards. Beginning in 2021, selection of office visit levels 2 through 5 may be made using the current framework, MDM, or time. Reference times will be the "typical times" as described in the CPT office visit codes (e.g., currently 15 minutes for a level 3 established patient visit CPT code 99213). Also starting in 2021, physicians may choose their documentation methodology for each visit (current framework, MDM, or time) for level 2 through 5 visits. Finally, for 2021 and subsequent years, the audit standard for level 2 through 4 visits will be set to the minimum level 2 standard. Level 5 visits will be audited against the level 5 criteria of the visit selection approach chosen by the physician for a given visit (e.g., level 5 MDM criteria).

Multiple service payment reduction. CMS believes that duplicative resource allocation (and overpayment) occurs when a physician furnishes both an E/M office visit and a minor procedure (i.e., having a 0-day or 10-day global period) to a single beneficiary on the same day. In this situation, CMS proposed that a 50% payment reduction be applied to the least expensive of the multiple services provided (office visit or procedure). This proposal is similar to CMS' longstanding Multiple Procedure Payment Reduction (MPPR) policy for same day 90-day global procedures (a 50% reduction applied to the second and subsequent procedures). CMS further proposed to maintain budget neutrality by reallocating the 6.7 million RVUs saved by the proposed multiple service adjustment to newly-proposed add-on codes for additional resources for primary care and non-procedural specialty visits (discussed further below).

Although MedPAC supported the proposed payment reduction, most commenters were strongly opposed. Some cited the existing restrictions on visit/procedure combination

reporting already imposed by requirements for use of the -25 modifier and others noted the accounting for resource overlap that occurs during the RUC valuation process for minor procedures. Objections were raised that extension of the MPPR policy to a visit/procedure combination was inappropriate and commenters noted the absence of an explicit rationale for setting the proposed reduction at 50%. CMS disagrees that resource overlap is accurately accounted for by -25 modifier usage requirements and the RUC valuation process or that building upon the existing MPPR is unreasonable. CMS, however, notes with great concern comments from physician societies and patient advocacy groups indicating that the proposed reduction will create a perverse incentive for physicians to maintain reimbursement levels by scheduling the office visit and the minor procedure on different days. Commenters also worried about incentivizing fractured rather than coordinated care and about the inconvenience of sequential appointments impairing the beneficiary's experience of care. CMS remains convinced that resource duplication is occurring when E/M services and minor procedures are combined but is also persuaded by broad stakeholder consensus about the likely though unintended consequence of splitting the visit/procedure combination into separate appointments. Therefore, CMS is not finalizing the proposed reduction to payment when E/M visits are combined with minor procedures on a single day. CMS states an intention to further consider approaches to accounting for overlapping resources without impairing beneficiary access to appropriate care, as well as strategies for discouraging scheduling manipulations primarily designed to increase physician reimbursement.

Payment simplification and burden reduction. Having approached the previously identified deficiencies in E/M coding through simplified documentation, CMS similarly chose to address concerns about E/M payment through "simplified payment". CMS believed that the proposed payment changes would also reduce documentation burden. CMS proposed to pay a single rate for level 2 through 5 office visits, one rate for each of the new and established patient code families. Inputs for determining the proposed blended code rates were based on Medicare claims data from CY 2012 - CY 2017 and the rates for levels 2 through 5 for 2019 were projected to be $135 for new patients and $93 for established patients. Burden reduction would occur as documentation previously required to distinguish among visit levels would be reduced to the proposed level 2 audit standard and the volume of audit activities would decrease.

Commenters shared CMS' belief that current E/M coding and DGs are seriously flawed but nearly all strongly opposed the payment simplification proposal. Common objections included highly variable consequences at the specialty, practice, and individual physician levels; payment rates that inherently are not resource-based; impacts upon other payers who incorporate the Medicare RBRVS into their rate-setting methods; and failure to account for resources required to treat the most complex beneficiaries, with potential unintended consequences of limiting their access to care or of inducing fragmentation of their care into multiple shorter visits. Many commenters urged CMS to await the work already underway to revisit E/M office visit coding (e.g., by the AMA and its committees).

While continuing to support the rationale for the proposed payment simplification, CMS acknowledges that the proposal insufficiently accounted for resource costs incurred in caring for the most complex patients (for whom level 5 visits are typical), thereby impairing payment accuracy for all office visits. CMS notes that levels 3 and 4 visits together account for about 75 percent of all new patient office visits and nearly 90 percent of all established visits, so that blended payment rates for levels 2 through 4 accurately reflect resources expended in their care. CMS, therefore, finalizes the proposal to simplify payment with modifications for implementation beginning January 1, 2021 and consisting of:

- a single blended payment rate for levels 2 through 4 based upon inputs derived using frequency-weighted claims data from the preceding five years, and
- individual payment rates for levels 1 and 5 based on current inputs.

Table 21 from the rule lists the inputs that CMS will use in rate development; the inputs could require adjustment for interval events such as CPT code changes or future legislative provisions. CMS concludes by noting that the finalized implementation timeframe will allow time for CMS responses to interval work done by stakeholders.

Table 21: Finalized Inputs for E/M Office/Outpatient Codes for 2021

HCPCS	Physician Time	Work RVU	Malpractice RVU	Sum of Direct PE Inputs
99201	17.00	0.48	0.05	**$13.97**
99202	34.43	1.76	0.17	**$24.37**
99203	34.43	1.76	0.17	**$24.37**
99204	34.43	1.76	0.17	**$24.37**
99205	67.00	3.17	0.28	**$30.92**
99211	7.00	0.18	0.01	**$11.31**
99212	30.26	1.18	0.08	**$20.41**
99213	30.26	1.18	0.08	**$20.41**
99214	30.26	1.18	0.08	**$20.41**
99215	55.00	2.11	0.14	**$27.83**

Recognizing added resource costs. Medicare claims data support that E/M visits are furnished by nearly all specialties but represent a greater share of total allowed services for physicians who do not routinely furnish procedural interventions or diagnostic tests (e.g., primary care physicians, neurologists, endocrinologists, and rheumatologists). Therefore, documentation burden may be disproportionately high for physicians furnishing primary care and nonprocedural specialty office visits. Claims data also show that the most common primary care office visit furnished is at level 4 and that nonprocedural specialist office visits are most often submitted at levels 4 and 5. Based upon their office visit practice patterns, CMS believed that primary care and nonprocedural specialist physicians would be disproportionately negatively affected by the proposed blended office visit rates for levels 2 through 5. CMS proposed new, add-on, G-codes to provide additional resources (beyond the new blended rates) to account for the greater extent and complexity of resources required to deliver primary care and nonprocedural specialty care services (GPC1X for primary care and GCG0X for

nonprocedural specialty care). GPC1X would be applicable to levels 2 through 5 established patient visits, while GCG0X could be added onto new and established patient levels 2 through 5 visits. No specific documentation requirements were proposed for the G-codes.

Many commenters requested clarification of the definition of primary care services that could trigger appropriate use of GPC1X, particularly when such services are performed by physicians from other than traditional primary care specialties. CMS responds that the primary care nature of a visit generally will be easily inferred from the diagnoses, physician specialty identifier, and management plan as contained on the claim and/or in the medical record. The American Academy of Family Practice (AAFP) provided a definition of primary care services and stated that services furnished by practitioners outside of the "core primary care specialties" do not meet the definition. The AAFP also stated that GPC1X also should be applicable to new patients. Other commenters questioned the disparity between the proposed inputs for valuating GCP1X versus those for GCG0X. The AAFP also opposed the creation of GPC1X, suggesting instead a 15 percent payment increase to physicians who self-designate as family medicine, internal, medicine, pediatrics, or geriatrics practitioners. CMS agreed that GPC1X should be applicable to new patients and should have the same resource inputs as CGC0X.

Many commenters did not support an add-on payment for nonprocedural specialty care resources. Objections included insufficient explanation by CMS for selecting specialties to be included in the descriptor of GCG0X; specialty-specific payment is prohibited by statute; suggestions for additional specialties that merited inclusion; and questioning the link between Medicare enrollment specialty and patient complexity. Other commenters objected conceptually to using add-on codes to make payment adjustments and/or found the adjustment to be insufficient to compensate for the proposed blended office visit payments. Multiple commenters were concerned about potential new documentation burden associated with using GCG0X. CMS anticipates that in most cases the diagnoses, physician specialty identifier, physician billing history, and management plan as contained on the claim and/or in the medical record will provide sufficient documentation for appropriate use of GCG0X but further states that physicians of specialties not listed in the code descriptor may more often need to add specific documentation for their use of this code.

CMS finalizes the proposals for codes and payments for GPC1X and GCG0X with modifications:

- the descriptors for these two codes will be modified as reflected in Table 22 (e.g., adding specialties to GCG0X);
- both codes will be applicable to new and established patient levels 2 through 4 visits;
- valuations for the two codes will be derived using identical resource inputs (i.e., those proposed for valuing GCG0X);
- clarifying that both codes could be appended to a single visit in very rare circumstances; and

- the finalized codes and valuations will be implemented beginning January 1, 2021.

Table 22: Finalized Code Descriptors for Visit Complexity Add-ons	
HCPCS	**Descriptor**
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 level 2 through 4 office/outpatient evaluation and management visit, new or established)
GCG0X	Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology. (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established)

Coding for Extended Services. In response to stakeholder feedback about the challenges in using existing prolonged face-to-face service CPT codes with office visits (e.g., duration of additional time required to bill compliantly), CMS proposed a new, add-on G-code GPRO1 that would require 30 minutes of additional effort (rather than the hour of existing CPT code 99354) and proposed a work value based on one-half of the work for CPT code 99354. Many commenters supported this proposal as an isolated change that should be rapidly implemented. Other commenters raised questions about required documentation, what duration of office visit would trigger applicability of GPRO1, and details about measuring the additional time. CMS responds that face-to-face time but no additional documentation would be required. After considering several approaches to measuring visit duration and add-on code time, CMS finalizes the new, add-on code GPRO1and its proposed valuation with modifications and clarifications:

- the code will be renamed "extended" rather than "prolonged" service; the valuation is finalized without change;
- the code is applicable to new and established levels 2 through 4 office visits;
- time will be measured as total face-to-face time of the visit (i.e., overall duration) and will be defined as a time range (illustrated in Table 24A and derived from averaging intraservice times for levels 2 through 4 office visits and adding the 15 minute-midpoint of the extended service code's duration); and
- the finalized code will be available for reporting beginning January 1, 2019.

Table 24A: Minutes Spent on Extended Outpatient Visits (Established and New Patients)					
Established Patient			New Patient		
Level	Minutes Spent	Codes reported	Level	Minutes Spent	Codes Reported
1	N/A		1	N/A	
2	34-69	99212/3/4+extended services G-code	2	38-89	99203/4/5+extended services G-code
3			3		
4			4		
5	70+	99215+99354	5	90+	99205+99354

Practice Expense per hour (PE/HR) Calculation Adjustment. CMS noted that establishing a single blended 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 proposed to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes discussed above) of approximately $136, based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. Many commenters noted significant, if unintended, consequences of this proposal throughout the entire PFS. Most also stated that insufficient information was provided by CMS about the methodology used and actual calculations to further comment meaningfully. After considering these objections, CMS is not finalizing a separate PE/HR for E/M office visits.

Alternatives Considered. CMS states having considered multiple other options for simplifying coding, documentation, and payment for E/M services in general and office visits in particular. CMS refers to the proposed rule wherein the alternative of blended payment rates for levels 2 through 4 new and established patient office visits while maintaining separate level 5 payment was discussed (83 FR 35847). Reasons for not selecting that alternative initially included maintaining outdated coding and documentation distinctions; less accurate accounting for resource costs for various visit types; and greater need for program integrity mechanisms required to distinguish among compliant usage of more visit levels. CMS solicited comments about the alternative of using the patient relationship code modifiers developed to satisfy MACRA requirements and that are available for voluntary reporting as of January 1, 2018 as an approach to E/M payment adjustments. Opposition was voiced by the AAFP who stated that the patient relationship modifiers were not designed to reflect visit complexity or to adjust payment.

c. Impacts

CMS presents estimates of the specialty level impacts of the E/M payment and coding policies as finalized for 2021 implementation, calculated as if they were implemented for 2019 in Table 24C. Impact estimates reflect adoption of blended payment rates for levels 2 through 4 and established patient office visits, keeping separate rates for level 5 visits, and implementing add-on codes of equal rates to account for resources required to

furnish primary care and nonprocedural specialty care visits. Overall impacts would generally increase payments for specialties who disproportionately report lower level visits and for those who often perform minor procedures on the same day as office visits. Payment decreases to specialties that predominantly furnish higher level visits would be significantly mitigated by the add-on G-codes for additional primary care and nonprocedural specialty resources and the continued availability of level 5 visit codes and associated payments. Finally, CMS notes that the overall number of RVUs allocated to E/M office services will be increased relative to other PFS services and would very likely trigger a budget neutrality adjustment to the PFS conversion factor.

TABLE 24C: Estimated Specialty Level Impacts of Final E/M Payment and Coding Policies if Implemented for 2019

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$239	0%	0%	0%	0%
Anesthesiology	$1,981	-1%	0%	0%	-2%
Audiologist	$68	-1%	1%	0%	0%
Cardiac Surgery	$294	-1%	-1%	0%	-2%
Cardiology	$6,618	-1%	-1%	0%	-2%
Chiropractor	$754	-1%	0%	0%	-1%
Clinical Psychologist	$776	-1%	1%	0%	0%
Clinical Social Worker	$728	-2%	2%	0%	0%
Colon And Rectal Surgery	$166	0%	1%	0%	0%
Critical Care	$342	-2%	-1%	0%	-3%
Dermatology	$3,486	1%	3%	0%	4%
Diagnostic Testing Facility	$733	0%	-5%	0%	-5%
Emergency Medicine	$3,121	-2%	-1%	0%	-2%
Endocrinology	$482	-1%	-1%	0%	-2%
Family Practice	$6,208	1%	1%	0%	2%
Gastroenterology	$1,757	-2%	-1%	0%	-3%
General Practice	$429	2%	1%	0%	3%
General Surgery	$2,093	0%	0%	0%	-1%
Geriatrics	$197	-1%	-1%	0%	-1%
Hand Surgery	$214	1%	1%	0%	3%
Hematology/Oncology	$1,741	0%	-1%	0%	0%
Independent Laboratory	$646	-1%	3%	0%	3%
Infectious Disease	$649	-1%	-1%	0%	-1%
Internal Medicine	$10,767	0%	0%	0%	0%
Interventional Pain Mgmt	$868	1%	2%	0%	3%
Interventional Radiology	$386	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$149	-1%	-1%	0%	-2%
Nephrology	$2,190	-1%	-1%	0%	-2%
Neurology	$1,529	-1%	0%	0%	-1%
Neurosurgery	$804	-1%	-1%	0%	-1%
Nuclear Medicine	$50	-1%	-1%	0%	-3%
Nurse Anes / Anes Asst	$1,242	-2%	0%	0%	-2%
Nurse Practitioner	$4,065	2%	1%	0%	3%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Obstetrics/Gynecology	$638	2%	2%	0%	5%
Ophthalmology	$5,448	-1%	-2%	0%	-3%
Optometry	$1,309	0%	-1%	0%	-1%
Oral/Maxillofacial Surgery	$68	0%	0%	0%	1%
Orthopedic Surgery	$3,743	0%	1%	0%	1%
Other	$31	-1%	3%	0%	2%
Otolarngology	$1,210	3%	3%	0%	5%
Pathology	$1,165	-1%	-1%	0%	-2%
Pediatrics	$61	1%	0%	0%	1%
Physical Medicine	$1,107	-1%	0%	0%	-2%
Physical/Occupational Therapy	$3,950	-1%	-2%	0%	-3%
Physician Assistant	$2,457	2%	1%	0%	4%
Plastic Surgery	$377	0%	0%	0%	1%
Podiatry	$1,974	4%	6%	0%	10%
Portable X-Ray Supplier	$99	0%	0%	0%	0%
Psychiatry	$1,187	3%	2%	0%	5%
Pulmonary Disease	$1,715	-1%	-1%	0%	-2%
Radiation Oncology And Radiation Therapy Centers	$1,766	-1%	-1%	0%	-1%
Radiology	$4,911	-1%	-1%	0%	-2%
Rheumatology	$541	0%	-1%	0%	-1%
Thoracic Surgery	$358	-1%	-1%	0%	-2%
Urology	$1,738	2%	3%	0%	4%
Vascular Surgery	$1,148	0%	-2%	0%	-2%
TOTAL	$92,771	0%	0%	0%	0%

d. Emergency Department and Other E/M Visit Settings

CMS confirms that no changes will be made at this time to inpatient E/M codes due to concerns about the interaction with the hospital conditions of participation. CMS further confirms that no changes are being made to the E/M codes for emergency department visits because of a large variety of concerns (including medical-legal ones) raised in public comments in the 2018 PFS rule. CMS reiterates the possibility of expanding reform efforts more broadly to additional sections of the E/M visit code set in future years.

e. Implementation Date

CMS proposed to implement its new polices effective January 1, 2019 but indicated a willingness to consider delaying implementation and invited comments. Most commenters urged CMS not to finalize many of the proposals and to at least delay implementation of many changes; 2019 implementation was supported for proposals to eliminate home visit justification and to reduce redundant history and physical examination data entry in the medical record. Delay would allow for modifications to record templates and clinical workflows as well as physician education and office staff retraining. Several commercial insurers and EHR-related associations commented that

the industry would need more time to prepare, with some recommending delay until the necessary IT structure is in place. Other insurer concerns included impaired ability to understand the actual complexity of care being delivered to their enrollees; disincentivizing care of complex patients; and eliminating medical record information used to inform payments, risk adjustments, and HEDIS scores. Some insurers recommended that CMS work with the AMA on alternative policies.

CMS responses include finalizing for 2019 the home visit justification and medical record documentation redundancy proposals; not finalizing extending the MPPR policy to visits combined with same-day minor procedures; and modifying and delaying the finalized payment changes until January 1, 2021.

I. Teaching Physician Documentation Requirements for Evaluation and Management Services

CMS proposed to revise the regulations for teaching physician documentation to require 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. Extensive and often duplicative record entries made personally by the teaching physician would no longer be required. Most commenters were very supportive; a few were concerned that the reduced requirements might lessen the involvement of the teaching physician. CMS notes that the teaching physician remains responsible for the beneficiary's care and for the accuracy of information in the medical record about that care. CMS finalizes the proposal without modification through changes to §§415.172(b) and 415.17.

J. GPCI Comment Solicitation

CMS revises the GPCIs every 3 years. The next GPCI update will be next year for the CY 2020 PFS. Commenters have raised concerns about the accuracy of the residential rent data source that CMS uses as a proxy for the physician office rent component of the practice expense GPCI. CMS will continue efforts to identify a nationally representative commercial rent data source.

CMS requested comments on potential sources of commercial rent data for potential use in the next GPCI update for CY 2020**.** CMS acknowledges the comments it received and will consider these for future rulemaking.

K. Therapy Services

1. Repeal of the Therapy Caps

From 1998 through 2017, therapy services were subject to annual per beneficiary cap on expenditures. There was one cap for physical therapy (PT) and speech language pathology (SLP) services and another cap for occupational therapy (OT) services. The

caps were initially equal to $1,500 per year. In subsequent years, the cap was increased by the Medicare Economic Index (MEI).

Section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) repealed the caps effective January 1, 2018. However, the new law also requires that a modifier be included on the Medicare claim once the prior therapy cap amounts have been reached. For 2018, therapy providers are required to use the KX modifier when annual per beneficiary expenditures exceed $2,010 for PT and SLP services combined, and $2,010 for OT services. After the beneficiary's incurred expenditures for outpatient therapy services exceed these thresholds, claims for outpatient therapy services without the KX modifier are denied.

Along with the KX modifier thresholds, the law retains a medical review (MR) process. Under the prior process, all claims for therapy services above $3,700 were subject to manual medical review. Under the revised process, the law establishes a targeted MR process for therapy services above $3,000. The $3,000 threshold is retained until 2028 at which time it is indexed annually by the MEI. The MR threshold is $3,000 for PT and SLP services and $3,000 for OT services. The law retains the provider liability procedures which first became effective January 1, 2013, extending limitation of liability protections to beneficiaries who receive outpatient therapy services, when services are denied for certain reasons, including failure to include a necessary KX modifier.

2. Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

BBA of 2018 established a provision that requires therapy services that are furnished in whole or in part by a therapy assistant to be paid at 85 percent of the PFS amount on or after January 1, 2022. The provision only applies to therapy services paid under the PFS (such as to therapists in private practice, outpatient hospitals, rehabilitation agencies, skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities). The provision does not apply to critical access hospitals.

CMS did not believe SLPs use therapy assistants and only proposed to require modifiers when services are furnished in whole or in part by a physical therapist assistant (PTA) or an occupational therapist assistant (OTA). Section 1834(v)(2)(B) of the Act requires that each
bill submitted for an outpatient PT or OT service furnished in whole or in part by a therapy assistant on or after January 1, 2020, must include the established modifier even though the payment reduction will not apply until January 1, 2022.

CMS proposed to define "therapy assistant" as an individual who meets the personnel qualifications set forth at §484.4 of the regulations for a PTA and OTA, respectively. It also proposed that the two new therapy modifiers would be used to identify services furnished in whole or in part by a PTA or an OTA; and, that these new therapy modifiers would be used instead of the GP and GO modifiers that are currently used to report PT and OT services delivered under the respective plan of care.

Effective for dates of service on and after January 1, 2020, CMS proposed that five therapy modifiers will be used to track outpatient therapy services instead of the current three. These five therapy modifiers include two new therapy modifiers to identify PT and OT services furnished by PTAs and OTAs, respectively, and three revised therapy modifiers – GP, GO and GN − that will be used when PT, OT, and SLP services, respectively, are fully furnished by therapists or when fully furnished by or incident to physicians and non-physician practitioners (NPPs include physician assistants, nurse practitioners and clinical nurse specialists). CMS proposed the following:

- New-PT Assistant services modifier (to be used instead of the GP modifier currently reported when a PTA furnishes services in whole or in part): Services furnished in whole or in part by a physical therapist assistant under an outpatient physical therapy plan of care;
- New-OT Assistant services modifier (to be used instead of the GO modifier currently reported when an OTA furnishes services in whole or in part): Services furnished in whole or in part by occupational therapy assistant under an outpatient occupational therapy plan of care;
- Revised GP Modifier-Services fully furnished by a physical therapist or by or incident to the services of another qualified clinician–physician or NPP−under an outpatient physical therapy plan of care;
- Revised GO Modifier-Services fully furnished by an occupational therapist or by or incident to the services of another qualified clinician–physician or NPP−under an outpatient occupational therapy plan of care; and
- Revised GN Modifier- Services fully furnished by a speech-language pathologist or by or incident to the services of another qualified clinician–physician or NPP−under an outpatient speech-language pathology plan of care.

CMS anticipated allowing voluntary reporting of the new modifiers at some point during 2019, which it planned to announce to contractors and therapy providers through a Change Request, as part of the usual change management process.

PTAs and OTAs are not permitted by law to furnish therapy services “incident to” a physician or NPP service in an office setting. Therefore, the new PTA and OTA therapy modifiers could not be used when the rendering practitioner is a physician or NPP.

Based on its proposal, the new therapy modifiers would be required to be used whenever a PTA or OTA furnishes all or part of any covered outpatient therapy service. CMS proposed to define “in part,” to mean any minute of the outpatient therapy service that is therapeutic in nature, and that is provided by the PTA or OTA when acting as an extension of the therapist. This definition would exclude non-therapeutic services such as scheduling the next appointment, greeting and gowning the patient, preparing or cleaning the room.

CMS received numerous comments on these issues. Of particular importance, several commenters opposed the structure proposed for the modifiers. The commenters noted that under the proposed structure new PTA-and OTA-specific systems would need to be

duplicated creating confusion. Instead, these commenters proposed to add the new therapy assistant modifiers to the same claim line of service alongside the existing GP and GO modifiers. They argued that this would eliminate the administrative burden on therapists since only therapy assistants would be required to use the new modifiers and charge systems could remain hardcoded to default to GP or GO modifiers. CMS agrees with these commenters and is not finalizing the new modifiers for therapy assistant services as therapy modifiers. Instead, CMS will use the two new modifiers for therapy assistant services as a type of payment modifier used alongside of, instead of replacing, the GP and GO therapy modifiers, to identify the services furnished in whole or in part by PTAs or OTAs that will be tied to the reduced payment for the respective PT or OT discipline in CY 2022.

Many commenters expressed concerns about different aspects of its proposed interpretation of the statutory reference to services furnished "in whole or in part" by PTAs and OTAs. In its review of section 1834(v)(1) of the Act, CMS believes that the phrase "in part" could be read to mean that if a therapy assistant participates only in a very small (so insubstantial as to not be meaningful) portion of the service, the discounted payment rate would not apply. Specifically, CMS believes it would be appropriate to specify that a therapy assistant is considered to furnish a therapy service "in part" when they perform more than 10 percent of the service. CMS provides an example that the modifiers apply when more than 10 percent of a service is furnished by the therapy assistant, 1.5 minutes of a 15-minute unit could be furnished by the PTA or OTA without being subject to the discounted payment rate.

In summary, CMS finalizes the establishment of two modifiers, one to identify services furnished in whole or in part by PTAs and the other to identify services furnished in whole or in part by OTAs. CMS also finalizing its proposal to define PTAs and OTAs as those individuals meeting the personnel qualifications set forth in part 484.

Instead of finalizing the new modifiers to identify services furnished by PTAs and OTAs as therapy modifiers, CMS adopts a final policy to use these new modifiers as a payment modifier that will be appended on the same line of service with the respective PT or OT therapy modifier. This modified approach necessitates revisions to the proposed descriptors of the new CQ and CO modifiers, and allows CMS to proceed without making the proposed revisions to the current descriptors for the three therapy modifiers − GP, GO and GN. CMS finalizes the new payment modifiers as follows.

- CQ Modifier: Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- CO Modifier: Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

CMS is not revising the three therapy modifiers as it had proposed. Instead, CMS will continue in effect, unmodified, as follows:

- GP – services delivered under an outpatient physical therapy plan of care.

- GO − services delivered under an outpatient occupational therapy plan of care.
- GN − services delivered under an outpatient speech-language pathology plan of care.

Instead of finalizing its proposed definition of a service that is furnished in whole or in part by a PTA or OTA as a service for which any minute of a therapeutic service is furnished by a PTA or OTA, CMS finalizes a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA. CMS anticipates addressing application of the therapy assistant modifiers and the 10 percent standard more specifically, including their application for different scenarios and types of services, in rulemaking for CY 2020.

3. Proposed Functional Reporting Modifications

Since January 1, 2013, all providers of outpatient therapy services, including PT, OT, and SLP services, have been required to include functional status information on claims for therapy services. In response to the Request for Information (RFI) on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), CMS received comments requesting burden reduction related to the functional reporting requirements that were adopted to implement the requirements of section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act (MCTRJCA) of 2012, effective January 1, 2013.

CMS goes through the history of functional reporting and its detailed requirements as well as the public comments that it has received requesting that the agency share the reporting results and suggesting changes to make it less burdensome. The majority of commenters urged CMS to substantially revise and repurpose functional reporting requirements for other programmatic purposes or to eliminate the functional reporting requirements altogether.

In response to these comments, CMS indicated that it has reviewed and analyzed the functional reporting data internally but did not find the results particularly useful in considering how to reform payment for therapy services as an alternative to the therapy caps. For this reason, CMS has not publicly shared functional reporting results. In the meantime, section 50202 of BBA of 2018 reformed therapy payment by eliminating the therapy caps. Because section 3005(g) of MCTRJCA was not codified into the Act and did not specify how long functional reporting should last, CMS does not believe that functional reporting was intended to last indefinitely.

Given that functional reporting is overly complex and burdensome to report and that continuing to collect more years of these functional reporting data will not be helpful to inform future analyses, CMS proposed to discontinue the functional reporting requirements for services furnished on or after January 1, 2019. Accordingly, with the conclusion of the functional reporting system for dates of service after December 31, 2018, CMS proposed to eliminate the applicable regulations that require functional reporting as a condition of payment, make the relevant claims processing systems edits to

no longer require functional reporting, and delete the applicable non-payable HCPCS G-codes specifically developed to implement functional reporting.

Many commenters supported the proposal to eliminate the functional reporting requirements for outpatient therapy services and urged CMS to end these requirements for reporting and documenting the G-codes. CMS notes that its documentation instructions continue to require therapists document in the beneficiary's medical record, either evaluation or in the plan of care, measurable beneficiary physical function.

After consideration of the public comments, CMS finalizes its proposed changes to discontinue the functional reporting requirements for outpatient therapy services furnished on or after January 1, 2019. Specifically, CMS removes the following regulatory requirements: (1) conditions of payment at §§410.59(a)(4), 410.60(a)(4), 410.62(a)(4), and 410.105(d) that require claims for OT, PT, SLP, and Comprehensive Outpatient Rehabilitation Facility (CORF) PT, OT, and SLP services, respectively, to contain prescribed information on patient functional limitations; and, (2) the functional reporting-related phrase that requires the plan's goals to be consistent with functional information on the claim at §410.61(c) for outpatient PT, OT, and SLP services and at §410.105(c)(1)(ii) for the PT, OT, and SLP services in CORFs. In addition to amending these regulations, CMS is ending the requirements for the reporting and documentation of functional limitation G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and severity modifiers (in the range CH through CN) for outpatient therapy claims with dates of service on and after January 1, 2019.

Instead of deleting the HCPCS G-codes effective for CY 2019 as proposed, CMS finalizes a modification of that proposal to retain the set of 42 non-payable HCPCS G-codes until CY 2020. CMS explains that this will allow time for therapy providers and other private insurers who currently use these HCPCS G-codes for purposes of functional reporting to update their billing systems and policies. This will also ensure that claims that inadvertently contain any of these G-codes during 2019 can be processed, and are not unnecessarily returned or rejected. In addition, the retention of HCPCS G-codes through 2019 will also allow physical and occupational therapists to report six of these non-payable HCPCS G-codes and the measures developed from them for purposes of meeting the MIPS program requirements which are found in section III.I.3. of this final rule.

CMS states that it also intends to revise its manuals regarding the application of the functional reporting requirements in our IOM, Pub. 100-02, Medicare Benefits Policy Manual, Chapters 12 and 15, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 5.

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

Consistent with the statutory provisions in section 1847A of the Act, many Part B drug payments are based on the Average Sales Price (ASP) methodology and, by statute, include an add-on payment of 6 percent of the ASP amount. Some Part B drugs are based

on wholesale acquisition cost (WAC) such as single-source drugs without ASP data. The add-on percentage for drug payments made under section 1847A of the Act is typically applied to the ASP; in certain situations, the same 6 percent add-on is also applied to the WAC for Part B drug payments. Payment for Part B drugs may be based on WAC and the 6 percent add-on payment in the following situations:

- For single source drugs, payment is made using the lesser of ASP or WAC (section 1847A(b)(4) of the Act) and a 6 percent add-on payment is required to be applied regardless of whether WAC or ASP is less (section 1847A(c)(4)).
- For drugs and biologicals where ASP price data is unavailable during the first quarter of sales, the Secretary may determine the payment amount for the drug or biological based on the WAC or payment methodologies in effect on November 1, 2003 (section 1847A(c)(4) of the Act). CMS notes this provision does not specify that an add-on percentage be applied if WAC based-payment is used, nor is an add-on percentage specified in the implementing regulations (§419.904(e)(4)).[23]
- When Medicare Administrative Contractors (MACs) determine pricing for drugs that do not appear on the ASP pricing files and for new drugs.[24]

CMS discusses the statutory differences in the incorporation of discounts in ASP and WAC. As defined in section 1847A(c)(3) of the Act, the ASP is net of many discounts such as volume discounts, prompt pay discounts, cash discounts, and rebates (other than rebates under the Medicaid drug rebate program). In contrast, as defined in section 1847A(c)(6)(B) of the Act, WAC is defined as the manufacturer's list price for the drug or biological to wholesalers or direct purchases in the US, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available as reported in wholesale price guides or other publications of drug or biological pricing date. Because WAC-based pricing does not include discounts, it typically exceeds the ASP.

CMS and others, including MedPAC,[25] the Office of the Assistant Secretary for Planning and Evaluation (ASPE),[26] and the OIG,[27] have raised concerns about the use of a 6 percent add-on payment for both ASP and WAC, especially since this add-on payment for expensive drugs may create an incentive for the use of more expensive drugs. The June 2017 MedPAC Report to Congress included a recommendation to reduce WAC-based payment to WAC plus 3 percent.

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[23] A discussion of the application of the add-on payment to WAC-based payments during a period where partial ASP data is available in the 2011 PFS final rule (75 FR 73465 through 73466).
[24] This is discussed in the Medicare Claims Processing Manual: Chapter17, Section 1.3.
[25] The MedPAC June 2017 Report to Congress is available at http://www.medpac.gov/docs/default-source/reports/june17_reporttocongress_sec.pdf.
[26] The ASPE March 8, 2016 Issue Briefing is available at https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives.
[5]The OIG report is available at https://oig.hhs.gov/oei/reports/oei-12-13-00040.asp.

CMS proposed that effective January 1, 2019, WAC based payments for Part B drugs made under section 1847A(c)(4) of the Act utilize a 3 percent add-on payment in place of the 6 percent add-on payment that is currently applied. CMS noted that a fixed percentage is consistent with other provisions of section 1847A of the Act that specify fixed add-on percentage of 6 percent (1847A(b)) or 3 percent (section 1847A(d)(3)(C)). This proposal was also consistent with recent MedPAC recommendations. If this proposal were finalized, CMS would also make the changes in the Claims Processing Manual to allow MACs to use an add-on percentage of up to 3 percent for WAC-based new drugs.

To conform the regulation text more closely to the statutory language at section 1847A(c)(4) of the Act, CMS proposed to strike the word "applicable" from §414.904(e)(4) to describe the payment methodologies in effect on November 1, 2003.

CMS noted this proposal does not include WAC-based payments for single source drugs under section 1847A(b) of the Act; this provision of the statute specifies that the payment is 106 percent of the lesser of ASP or WAC. In addition, this proposed policy would not alter the OPPS payment limit (95 percent of the published Average Wholesale Price (AWP)).

Many commenters expressed concerns about the proposed add-on reduction, including concerns that because of the sequester reduction the proposed lower add-on would result in an add-on payment of 1.35 percent. CMS understands these concerns but notes that the proposed changes is based on Medicare payment policy and is independent of the sequestration.

In response to comments that the 6 percent markup is intended to account for specific costs, such as handling, storage and other administrative expenses, CMS states that neither Section 1847 of the ACT nor the accompanying Conference Report (see Conference Report on H.R. 1, November 20, 2003), discuss the purpose of the 6 percent add-on. In addition, CMS notes there is no consensus on the intent of the add-on.[28] In addition, CMS believes that if the add-on is intended to account for administrative complexity, handling, storage and other overhead costs these factors are not considered to be exactly proportional to current drug prices. CMS notes that the application of the 6 percent add-on results in large dollar payments for new drugs that are proportional to the price of the drug and that overhead costs for most new drugs and biological are generally comparable to the overhead costs for most other injectable Part B drugs. In general, CMS does not believe that this reduction will reduce margins for Part B drugs to an extent that would significantly and negatively affect providers.

In response to concerns about the potential negative effects on patients, including fewer physician offices providing new drugs and shifts to hospital outpatient departments, CMS believes that the scope of these changes is modest and the brief reduction in payments

[28] MedPAC Report to Congress: Medicare and the Health Care Delivery System June 2016, http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0, page 127).

will not impair access to new drugs or shift patient care to other settings. In addition, the reduction in the WAC-based payment add-on can positively impact beneficiaries out of pocket costs.

In response to comments, CMS acknowledges that ASP-based payments may exceed payments based on WAC if the percentage for the WAC add-on is smaller than the ASP add-on. CMS notes it does not have the authority to change the add-on for WAC based payments made under section 1847A(b)(4) of the Act or payments based on the ASP. CMS also acknowledges that manufacturers may increase Part B drug prices and that price increases could apply to both list prices like WAC and market prices, such as ASP. CMS plans to continue ongoing work to address concerns about high drug prices.

After consideration of comments, CMS finalizes its proposal to reduce the add-on percentage for WAC based payments for new drugs. Effective January 1, 2019, WAC based payments for new Part B drugs made under section 1847A(c)(4) of the Act, will utilize a 3 percent add-on. This change does not apply to single source drugs or biological paid under section 1847A(b)(4) of the Act where payment is made using the lesser of ASP or WAC; section 1847A(b)(1) of the Act requires that a 6 percent add-on be applied regardless of whether WAC or ASP is less.

Several commenters also opposed CMS' intent to make corresponding changes to Chapter 17 of the Medicare Claims Processing Manual that would apply a 3 percent add-on payment determination made by MACS for new drugs and biological. CMS notes that the discussion in the proposed rule was intended to provide notice of a potential corresponding subregulatory change to align with the proposed regulatory policy. Because the policy has been finalized, CMS will issue Manual instructions addressing contractor pricing for new Part B drugs. CMS states that it plans to utilize a variable percentage that would use an add-on payment that is up to 3 percent to address the wide range of Part B drug prices. CMS notes that section 1847(A)(c)(5) of the Act provide CMS authority to issue program instructions to implement section 1847A of the Act.

M. Potential Model for Radiation Therapy

Section 3(b) of the Patient Access and Medicare Protection ACT (PAMPA) required the Secretary of HHS to submit to Congress a report on the development of an episodic APM for payment under the Medicare program under title XVIII of the Act for radiation therapy (RT) services furnished in non-facility settings. In this Report to Congress, delivered in November 2017, CMS discusses the current status of RT services and payment, and reviewed model designs for a potential APM for RT services.[29]

CMS believes that radiation oncology is a promising area for bundled payments and will continue to use public information and stakeholder feedback to develop, design a test a potential model for RT services under the authority of section 1115A of the Act.

[29] Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services. https://innovation.cms.gov/Files/reports/radiationtherapy-apm-rtc.pdf.

III. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule

1. Background

Under a provision of law implemented January 1, 2018, CMS sets clinical laboratory fee schedule (CLFS) rates based on the weighted median of private payer rates reported by "applicable laboratories." CMS collects data from applicable laboratories every three years. Applicable laboratories will next report private payer rates from January 1, 2020 through March 31, 2020 for services furnished between January 1, 2019 to June 30, 2019.

An applicable laboratory is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA)) that bills Medicare Part B under its own National Provider Identifier (NPI) and receives more than 50 percent of its Medicare revenues during the 6-month data collection period from the PFS and CLFS. Using authority provided in the statute, CMS exempts clinical laboratories receiving less than $12,500 in Medicare revenues for CLFS services during the 6-month data collection period from having to report private payer rates.

In the proposed rule, CMS discussed stakeholders concerns that 2018 CLFS payments rates are based on reporting from a relatively small number of laboratories and does not reflect payment rates for most hospital-based laboratories. Other stakeholders were concerned that the low expenditure threshold excluded most physician office laboratories and many small independent laboratories from reporting.

In response to stakeholder feedback and in the interest of facilitating this goal, CMS solicited public comments on other approaches that would provide more applicable information to use in establishing CLFS payment rates.

2. Changes to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

CMS proposed to remove payments from Medicare Advantage (MA) plans from the denominator of the fraction that is used to determine whether a laboratory received more than 50 percent of its revenues from PFS and CLFS services (the numerator in the majority of Medicare revenues threshold calculation). CMS believed that excluding MA plan revenues from total Medicare revenues will result in more laboratories of all types meeting the majority of Medicare revenues threshold and reporting private payer rates. If finalized, CMS would revise paragraph (3) of the definition of applicable laboratory at §414.502 accordingly. CMS provided a summary of the distribution of reported records from the first data collection period (Table 25) and noted that this proposal might not impact the CLFS because the largest laboratories with the highest test volumes will continue to dominate the weighted median of private payor rates.

The proposed rule stressed that its proposed policy of considering MA plan revenues as "private payor" payments would only be applicable for this provision and would have no

bearing on how CMS considers MA plan payments in other contexts. CMS has taken this position because section 1834A(a)(8)(B) defines a "Medicare Advantage plan under Part C" as a type of private payor for reporting of private payor rates. CMS believed it is more logical to consider MA plan payments as non-Medicare both for determining applicable laboratory status and for reporting private payor rates.

Many commenters supported this proposal. Some stakeholders objected to this proposal because it would increase the administrative reporting burden for additional laboratories without having a perceptible impact on CLFS. These commenters agreed with CMS' observation that this proposal might not impact the CLFS but would increase burden. In response, CMS states it estimates that excluding MA plan payments from total Medicare revenues (the denominator) of the majority of Medicare revenues threshold, and keeping the numerator constant (revenues from the CLFS and/or PFS) yielded an increase of 49 percent in the number of laboratories meeting the majority of Medicare revenues threshold. CMS clarifies that although it did state that it did not expect the additional reported data to have a predictable direct impact on CLFS rates, it cannot predict whether the additional applicable laboratories reporting applicable information are paid at a higher or lower private payor rate as compared to other laboratories that previously reported and whether the private payor rate volume of services performed by these additional applicable laboratories is significant enough to make as impact on the weighted median of private payor weights. CMS believes that receiving additional applicable information from more laboratories of all laboratory types outweighs the additional reporting burden on laboratories.

CMS finalizes its proposal to modify the definition of applicable laboratories to exclude MA plan revenues from total Medicare revenues (the denominator of the majority of Medicare revenues threshold and revises the definition of applicable laboratory at §414.502, paragraph (3).

A commenter recommended that CMS also remove prescription drug payments under Medicare Part D from the description of total Medicare revenues in the applicable laboratory definition. The commenter stated that including Part D payments is illogical because there is no circumstance under which such payments would be related to laboratory testing. CMS will take the commenter's suggestion into consideration for future refinements but notes if the commenter is correct, then whether or not Part D payments are included or excluded from the denominator would have no effect on the calculation.

3. Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

CMS continues to consider additional refinements to its policies that could lead to including even more applicable information for the next data-reporting period. To that end, in the proposed rule, CMS considered alternative approaches suggested by stakeholders for defining an "applicable laboratory" even though some of these suggestions were previously considered and rejected in prior rulemaking.

Using Form CMS-1450 UB 04 (and Electronic Equivalent, 8371) 14X Type of Bill (TOB) to Determine the Majority of Medicare Revenues and Low Expenditure Thresholds. Some commenters expressed concern that the NPI-based definition of applicable laboratory did not capture all of the hospital outreach laboratories and suggested using the revenues from services reported on the Form CMS-1450 (approved OMB number 0938-0997) 14X Type of Bill (TOB), which is only used by hospital outreach laboratories to determine whether a laboratory is an applicable laboratory or exempt from reporting under the low expenditures threshold. The CMS-1450 14X TOB is the uniform bill (also known as UB-04) for institutional providers.

In the proposed rule, CMS solicited public comments on revising the definition of applicable laboratory to permit the revenues identified on the Form CMS-1450 14X TOB to be used instead of the revenues associated with the NPI that the laboratory uses in order to determine whether it meets the majority of Medicare revenue thresholds (and the low expenditure threshold). Under this approach, the applicable revenues would be based on the bills used for hospital laboratory services, provided to non-patients, which are paid under Medicare Part B.

Among other concerns, CMS believed this approach would be inconsistent with the statute. By virtue of the majority of Medicare revenues threshold, the statute defines applicable laboratory in such a way that not all laboratories qualify as applicable laboratories. CMS thought that if it used the 14X bill type to define an applicable laboratory, all hospital outreach laboratories that use the 14X bill type would meet the majority of Medicare revenues threshold and none of them would be excluded. CMS was also concerned about the burden associated with reporting and the time required to develop and implement the information systems necessary to collect private payor data before the start of the next data collection period, January 1, 2019.

CMS received conflicting comments – some commenters supported the proposal and others were opposed to this approach. Supporters believed the proposal allows hospital outreach laboratories that do not have an NPI separate from the hospital to qualify as an applicable laboratory and report applicable information. Commenters noted that this refinement would require hospital outreach laboratories to have the same obligation as other laboratories. Commenters opposing the proposal were concerned about the additional administrative burden and operational feasibility.

In response to concerns that hospitals would to have sufficient time to develop systems to collect applicable information before the next data reporting period, CMS notes that the next data collection period is January 1, 2019 through June 30, 2019 and the next data reporting period begins January 1, 2020 and ends March 31, 2020. CMS believes that hospitals could use the time before and during the next data collection period to develop processes to collect applicable information and to use the 6-month window to determine applicable laboratory status and retroactively collect applicable information to report before the close of the next data-reporting period (March 31, 2020).

In response to concerns about low volume hospital outreach laboratories, the policy for laboratories receiving less than a minimum in CLFS revenues remains unchanged. Hospital outreach laboratories that do not receive at least $12,500 in CLFS revenues on the 14X TOB during a data collection period would be exempt from the reporting requirements.

CMS recognizes the additional burden on the hospital industry, but based on comments received it believes that the additional data collected from hospital outreach laboratories outweighs the potential burden. CMS finalizes the use of Form CMS-1450 14X TOB to define applicable laboratories for the next data collection period (January 1, 2019 through June 30, 2019) and the next data reporting period (January 1, 2010 and ends March 31, 2020) subject to other regulatory and subregulatory requirements. CMS finalizes modification of applicable laboratory to also include 14X TOB revenues and will revise paragraph (2) of the definition of applicable laboratory at §414.502. CMS notes that if the data from hospital outreach laboratories does not result in a significant change in the weighted median of private payor rates, it will revisit the use of the CMS-1450 14X TOB in future rulemaking.

A commenter suggested that CMS develop an "adjustment factor" based on a hospital's payment-to-charges ratio to estimate laboratory revenues received from the IPPS and OPPS. CMS will take the commenter's suggestion into consideration for future rulemaking.

Using CLIA Certificate to Define Applicable Laboratories. CMS addressed this suggestion in prior rulemaking (80 FR 59392 and 81 FR 41045). Under this approach, the majority of Medicare revenues threshold and low expenditure threshold would be determined at the CLIA certificate level instead of the NPI level. Among other reasons that CMS previously rejected this suggestion is that the CLIA certificate is not associated with Medicare billing. Unlike the NPI, the CLIA certificate cannot be used to identify revenues for specific services. Nevertheless, CMS again solicited comments on using CLIA certificate as the mechanism to identify whether a laboratory receives the majority of its revenues from PFS or CLFS services.

Many commenters did not support using the CLIA certificate to define applicable laboratory for many reasons, including the administrative complexity. CMS agrees that defining applicable laboratory by the CLIA certificate would result in substantial administrative burden for the laboratory industry.

4. Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory

Using authority provided in the statute, CMS exempts clinical laboratories receiving less than $12,500 in Medicare revenues for CLFS services during the 6-month data collection period from reporting private payer rates. The $12,500 low expenditure threshold is intended to balance between collecting sufficient data to calculate a weighted median that reflects the private market rate for a laboratory test and minimizing the reporting burden

for laboratories that receive a relatively small amount of revenues under the CLFS. CMS estimated that it was able to exclude 95 percent of physician office laboratories from reporting and 55 percent of independent laboratories but retain reporting for 92 percent and 99 percent of CLFS spending in physician office laboratories and independent laboratories respectively.

In response to concerns from stakeholders that the low expenditure threshold is resulting in incomplete data, and therefore, inaccurate CLFS pricing, CMS requested public comment on whether it should reduce the low expenditure threshold to $6,250. CMS also indicated that physician offices are generally not prepared to report private payer data and doing so would be a significant administrative burden on physician's offices but would have minimal overall impact on payment rates. Nevertheless, CMS provided the opportunity for public comment in the event some physician office laboratories and small independent laboratories want to report applicable information. CMS also solicited public comments on increasing the low expenditure threshold from $12,500 to $18,750 so that fewer laboratories would have to report private payer rates.

Decreasing the Low Expenditure Threshold. Many commenters were opposed to reducing the low expenditure threshold because of the administrative burden. Commenters noted that physician office laboratories and small independent laboratories do not have staffing or resources available to collect this information. CMS appreciates the comments and will consider this input as it continues to evaluate this policy in the future.

A few commenters suggested alternative approaches that allowed laboratories to voluntarily report applicable information. In response, CMS discusses how the statute imposes parameters on the collection and reporting of private payor information. CMS also believes that the statute supports its policy to prohibit information other than statutorily specified private payor rate information from being reported and used to set CLFS payments. Thus, CMS believes its policy to not allow voluntary reporting is the most appropriate interpretation of the statute.

Increasing the Low Expenditure Threshold. Several commenters did not support raising the threshold because it would further reduce the amount of applicable information reported from small laboratories. A few commenters suggested CMS not make any changes and to allow the program to mature before making changes. CMS agrees and will consider this input as it continues to evaluate this policy in the future.

Additional Comments Received. Many commenters expressed concerns about CMS' implementation of the new private payor rate-based CLFS. Commenters encourage CMS to develop payment rates through a statistically valid process that ensures all the private payer data collected accurately represents all sectors of the laboratory market. CMS discusses how its methodology is consistent with section 1834A of the Act. It believes the data used to calculate 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates per test. CMS notes that finalizing the use of the

Form CMS-1450 14X TOB to define applicable laboratories will provide applicable information from a broader segment of the laboratory industry.

Many commenters stated that the administrative burden for the first data reporting period was overwhelming and offered suggestions, including use of a data aggregation system, to reduce the reporting burden. In response, CMS notes that section 1834A(a)(6) of the Act permits the Secretary, beginning with January 1, 2019, to establish rules to aggregate reporting in situations where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test. CMS did not propose or solicit comments on implementing aggregate data reporting but will take the suggestions into consideration for future refinements.

To reduce administrative burden for the next data-reporting period, CMS will allow reporting entities the option to condense certain applicable information at the TIN-level, instead of reporting for each applicable laboratory individually at the NPI level. CMS will provide information about this option through subregulatory guidance.

B. Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule

Medicare pays for ambulance services under a fee schedule. Since July 1, 2008, Congress has temporarily enacted provisions of the Act that increase payment for ground ambulance services as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts were increased by 3 percent each year from July 1, 2008 through December 31, 2017.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts were increased by 2 percent each year from July 1, 2008 through December 31, 2017

These provisions were most recently extended by the Bipartisan Budget Act of 2018 (BBA) through December 31, 2022. CMS proposed to revise its regulations to conform to this statutory requirement.

a. Ground Ambulance Services in Super Rural Areas

Using authority provided by the statute, CMS increased payments rates by 22.6 percent for ambulance transports originating in "super rural" areas (areas comprising the lowest 25th percentile of all rural populations arrayed by population density.) Known as the "super rural" bonus, this additional payment has expired and been extended several times. Congress has extended the "super rural" bonus most recently in the BBA 2018 through December 31, 2022. CMS is proposing to revise its regulations to conform to the statutory provision.

b. Ground Ambulance Transports for ESRD Patients

The law requires Medicare to apply a 10 percent reduction for non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services. BBA 2018 increases the reduction from 10 percent to 23 percent effective for ambulance services furnished on or after October 1, 2018. CMS is conforming its regulation to the statutory provision.

CMS finalizes its proposal, without modification, to revise §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

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

The payment rates for RHCs and FQHCs are designed to reflect the cost of all the services and supplies that are furnished to a patient in a single day. The rates are not adjusted for the complexity of the health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

1. Payment for Care Management Services

CMS finalizes without change its proposal to add a new CPT code 994X7 (finalized as 99491) for 2019. New CPT code 99491 will correspond to 30 minutes or more of Chronic Care Management furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487. For RHCs and FQHCs, CMS finalizes its proposal to add CPT code 99491 as a general care management service and to include it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs will be paid for G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491.

As proposed, CMS revises section 405.2464 to reflect the payment methodology that was finalized in the 2018 PFS and to incorporate the addition of new CPT codes to HCPCS G0511.

Commenters requested clarification of how including new CPT code 99491 would impact the payment rate for HCPCS code G0511 and asked for assurance that doing so would not result in a lower payment rate for G0511. CMS replied that the 2019 payment rate for G0511 is expected to be higher than the payment rate for the code without including CPT code 99491. In response to a request from a commenter, CMS declined to incorporate an adjustment for code 99491 for the additional cost of providing care management services to people with limited English proficiency.

2. Communication Technology-Based Services and Remote Evaluation

CMS finalizes as proposed separate payment for certain communication technology-based services beginning in 2019. Separate payment is made available for a "Brief Communication Technology-based Service" that is a "virtual check-in" and for remote

evaluation of recorded video and/or images. CMS states that it recognizes that it may be beneficial to both the patient and the RHC or FQHC to use communications-based technology to determine the best available course of action for a health issue. CMS hopes that the availability of such services will, for example, prevent unnecessary visits, particularly for beneficiaries who live in rural areas where transportation is limited and distances to clinics are far.

For RHCs and FQHCs, CMS finalizes payment for communication technology-based services or remote evaluation services when at least 5 minutes of communications-based technology or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who 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 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, since in those situations the services are already paid as part of the RHC or FQHC per-visit payment.

CMS finalizes 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 (proposed as HCPCS code GVCI1 but finalized as G2012) for communication technology-based services, and HCPCS code proposed as GRAS1 (finalized as HCPCS code G2010) for remote evaluation services. RHCs and FQHCs will be able to bill the Virtual Communications G-code either alone or with other payable services. CMS will update this code annually based on the PFS amounts.

CMS also finalizes as proposed to waive the RHC and FQHC face-to-face requirements when these services are furnished to an RHC or FQHC patient. Coinsurance will apply to FQHC claims, and coinsurance and deductibles will apply to RHC claims for these services.

CMS considered adding communication technology-based and remote evaluation services as an RHC or FQHC standalone service (paid at the lesser of total charges or the PPS rate), but believes they do not meet the requirement of billable visits for these settings and this approach would be inconsistent with its goal of obtaining efficiencies. In addition, CMS also considered allowing RHCs and FQHCs to bill HCPCS codes G2012 or G2010 separately on an RHC or FQHC claim. CMS rejected this option because it believes that a combined G code is less burdensome.

Commenters requested that CMS investigate its authority to allow FQHCs to serve as distant site providers for telehealth services. CMS, noting that telehealth and virtual communications services are separate and distinct services, reviews the statutory description of telehealth originating sites which includes RHCs and FQHCs (section 1834(m)(4) of the SSA). On the other hand, RHCs and FQHCs are not permitted to be a distant site for telehealth services (section 1834(m)(1) of the SSA).

Other commenters suggested that payment for a G-code for communication technology-based and remote evaluation services using virtual communication should be equivalent to a regular in-person FQHC visit. CMS disagrees and states that these services do not meet the requirements for an RHC or FQHC billable visit. CMS also points out, in response to comments, that it does not have the authority to waive coinsurance amounts for these services and that RHCs and FQHCs should make sure to inform their patients that coinsurance applies.

Some commenters pointed to issues with how such services are reported on RHC cost reports – in a section for non-reimbursable costs. CMS indicates that these comments will be carefully considered in issuing any sub-regulatory guidance for reporting these services.

In response to commenters recommending that timeframe restrictions for billing virtual communication services should be eliminated, CMS replies that since virtual communication payment is designed to provide payment to the RHC or FQHC when there is no billable visit, time restrictions are necessary to avoid duplicate payments. CMS also clarifies that the RHC or FQHC will be able to bill for the virtual communication services (assuming all other requirements are met) even if a patient is subsequently seen within 7 days in an emergency room, urgent care center, or by a non-RHC or FQHC practitioner, or has a non-billable service in the RHC or FQHC such as an injection.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

1. Background

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. AUC are a set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. AUC must be integrated into the clinical workflow.

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). CMS notes it did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified clinical decision support mechanisms (CDSMs) by January 1, 2017; therefore, ordering

professionals were not required to consult CDSMs and furnishing professionals were not able to report information on the consultation by January 1, 2017.

In the 2016 PFS final rule, CMS primarily addressed the first major component under section 1834(q)(2) – the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1). CMS finalized that an "applicable imaging service" must be an advanced imaging service as defined in section 1834(e)(1)(B) of the Act, which defines "advanced diagnostic imaging services" to include diagnostic magnetic resonance imaging, computed tomography, nuclear medicine (including positron emission tomography), and other diagnostic imaging services CMS may specify in consultation with physician specialty organizations and other stakeholders. However, the definition excludes x-ray, ultrasound and fluoroscopy services.

CMS defined the term provider-led entities (PLE) to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the National Comprehensive Cancer Network. Qualified PLEs may also collaborate with third parties. In June 2016, CMS identified 11 qualified PLEs.[30]

In the 2017 PFS final rule, CMS primarily addressed the second major component of the AUC program - the identification of qualified CDSMs that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. CMS defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific condition. In June 2017, CMS identified 6 qualified CDSMs and 9 CDSMs with preliminary qualifications.[31]

In the 2018 PFS final rule, CMS addressed the third major component of the AUC program under section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. CMS established a January 1, 2020 effective date for the ACU consultation and reporting requirements. A voluntary period was also established during which ordering professionals can begin reporting limited information on Medicare claims from July 2018 through December 2019. On January 1, 2020, CMS will begin an educational and operations testing period during which claims will continue to be paid whether or not they correctly include AUC consultation information. CMS also established the information furnishing professionals must report on Medicare claims for advanced diagnostic imaging services. Proposed clarifying revisions are discussed below.

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements, including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to significant hardship. In the 2017 PFS final rule, CMS specified the circumstances under which AUC consultation and reporting requirements are not applicable.

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[30] The list of qualified PLEs can be accessed at https://www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

[31] The list of qualified CDSMs can be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.

The fourth major component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. This section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. In the 2017 PFS final rule, CMS finalized the first list of priority clinical areas[32] that may serve as part of the basis for identifying outlier ordering professionals. CMS notes that because it established a start date of January 1, 2020 for AUC consultation and reporting requirements, it will not have identified any outlier ordering professionals by that date.

2. Proposals for Continuing Implementation

CMS proposed to amend §414.94, "Appropriate Use Criteria for Certain Imaging Services" to reflect the proposals related to applicable settings, consultations by ordering professionals, reporting AUC consultation information, claims-based reporting, and significant hardship exceptions. CMS will continue to post information about the AUC program on the CMS website at www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

a. Expanding Applicable Settings

Section 1834(q)(1)(D) of the Act specifies that AUC consultation and reporting requirements apply only in an applicable setting which means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. CMS proposed to revise the definition of an applicable setting to add an independent diagnostic testing facility (IDTF). CMS believed the addition of IDTFs to the definition of applicable setting would ensure that the AUC program is in place across outpatient settings in which outpatient diagnostic imaging services are furnished. CMS noted that the application of the AUC program is not only limited to applicable settings, but also to services for which payment is made under applicable payment systems (the PFS, the OPPS, and the ASC payment system).

The majority of commenters supported adding IDTF to the definition of applicable setting. A few commenters suggested that CMS wait 3 to 5 years before expanding the definition of the applicable setting until CMS and impacted stakeholders have experience with the program. A few commenters requested the definition of applicable setting be further expanded. CMS disagrees that expanding the definition of applicable settings will add complexity to the program. Because it did not propose adding additional applicable settings besides IDTFs, it will not further expand but will monitor claims for advanced diagnostic imaging services to determine if additional applicable settings should be considered.

[32] The first list of priority clinical areas includes coronary artery disease (suspected or diagnosed, suspected pulmonary embolism, headache (traumatic and non-traumatic), hip pain, low back pain, shoulder pain (includes suspected rotator cuff injury), cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain.

After considering comments, CMS finalizes its proposal to revise the definition of applicable settings under §414.94(b) to include an IDTF.

b. Consultations by Ordering Professionals

Section 1834(q)(1)(E) of the Act defines the term "ordering professional" as a physician (defined in section 1861(r)) or a practitioner (defined in section 1842(b)(18)(C)) who orders an applicable imaging service. The AUC consultation requirement applies to these ordering professionals.

In response to the 2018 PFS proposed rule, CMS received several comments requesting clarification about who is required to perform the AUC consultation. Some commenters recommended that CMS strictly interpret the statutory language and only allow the ordering clinician to perform the AUC consultation and others recommended that CMS allow others to perform the AUC consultation on behalf of the clinician.

CMS proposed that the AUC consultation 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 NPI will be listed on the order for an advanced imaging service. CMS proposed the consultation may be performed by auxiliary personnel incident to the ordering physician's or non-physician practitioner's professional service. CMS noted that the ordering professional is ultimately responsible for the AUC consultation. It is the ordering professional (identified as the furnishing professional on the claim) that could be identified as an outlier professional and become subject to prior authorization based on their ordering pattern.

Some commenters were completely against this proposal because they believed it would undermine the intent of the AUC program and increase administrative burden. The vast majority of commenters, however, agreed that expanding beyond the ordering professional allows flexibility and will reduce the burden on the ordering professional. Commenters requested clarification about the term "auxiliary personnel" and some recommended additional regulatory language to more specifically identify the scope of individuals who could perform the AUC consultation.

CMS agrees that the proposed language could cause confusion and appreciates the various and diverse suggestions among commenters regarding precisely who, beyond the ordering professional, should be eligible to perform the AUC consultation. CMS agrees with the view of most commenters that the ordering professional should have flexibility to delegate the AUC consultation task. CMS believes that the individual who uses the CDSM is working under the ordering professional, and that the individual should be available to discuss the results of the consultation with the ordering professional.

CMS does not believe it is appropriate to specify the scope of individuals who can perform the AUC consultation as auxiliary personnel. CMS concludes that allowing

clinical staff to perform the AUC consultation under the direction of the ordering professional is more appropriate to the AUC than "incident to" and is responsive to comments. Clinical staff will have a level of knowledge that allows for effective communication of orders, interact with the AUC, and engage with the ordering professional.

In response to comments, CMS modifies its proposal and finalizes at §414.94(j)(2) to specify that, when not personally performed by the ordering professional, the consultation with a qualified CDSM may be performed by clinical staff under the direction of the ordering professional.

c. Reporting AUC Consultation Information

Section 1834(q)(4)(B) of the Act requires that payment for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. In the 2018 PFS final rule, CMS specified only that "furnishing professionals" must report AUC consultation information. Many stakeholders interpreted this to mean that AUC consultation information would be required only on practitioner claims.

To better reflect the statutory language, CMS proposed to revise its regulations at §414.94(k) to clarify that AUC consultation information must be reported on all claims paid under applicable payment systems without exclusion. CMS believed that the claims furnished from both furnishing professionals and facilities must include AUC consultation information: the practitioner's claim for the professional component and the provider's or supplier's claim for the facility portion or TC of the imaging service.

Some commenters appreciated the clarification of the requirement and other commenters opposed the reporting of AUC consultation information on all claims, specifically the facility claims. A few commenters expressed concern that requiring two sources of AUC consultation information could result in situations where one source was inaccurate or provides conflicting information. CMS notes it does not match or compare separate claims for the PC and TC or facility portion of an advanced diagnostic imaging service.

After consideration of comments, CMS finalizes its proposal to revise §414.94(k) to clearly reflect the scope of claims for which AUC consultation information must be reported, and to make this requirement consistent with section 1834(q)(4)(B) of the Act.

d. Claims-based Reporting

In the 2018 PFS proposed rule, CMS proposed to establish a series of G-codes and HCPCS modifiers to capture AUC consultation information on Medicare claims. As discussed in the 2018 PFS final rule, CMS received numerous public comments objecting to this proposal. Many commenters suggested using a unique consultation identifier (UCI) instead of using combinations of G-codes and modifiers. CMS did not finalize a

proposal and planned to conduct stakeholder outreach during 2018 to develop a standard taxonomy for an identifier and explore options of where to place an identifier on claims.

CMS discussed the various suggestions stakeholders have made for a taxonomy that could be used to develop a UCI to report the required information. CMS noted that the majority of UCI suggestions would not allow CMS to attribute the CDSM used or the AUC adherence status (adherent or not adherent, or not applicable) to a specific imaging service. CMS concluded it is not feasible to create a uniform UCI taxonomy, determine a location of the UCI on the claims forms, obtain the support and permission by national bodies to use claim fields for this purpose, and solve the underlying UCI limitations. CMS stated that existing coding structures (such as G-codes and modifiers) would allow CMS to establish reporting requirements prior to January 1, 2020.

CMS proposed to use established coding methods, G-codes and modifiers, to report the required AUC information on Medicare claims.

The majority of commenters agreed with the proposal to use G-codes and modifiers to append AUC information on claims. Commenters acknowledged difficulties with this approach, including workflow challenges, but no better alternative is currently available.

In response to concerns about CMS' ability to issue G-codes in a timely fashion to qualifying new CDSMs, CMS believes this can be accomplished. It believes it can issue G-codes for CDSMs that are already qualified and could secure additional G-codes with general descriptors to describe newly qualified CDSMs. CMS does not think the use of one generic G-code to describe that a qualified CDSM was consulted would satisfy the statutory requirement. CMS agrees with commenters that when multiple imaging services are reported on a single claim, it will not be possible to pair the G-code describing which CDSM was consulted with the corresponding imaging service. CMS notes it will explore options to resolve this issue besides requiring the furnishing professional to split the claim. In response to a suggestion to use CPT codes instead of G-codes, CMS is concerned that CPT codes could not be issued timely but will look into this suggestion. CMS agrees with commenters that CDSMs should include the G-codes and modifiers in their certification or documentation and states it would like CDSMs to do this as the specific G-codes and modifiers become available. CMS notes that if CDSMs do not make these adjustments, it will consider imposing a requirement in regulation.

Other commenters disagreed with the proposal, and recommended CMS not require claims-based reporting until a UCI can be reported on claims. Some commenters suggested CMS use information transmitted directly from qualified CDSMs to CMS instead of claims-based reporting. CMS agrees that G-codes and modifiers may not be ideal and will continue to discuss with stakeholders the potential to use a UCI in the future. CMS notes there are many outstanding issues related to using a UCI including disagreement among stakeholders regarding whether the UCI would contain taxonomy and embed meaningful information. In addition, CMS notes that it would be necessary to

establish a field to report a UCI on claims and it would be several years before the form could be updated.

CMS finalizes its proposal to use G-codes and modifiers to report consultation information on claims. CMS acknowledges suggestions on additional modifiers and will consider these during implementation.

e. Significant Hardship Exceptions to Consulting and Reporting Requirements

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements under section 1834(q)(4)(B) of the Act. In the 2017 PFS final rule, CMS aligned the significant hardship exception with the Medicare EHR Incentive Program exception. In the 2018 PFS proposed rule, with the payment adjustments under the Medicare EHR Incentive Program sunsetting, CMS proposed to align the significant hardship exception with the significant hardship exception for MIPS. In response to comments, CMS did not finalize this proposal.

CMS proposed criteria specific to the AUC program for the significant hardship exception that are independent of other programs. The proposed criteria for an AUC consultation significant hardship exception include:

- Insufficient internet access – specific to the location where an advanced diagnostic imaging service is ordered by the ordering professional;
- EHR or CDSM vendor issues – including situations where ordering professionals experience temporary technical problems, installations or upgrades that temporarily impede access to the CDSM, vendors cease operations, or CMS de-qualifies a CDSM; or
- Extreme and uncontrollable circumstances – including disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems.

CMS also proposed that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. The attestation must be supported with documentation of significant hardship. Ordering professionals attesting to a significant hardship would communicate that information, along with the AUC consultation information, to the furnishing professional with the order. This information would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. Claims for advanced diagnostic imaging services that include a significant hardship exception modifier would not be required to include AUC information.

In response to comments, CMS discusses the differences between the AUC program and the Quality Payment Program (QPP) and why participation in the QPP does not except clinicians from the AUC program. In response to commenters requesting a low-volume threshold as a significant hardship category, CMS does not believe that low volume would impede clinicians from consulting AUC through a CDSM. It also does not believe it has the authority to include exceptions beyond the scope of those specified in the Act.

CMS also disagrees with suggestions that being a new physician or conducting clinical research are appropriate hardship categories.

In response to comments expressing concerns about the emergency services exception, CMS states that section 1834(q)(4)(C)(i) of the Act provides for an exception to the AUC requirements for a service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. CMS has no evidence this was a drafting error and that the intent was to reference section 1867(a) of the Act which would allow an exception based on the clinician's judgment. CMS does agree that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed.

In responses to commenters with specific requests for clarification around the proposed significant hardship exception categories, CMS provides some additional examples for insufficient internet access, EHR or CDSM vendor issues, and extreme and uncontrollable circumstances. CMS expects to provide further details and clarification in claims processing instructions.

CMS finalizes the significant hardship categories of insufficient internet access, EHR or CDSM vendor issues, and extreme and uncontrollable circumstances. CMS also finalizes its proposal to allow ordering professionals experiencing a significant hardship to self-attest and include that information on the order for the advanced diagnostic imaging service, which the furnishing professional or facility would add to the Medicare claim for the service by appending a HCPCS modifier identifying the ordering professional's self-attested significant hardship category.

f. Identification of Outliers

CMS acknowledges the comments it received on a possible methodology, including data elements and thresholds that CMS should consider when identifying outliers. It is interested in stakeholders' input on how outliers could be determined for the AUC program. CMS expects to address outlier identification and prior authorization in the 2022 or 2023 PFS rulemaking cycle.

3. Information Collection Requirements Regarding AUC Criteria

For the estimates related to ordering professionals, CMS uses "family and general practitioners." General practitioners are the largest group of practitioners who order applicable imaging services and would be required to consult AUCs. Based on the finalized change in the consulting requirement to allow ordering professionals to delegate the consultation to clinical staff working under the direction of the ordering professional, to interact with the CDSM, CMS used the medical assistant occupation code 31-9092 to calculate revised cost estimates.

To derive the burden associated with the January 1, 2020 implementation, CMS estimates it would take 2 minutes (0.033 hr.) at $16.15/hour for clinical staff to consult with a

qualified CDSM. Based on market research and claims data, CMS anticipates 43,181,818 AUC consultations. CMS estimates that 90-percent of the AUC consultations could be performed by auxiliary personnel, with the remaining 10 percent performed by ordering professionals. In aggregate, CMS estimates an annual burden of 1,425,500 hours at a cost of approximately $70,001,700.

E. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Under the Medicaid Promoting Interoperability Program, Medicaid EPs and eligible hospitals can receive incentive payments for the adoption, implementation, upgrade, and meaningful use of Certified Electronic Health Record Technology (CEHRT). To demonstrate meaningful use of electronic health records (EHR)technology, the EHR user is required to report clinical quality measures selected by CMS or a state and submit them in the form and manner specified by CMS or the state. In selecting electronic clinical quality measures (eCQMs) for EPs to report, Section 1848(o)(2)(B)(iii) of the Act requires the Secretary to avoid redundant or duplicative reporting.

For 2017, Medicaid EPs were required to report on any six eCQMs relevant to the Eps' scope of practice. CMS expressed, in the FY 2018 Hospital Inpatient Prospective Payment System final rule establishing that requirement, that it was their intention to align the eCQM requirements with those for Medicare quality improvement programs to the extent practical.[33]

2. eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2019

CMS finalizes without change its proposal to align the eCQMs for Medicaid EPs for 2019 with those available for MIPS eligible clinicians for the 2019 performance period by making the list of quality measures for Medicaid EPs the same as the list finalized for MIPS.

According to CMS, aligning the eCQMs for the two programs will reduce burden for Medicaid EPs who are also participating in MIPS and will encourage more EP participation in Medicaid. CMS expects the change to require only minor adjustments to state systems.

[33] Final Rule: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices" (82 FR 37990, 38487).

CMS finalizes without change its proposal that the Medicaid EPs will report on any six eCQMs that are relevant to the EPs' scope of practice. CMS points out that this practice improved flexibility for the 2017 reporting as finalized in the FY 2018 Hospital Inpatient Prospective Payment System final rule and aligns with the MIPS data submission requirement. At least one of those measures is required to be an outcome measure (or if an applicable outcome measure is not available or relevant, one other high priority measure).

In response to commenters' concerns, if a Medicaid EP finds that no outcome or high priority measure is applicable to their scope of practice, the provider can report on six non-outcome and non-high priority measures that are applicable to his or her scope of practice.

CMS finalizes its proposal without change to use the following methods to identify high priority measures:

- Use the high priority measures identified for eligible clinicians under the MIPS program;
- Include as high priority measures those available eCQMs in previous year's "Core Sets" that are also on the MIPS list of eCQMs. CMS is required to develop and annually update two sets of quality measures that states may voluntarily report. The measures specifically focus on populations served by the Medicaid and CHIP programs. These Core Sets are comprised of quality measures for children (the Child Core Set) and for adults (Adult Core Set). CMS notes that because the child and adult Core Sets are released at the beginning of each year, it is not be possible to update the list of high-priority eCQMs with those added to the current year's Core Sets. The eCQMs that are available for EPs to report in 2019 that are both part of the Core Sets and on the MIPs list are:
    - CMS2, "Preventive Care and Screening: Screening for Depression and Follow-Up Plan"
    - CMS4, "Initiation and Engagement of Alcohol and Other Drug Dependence Treatment"
    - CMS122, "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)"
    - CMS125, "Breast Cancer Screening"
    - CMS128, "Anti-depressant Medication Management"
    - CMS136, "Follow-Up Care for Children Prescribed ADHD Medication (ADD)"
    - CMS153, "Chlamydia Screening for Women"
    - CMS155, "Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents"
    - CMS165, "Controlling High Blood Pressure"
- Give each state the flexibility to identify which of the available eCQMs selected by CMS are high priority measures for EPs in that state, with review and approval from CMS, through their State Medicaid HIT Plans; this is similar to the flexibility granted states to modify the definition of Meaningful Use at §495.332(f).

CMS finalizes without change its proposal for the reporting period for EPs in the Medicaid Promoting Interoperability Program to be for a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year. For EPs demonstrating meaningful use for the first time, the eCQM reporting period will continue to be any continuous 90-day period consistent with existing rules.

CMS received feedback as requested on a possible proposal for future years in which CMS would include the child and adult Core Sets as eCQM reporting options for Medicaid EPs. As noted in the preamble of the proposed rule, doing so would increase EP utilization of these measures and provide states with better data to report, according to CMS. Most commenters supported this approach for future years. One felt that it would add burden for providers. CMS, however, disagrees that adding these measures as options for providers would add burden and indicates that it intends to reevaluate the proposal for 2020 and beyond.

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

Consistent with statute, CMS established in prior rules that no Medicaid EP can receive an incentive payment after December 31, 2021. To ensure that deadline is met, CMS finalizes without change its proposal to amend section 495.4 to establish an EHR reporting period and an eCQM reporting period of any continuous 90-day period within 2021 provided that the end date is before October 31, 2021. States will be allowed to establish an alternative earlier end date for those periods within 2021 for any continuous 90-day period within 2021. Such an alternate date may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting in that state.

In response to a commenter's concern that states setting earlier dates will increase burden on Medicaid EPs, CMS states that it may consider in future rulemaking proposing that no state may set a reporting period deadline for 2021 that is earlier than June 30, 2021 or an attestation deadline that is earlier than July 1, 2021. CMS welcomes input from states and interested parties on whether any state would need more than 6 months to process and disburse incentive payments.

CMS notes that a similar timing issue would arise with respect to hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021, but it doesn't expect that there will be any hospitals eligible for those payments in 2020 or 2021. CMS did not propose any changes with respect to hospital timelines.

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

CMS finalizes without change its proposals on the following measures:

- Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement). CMS amends the threshold for the two measures of

Objective 6 (Coordination of Care through Patient Engagement). Instead of phasing up from 5% over time, the threshold for the two measures will remain at 5% for 2019 and subsequent years. CMS notes that it has received feedback that the two measures present the largest barriers to demonstrating meaningful use especially in rural areas and safety net clinics. Because Medicaid patients have low rates of internet access, internet literacy and health literacy, this functionality is not highly used by this patient population.

- Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure). CMS amends the syndromic surveillance reporting measure (§495.24(d)(8)(i)(B)(2)). It eliminates language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. The amended measure will allow for any EP as defined by the state or local public health agency to submit such data.

F. Medicare Shared Savings Program (MSSP)

CMS reviews the regulatory history of the MSSP program and notes that it has historically used the annual PFS rules to address quality reporting for the program. CMS states that the MSSP program is intended to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and to reduce the rate of Medicare spending growth by forming or participating in ACOs.

CMS finalized proposed changes for the 2019 performance year and subsequent years to quality performance measures in two areas: Patient Experience of Care Survey measures and CMS Web Interface and Claims-Based measures.

Changes to CAHPS Measure Set
CMS reviews the background describing the use of the CAHPS survey for quality measures under MSSP. For performance year 2018, 31 quality measures are used to determine ACO quality performance. They are submitted through the CMS Web Interface and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey. That survey is based on the Clinician and Group CAHPS (CG-CAHPS) survey which is maintained by the Agency for Healthcare Research and Quality.

CMS finalizes several changes to the quality measure set used to assess quality performance of ACOs under the Shared Savings Program and indicates that the changes would enhance patient and caregiver experience and would better align with MIPS.

CMS finalizes as proposed to begin scoring 2 summary survey measures (SSMs) that are already collected but are currently used only for information purposes:

- ACO-45, CAHPS: Courteous and Helpful Office Staff, and
- ACO-46: CAHPS: Care Coordination.

The measures will be scored and included in the ACO quality determination starting in 2019. Consistent with existing rules regarding scoring of new quality measures, the additional SSMs will be pay-for-reporting for all ACOs for 2 years (PY 2019 and 2020). The measures will then phase into pay-for-performance for ACOs in their first agreement period in the program according to the schedule in Table 26 beginning in performance year 2021. Both of these SSMs are currently designated by AHRQ as CG-CAHPS core measures. For performance year 2016, the mean performance rates across all ACOs for these two measures were 87.18 for Care Coordination and 92.12 for Courteous and Helpful Office Staff.

Most commenters supported the proposal to begin scoring the 2 SSMs. Some commenters expressed reservations about ACO-45 – including that an office staff measure does not impact outcomes, and that some ACOs have little impact on the performance of individual providers' office staff. One suggested that ACO-45 be expanded to include medical assistants and nurses. CMS disagrees with commenters who suggest that ACO-45 has nothing to do with quality outcomes -- stating that it considers the patient's experience of care to be a quality outcome. In addition, CMS will consider adding medical assistants and nurses in the future.

CMS sought comment on potentially converting the Health and Functional Status SSM (ACO-7) to pay-for-performance in the future. CMS has not done so to date because of concerns that the scores may reflect the underlying health of beneficiaries of ACO providers rather than the quality of care provided by the ACO. Commenters generally agreed with those concerns. As a result, CMS indicates that it will need to undertake additional analytic work before possibly considering this change for future updates.

Some commenters raised questions about the applicability of the CAHPS for ACOs to institutional providers. CMS reviewed its policy which is to exclude beneficiaries from CAHPS sampling if 100 percent of their primary care service visits were performed in an institutional setting. After reviewing this sampling process, however, CMS has determined that, beginning with the 2018 performance year, it will exclude beneficiaries if their last primary care service visit during the sampling timeframe was performed in an institutional setting.

Changes to Web Interface and Claims-based Quality Measure Sets

CMS restates its objective to streamline measurements of quality and to reduce regulatory burden. It reviews its Meaningful Measures Initiative.[34] Under that initiative, CMS committed to assessing only those core issues most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. CMS notes that in doing so, it considers the reporting requirements for other initiatives including the MIPS and Million Hearts Initiative.

[34] See CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LANSummit, October 30, 2017, available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html.

CMS finalizes without change its proposal to reduce the total number of measures in the MSSP quality measure set by eliminating the following measures. CMS will retire the following claims-based quality measures which it states have a high degree of redundancy and overlap with other measures that remain in the measure set:

- ACO-35-Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)
- ACO-36-All-Cause Unplanned Admissions for Patients with Diabetes
- ACO-37-All-Cause Unplanned Admission for Patients with Heart Failure

CMS will also remove:

- ACO-44-Use of Imaging Studies for Low Back Pain because its denominator (beneficiaries ages 18 – 50) is often too small to make the measure meaningful. Further, its removal would align with its removal from MIPS.

Because those measures are claims-based and do not impose any reporting burden on ACOs, CMS will continue to provide information to ACOs on their performance so that they could use them in their quality improvement activities. This information will be provided through a new quarterly claims-based quality outcome report that ACOs will begin receiving in 2018.

Most commenters agreed with the removal of these measures; however, one warned CMS to carefully consider the balance between burden reduction and maintaining a robust measure set. Some commenters opposed the removal of ACO-36 without a comparable diabetes measure to replace it. CMS responded by citing other measurers that include performance for ACO beneficiaries with diabetes. MedPAC opposed the removal of ACO-44 because of the widespread use of imaging for beneficiaries with non-specific low back pain. It recommended that CMS expand the measure to include beneficiaries over the age of 50. CMS replied that it isn't the measure steward but has raised the issue and will coordinate with the steward on any potential future changes.

CMS sought comment on the possibility of adding the Skilled Nursing Facility Quality Reporting Program (SNFQRP) measure "Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facilities" to the MSSP quality measure set in future rulemaking. This measure differs from now eliminated ACO-35 because the SNFQRP measure looks only at unplanned, potentially preventable readmissions for Medicare FFS beneficiaries within 30 days of discharge to a lower level of care from a SNF, while ACO-35 assesses readmissions from a SNF, regardless of cause, that occur within 30 days following discharge from a hospital. As a result, the SNFQRP measure would have less overlap with ACO 8 (Risk-Standardized All Cause Readmission measure) than does ACO-35 (SNFRM). Most commenters were opposed to this addition – indicating that few ACOs have input in the care processes for SNFs, and that the measure is duplicative with ACO-8, among other reasons.

CMS reiterates that it is aligning with the CMS Web Interface as used under the Quality Payment Program so changes made to QPP measures apply to ACOs as well. As such,

CMS notes that elsewhere in the rule it has finalized changes to QPP Web Interface measures. Consistent with the changes to QPP measures as finalized, ACOs will no longer be responsible for reporting the following measures beginning with performance year 2019:

- ACO-12 (NQF #0097) Medication Reconciliation Post-Discharge
- ACO-15 (NQF #0043) Pneumonia Vaccination Status for Older Adults
- ACO-16 (NQF #0421) Preventive Care and Screening: Body Mass Index(BMI) Screening and Follow Up
- ACO-41 (NQF #0055) Diabetes: Eye Exam
- ACO-30 (NQF #0068) Ischemic Vascular Disease (IVD): Use of Aspirinor another Antithrombotic

Finally, CMS proposed to add ACO-47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. Based on measures finalized for the QPP, this measure was not added to the ACO measures in the final rule.

Table 26, reproduced below, shows the entire quality measure set for the Shared Savings Program for PYs beginning with 2019. Table 27, also reproduced below, provides a summary of the number of measures by domain and the total domain weights that will be used for scoring purposes under the Shared Savings Program quality performance standards for performance year 2019 and subsequent performance years.

TABLE 26: Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2019

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF N/A AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Provider		NQF N/A AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 45	CAHPS: Courteous and Helpful Office Staff	X[1]	NQF #N/A AHRQ	Survey	R	R	P
	ACO - 46	CAHPS: Care Coordination	X[1]	NQF #N/A AHRQ	Survey	R	R	P

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
Care Coordination/ Patient Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO - 38	Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO - 43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment)[2]		AHRQ	Claims	R	P	P
	ACO - 13	Falls: Screening for Future Falls		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 18	Preventive Care and Screening: Screening for Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO - 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO - 20	Breast Cancer Screening		NQF #2372 NCQA	CMS Web Interface	R	R	P
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease		NQF #N/A CMS	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Depression		Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes		Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension : Controlling High Blood Pressure		NQF #0059 NCQA	CMS Web Interface	R	P	P

[1] Measures that are currently collected as part of the administration of the CAHPS for ACO survey, but will be considered new measures for purposes of the pay-for-performance phase-in.
[2] The language in parentheses has been added for clarity and no changes have been made to the measure.

Table 27: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2019				
Domain	**Number of Individual Measures**	**Total Measures for Scoring Purposes**	**Total Possible Points**	**Domain Weight**
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/Patient Safety	4	4 measures	8	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

G. Physician Self-Referral Law

Section 50404 of BBA of 2018 codified certain regulatory clarifications CMS made with respect to Stark law provisions for certain writing and signature requirements for compensation arrangements as well as holdover arrangements. Specifically, the law amended section 1877(h)(1) of the Act to clarify the following for writing and signature requirements:

- Parties to a compensation arrangement that is required to be in writing may satisfy the writing requirement through a collection of documents (including contemporaneous documents that evidence the course of conduct between the parties) and through such other means as the Secretary may determine.
- Parties to a compensation arrangement that is required to be signed and in writing may satisfy the signature requirement by obtaining the requisite signatures as late as 90 consecutive calendar days after the date the compensation arrangement became noncompliant as long as the compensation arrangement otherwise complies with all of the criteria of the applicable exception.

Writing Requirement. CMS finalizes without modification its proposal to add to its regulations a special rule for a Stark law compensation arrangement exception that specifies the writing requirement may be satisfied by a collection of documents, including contemporaneous documents, evidencing the course of conduct between the parties. CMS codifies the policy on this issue in a new paragraph (e) of §411.354 of its regulations.

Signature Requirements. CMS notes that the BBA of 2018 provision for certain arrangements involving temporary noncompliance with signature requirements differs from current CMS policy in that the requirement under the BBA of 2018 (i) is not limited to specific exceptions and (ii) entities are not limited to using this rule once every 3 years for the same referring physician. CMS proposed to amend its regulation at §411.353(g) to apply the signature requirements broadly under the Stark law regulations; to remove references to occurrence of referrals or payment of compensation during the 90-day period when the signature requirement is not met; and to delete the limitation on use of the rule once every 3 years with respect to the same physician. CMS finalizes its proposal without modification.

The effective date of section 50404 is February 9, 2018, and CMS states with respect to the statutory clarification for arrangements involving temporary noncompliance with signature requirements under section 1877(h)(1)(E) that, beginning February 9, 2018, parties who satisfy the statutory requirements under that section may use them, including those who would otherwise have been barred from using the special rule under §411.353(g)(1) because of the 3-year limitation under §411.353(g)(2).

Holdover Arrangements

As noted above, section 50404 of the BBA of 2018 also codified requirements relating to lease and personal service holdover arrangements. The law clarified the following:

- Payments made by a lessee to a lessor under a holdover lease arrangement of office space or equipment shall not be considered a compensation arrangement where (i) the holdover lease arrangement immediately follows a lease of at least one year in length that met existing requirements under section 1877(e)(1)(A) or (B) of the Act, (ii) the holdover lease arrangement is under the same terms and conditions as the immediately preceding arrangement; and (iii) the holdover arrangement continues to meet requirements under such section 1877(e)(1)(A) or (B).

- Remuneration from an entity under a holdover personal service arrangement shall not be considered a compensation arrangement where (i) the holdover personal service arrangement immediately follows a personal service arrangement for a term of at least one year in length that met existing requirements under section 1877(e)(1)(A) of the Act, (ii) the holdover personal service arrangement is under the same terms and conditions as the immediately preceding arrangement; and (iii) the holdover arrangement continues to meet requirements under such section 1877(e)(1)(A).

CMS believes that these statutory provisions effectively mirror the existing regulatory clarifications; thus, the agency did not propose to make changes to its regulations.

H. Physician Self-Referral Law Update

Stark law generally prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or immediate family member) has a financial relationship. The statute and regulations list DHS which CMS defines in its Code List (i.e., list of applicable CPT/HCPCS codes). The Code List establishes four DHS categories as well as identifies items and services that may qualify for exceptions for (i) EPO and other dialysis-related drugs furnished in or by an ESRD facility or (ii) preventive screening tests, immunizations or vaccines.

CMS updates the Code List each year. CMS reports that it did not receive any comments on the Code List that was effective January 1, 2018. The update list for 2019 is available on the CMS website at
http://www.cms.gov/Medicare/Fraud-and-

Abuse/PhysicianSelfReferral/List_of_Codes.html. Tables 28 and 29 of the final rule show the additions and deletions to the comprehensive Code List which will be effective January 1, 2019 as well as codes used to identify items and services that may qualify for the exceptions noted above.

IV. Regulatory Impact Analysis

A. RVU Impacts

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality.

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2018 with payment rates for 2019 using 2017 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that the average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Prior to 2015, the annual update to the PFS conversation factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 through 2025. For 2019, the specified MACRA update had been 0.5 percent, before applying other adjustments. Section 53106 of the Bipartisan Budget Act of 2018 revised the update adjustment factor for 2019 to 0.25 percent before applying any other adjustments.

The CF for 2019 is $36.0391, which reflects the 0.25 percent update adjustment factor specified under BBA of 2018 and a budget neutrality adjustment of -0.14 percent (2018 conversion factor of $35.9996*1.0025*0.9986). The 2019 anesthesia conversion factor is $22.2730, which reflects the same adjustments and an additional adjustment due to an update to the malpractice risk factor for anesthesia specialty. See Tables 92 and 93 from the final rule, are reproduced below.

Table 92: Calculation of the Final 2019 PFS Conversion Factor		
Conversion Factor in effect in 2018		**$35.9996**
Statutory Update Factor	0.25 percent (1.0025)	
2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
2019 Conversion Factor		**$36.0391**

TABLE 93: Calculation of the Final 2019 Anesthesia Conversion Factor		
2018 National Average Anesthesia Conversion Factor		**$22.1887**
Update Factor	0.25 percent (1.0025)	
2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
2019 Practice Expense and Malpractice Adjustment	0.27 percent (1.0027)	
2019 Conversion Factor		**$22.2730**

Table 94 (included at the end of this section) shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).

2019 PFS Impact Discussion

The most widespread specialty impacts of the RVU changes are generally related to changes to RVUs for specific services resulting from the misvalued code initiatives, including the establishment of RVUs for new and revised codes. CMS notes that the estimated impacts for many specialties differ significantly between the proposed and final rules. This is due in large part to CMS not finalizing its E/M proposal for 2019 that would have established a single E/M payment rate for new patients and a single PFS rate for established E/M visits levels 2-5 as well as other adjustments.

Some specialties, including, for example, clinical psychologists, vascular surgery, interventional radiology, and podiatry will see increases relative to other specialties. CMS attributes these changes to increases in value for particular services, updates to supply and equipment pricing, and implementation of new payment policies associated with communication technology. Other specialties, including diagnostic testing facilities, independent labs, pathology, and ophthalmology will experience decreases in payments relative to other specialties for similar reasons as well as continued implementation of code-level reductions being phased-in over several years (e.g., allocation of indirect PE for some office-based services).

Column F of Table 94 shows the estimated 2019 combined impact on total allowed charges by specialty of all the RVU and other changes. These impacts range from an increase of 3 percent for clinical psychologists, increase of 2 percent for clinical social worker, interventional radiology, podiatry, and vascular surgery to a decrease of 5 percent for diagnostic testing facility, and decrease of 2 percent for independent laboratory and pathology.

TABLE 94: 2019 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Allergy/Immunology	$239	0%	-1%	0%	-1%
Anesthesiology	$1,982	0%	0%	0%	0%
Audiologist	$68	0%	1%	0%	1%
Cardiac Surgery	$293	0%	0%	0%	0%
Cardiology	$6,616	0%	0%	0%	0%
Chiropractor	$754	0%	-1%	0%	-1%
Clinical Psychologist	$776	0%	3%	0%	3%
Clinical Social Worker	$728	0%	3%	0%	2%
Colon and Rectal Surgery	$166	0%	1%	0%	1%
Critical Care	$342	0%	-1%	0%	-1%
Dermatology	$3,489	0%	1%	0%	1%
Diagnostic Testing Facility	$734	0%	-5%	0%	-5%
Emergency Medicine	$3,121	0%	0%	0%	0%
Endocrinology	$482	0%	0%	0%	0%
Family Practice	$6,207	0%	0%	0%	0%
Gastroenterology	$1,754	0%	0%	0%	0%
General Practice	$428	0%	0%	0%	0%
General Surgery	$2,090	0%	0%	0%	0%
Geriatrics	$197	0%	0%	0%	0%
Hand Surgery	$214	0%	0%	0%	0%
Hematology/Oncology	$1,741	0%	-1%	0%	-1%
Independent Laboratory	$646	0%	-2%	0%	-2%
Infectious Disease	$649	0%	0%	0%	-1%
Internal Medicine	$10,766	0%	0%	0%	0%
Interventional Pain Mgmt	$868	0%	1%	0%	1%
Interventional Radiology	$384	1%	1%	0%	2%
Multispecialty Clinic/Other Phys	$149	0%	0%	0%	0%
Nephrology	$2,188	0%	0%	0%	0%
Neurology	$1,529	0%	0%	0%	0%
Neurosurgery	$802	0%	0%	0%	0%
Nuclear Medicine	$50	0%	-1%	0%	-1%
Nurse Anes / Anes Asst	$1,242	0%	0%	0%	0%
Nurse Practitioner	$4,060	0%	0%	0%	0%
Obstetrics/Gynecology	$637	0%	0%	0%	0%
Ophthalmology	$5,451	0%	-1%	0%	-1%
Optometry	$1,309	0%	-1%	0%	-1%
Oral/Maxillofacial Surgery	$67	0%	0%	0%	0%
Orthopedic Surgery	$3,741	0%	0%	0%	0%
Other	$31	0%	4%	0%	4%
Otolaryngology	$1,222	0%	0%	0%	0%
Pathology	$1,165	0%	-1%	0%	-2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Pediatrics	$61	0%	0%	0%	0%
Physical Medicine	$1,107	0%	0%	0%	0%
Physical/Occupational Therapy	$3,950	0%	-1%	0%	-1%
Physician Assistant	$2,438	0%	0%	0%	0%
Plastic Surgery	$376	0%	0%	0%	0%
Podiatry	$1,974	0%	2%	0%	2%
Portable X-Ray Supplier	$99	0%	1%	0%	1%
Psychiatry	$1,187	0%	1%	0%	1%
Pulmonary Disease	$1,714	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	$1,765	0%	0%	0%	-1%
Radiology	$4,907	0%	0%	0%	0%
Rheumatology	$541	0%	0%	0%	0%
Thoracic Surgery	$357	0%	0%	0%	0%
Urology	$1,738	0%	1%	0%	1%
Vascular Surgery	$1,141	0%	2%	0%	2%
Total	$92,733	0%	0%	0%	0%

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

The following is an explanation of the information for Table 94:

- Column A (Specialty): Identifies the specialty for which data is shown.

- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2017 utilization and 2018 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.

- Column C (Impact of Work RVU Changes): This column shows the estimated 2019 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

- Column D (Impact of PE RVU Changes): This column shows the estimated 2019 impact on total allowed charges of the changes in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2019 impact on total allowed charges of the changes in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2019 combined impact on total allowed charges of all the changes in the previous columns

For illustrative purposes, CMS shows the estimated specialty level impacts associated with implementing its finalized policies for E/M coding and payment in 2019, rather than delaying until 2021. Table 95 in the final rule shows the estimated impacts of adopting single payment rates for new and established patient E/M visit levels 2-4, keeping separate rates for new and established patient E/M visit level 5 and adopting add-on codes with equal rates to adjust for the inherent visit complexity of primary care and non-procedural specialty care. These impacts range from an increase of 10 percent for podiatry, increase of 5 percent for otolaryngology and psychiatry to a decrease of 5 percent for diagnostic testing facility, and decrease of 3 percent for critical care, gastroenterology, nuclear medicine, ophthalmology, and physical/occupational therapy.

B. Impacts of Other Proposals

The expected impacts of some of the changes in this final rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to telehealth, payments to provider-based departments of hospitals paid under the PFS, WAC-based payments for Part B drugs, regulations associated with the ambulance fee schedule, clinical laboratory fee schedule, AUC criteria for advanced diagnostic imaging services, and the physician self-referral law, among other proposals.

C. Changes Due to the Quality Payment Program

CMS estimates in the final rule that approximately 54 percent of the nearly 1.5 million clinicians billing to Part B (797,990) will be assigned a MIPS score for 2021 because others will be ineligible for or excluded from MIPS. This is more than 10 percentage points higher than what CMS estimated using legacy data from PQRS. Table 97, reproduced below, provides the details of clinicians' MIPS eligibility status for 2021 MIPS payment year using the proposed and finalized assumptions. CMS notes it was difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policy; CMS assumed 33 percent of the opt-in eligible clinicians that participated in PQRS will elect to opt-in to the MIPS program. Using the updated data, CMS observed a decrease of about 14,000 clinicians compared to the proposed rule in the "opt-in eligibility" category.

Table 97: Description of MIPS Eligibility Status for CY 2021 MIPS Payment Year Using the Proposed and Finalized Assumptions***					
		Proposed rule estimates		Final Rule estimates †	
		Legacy data*		QPP Year 1 data	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)******	**Number of Clinicians**	**PFS allowed charges ($ in mil)******
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	186,549	43,546	199,236	47,653
	Do not participate in MIPS	31,921	7,605	17,376	3,916
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	389,670	10,262	553,475	13,662
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low- volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	42,025	2,099	27,903	1,380
Total Number of MIPS Eligible Clinicians		650,165	63,512	**797,990****	66,611
Not MIPS eligible					
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	482,574	11,695	390,244	9,290
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all3 low-volume threshold criteria)	Not applicable	88,070	690	77,617	404
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	302,172	13,688	209,403	9,735

Table 97: Description of MIPS Eligibility Status for CY 2021 MIPS Payment Year Using the Proposed and Finalized Assumptions***					
		Proposed rule estimates		Final Rule estimates †	
		Legacy data*		QPP Year 1 data	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)****	**Number of Clinicians**	**PFS allowed charges ($ in mil)****
Total Number of Clinicians Not MIPS Eligible		872,816	26,073	677,264	19,429
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,522,981	89,585	1,475,254	86,040

*Participation in MIPS defined as previously submitting quality or EHR data for PQRS.
Group reporting based on 2016 PQRS group reporting.
** Updated Estimated MIPS Eligible Population
*** Facility-based eligible clinicians are not modeled separately in this table and are captured in the individual eligible category. This table does not consider the impact of the MAQI Demonstration waiver. This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 22,000 clinicians and $3.7 billion in PFS allowed charges).
† These estimates reflect the finalized policies, which differ from the proposed rule (that is, change in MIPS eligible clinician types and those identified as QPs).

In the aggregate, CMS estimates that for the 2021 payment year, it would redistribute about $310 million in payment adjustments on a budget neutral basis. The maximum positive payment adjustments are 4.7 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS observes that the decrease in the funds available for redistribution and the maximum positive payment adjustment from the proposed rule to the final rule is due to the change in the data sources used to estimate final scores for MIPS eligible clinicians and the decrease in the additional performance threshold. CMS estimates that 91.2 percent of eligible clinicians will have a positive or neutral payment adjustment and 8.8 percent will have a negative payment adjustment. Table 99, reproduced below, shows the impact of payments by practice size and whether clinicians are expected to submit data to MIPS.[35] CMS estimates that clinicians in small practices (1-15 clinicians) participating in MIPS would perform as well as or better than mid-size practices.

[35] The proposed rule estimated MIPS participation and performance using historical PQRS and EHR data and the final rule presents the results from the analysis of MIPS 2019 performance period data, which was not available in time for the analysis of the proposed rule.

Table 99: MIPS Estimated Payment Year 2021 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*					
Practice Size*	**Number of MIPS eligible clinicians**	**Percent Eligible Clinicians with Positive or Neutral Payment Adjustment**	**Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment**	**Percent Eligible Clinicians with Negative Payment Adjustment**	**Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount****
Among those submitting data***					
1) 1-15	140,251	80.1%	47.2%	19.9%	1.2%
2) 16-24	41,226	86.1%	41.4%	13.9%	1.1%
3) 25-99	185,140	89.8%	48.6%	10.2%	1.3%
4) 100+	413,997	96.1%	69.0%	3.9%	2.0%
Overall	**780,614**	**91.2%**	**58.8%**	**8.8%**	**1.5%**
Among those not submitting data					
1) 1-15	15,680	0.0%	0.0%	100.0%	-6.3%
2) 16-24	629	0.0%	0.0%	100.0%	-6.6%
3) 25-99	860	0.0%	0.0%	100.0%	-6.6%
4) 100+	207	0.0%	0.0%	100.0%	-6.9%
Overall	**17,376**	**0.0%**	**0.0%**	**100.0%**	**-6.4%**

*Practice size is the total number of TIN/NPIs in a TIN

** 2016 and 2017 data used to estimate 2019 performance period payment adjustments. Payments estimated using 2016 and 2017 dollars.

***Includes facility-based clinicians whose quality data is submitted through hospital programs.

CMS estimates that approximately 165,000 to 220,000 clinicians will become QPs and a total of $600 to $800 million in incentive payments will be made for the 2021 payment year.

Limitations of CMS Analysis

Importantly, CMS describes several limitations to the analysis underlying the tables. CMS bases its analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility, participant lists using the APM Participation List for the first snapshot date of the 2018 QP performance period, the 2018 QPP Year 1 data and CAHPS for ACOs. CMS updated its analysis in the final rule by using actual MIPS performance data. CMS notes the scoring model does not reflect the growth in Advanced APM participation between 2018 and 2019 because that data are

not available at the detailed level needed for the scoring analysis. CMS also notes that given these limitations and others, there is considerable uncertainty around its estimates.

D. Impact on Beneficiaries

CMS notes that there are a number of changes in this final rule that would have an effect on beneficiaries. In general, CMS believes that many of the changes will have a positive impact and improve the quality and value of care provided to beneficiaries.

Most of the policy changes could result in a change in beneficiary liability as relates to coinsurance. For example, the 2018 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $109.80 which means in 2018 a beneficiary would be responsible for 20 percent of this amount, or $21.96. Based on this final rule, using the estimated 2019 CF, the 2019 national payment amount in the nonfacility setting for CPT code 99203 is $109.92 which means that in 2019, the beneficiary coinsurance would be $21.98.

E. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the proposed rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. CMS estimates that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $859 (8.0 hours x $107.38) and the total cost of reviewing this regulation is $5,102,275 ($859 x 5,943 reviewers).