2017

A Summary of the Centers for Medicare and Medicaid Services (CMS) Calendar Year (CY) 2018 Physician Fee Schedule Proposed Rule

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Overview

On July 13, 2017, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2018 Medicare Physician Fee Schedule (MPFS) proposed rule, which addresses changes to the physician fee schedule and other Medicare Part B payment policies to reflect CMS' perception of changes in medical practice and the relative value of services, as well as changes in the statute. Specifically, this proposed rule includes discussions and proposals regarding:

- Potentially Misvalued Codes
- Telehealth Services
- Establishing Values for New, Revised, and Misvalued Codes
- Establishing Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital
- Evaluation & Management (E/M) Guidelines and Care Management Services
- Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
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- the 2018 PQRS Payment Adjustment
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- MACRA Patient Relationship Categories and Codes
- Medicare Diabetes Prevention Program

Page numbers in the summary refer to the public display version of the proposed rule which can be viewed here. Comments will be accepted through **September 11, 2017**. The final rule should be released in early November 2017.

Provisions of the Proposed Rule for PFS (p. 17)

Determination of Practice Expense Relative Value Units (PE RVUs) (p. 23)

Changes to Direct PE Inputs for Specific Services: PE Inputs for Digital Imaging Services (p. 42)

In the CY 2017 PFS final rule, CMS finalized a proposal to add a professional PACS workstation (ED053) used for interpretation of digital images to a series of CPT codes and to address costs related to the use of film that had previously been incorporated as direct PE inputs for these services. A stakeholder expressed concern about our decision not to include the professional PACS workstation in a series of vascular ultrasound codes that use technical PACS workstations. The stakeholder indicated that the vascular ultrasound codes in question do make use of a professional PACS workstation, and that the dominant specialty provider requirement (that is, that the code's dominant specialty provider being diagnostic radiology) would exclude codes for which the professional PACS workstation is typical based on a mistaken assumption. The stakeholder stated that to furnish vascular

ultrasound services following the transition from film to digital imaging, both a technical and a professional PACS workstation are required, regardless of whether the practitioner furnishing the service is a radiologist, cardiologist, neurologist, or vascular surgeon. Based on this information, C***MS seeks comments regarding whether or not the use of the professional PACS workstation would be typical in the following list of CPT and HCPCS codes: CPT codes 93880, 93882, 93886, 93888, 93890, 93892, 93893, 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971, 93975, 93976, 93978, 93979, 93980, 93981, 93990, and 76706, and HCPCS code G0365.*** CMS will consider information submitted in comments to determine whether the professional PACS workstation should be included as a direct PE input for these codes.

Changes to Direct PE Inputs for Specific Services: Standardization of Clinical Labor Tasks (Preservice Clinical Labor for 0-Day and 10-Day Global Services) (p. 44)

Several years ago, the RUC's PE Subcommittee reviewed the preservice clinical labor times for CPT codes with 0-day and 10-day global periods and concluded that these codes are assumed to have no preservice clinical staff time (standard time of 0 minutes) unless the specialty can provide evidence that the preservice time is appropriate. However, CMS notes that for CY 2018, 41 of the 53 reviewed codes with 0-day or 10-day global periods include preservice clinical labor of some kind, suggesting that it is typical for clinical staff to prepare for the procedure prior to the patient's arrival. Because 77 percent of the reviewed codes for the current calendar year deviate from the "standard," ***CMS is seeking comment on the value and appropriate application of the standard in our review of RUC recommendations in future rulemaking.*** In reviewing the inputs included in the direct PE inputs database, CMS found that for the 1,142 total 0-day global codes, 741 of them had preservice clinical labor of some kind (65 percent). ***CMS is seeking comment specifically on whether the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking.***

Changes to Direct PE Inputs for Specific Services: Standardization of Clinical Labor Tasks (Obtain Vital Signs Clinical Labor) (p. 46)

CMS traditionally assigned a clinical labor time of 3 minutes for the "Obtain vital signs" clinical labor activity, based on the amount of time typically required to check a patient's vitals. Over time, that number of minutes has increased as codes are reviewed, and many of the reviewed codes for the current CY 2018 rulemaking cycle have a recommended clinical labor time of 5 minutes for "Obtain vital signs," based on the understanding that these services are measuring two additional vital signs: the patient's height and weight. CMS believes this change is likely due to changes in review standards, perhaps in conjunction with changes in medical practice, and that the change in the minutes assigned for the "Obtain vital signs" task for newer-reviewed services is detrimental to relativity among PFS services. ***Therefore, CMS is proposing to assign 5 minutes of clinical labor time for all codes that include the "Obtain vital signs" task, regardless of the date of last review. CMS is proposing to assign this 5 minutes of clinical labor time for all codes that include at least 1 minute previously assigned to this task. CMS is also proposing to update the equipment times of the codes with this clinical labor task accordingly to match the changes in clinical labor time.*** For codes that were not recently reviewed and for which CMS lacked a breakdown of how the equipment time was derived from the clinical labor tasks, CMS could not determine if the equipment time included time assigned for the "Obtain vital signs" task. In these cases, ***CMS is proposing to adjust the equipment time of any equipment item that matched the clinical labor time of the full service period to match the change in the "Obtain vital signs" clinical labor time.*** The proposed list of all codes affected by these proposed vital signs changes to direct PE inputs is available on the CMS website under downloads for the CY 2018 PFS proposed rule.

Changes to Direct PE Inputs for Specific Services: Standardization of Clinical Labor Tasks (Establishment of Clinical Labor Activity Codes) (p. 47)

Beginning for the CY 2019 PFS rulemaking cycle, CMS understands that the RUC intends to standardize clinical labor tasks and assign them a clinical labor activity code. CMS believes this could help CMS simplify and standardize the hundreds of different clinical labor tasks currently listed in the direct PE database. To help facilitate this transition to the new clinical labor activity codes, CMS has developed a crosswalk to link the old clinical labor tasks to the new clinical labor activity codes. This crosswalk is for informational purposes only, and would not change either the direct PE input values or the PE RVUs for codes. ***For CY 2018 rulemaking, CMS is displaying two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks as described by the new listing of clinical labor activity codes.*** These lists are available on the CMS website under downloads for the CY 2018 PFS proposed rule.

Changes to Direct PE Inputs for Specific Services: Equipment Recommendations for Scope Systems (p. 48)

Following several proposals and final policies included in the CY 2017 PFS final rule related to scope systems, CMS is making further proposals to continue clarifying scope equipment inputs, and seeks comments regarding the new set of scope proposals. ***First, CMS is seeking comment on several potential categories of scope system PE inputs. CMS is considering creating 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 believes that creating and pricing a single scope equipment code for each category would help provide additional clarity. CMS is seeking public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

For CY 2018, CMS is also proposing two minor changes to PE inputs related to scopes. ***CMS is proposing to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures.*** If this proposal were to be finalized, CMS would remove the equipment time for the separate light source from CPT codes that include the scope video system. ***CMS is also proposing an increase to the price of the scope video system of $1,000.00 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.).*** CMS seeks comments on the inclusion of the LED light in the scope video system, and the appropriate pricing of the system with the inclusion of these additional equipment items.

CMS anticipates adopting detailed changes to scope systems at the code level through rulemaking for CY 2019. CMS is not proposing any additional pricing changes to scope equipment for CY 2018 due to the proposed reorganization into a single type of scope equipment for each of the five scope categories. However, CMS would consider updating prices for these equipment items through the public request process for price updates, or based on information submitted as part of RUC recommendations.

Changes to Direct PE Inputs for Specific Services: Clarivein Kit for Mechanochemical Vein Ablation (p. 52)

After CMS finalized work RVUs and direct PE inputs for two new codes related to mechanochemical vein ablation, CPT codes 36473 and 36474, in the CY 2017 PFS final rule, stakeholders requested that a Clarivein kit supply item (SA122) be added to the direct PE inputs for CPT code 36474, the add-on code for ablation of subsequent veins. They stated that the Clarivein kit was accidentally omitted from the RUC recommendations, and that an additional kit is necessary to perform the service described by the add-on procedure. ***CMS is soliciting comment regarding the use of multiple kits during procedures described by the base and add-on***

codes to determine whether or not this supply should be included as a direct PE input for CPT code 36474 for CY 2018.

Changes to Direct PE Inputs for Specific Services: Removal of Oxygen from Non-Moderate Sedation Post-Procedure Monitoring (p. 52)

After finalizing the creation of separately billable codes for moderate sedation during the CY 2017 PFS final rule, CMS received additional recommendations to remove the oxygen gas supply item (SD084) from a series of CPT codes that were previously valued with moderate sedation as an inherent part of the procedure. Because oxygen gas is included in the moderate sedation pack contained within the separately billed moderate sedation codes, CMS believes that the continued inclusion of the oxygen gas in these codes is a duplicative supply. ***CMS is therefore proposing to remove the oxygen gas from the codes included on Table 4.***

Changes to Direct PE Inputs for Specific Services: Technical Corrections to Direct PE Input Database and Supporting Files (p. 53)

CMS is proposing to correct several inconsistencies in the direct PE database as described below and reflected in the CY 2018 proposed direct PE input database displayed on the CMS website.

For CY 2018, CMS is proposing to address the following inconsistencies:

- For CPT code 96416 (Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump) to improve payment accuracy, CMS is proposing to add 6 additional minutes of RN/OCN clinical labor (L056A), 4 minutes for the "Review charts by chemo nurse regarding course of treatment & obtain chemotherapy-related medical hx" task, and 2 minutes for the "Greet patient and provide gowning" task. CMS is proposing to add 1 quantity of the IV infusion set supply (SC018) and to lower the quantity from 2 to 1 of the 20 ml syringe supply (SC053). CMS is proposing to add 1800 minutes for the new ambulatory IV pump equipment, and to increase the equipment time of the medical recliner chair (EF009) from 83 minutes to 89 minutes to match the increase in RN/OCN clinical labor.
- For CPT code 91200 (Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report), CMS proposes to change the postservice work time from 5 minutes to 3 minutes, which also results in a refinement in the total work time for the code from 18 minutes to 16 minutes.
- CMS is proposing the direct PE refinements the to codes found on Table 5, to address a series of discrepancies CMS identified between the finalized direct PE inputs and the values entered into the database from previous calendar years.

The proposed PE RVUs displayed in Addendum B on CMS' website were calculated with the inputs displayed in the CY 2018 proposed direct PE input database.

Changes to Direct PE Inputs for Specific Services: Updates to Prices for Existing Direct PE Inputs (p. 56)

For CY 2018, CMS is proposing to update the price of thirteen supplies and one equipment item in response to the public submission of invoices, as detailed in Table 14: Invoices Received for Existing Direct PE Inputs. CMS is not proposing to update the price of the blood warmer (EQ072), the cell separator system (EQ084), or the photopheresor system (EQ206) equipment items as CMS was unable to verify the accuracy of the submitted invoice. CMS is also not proposing to update the price of the DNA image analyzer (ACIS) (EP001) equipment item, due to the inclusion of many components on the submitted invoice that are not part of the price of the DNA image analyzer; to price these equipment items accurately, CMS believes that CMS need additional information.

CMS continue to use the current price for these equipment items pending the submission of additional pricing information. CMS welcome the submission of updated pricing information regarding these equipment items through valid invoices from commenters and other stakeholders.

CMS is also proposing to change the name of the ED050 equipment from the "PACS Workstation Proxy" to the "Technologist PACS workstation" to alleviate potential confusion with the professional PACS workstation (ED053).

Adjustment to Allocation of Indirect PE for Some Office-Based Services (p. 58)

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. When direct PE inputs for a service are very low, 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 these cases, stakeholders have suggested that this allocation methodology does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. Among the services most affected by this anomaly are the primary therapy and counseling services available to Medicare beneficiaries for treatment of behavioral health conditions, including substance use disorders.

CMS agrees that the resulting site of service differential for these services seems unlikely to reflect the relative resource costs for the practitioners furnishing these services in nonfacility settings. ***Consequently, CMS believes it would be appropriate to modify the existing methodology for allocating indirect PE RVUs in order to better reflect the relative indirect PE resCMS is ources involved in furnishing these kinds of services in the nonfacility setting. Specifically, CMS identified HCPCS codes that describe face-to-face services, have work RVUs greater than zero, and are priced in both the facility and nonfacility setting. From among these codes, CMS further selected those with the lowest ratio of nonfacility PE RVUs for each work RVUs, specifying a ratio of less than 0.4 as an appropriate threshold based on several factors, including the range of nonfacility PE RVU to work RVU ratios among the codes identified.*** These criteria identified fewer than 50 codes, most of which are primarily furnished by behavioral health professionals, for a potential modification to the indirect PE allocation methodology.

For these codes, which CMS does not specify in the preamble, CMS believes it would be appropriate to establish a minimum nonfacility indirect PE RVU that would be a better reflection of the resources involved in furnishing these services. ***CMS proposes to set the nonfacility indirect PE RVUs for these codes using the indirect PE RVU to work RVU ratio for the most commonly furnished office-based, face-to-face service (CPT 99213) as a marker. Specifically, for each of these outlier codes, CMS proposes to compare the ratio between indirect PE RVUs and work RVUs that result from the preliminary application of the standard methodology to the ratio for the marker code, CPT code 99213. This proposed change in the methodology would then increase the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios***. CMS believes this approach reflects a reasonable minimum allocation of indirect PE RVUs, but CMS does not currently have empirical data that would be useful in establishing a more precise number.

In developing the proposed PE RVUs for CY 2018, CMS proposes to implement only one quarter of this proposed minimum value for nonfacility indirect PE for the outlier codes for this year. In making significant changes to the PE methodology in previous years, CMS has implemented such changes using 4 year transitions, based largely on concerns that some specialties experience significant payment reductions with changes in PE relativity, and a transition period allows for a more gradual adjustment for affected practitioners. Under the approach CMS is proposing, CMS estimate that approximately $40 million, or approximately 0.04 percent of

total PFS allowed charges, would shift within the PE methodology for each year of the proposed 4-year transition, including for CY 2018.

CMS is also proposing to exclude the codes directly subject to this proposed change from the misvalued code target calculation because the proposed change is a methodologic al change to address an anomaly produced by our indirect PE allocation process as opposed to a change to address misvalued codes. The PE RVUs displayed in Addendum B on the CMS website were calculated with the one quarter of the indirect PE adjustment factor implemented.

Determination of Malpractice Relative Value Units (MP RVUs) (p. 62)

MP RVUs, on average, represent approximately 4.3% of payment (p. 76). To calculate the malpractice (MP) RVUs for paying physician fee schedule services, CMS relies on a methodology based on three factors:

(1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners;
(2) Service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and
(3) An intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU

MP Premium Data. CMS uses MP premium data to update the MP GPCIs and the MP RVUs. In CY 2017, CMS utilized updated MP premium data to finalize the latest GPCI update (which was the 8th GPCI update). CMS, however, did not propose to use the updated MP premium data to propose updates for the specialty risk factors component of calculating MP RVUs (p. 63). This was due to the fact that CMS has previously finalized a policy that would update the specialty-risk factor component once every 5 years. Statute, however, requires that the GPCI data be updated at least once every 3 years. Therefore, because both components rely on the use of MP premium data, ***CMS proposes to use the most recent data for MP RVUs for 2018 and to align the update of MP premium data and MP GPCIs to once every 3 years*** (p. 64). ***CMS is also seeking comment on methodologies and sources it might use to improve the next update of the MP premium data***.

Methodology for Proposed Revision of Resource-Based Malpractice RVUs. CMS outlines the current methodology used for obtaining specialty specific MP premium data that reflect geographic cost differentials (p. 65). CMS notes that for some specialties MP premiums were not available from the rate filings in at least 35 states (the threshold for which it will include the specialty specific data). In those instances were CMS did not have sufficient data for a specialty, CMS performed a crosswalk to a similar specialty for which it did have data (*See* Table 6). ***CMS seeks comment on the appropriateness of the crosswalks developed for use in calculating MP RVUs*** (p. 66). CMS had sufficient data for 43 specialty types to develop the specialty specific MP risk factors. They can be found in Table 8. The specialty specific premium data is available for review on the CMS Web site.

CMS describes the current methodology for calculating the specialty risk factors for MP RVUs beginning on p. 68.

- *Index*. CMS uses these risk factors as an index that is calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowers premiums for which it had sufficient and reliable data (which was allergy and immunology) (p. 70).
- *Technical Component (TC) Only Services*. In CY 2015, CMS updated the premium data for independent diagnostic testing facilities (IDTFs). The data used for this update was from a 2009 survey conducted by the Radiology Business Management Association (RBMA). In 2015, RBMA submitted additional data collected from IDTFs in 2014. CMS declined to use the data because it believed further study was

necessary. ***CMS seeks comment on appropriate, comparable data sources for the broader set of technical component services*** (p. 71). ***CMS also seeks comment on whether the data for IDTFs are "comparable and appropriate as a proxy for the broader set of TC services***. CMS notes that in the next update of specialty risk factors it plans to collect more data across a broader set of TC services (not just for radiology) (e.g. cytotechnologists and cardiovascular technologists). In the meantime, ***CMS proposes to assign a TC risk factor of 1.0 (i.e. the lowest physician specialty risk factor).***

- *Low Volume Service Codes*. CMS will use "expected specialties" instead of claims data to determine the specialty mix for low volume services ("99 or fewer allowed services") (to address concerns about variability in PE RVUs). ***CMS requests comment on the propose to use the service-level overrides to determine specialty mix for low volume services and the list of overrides (available for review on the CMS website).***
- *New and Revised Codes*. ***CMS proposes to eliminate the general use of an MP-specific specialty-mix crosswalk for new and revised codes*** (given the new proposed methodology) (p. 74). CMS notes that it would continue to consider specific recommendations from the public and the RUC regarding specialty mix assignments particularly in cases where coding changes are expected to result in differential reporting of services by specialty (or where the codes are expected to be "low-volume").

Using the specialty-specific index and based on the specialty mix of those billing a code, CMS then calculates the resource based MP RVUs for each HCPCS code that has a PE RVU. The proposed MP RVUs can be found in Addendum B.

Medicare Telehealth Services (p. 77)

Adding Services to the List of Medicare Telehealth Services (p. 80)

CMS reminds stakeholders that requests to add services to the list of Medicare telehealth services must be received no later than December 31 of each calendar year to be considered for the next rulemaking cycle (p. 81). The following requests were received in CY 2016 for inclusion in 2018 organized by the two categories for telehealth services created by Medicare

(1) Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services.

- G0296 (*Counseling visit to discuss need for lung cancer screening using low dose ct scan (LDCT)(services is for eligibility determination and shared decision making)*): In response to a request that this code be added, CMS believes that the service described by this code is sufficiently similar to office visits currently on the telehealth list and that all components of the service can be furnished via interactive telecommunications technology. Therefore, ***CMS proposes to add G0296 to the list of Medicare telehealth service under Category 1*** (p. 83)***.***

- CPT 90839 (*Psychotherapy for crisis; first 60 minutes)* and 90840 (*Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)*): In response to a request that these codes be added, CMS found these services similar to the psychotherapy services currently on the telehealth list even though the code describes patient in need of more urgent care. CMS did not that one element of the services in the CPT prefatory language might not be able to be furnished via telehealth: "mobilization of resources to defuse the crisis and restore safety." Therefore, ***CMS proposes to add CPT 90839 and 90840 to the list of Medicare telehealth service under Category 1 with the explicit condition of payment that the distant site practitioner be able to mobilize resources at the originating site to defuse the crisis and***

restore safety when applicable (p. 83)**.** ***CMS specifically seeks comment on whether its assumption that a remote practitioner is able to mobilize resources at the originating site to "defuse the crisis and restore safety" is valid*** (p. 84).

- CPT 90785 (*Interactive complexity (List separately in addition to the code for the primary procedure*): Based on CMS' own review, ***CMS proposes to add CPT 90785 to the list of Medicare telehealth services*** (p. 84).

- CPT 96160 (*Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument*) and 96161 (*Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument)*): Based on CMS' own review, ***CMS proposes to add CPT 96160 and 96161 to the list of Medicare telehealth services*** (p. 84). CMS notes that these services might not ordinarily be furnished in person with a physician or billing practitioner. CMS also notes that services that are not considered face-to-face do not need to be on the list of Medicare telehealth services. Therefore, ***CMS notes that these services would only be considered Medicare telehealth services when billed with a based code that is also on the telehealth list*** (p. 85).

- G0506 (*Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service)*): Based on CMS' own review, ***CMS proposes to add G0506 to the list of Medicare telehealth services*** (p. 84). CMS notes that this service might not ordinarily be furnished in person with a physician or billing practitioner. CMS also notes that services that are not considered face-to-face do not need to be on the list of Medicare telehealth services. Therefore, ***CMS notes that this service would only be considered Medicare telehealth services when billed with a based code that is also on the telehealth list*** (p. 85).

(2) Services that are not similar to the current list of telehealth services, (This includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient.)

CMS declined to add the following services to the list of telemedicine services:

- Physical and Occupational Therapy and Speech-Language Pathology Services: In declining to add the following codes to the list of telemedicine services, CMS noted that statute defines the types of practitioners who may furnish and bill for telehealth services and that physical therapists, occupational therapists, and speech-language pathologists are not on the list. CMS had previously stated this be the request was resubmitted for consideration only when provided by eligible distant site practitioners. CMS was not inclined to do so given that the codes are furnished by therapy professionals over 90 percent of the time (p. 88). CMS also notes that several of the codes require direct manipulation of the patient (p. 89).
    - Deleted CPT 97001/New CPT 97161 (*Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated*

characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome.)

- Deleted CPT 97002/New CPT 97162 (*Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome*)
- Deleted CPT 97003/New CPT 97165 (*Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component*)
- Deleted CPT 97004/New CPT 97166 (*Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component)*)
- CPT 97110 (*Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility*)
- CPT 97112 (*Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities*)
- CPT 97116 (*Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)*)
- CPT 97535 (*Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes*)
- CPT 97750 (*Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes*)
- CPT 97755 (*Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes*)
- CPT 97760 (*Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes*)

- CPT 97761 (*Prosthetic training, upper and/or lower extremity(s), each 15 minutes*)
- CPT 97762 (*Checkout for orthotic/prosthetic use, established patient, each 15 minutes*)

- Initial Hospital Care Services: CMS previously considered the addition of these codes. CMS continues to believe that while "initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's treatment during the hospital course." (p. 90). CMS also noted that it believed that beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other codes that are already on the list of Medicare telehealth services (including subsequent hospital care, follow-up telehealth inpatient and ED consultations, and initial and follow-up critical care telehealth consultations) (p. 91).
  - CPT 99221 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.*)
  - CPT 99222 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.*)
  - CPT 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)*

- Online E/M By Physician/QHP: CPT 99444 (*Online evaluation and management service provided by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network*): CMS restated its previous rationale for not including this on the list of Medicare telehealth services: it is non-covered service (p. 91).

- Monthly Capitation Payment (MCP) for ESRD-related services for home dialysis, by age: CMS continues to believe that these services contain the critical element of a required face-to-face clinical examination of the vascular access site (p. 93). While CMS does not propose to add the following codes to the list of telemedicine services, ***CMS is interest in input about current clinically accepted care practices and to what extent telecommunications technology can be used to examine the access site (including frequency of the evaluation of the access site).***
  - CPT 90963 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2– 11 years of age*

to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older)

- CPT 90967 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age); 90968 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age); and 90969 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age); and 90970 (End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older*)

The full proposed list of telehealth services is provided in a download on the CMS Web site.

Elimination of the Required Use of the GT Modifier (p. 94)

CMS current requires claims to include the appropriate CPT or HCPCS code for the professional service along with the telehealth modifier GT (*via interactive audio and video telecommunications systems*).[1] In CY 2017, CMS finalized a new place of service (POS) code describing services furnished via telehealth. CMS believes that the POS code and modifier requirement are redundant and, therefore, ***CMS proposes eliminate the required use of the GT modifier on professional claims*** (p. 95). CMS notes that institutional claims are not required to use a POS code when submitting claims, and therefore distant site practitioners billing under CAH Method II must continue to use the GT modifier on institutional claims.

Comment Solicitation on Medicare Telehealth Services (p. 95)

While CMS is restricted by statute on what it is allowed to cover, ***CMS seeks input on how it might "further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies"*** (p. 96).

Comment Solicitation on Remote Patient Monitoring (p. 96)

CMS seeks comment on whether to make separate payment for CPT codes that describe remote patient monitoring. CMS notes that these would by definition not be Medicare telehealth services. Using the examples of physician interpretation of an actual electrocardiogram or electroencephalogram, these services "involved the interpretation of medical information without a direct interaction between the practitioner and the beneficiary" and are therefore paid the same as in-person services without additional requirements of originating sites and the use of the telemedicine POS code.

CMS seeks specific comment on currently bundled code, CPT 99091 (Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time).

- CMS seeks input on its status indicator, valuation, and the circumstances under which the code could be reported for separate payment (including how to differentiate the time related to these services from other services, including Chronic Care Management services) (p. 97).
- CMS seeks input on the value of these services.

[1] In Federal telemedicine demos in Alaska and Hawaii, claims are submitted with the appropriate CPT or HCPCS code for the professional service along with the telehealth modifier GQ if the telehealth services are performed "via an asynchronous telecommunications system." (p. 94). These types of claims would continue to use the GQ modifier.

- CMS seeks input on what protections might be necessary to assure that beneficiaries are properly informed that they are receiving remote monitoring services given that the beneficiary would be subject to cost sharing.
- CMS seeks input on information on which it could rely to make potential utilization assumptions if they were to make it payment for CY 2018 (or in the future).

CMS also seeks input on other existing codes that describe extensive use of communications technology for consideration in future rulemaking (p. 97)**,** including CPT 99090 (*Analysis of clinical data stored in computers (eg, ECGs, blood pressures, hematologic data)*).

Proposed Potentially Misvalued Services Under the Physician Fee Schedule (p. 99)

As part of CMS' ongoing RVU refinement process, CMS plans to continue its review of potentially misvalued codes of the upcoming years. CMS reviewed its process and states that it requests recommendations from the RUC and other public commenters. In addition to the codes CMS identifies, the RUC also identifies misvalued codes for review. CMS also identifies potentially misvalued codes via its public nomination process. CMS notes that it plans to continue its work to examine potentially misvalued codes. CMS states that since CY 2009 it has reviewed approximately 1,700 potentially misvalued codes and assigned appropriate work RVUs and Direct PE inputs as a result of the review (p. 103).

CY 2018 Identification and Review of Potentially Misvalued Services (p. 104)

Public Nomination. CMS reviewed its public nomination process for potentially misvalued codes.

- Since the CY 2017 Medicare Physician Fee Schedule Final Rule, CMS received a nomination for one code: CPT 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*). The request was received with supporting documentation requesting that the code value be increased to 14.23. ***CMS proposes to add this code as a potentially misvalued code*** (p. 106).

- CMS previously requested input on the values for dialysis vascular access codes (CPT 36901 through 36909). CMS notes that stakeholders have presented concern about the "typical patient" included in the CY 2017 RUC recommendations. Therefore, ***CMS seeks additional input and data regarding the potentially misvalued work RVUs for CPT 36901-36909*** (p. 106).

- CMS notes that it has received conflicting data for Direct PE inputs for CPT 88184 (*Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker*) and 88185 (*Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)*). Therefore, ***CMS proposes CPT 88184 and 88185 as potentially misvalued codes*** (p. 107). CMS notes that stakeholders have noted that previously finalized clinical labor and supplies are no longer accurate.

- CMS has received input that the Work RVUs for ED visits may not reflect the full resources involved in furnishing these services and are undervalued "given the increased acuity of the patient population and the heterogeneity of the sites (e.g. freestanding and off-campus emergency departments). Therefore, ***CMS seeks input on whether CPT codes 99281-99385 (Emergency department visits for the evaluation and management of a patient) should be reviewed as misvalued codes*** (p. 107).

Code Screens. In recent years, CMS has prioritized the following codes screens for identifying codes for the misvalued code initiative:

- Codes with low work RVUs commonly billed in multiple units per single encounter
- Codes with high volume and low work RVUs
- Codes with site-of-service-anomalies
- E/M codes
- PFS high expenditure services
- Services with standalone PE procedure time
- Services with anomalous time
- Contractor Medical Director identified potentially misvalued codes
- Codes with higher total Medicare payments in office than in hospital or ASC
- Publicly nominated potentially misvalued codes
- 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25

CMS does not propose any new screens for CY 2018. However, ***CMS seeks comment on the best approach for developing screens and new screens it might consider for use in future rulemaking*** (p. 108).

Payment Incentive for the Transition from Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services (p. 109)

The Consolidated Appropriations Act of 2016 reduces payment amounts under the PFS for the technical component (including the technical component of a global service) of imaging services that are X-rays taken using film by 20 percent effective for services furnished beginning January 1, 2017. CMS previously finalized Modifier FX to be reported on claims for imaging services that are X-rays taken using film beginning on January 1, 2017.

The statute also provides for a 7 percent cut in payments for imaging services under the PFS that are X-rays using computed radiography technology[2] (including the X-ray component of a packaged service) in CYs 2018, 2019, 2020, 2021, or 2022. The statute also provides for a 10 percent reduction for such imaging services taken using computed radiography technology in CY 2023 or a subsequent year. ***CMS proposes to establish a new modifier to be used on claims beginning January 1, 2018 for the technical component of X-rays (including the X-ray component of a packaged service) taken using computed radiography technology*** (p. 109). This will allow CMS to implement the statutory 7 percent reduction for these services for CYs 2018-2022 and 10 percent reduction for CY 2023 or a subsequent year (p. 110).

Proposed Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments (PBDs) of a Hospital (p. 111)

Background

CMS continued to monitor concerns that the trends in hospital acquisition of physician practices and increased delivery of physician services in a hospital setting have led to total higher Medicare payments. When care is delivered in a hospital Provider Based Department (PBD), Medicare makes two payments: one for the facility fees (under the OPPS) and the other for the physician's professional services (under the Physician Fee Schedule). Medicare and other stakeholders have been concerned that the total of those two payments are higher for

[2] Computed radiography technology is defined as "cassette-based imaging that utilizes an imaging plate to create the image involved." (p. 109).

many services when billed out of a PBD than they were when they were previously provided in the physician office setting.

The Bipartisan Budget Act of 2015 included a provision that "applicable items and services"[3] furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered OPD service . . . for purposes of payment under the OPPS and will instead be paid 'under the applicable payment system; under Medicare Part B." The statute defines "off-campus outpatient department of a provider" as "a department of a provider . . . that is not located on the campus of such provider, or within the distance from a remote location of a hospital[4] facility." The statute also excepts from that definition "an off-campus PBD that was billing . . . with respect to covered OPD services furnished prior to" November 2, 2015." CMS previously finalized that the "applicable payment system" for the provisions covered by the Bipartisan Budget Act of 2015 would be the Medicare Physician Fee Schedule (MPFS). That is, most nonexcepted items and services furnished by off-campus PBDs will be paid under the MPFS. These provisions for 2017 were implemented as an interim final rule. CMS proposes to set the payment policies for 2018 in this year's proposed rule and states that it anticipates responding to public comments and "finalizing the CY 2017 interim final rule in future PFS rulemaking." (p. 111). CMS notes that the coding and billing mechanisms that make payments to hospitals for nonexcepted "items and services" furnished by nonexcepted off-campus PBDs are similar to those CMS already uses to pay for the Technical Component (TC) of services paid for under the MPFS. ***CMS proposes to maintain this mechanism in 2018*** (p. 112).

Establishment of Payment Rates (p. 113)

In creating the new payment mechanism, CMS sought to ensure that the relativity in OPPS payment rates was maintained under the relative payment system of the MPFS. Therefore, ***CMS had established a transitional policy of site-specific rates under the MPFS for the TC of nonexcepted "items and services" furnished by nonexcepted off-campus PBDs based on the OPPS payment for those services and scaled down by 50 percent ("the PFS Relativity Adjuster")*** (p. 113). CMS set the PFS Relativity Adjuster based on claims data received after providers were required to begin using the ~PO modifier to signal that it was a service "billed by an off-campus department of a hospital paid under the OPPS other than a remote location, a satellite facility, or a dedicated emergency department (ED)."[5] CMS' analysis of the payment rates between the OPPS and MPFS for the codes most frequently billed with the ~PO modifier can be found in Table 9. CMS also created exceptions to the application of the 50 percent PFS Relativity Adjuster (p. 119):

- Certain services reflected with a status indicator of "A" in Addendum B. These services can be paid for under the MPFS, Clinical Lab Fee Schedule, or the Ambulance Fee Schedule without a payment reduction.
- Drugs and biologicals separately payable under the OPPS (status indicator "G" or "K" in Addendum B) continue to be paid under the ASP +6 payment methodology.
- Drugs and biologicals unconditionally packaged and not separately payable (status indicator "N" in Addendum B) are bundled into the PFS payment and not paid separately to hospitals.

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[3] The statutory definition of "applicable items and services" specifically excludes items and services furnished by a dedicated emergency department. Therefore, these items and services will continue to be paid under the OPPS.

[4] Current regulation defines "remote location of a hospital" as "a facility or an organization that is either created by, or acquired by a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider . . ."

[5] CMS provides an example for the most commonly billed with modifier ~PO, G0463 (*Hospital outpatient clinic visit for assessment and management of a patient*) which is paid under APC 5012 (*Level 2 Examinations and Related Services*). CMS mapped these services to CPT 99213 and 99214 office visit codes (pp. 114-115)

For purposed of administering this overall payment policy, these services are billed on the institutional claim using the ~PN modifier (Nonexcepted service provided at an off-campus, outpatient provider-based department of a hospital) (p. 119). (*See also,* CMS Transmittal 3685, Change Request 9930 (December 22, 2016)).

CMS noted that the 50 percent PFS Relativity Adjuster was intended to be a transitional policy until it obtained more precise data. CMS stated that it does not yet have more precise data (and does not expect to until after the end of CY 2017) (p. 120). However, CMS continues to remain concerned that that the PFS Relativity Adjuster for CY 2017 could result in "greater overall payments to hospitals for services furnished by nonexcepted off-campus PBDs than would otherwise be paid under the PFS in the non-facility setting. Therefore, ***CMS proposes to revise the PFS Relativity Adjuster for nonexcepted "items and services" furnished by nonexcepted off-campus PBDs to 25 percent of the OPPS payment rate*** (p. 122). ***CMS also seeks comment on whether it should adopt a different PFS Relativity Adjuster (e.g 40 percent) to represent a middle ground between ensuring adequate hospital payments and ensuring that hospitals are not paid more than others paid through the PFS nonfacility rate*** (p. 123).[6]

Geographic Adjustments (p. 124)

In CY 2017, in order to parallel the geographic adjustments (using the hospital wage index) made under the OPPS, CMS created class-specific geographic practice cost indices (GPCIs) to adjust the site-specific, Technical Component (TV) rates for nonexcepted "items and services" furnished in nonexcepted off-campus PBDs. CMS believed it was necessary to anchor these adjustments to the calculations based on the hospital wage index because the MPFS GPCIs that would otherwise apply are not based on the hospital wage index areas. ***CMS proposes to continue to maintain a class-specific set of GPCIs as it has done in 2017*** (p. 124).

Coding Consistency (p. 125)

CMS notes that while in most cases the same HCPCS codes are used to identify certain services under both the OPPS and the MPFS, there are exceptions for which it must account:

- **E/M Services**. Under the MPFS, providers rely on the 5 levels of CPT codes (with new and established patient variations. Under the OPPS, however, all similar visits are identified by a single code: G0463 (*Hospital Outpatient Clinic Visit*). ***CMS proposes to maintain the current MPFS payment rate for G0463 based on the application of the PFS Relativity Adjuster to the OPPS payment rate*** (p. 125).
- **Certain Radiation Treatment Delivery and Imaging Guidance Services**. Under the MPFS, CMS developed G codes to describe radiation treatment delivery services furnished in the physician office setting. This is due to a statutory provision requiring the consideration of certain coding and payment inputs). These codes are *not* recognized under the OPPS (where payment is based on a set of CPT codes). ***CMS proposes to maintain that nonexcepted off campus PBDs will bill the G codes for these radiation treatment deliver services using the ~PN modifier (even though the PFS Relativity Adjust does not apply to these services because the G codes already reflect payment under the MPFS)*** (p. 126) ***and payment will be set to reflect the TC rate for the code under the MPFS***.

OPPS Payment Adjustments (p. 126)

CMS continued to incorporate the claims processing logic under the OPPS packaging payment rates and the multiple procedure payment reduction (MPPR). ***CMS proposes to maintain the OPPS payment policies for Comprehensive APCs, packaged items and services, and the MPPR "to maintain the integrity of the PFS***

[6] CMS notes that its ability to estimate the change in OPPS and MPFS payments is not very precise and, while it intents to more accurately make estimates the differential between the update factors in the future, simply notes that "the differential between the OPPS and PFS payment update for CY 2018 is a factor that suggests that the proposed PFS Relativity Adjuster may overestimate PFS nonfacility payment relative to OPPS payments." (p. 124).

Relativity Adjuster (p. 126). ***In addition, CMS believes it would be inappropriate to incorporate the following other OPPS payment adjustments***[7] (p. 127):

- Outlier payments
- The rural sole community hospital (SCH) adjustment
- The cancer hospital adjustments
- Transitional outpatient payments
- The hospital outpatient quality reporting payment adjustment; and
- The inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service.

Additional Provisions

- **Supervision Rules.** CMS noted that supervision rules that apply for hospitals continue to apply for nonexcepted off-campus PBDs that furnish nonexcepted items and services (pp. 129-130).
- **Beneficiary Cost-Sharing**. CMS noted that the cost-sharing rules of the MPFS continue to apply for all non-excepted items and services furnished by non-excepted off-campus PBDs (i.e. 20 percent of the fee schedule amount) (p. 130).
- **CY 2019 and Future Years**. CMS believes it will have more complete data in time to include rate setting proposals for CY 2019. CMS recognizes that the use of the PFS Relativity Adjuster means that certain specialties, service lines, and non-excepted off-campus PBD types might have total Medicare payments for the same services that are either higher or lower than when billed in the physician office setting. CMS is concerned that this could continue to perpetuate incentives that Congress sought to eliminate. CMS believes that the current proposal allows institutions to continue to use the facility claim form, but that CMS will use collected data to determine with the current adjustments are appropriate. ***CMS requests comments on potential changes to its methodology that would account specialty-specific patterns*** (p. 131).

Proposed Valuation of Specific Codes (p. 132)

Process for Valuing New, Revised, and Potentially Misvalued Codes (p. 132)

In this section, CMS describes the process for valuing new, revised and misvalued codes, providing a history of the prior 5-year review process and the transiton to the new process finalized in CY 2015.

Methodology for Proposing Work RVUs (p. 133)

For CY 2018, CMS generally proposed RUC-recommended work RVUs for new, revised, and potentially misvalued codes based on its understanding that the RUC generally considers the kinds of concerns the agency has historically raised regarding appropriate valuation of work RVUs. However, CMS did identify some concerns and has included descriptions of potential approaches it might have taken in developing work RVUs that differ from the RUC recommended values. CMS seeks comment on both the RUC-recommended values as well as the alternatives considered.

Table 10 contains a list of codes for which CMS proposed work RVUs; this includes all codes for which CMS received RUC recommendations by February 10, 2017.

[7] CMS noted that since Community Mental Health Centers (CMHCs) are ineligible to be a "provider-based" to a hospital and is providing partial hospitalization programs (PHPs), a nonexcepted off campus PBD would be eligible for PHP payment if the entity also enrolls and bills as a CMHC for payment under the OPPS (p. 127). CMS also allowed for PHP services to be billed by a nonexcepted off-campus hospital-based PBD under the PFS at the CMHC per diem rate (p. 128). CMS notes, however, that they are not requiring PHPs to enroll as CMHCs (p. 129).

Methodology for Proposing the Direct PE Inputs to Develop PE RVUs (p. 139)

Table 11 details CMS' proposed refinements of the RUC's direct PE recommendations at the code-specific level. 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 proposed PE RVUs. Nearly half of the proposed refinements listed in Table 11 result in changes under the $0.30 threshold and are unlikely to result in a change to the proposed RVUs.

Proposed Valuation of Specific Codes for CY 2018 (p. 145)

The table below highlights CMS' work and PE value proposals and alternatives considered for selected codes found on pages 145-233. A full discussion of CMS' rationale for these proposals can be found in the rule.

TABLE: Proposed Valuation of Specific Codes for CY 2018 (including CMS alternatives considered)

Service(s)	Proposed Work Valuation	Proposed PE Valuation
Anesthesia Services for Gastrointestinal (GI) Procedures (CPT codes 007X1, 007X2, 008X1, 008X2, and 008X3)	For CY 2018, ***CMS proposes the RUC-recommended base units without refinement for CPT codes 007X1 (5.00 base units), 007X2 (6.00 base units), 008X1 (4.00 base units), 008X2 (4.00 base units) and 008X3 (5.00 base units).*** CMS considered 3.00 base units (the 25th percentile survey result) for CPT code 008X2 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy), based on its comparison of the surveyed post-induction anesthesia-intensity allocation for CPT code 008X2 to codes with similar allocations (CPT code 01382 (Anesth dx knee arthroscopy)). ***CMS seeks comment on its proposed and alternative value for CPT code 008X2.***	
Muscle Flaps (CPT codes 15734, 15736, 15738, 157X1, and 157X2)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT codes 15734 (a work RVU of 23.00), 15736 (a work RVU of 17.04), 15738 (a work RVU of 19.04), 157X1 (a work RVU of 13.50), and 157X2 (a work RVU of 15.68).*** For CPT code 157X1, CMS considered a work RVU of 12.03, crosswalking to CPT code 36830 (Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (eg, biological collagen, thermoplastic graft)). CMS considered a potential crosswalk to another code in the same family, CPT code 36830, which also shares the same intraservice time with CPT code 157X1 but differs by only 8 minutes of total time. ***CMS seeks comment on whether the RUC recommendation is appropriate given the significant variation in intensity among these services.*** CMS considered a work RVU of 14.63 for CPT code 157X2 (survey 25th percentile), crosswalking to CPT code 36833 (Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has the	CMS considered refining the clinical labor time for "Check dressings & wound/home care instructions" for CPT code 157X1 from 10 minutes to 5 minutes. ***CMS seeks comment on the typical time input for checking dressings, and whether removing and replacing dressings, would typically take place during the intraservice or postservice period.*** ***CMS seeks comments regarding the use of the new "plate, surgical, mini-compression, 4 hole" (SD189) supply included in CPT code 157X1, including whether use of this supply would be typical, and if so, whether it should be included in the work description.*** CMS notes that SD189 is mentioned in the direct PE recommendations, but the supply does not appear in the work description. In the work description, the fixation screws are applied to the orbital rim and lateral nasal wall, not the surgical plate.

	same intraservice time, 1 minute of additional total time, and a work RVU of 14.50. ***CMS seeks comment on the effect that an alternative work RVU of 14.50 would have on relativity among the codes in this family.***	
Application of Rigid Leg Cast (CPT code 29445)	For CY 2018, ***CMS proposes the RUC-recommended work RVU of 1.78 for CPT code 29445.***	For the direct PE inputs, ***CMS proposes to refine the clinical labor time for "Check dressings & wound/home care instructions" from 5 minutes to 3 minutes, as the additional 2 minutes of clinical labor time that CMS proposes to remove would take place during the monitoring time following the procedure and be accounted for in that clinical labor time.*** CMS also considered refining the clinical labor time for "Remove cast" from 22 minutes to 11 minutes: 1 minute for room prep, 10 minutes for assisting the physician, and 0 minutes for the additional activities described in the RUC recommendations, which would have only taken place during the initial casting. ***CMS seeks comment on whether the initial application of a new cast would be typical for CPT code 29445.*** According to Medicare claims data for CPT code 29445, three or more castings took place for 52 percent of beneficiaries, which suggests that three or more castings may be the typical case. A single casting only took place for 30 percent of services reported with CPT code 29445.
Strapping Multi-Layer Compression (CPT codes 29580 and 29581)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT code 29580 (a work RVU of 0.55) and CPT code 29581 (a work RVU of 0.60);*** however, CMS is concerned about the changes in preservice time reflected in the specialty surveys compared to the RUC-recommended work RVUs. ***CMS is seeking comment on whether the alternative values considered would be more appropriate.***	
Control Nasal Hemorrhage (CPT codes 30901, 30903, 30905, and 30906)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT codes 30901 (a work RVU of 1.10), 30903 (a work RVU of 1.54), 30905 (a work RVU of 1.97), and 30906 (a work RVU of 2.45).*** For CPT code 30903 (Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method), CMS considered a work RVU of 1.30 (the 25th percentile survey result), which would	***CMS proposes to use the RUC-recommended direct PE inputs for CPT codes 30901, 30903, 30905, and 30906, with standard refinements to the equipment times to account for patient monitoring times.*** CMS noted that as part of its recommendation, the RUC informed the agency that the specialty societies presented evidence stating that the 1995 valuations for these services factored in excessive times,

	have been further supported by CPT codes 36584 and 51710 which have similar service times to the median survey results. For CPT code 30905 (Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; initial), CMS considered a work RVU of 1.73. ***CMS seeks comment on whether a work RVU of 1.73 would potentially affect relativity among the codes in this family.*** For CPT code 30906 (Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent), CMS considered a work RVU of 2.21. ***CMS seeks comment on whether a work RVU of 2.21 would potentially improve relativity among the codes in this family.*** ***While CMS proposes the RUC-recommended values, it seeks comment on whether its alternative values would be more appropriate.***	specifically to account for infection control procedures that were necessary at that time due to the prevalence of HIV/AIDS. The specialty societies also noted that increased availability and use of blood thinner medications compared to those available in 1995, has increased the difficulty and intensity of these procedures. ***CMS seeks additional information regarding the presumption that the relative resource intensity of these services, specifically, would be affected by the commercial availability of additional blood thinner medications. Additionally, CMS seeks comments on the prevalence of HIV/AIDS and whether the work related to infection control procedures would be relative across many PFS services or specifically related to nasal hemorrhage control procedures.***
Tracheostomy (CPT codes 31600, 31601, 31603, 31605, and 31610)	***CMS proposes the RUC-recommended work RVUs for all five codes in this family; a work RVU of 5.56 for CPT code 31600, a work RVU of 8.00 for CPT code 31601, a work RVU of 6.00 for CPT code 31603, a work RVU of 6.45 for CPT code 31605, and a work RVU of 12.00 for CPT code 31610.*** CMS considered a work RVU of 6.50 for CPT code 31601. ***CMS seeks comment on the effect that this alternative value would have on relativity compared to other PFS services, especially since the survey data does not suggest an increase in the time required to perform the procedure.*** CMS considered a work RVU of 4.77 for CPT code 31605. ***CMS seeks comments on the methodology used to determine the RUC-recommended work RVU and intraservice work time.*** CMS is concerned that the number of respondents (20) is below the threshold typically required for submission of a survey, and the effect of using survey results only from physicians who had personal experience performing the procedure (20 respondents). ***CMS seeks comment on the effect that an alternative work RVU of 4.77 would***	***CMS proposes the RUC-recommended direct PE inputs for all five CPT codes in this family without refinements, and seeks comment.***

	have on the relativity of this service compared to other services in this family of codes and compared to other PFS services, taking into account that CPT code 31605 describes a difficult and dangerous life-threatening emergency procedure. CMS considered a work RVU of 6.50 for CPT code 31610 based on a direct crosswalk to CPT code 31601 (Incision of windpipe). ***CMS seeks comment on whether the unusual volume of physician work time included in the postoperative visits for CPT code 31610 contributed to the negative derived intensity reported by the survey data. Considering that the other codes in this family have 0-day global periods, CMS considered and seeks comment on whether a 0-day global period should be assigned to CPT code 31610.***	
Bronchial Aspiration of Tracheobronchial Tree (CPT codes 31645 and 31646)	For CY 2018, ***CMS proposes the RUC-recommended work RVU of 2.88 for CPT code 31645 and the RUC-recommended work RVU of 2.78 for CPT code 31646.*** CMS considered a work RVU of 2.72 for CPT code 31645, crosswalking to CPT code 45347 (Sigmoidoscopy, flexible; with placement of endoscopic stent). CMS has concerns regarding the decrease in intraservice and total time compared to the current values (it is important to note how these related codes have been affected by the creation of separately billable codes for moderate sedation). CMS agrees that CPT code 31645 should be valued at a higher work RVU than CPT code 31622, however, ***CMS seeks comment on whether the work of moderate sedation was inadvertently included in the development of the recommended work RVU.*** CMS notes that as part of the CY 2017 PFS final rule, it finalized separate payment for moderate sedation. Following the creation of separately billable codes for moderate sedation, CPT code 31622 is currently valued at a work RVU of 2.53, not 2.78 as it was previously valued, and CMS does not believe it would be appropriate to continue to value CPT code 31645 as though moderate sedation was still an inherent part of the work of this service. As a result, CMS considered a direct crosswalk to CPT code 45347, which has the same intraservice time and 8 additional	For the direct PE inputs, ***CMS proposes to remove the oxygen gas (SD084) from CPT code 31645.*** This supply is included in the separately billable moderate sedation codes, and ***CMS proposes to remove the oxygen gas as recommended by the RUC PE Subcommittee as part of the removal of oxygen from non-moderate sedation post-procedure monitoring codes. CMS proposes to remove the equipment time for the IV infusion pump (EQ032) from CPT code 31645;*** infusion pump is contained in the separately reportable moderate sedation codes. ***CMS also proposes to remove the equipment time for the CO_2 respiratory profile monitor (EQ004) and the mobile instrument table (EF027) from CPT code 31645***, as they are not contained in the current composition of the code, and there was no rationale provided in the RUC recommendations for their inclusion. ***CMS proposes to increase the equipment time for the flexible bronchoscopy fiberscope (ES017) for CPT code 31645 consistent with standard equipment times for scopes. CMS also proposes to increase the equipment time for the Gomco suction machine (EQ235) and the power table (EF031) consistent with standard equipment times for non-highly technical equipment.*** For CY 2018, ***CMS proposes the RUC-recommended work RVUs for both codes in this family and are seeking comment on whether it***

	minutes of total time, at a work RVU of 2.72. CMS considered a work RVU of 2.53 for CPT code 31646, crosswalking to CPT code 31622 (Dx bronchoscope/wash). CMS agrees with the survey participants that these two codes are comparable to one another, but has concerns about valuation of CPT code 31646 using a cross reference to a code that included moderate sedation. CMS considered crosswalking CPT code 31646 (Bronchoscopy reclear airway) using the current CY 2017 valuation for CPT code 31622 (a work RVU of 2.53). ***For CY 2018, CMS proposes the RUC-recommended work RVUs for both codes in this family and are seeking comment on whether it should finalize refined values consistent with the implementation of separately billable codes for moderate sedation.***	***should finalize refined values consistent with the implementation of separately billable codes for moderate sedation.***
Cryoablation of Pulmonary Tumor (CPT codes 32998 and 32X99)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT codes 32998 (a work RVU of 9.03) and 32X99 (a work RVU of 9.03).*** However, CMS has concerns about the descriptions of the codes and the recommended valuations assuming that imaging guidance is inherent to the procedure. CMS' analysis of claims data from 2014 shows that existing CPT code 32998 is currently reported with one of the three imaging guidance codes (CPT codes 76940, 77013, or 77022) less than 50 percent of the time. ***CMS seeks comment on whether there is additional information that would help explain why the codes are being bundled despite what is reflected in the Medicare claims data.*** CMS considered a work RVU of 7.69 for CPT code 32998, that included approximately one half the value of the imaging guidance in the new codes that describe the work of both the procedure and the image guidance (that is, the sum of the current work RVU for CPT code 32998 and one-half of the work RVU for CPT code 77013 (the imaging guidance code most frequently billed with CPT code 32998 according to 2014 claims data)). CMS applied the same general rationale regarding the use of imaging guidance for new CPT code 32X99. Since the RUC recommended identical work RVUs for these codes, CMS also considered a work RVU of 7.69 for CPT 32X99.	***For CPT codes 32998 and 32X99, CMS proposes to use the RUC-recommended direct PE inputs with standard refinements.***

Artificial Heart System Procedures (CPT codes 339X1, 339X2, and 339X3)	***CMS proposes the RUC-recommended work RVU of 49.00 for CPT code 339X1, and proposes to assign contractor-priced status to CPT codes 339X2 and 339X3 as recommended by the RUC.*** CMS considered assigning contractor-priced status for CPT code 339X1 given concerns regarding the accuracy of the RUC-recommended work valuation, due to its low utilization and the resulting difficulties in finding enough practitioners with direct experience of the procedure for the specialty societies to survey. ***CMS seeks comment on the sufficiency of the survey data, especially since new technologies and those with lower utilization are typically contractor-priced. CMS seeks comment on alternative pricing for this CPT code 339X1.***	***CMS does not proposes any direct PE inputs, given it did not receive RUC-recommended PE information for CPT codes 339X1, 339X2, and 339X3.*** These three codes will be placed on the RUC's new technology list and will be re-reviewed by the RUC in 3 years.
Endovascular Repair Procedures (CPT codes 34X01, 34X02, 34X03, 34X04, 34X05, 34X06, 34X07, 34X08, 34X09, 34X10, 34X11, 34X12, 34X13, 34812, 34X15, 34820, 34833, 34834, 34X19, and 34X20)	CMS proposes the RUC-recommended work RVUs for all 20 codes in this family; a work RVU of 23.71 for CPT code 34X01, a work RVU of 36.00 for CPT code 34X02, a work RVU of 26.52 for CPT code 34X03, a work RVU of 45.00 for CPT code 34X04, a work RVU of 29.58 for CPT code 34X05, a work RVU of 45.00 for CPT code 34X06, a work RVU of 22.28 for CPT code 34X07, a work RVU of 36.50 for CPT code 34X08, a work RVU of 6.50 for CPT code 34X09, a work RVU of 15.00 for CPT code 34X10, a work RVU of 6.00 for CPT code 34X11, a work RVU of 12.00 for CPT code 34X12, a work RVU of 2.50 for CPT code 34X13, a work RVU of 4.13 for CPT code 34812, a work RVU of 5.25 for CPT code 34X15, a work RVU of 7.00 for CPT code 34820, a work RVU of 8.16 for CPT code 34833, a work RVU of 2.65 for CPT code 34834, a work RVU of 6.00 for CPT code 34X19, and a work RVU of 7.19 for CPT code 34X20. CMS considered a work RVU of 32.00 for CPT code 34X02 based on the survey 25th percentile, and further supported with a crosswalk to CPT code 48000 (Placement of drains, peripancreatic, for acute pancreatitis), which has the same intraservice time of 120 minutes and a work RVU of 31.95. CMS considered a work RVU of 40.00 for CPT code 34X04 based on the survey 25th percentile, crosswalking to CPT code 33534 (Coronary artery bypass, using arterial graft(s); 2 coronary arterial	***CMS proposes the RUC-recommended direct PE inputs without refinement for all 20 codes in the family.***

	grafts) which has a work RVU of 39.88. CMS considered a work RVU of 40.00 for CPT code 34X06 based on the survey 25th percentile. CMS considered a work RVU of 30.00 for CPT code 34X08 based on the survey 25th percentile and seek comment on whether a work RVU of 30.00 would improve relativity among the codes in this family. CMS notes that the RUC-recommended work RVU of 36.50 for CPT code 34X08 is higher than the RUC-recommended work RVU of 36.00 for CPT code 34X02. This is the inverse of the relationship between CPT codes 34X07 and 34X01, which describe the same procedures in a non-emergent state when a rupture does not take place. ***CMS seeks comment on whether the RUC-recommended work RVUs would create a rank order anomaly within the family by reversing the relationship between these paired codes when performed in an emergent state.*** CMS notes that if CPT codes 34X08 and 34X02 were valued at the survey 25th percentile, this potential rank order anomaly disappears; in this scenario, CMS considered valuing CPT code 34X08 at a work RVU of 30.00 and CPT code 34X02 at a work RVU of 32.00. ***CMS seeks comment on whether these alternative work values would improve relativity with the RUC-recommended work RVUs for CPT code 34X07 (22.28) and CPT code 34X01 (23.71), with an increment of approximately 1.50 to 2.00 RVUs between the two code pairs.*** For the eight remaining codes that describe endovascular access procedures, CMS considered assignment of a 0-day global period, instead of the RUC-recommended add-on (ZZZ) global period and subsequently adding back the preservice and immediate postservice work time, and increasing the work RVU of each code accordingly using a building block methodology. As add-on procedures, these eight codes would not be subject to the multiple procedure payment discount. CMS is concerned that the total payment for these services will be increasing in the aggregate based on changes in coding that alter MPPR adjustments, despite the information in the surveys that reflects a decrease in the intraservice time required to perform the procedures, and a decrease in their overall intensity	

	as compared to the current values. CMS considered a work RVU of 3.95 for CPT code 34X13, based on the RUC-recommended work RVU of 2.50 plus an additional 1.45 work RVUs. This additional work results from the addition of 38 total minutes of preservice work time and 30 minutes of postservice work time based on a crosswalk to CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) as valued by using the building block methodology. Using the same method, CMS considered a work RVU of: • 6.48 for CPT code 34812 based on maintaining the current 75 minutes of preservice work time and the current 30 minutes of postservice work time, with a total work RVU of 2.35, added to the RUC-recommended work RVU of 4.13; • 7.53 for CPT code 34X15 with the addition of 75 minutes of preservice work time and 27 minutes of postservice work time to match CPT code 34833; • 9.46 for CPT code 34820 based on maintaining the current 80 minutes of preservice work time and the current 30 minutes of postservice work time; • 10.44 for CPT code 34833 based on maintaining the current 75 minutes of preservice work time and the current 27 minutes of postservice work time; • 5.00 for CPT code 34834 based on maintaining the current 70 minutes of preservice work time and the current 35 minutes of postservice work time; • 8.35 for CPT code 34X19 with the addition of 70 minutes of preservice work time and 35 minutes of postservice work time to match CPT code 34834; and • 9.47 for CPT code 34X20 with the addition of 75 minutes of preservice work time and 27 minutes of postservice work time to match CPT code 34833.	
Selective Catheter Placement (CPT codes 36215, 36216, 36217, and	***CMS proposes the RUC-recommended work RVUs for each code in this family as follows: a work RVU of 4.17 for CPT code 36215, a work RVU of 5.27 for CPT code 36216, a work RVU of 6.29 for CPT***	***For the direct PE inputs, CMS proposes to refine the clinical labor time for the "Post- procedure doppler evaluation (extremity)" activity from 3 minutes to 1 minute for CPT codes 36215, 36216, and***

36218)	***code 36217, and a work RVU of 1.01 for CPT code 36218.*** CMS considered refinements to the intraservice work time for CPT code 36217 from 60 minutes to 50 minutes, consistent with the RUC's usual use of the survey median intraservice work time.	***36217.*** ***CMS proposes to remove the equipment time for the mobile instrument table (EF027) from CPT codes 36215, 36216, and 36217.***
Insertion of Catheter (CPT codes 36555, 36556, 36620, and 93503)	***CMS proposes the RUC-recommended work RVUs for each code in this family as follows: a work RVU of 1.93 for CPT code 36555, a work RVU of 1.75 for CPT code 36556, a work RVU of 1.00 for CPT code 36620, and a work RVU of 2.00 for CPT code 93503.***	***CMS proposes to remove the clinical labor time for the "Monitor pt. following procedure" activity and the equipment time for the 3-channel ECG (EQ011) for CPT code 36555. CMS proposes to remove the direct PE inputs related to moderate sedation from CPT code 36555 as they would now be included in the separately reported moderate sedation services. CMS proposes to refine the equipment times for the exam table (EF023) and the exam light (EQ168) to reflect changes in the clinical labor time.***
Insertion of PICC Catheter (CPT code 36569)	***For CY 2018, CMS proposes the RUC-recommended work RVU of 1.70 for CPT code 36569.***	***CMS proposes to remove the equipment time for the exam table (EF023), as this equipment item is a component part of the radiographic-fluoroscopic room (EL014) included in CPT code 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal).***
Esophagectomy (CPT codes 43107, 43112, 43117, 432X5, 432X6, and 432X7)	***CMS proposes the RUC-recommended work RVUs and work times for all six codes in the family as follows: a work RVU of 52.05 for CPT code 43107, a work RVU of 62.00 for CPT code 43112, a work RVU of 57.50 for CPT code 43117, a work RVU of 55.00 for CPT code 432X5, a work RVU of 63.00 for CPT code 432X6, and a work RVU of 66.42 for CPT code 432X7.*** ***CMS proposes the RUC-recommended work times for all six codes in this family,*** but considered removing 20 minutes from the preservice evaluation work time from all six of the codes in this family given concerns as to whether this additional evaluation time should be included for surgical procedures, due to the lack of evidence indicating that it takes longer to review outside imaging and lab reports for surgical services than for non-surgical services. CMS also considered refining the preservice positioning work time and the immediate postservice work time for all six of the codes in this family consistent with standard preservice and postservice work	***CMS proposes the RUC-recommended direct PE inputs for all six codes in the family without refinement.*** CMS considered changing the preservice clinical labor type for all six codes from an RN (L051) to an RN/LPN/MTA blend (L037D). CMS also considered removing the additional clinical labor time for the "Additional coordination between multiple specialties for complex procedures (eg, tests, meds, scheduling)" activity, consistent with preservice standards for codes with 90-day global periods.

	times allocated to other PFS services. CMS has concerns about the presence of two separate surveys conducted for the three new codes. The accompanying reference service list (RSL) is the main difference between the two surveys; the codes on the initial RSL had a median work RVU of 44.18, while the codes on the second RSL had a median work RVU of 59.64. This increase of 15.00 work RVUs between the two RSLs that accompanied the surveys appears to account for the increase in the work RVUs for the three new codes. The second survey may have overestimated the work required to perform these procedures, despite no change in the median intraservice work time for CPT codes 432X5 and 432X6. Given these concerns, CMS considered a work RVU of 50.00 for CPT code 432X5, a work RVU of 60.00 for CPT code 432X6, and a work RVU of 61.00 for CPT code 432X7, by using the survey median work RVU from the first survey for the three new codes. CMS considered a work RVU of 45.00 for CPT code 43107 based on the intraservice time ratio with CPT code 432X5 and a work RVU of 55.00 for CPT code 43117 based on the intraservice time ratio with CPT code 432X6. CMS considered a work RVU of 58.94 for CPT code 43112 based on a direct crosswalk to CPT code 46744 (Repair of cloacal anomaly by anorectovaginoplasty and urethroplasty, sacroperineal approach). CMS seeks comment on whether the alternative work RVUs that it considered may reflect the relative difference in work more accurately between the six codes in the family. CMS notes, for example, that these valuations correct the rank order anomaly between CPT codes 43112 and 43121 as noted in the RUC recommendations.	
Transurethral Electrosurgical Resection of Prostate (CPT code 52601)	For CY 2018, ***CMS proposes the RUC-recommended work RVU of 13.16 for CPT code 52601 and proposes to use the RUC-recommended direct PE inputs without refinements.*** CMS considered a work RVU of 12.29 for CPT code 52601 based on	

	a direct crosswalk to CPT code 58541 (Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less), which is one of the reference codes. ***CMS seeks comment on whether this alternative value might better reflect relativity***.	
Peri-Prostatic Implantation of Biodegradable Material (CPT code 55X87)	For CY 2018, ***CMS proposes the RUC-recommended work RVU of 3.03 for CPT code 55X87.*** CMS considered a work RVU of 2.68 calculated based on the intraservice time ratio between the key reference code (CPT code 49411) and the RUC-recommended intraservice time, and multiplying that against the work RVU for CPT code 49411 (3.57). This would have been further supported by a bracket of two crosswalk codes, CPT code 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured) which has a work RVU of 2.50 and CPT code 43252 Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy), which has a work RVU of 2.96. Compared with CPT code 55X87, these codes have identical intraservice and similar total times. ***CMS seeks comment on whether these alternative values should be considered, especially given the changes in time reflected in the survey data.***	CMS received invoices with pricing information regarding two new supply items: "endocavity balloon" and "biodegradeable material kit – periprostatic". ***For supply item "endocavity balloon," CMS proposes a price of $39.90. For the supply item "biodegradeable material kit – periprostatic," CMS proposes a price of $2850.00. For equipment item "endocavitary US probe", CMS proposes a per-minute price of $0.0639. CMS seeks public comments related to whether equipment item EQ250 (portable ultrasound) includes probes.***
Colporrhaphy with Cystourethroscopy (CPT codes 57240, 57250, 57260 and 57265)	For CY 2018, CMS proposes the RUC-recommended work RVUs for CPT code 57240 (a work RVU of 10.08), CPT code 57250 (a work RVU of 10.08), CPT code 57260 (a work RVU of 13.25), and CPT code 57265 (a work RVU of 15.00). CMS considered a work RVU of 9.77 for CPT code 57240, crosswalking to CPT code 50590 (Lithotripsy, extracorporeal shock wave), which has similar service times. ***CMS seeks comment on whether CPT code 57250 would be a relevant comparator for CPT code 57240, based on the described elements of each service and existing or surveyed service times, compared to CPT code 57240.*** CMS considered a work RVU of 11.47 for CPT code 57265, crosswalking to CPT code 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography) with similar service times. ***CMS seeks comment on how an alternative work RVU of 11.47 for***	***CMS proposes the RUC-recommended direct PE inputs for CPT codes 57240, 57250, 57260 and 57265 without refinements.***

	CPT code 57265 would affect relativity among PFS services, and on whether CPT code 57260 is a relevant comparator for CPT code 57265, considering differences in the described procedures and service times.	
CT Soft Tissue Neck (CPT codes 70490, 70491, and 70492)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs of 1.28 for CPT code 70490, 1.38 for CPT code 70491, and 1.62 for CPT code 70492.*** For CPT code 70490, CMS considered a work RVU of 1.07 based on a crosswalk to CPT code 72125 (Computed tomography, cervical spine; without contrast material). CMS also considered work RVUs of 1.17 for CPT code 70491 and 1.41 for CPT code 70492. ***CMS seeks comment on how relativity among other CT services paid under the PFS would be affected by applying the alternative work RVUs described above for CPT codes in this family.***	
Magnetic Resonance Angiography (MRA) Head (CPT codes 70544, 70545, and 70546)	***CMS proposes the RUC-recommended work RVUs of 1.20 for CPT code 70544, 1.20 for CPT code 70545, and 1.48 for CPT code 70546.***	***CMS proposes the following refinements to the RUC-recommended direct PE inputs.*** ***For the service period clinical labor activity "Provide preservice education/obtain consent," CMS proposes 5 minutes for CPT code 70544, 7 minutes for CPT code 70545, and 7 minutes for CPT code 70546 so that the times for this activity are consistent with other magnetic resonance (MR) services performed without-contrast materials, with-contrast materials, and without-and-with contrast materials, respectively. For the clinical labor task "Acquire images," CMS proposes to use the RUC-recommended clinical time of 26 minutes for CPT code 70544.*** CMS considered proposing 20 minutes of clinical time to maintain the relativity among the three codes in this family and for consistency with other MRA and magnetic resonance imaging (MRI) codes, which do not typically assign more clinical labor time to this task for services without contrast material than for services with contrast material. ***CMS seeks comments as to the appropriate time value for this clinical labor task.***
Magnetic Resonance	***CMS proposes the RUC-recommended work RVUs of 1.20 for CPT***	***CMS proposes several refinements to the RUC-recommended direct***

Angiography (MRA) Neck (CPT codes 70547, 70548, and 70549)	***code 70547, 1.50 for CPT code 70548, and 1.80 for CPT code 70549.***	***PE inputs for these services. For the service period clinical labor activity "Provide preservice education/obtain consent", CMS proposes 5 minutes for CPT code 70547, 7 minutes for CPT code 70548, and 7 minutes for CPT code 70549 so that the times for this activity are consistent with other MR services performed without contrast material, with contrast material, and without-and-with contrast material, respectively.*** ***For the intraservice clinical labor task acquire images, for CPT code 70547, CMS proposes to use the RUC-recommended 26 minutes.*** CMS considered applying 20 minutes to this clinical labor task, which would have maintained consistency with the 20 minutes recommended by the RUC for CPT code 70548 (the service that includes with-contrast material). ***CMS seeks comment as to the appropriate time value for this clinical labor task.***
CT Chest (CPT Codes 71250, 71260, and 71270)	***CMS proposes the RUC-recommended work RVUs of 1.16 for CPT code 71250, 1.24 for CPT code 71260, and 1.38 for CPT code 71270.*** For CPT code 71250, CMS considered maintaining the CY 2017 work RVU of 1.02. For CPT code 71260, CMS considered proposing a work RVU of 1.10 by applying the RUC-recommended increment between CPT code 71250 and 71260 (0.08) to CPT code 71260. For CPT code 71270, CMS considered a work RVU of 1.24 by applying the RUC-recommended increment between CPT codes 71260 and 71270 (0.22) to CPT code 71270. ***CMS seeks comment on whether its alternative values would improve relativity.***	
MRI of Abdomen and Pelvis (CPT codes 72195, 72196, 72197, 74181, 74182, and 74183)	***CMS proposes the RUC- recommended work RVUs of 1.46 for CPT code 72195, 1.73 for CPT code 72196, 2.20 for CPT code 72197, 1.46 for CPT code 74181, 1.73 for CPT code 74182, and 2.20 for CPT code 74183.***	***CMS proposes the RUC-recommended direct PE inputs.*** However, CMS considered 30 minutes for clinical labor task "Acquire images" for CPT codes 74181 and 74182, which appears to be more consistent with the codes in this family and more consistent with other MR codes. ***CMS seeks comments on whether using a structure that matches other MR code families would be more appropriate to value these clinical labor times.***

MRI Lower Extremity (CPT codes 73718, 73719, and 73720)	***CMS proposes the RUC-recommended work RVUs of 1.35 for CPT code 73718, 1.62 for CPT code 73719, and 2.15 for CPT code 73720.***	***CMS proposes the following refinements to the RUC-recommended direct PE inputs. For the service period clinical labor activity "Provide preservice education/obtain consent," CMS proposes 5 minutes for CPT code 73718, 7 minutes for CPT code 73719, and 7 minutes for CPT code 73720. Likewise, for the service period task "Prepare room, equipment, supplies," CMS proposes 3 minutes for CPT code 73718, 5 minutes for CPT code 73719, and 5 minutes for CPT code 73720.***
Abdominal X-ray (CPT codes 74022, 740X1, 740X2, and 740X3)	For CY 2018, ***CMS proposes the RUC-recommended work values for CPT codes 74022, 740X1, 740X2, and 740X3.*** For purposes of calculating the proposed RVUs, CMS used an even distribution of services previously reported as CPT codes 74010 and 74020 to CPT codes 740X2 and 740X3 instead of the RUC-recommended distribution because CMS thinks that the services previously reported with codes 74010 and 74020 will be reported in equal volume between the code representing two views and the code representing three views. ***CMS seeks comment on information that would help the agency improve on this distribution for purposes of developing final RVUs, including rationale for the distribution reflected in the RUC's utilization crosswalk.***	
Angiography of Extremities (CPT codes 75710 and 75716)	***CMS proposes the RUC-recommended work RVUs of 1.75 for CPT code 75710 and 1.97 for CPT code 75716.***	***CMS proposes to use the RUC-recommended direct PE inputs for both CPT codes 75710 and 75716, with the following refinements. For the clinical labor task "Technologist QC's images in PACS, checking for all images, reformats, and dose page," CMS proposes refinements consistent with the standard clinical labor times for tasks associated with the PACS Workstation.*** ***CMS also proposes to refine the clinical labor by removing the 2 minutes associated with the task "prepare room, equipment, and supplies."***
Radiation Therapy Planning (CPT codes 77261, 77262, and 77263)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs of 1.30 for CPT code 77261, 2.00 for CPT code 77262, and 3.14 for CPT code 77263.*** For CPT code 77263, CMS considered a work RVU of 2.60 based on a	

	crosswalk to CPT code 96111 (Developmental testing, (includes assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized developmental instruments) with interpretation and report), which has an identical intraservice time, and similar total time to the RUC-recommended time values for CPT code 77263. CMS considered using a work RVU of 2.60 for CPT code 77263 as a base for alternative valuations for CPT codes 77261 and 77262 by applying the ratio of the crosswalk work RVU of CPT code 96111 (Developmental test extend) to the RUC-recommended work RVU of CPT code 77263 (that is, 2.60/3.14=0.83) to the RUC-recommended work RVU for CPT code 77261 (that is, 0.83 x 1.30=1.08) and CPT code 77262 (that is, 0.83 x 2.0=1.66), which would have resulted in work RVUs of 1.08 for CPT code 77261 and 1.66 for CPT code 77262. ***CMS seeks comments on whether the alternative valuation would be more appropriate for these codes.***	
Pathology Consultation during Surgery (CPT codes 88333 and 88334)	***CMS proposes the RUC-recommended work RVU of 1.20 for CPT code 88333 and the RUC- recommended work RVU of 0.73 for CPT code 88334.***	For the direct PE inputs, ***CMS proposes to remove the clinical labor for the "Prepare room. Filter and replenish stains and supplies (including setting up grossing station with colored stains)" activity from CPT code 88333.*** ***CMS proposes to refine the clinical labor time for "Clean room/equipment following procedure" activity for CPT code 88333, consistent with the standard clinical labor time assigned for room cleaning when used by laboratory services. CMS seeks comments related to the equipment time assigned to the "grossing station w-heavy duty disposal" (EP015) for both CPT codes 88333 and 88334.***
Tumor Immunohistochemistry (CPT codes 88360 and 88361)	***CMS proposes the RUC-recommended work RVU of 0.85 for CPT code 88360 and the RUC-recommended work RVU of 0.95 for CPT code 88361.***	***CMS proposes to refine the clinical labor time for the "Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer" activity for both codes, consistent with the standard time for this clinical labor activity across different pathology services. For CPT code 88361, CMS proposes to remove the 1 minute of clinical labor time from the "Performing instrument calibration, instrument qc and start up and shutdown" and the "Gate areas to be counted by the***

		machine" activities. ***CMS proposes to remove the clinical labor time for "Clean room/equipment following procedure" for CPT codes 88360 and 88361. CMS also proposes to remove the clinical labor time for the "Verify results and complete work load recording logs" and the "Recycle xylene from tissue processor and stainer" activities for CPT codes 88360 and 88361.*** ***CMS proposes to refine the equipment time for the "Benchmark ULTRA auto slide prep & E- Bar Label system" (EP112) from 18 minutes to 16 minutes for both codes. CMS proposes to add 1 minute over the current value of 15 minutes to the EP112 equipment time to reach the aforementioned 16 minutes.*** ***For CPT code 88361, CMS proposes to maintain the current price of $195,000.00 for the DNA image analyzer (EP001) equipment. CMS considered refining the equipment time for the DNA image analyzer from 30 minutes to 5 minutes. CMS seeks comments on additional pricing information for the EP001 DNA image analyzer equipment, specifically invoices solely for this equipment containing a rationale for each component part, as well as the appropriate equipment time typically required for use in CPT code 88361.***
Cardiac Electrophysiology Device Monitoring Services (CPT codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, 93292, 93293, 93294, 93295, 93296, 93297, 93298, and 93299)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for the 19 CPT codes in this family that are valued with physician work as follows:*** 0.65 for CPT code 93279, 0.77 for CPT code 93280, 0.85 for CPT code 93281, 0.85 for CPT code 93282, 1.15 for CPT code 93283, 1.25 for CPT code 93284, 0.52 for CPT code 93285, 0.30 for CPT code 93286, 0.45 for CPT code 93287, 0.43 for CPT code 93288, 0.75 for CPT code 93289, 0.43 for CPT code 93290, 0.37 for CPT code 93291, 0.43 for CPT code 93292, 0.31 for CPT code 93293, 0.60 for CPT code 93294, 0.74 for CPT code 93295, 0.52 for CPT code 93297, and 0.52 for CPT code 93298. For CPT code 93293, CMS considered a work RVU of 0.91 and ***seeks comment on whether this alternative work RVU for this service would better maintain relativity between single and dual lead pacemaker systems and cardioverter defibrillator services.*** CMS	***CMS proposes the RUC-recommended direct PE inputs with the following refinements. CMS proposes to remove 2 minutes for "review charts" from CPT codes 93279, 93281, 93282, 93283, 93284, 93285, 93286, 93287, 93288, 93289, 93290, 93291, and 93292 to maintain relativity since it is not typically incorporated for similar PFS codes. CMS also proposes removing 2 minutes for "complete diagnostic forms, lab & X-ray requisitions" for the labor category "med tech/asst" (L026A). CMS seeks comment regarding whether this row was included in error. Also for the same group of CPT codes, CMS proposes standard refinements for the time for equipment items EF023 and EQ198.*** ***CMS proposes to use the RUC-recommended direct practice expense inputs and times for all other CPT codes in this family (CPT codes 93293, 93294, 93295, 93296, 93297, 93298, and 93299) without***

	considered reducing the work RVU for CPT code 93282 by 0.11 work RVUs and ***seeks comments on whether this alternative value would better reflect relativity between the single and dual lead systems that exist within pacemaker services and within cardioverter defibrillator services.*** CMS considered a proportionate reduction for CPT code 93289 to a work RVU of 0.69. For CPT code 93283, CMS considered a work RVU of 0.91 and ***seeks comment on whether this value would improve relativity.*** CMS considered an alternative crosswalk for CPT code 93293 (Pm phone r-strip device eval) (5 minutes intraservice time and 13 minutes total time) to CPT code 94726 (Pulm funct tst plethysmograp), which has 5 minutes intraservice time and 15 minutes total time and a work RVU of 0.26. ***CMS seeks comment its proposed and alternative valuations for this code.*** For CPT code 93294, CMS considered a work RVU of 0.55 and ***seeks comment on whether it would better align with the RUC-recommended service times, and whether its alternative value would better reflect the time and intensity involved in furnishing this service.*** For CPT code 93295, CMS considered a work RVU of 0.69, crosswalking to CPT code 76586, and ***seeks comment on whether its alternative value would better reflect the time and intensity involved in furnishing this service.*** CMS considered a work RVU of 0.37 for CPT code 93297. CMS also considered a work RVU of 0.37 for CPT code 93298 based on a crosswalk to CPT code 96446. ***CMS seeks comment on its proposed valuation and whether its alternative valuation would be more appropriate for this code.***	***refinement.***
Transthoracic Echocardiography (TTE) (CPT codes 93306, 93307, and 93308)	***For CY 2018, CMS proposes the RUC-recommended work RVUs for CPT codes 99306 (a work RVU of 1.50), 99307 (a work RVU of 0.92), and 99308 (a work RVU of 0.53).*** For CPT code 93306 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and	***CMS proposes the RUC-recommended direct PE inputs for CPT codes 93306, 93307, and 93308 without refinement.***

	with color flow Doppler echocardiography), CMS considered maintaining the CY 2017 work RVU of 1.30. For CPT code 93307 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography), CMS considered a work RVU of 0.80, crosswalking to services with similar service times (CPT codes 93880 (Extracranial bilat study), 93925 (Lower extremity study), 93939, 93976 (Vascular study), and 93978 (Vascular study)). For CPT code 93308 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study), CMS considered a work RVU of 0.43, crosswalking to CPT code 93292 (Wcd device interrogate) based on similar service times. For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT codes 93306, 93307, and 93308 and seek comments on whether its alternative values would better reflect the time and intensity of these services.***	
Stress Transthoracic Echocardiography (TTE) Complete (CPT codes 93350 and 93351)	***For CY 2018, CMS proposes the RUC-recommended work RVUs for CPT codes 93350 (a work RVU of 1.46) and 93351 (a work RVU of 1.75).***	***CMS proposes the following refinements to the RUC-recommended direct PE inputs for CPT codes 93350 and 93351. For both codes, CMS applied the standard formula in developing the minutes for equipment item ED053 (professional PACS workstation), which results in 18 minutes for CPT code 93350 and 25 minutes for CPT code 93351. CMS also proposes standard clinical labor times for providing preservice education/obtaining consent. CMS did not propose to include clinical labor time for the task setup scope since there is no scope used in the procedure and CMS does not agree with the RUC's statement that this replicates 5 minutes in CPT code 93015 when the RN prepares patients for 10-lead ECG. CMS proposes refinements to the equipment time for ED050 (PACS workstation proxy) for CPT code 93351, consistent with its standard equipment times for PACS Workstation Proxy.***
Pulmonary Diagnostic Tests	***CMS proposes the RUC-recommended work RVUs of 1.42 for CPT***	***CMS proposes to refine the clinical labor time for the "Provide***

(CPT codes 94621, 946X2, and 946X3)	***code 94621, 0.70 for CPT code 946X2, and 0.48 for CPT code 946X3.***	***preservice education/obtain consent" activity from 10 minutes to 5 minutes for CPT code 94621, which is the current time assigned for this task. CMS also proposes to refine the clinical labor time for the "Prepare and position patient/monitor patient/set up IV" activity from 5 minutes to 3 minutes for the same code.*** ***CMS proposes to refine the clinical labor time for the "Complete diagnostic forms, lab & X- ray requisitions" activity, consistent with the standard clinical labor time for this activity. CMS also proposes to refine the equipment times for CPT codes 94621 and 946X2 to account for 1:4 patient monitoring time, and to refine the equipment times for CPT code 946X3 consistent with standards for non-highly technical equipment.*** CMS considered refining the clinical labor time for the "pre exercise ECG, VC, Min Vent. Calculation" activity from 27 minutes to 15 minutes for CPT code 94621. CMS considered proposing this value of 15 minutes based on assigning 5 minutes apiece for the ECG, the MVV, and the spirometry. CMS also considered refining the clinical labor time for the "Clinical staff performs procedure" activity from 55 minutes to 35 minutes for CPT code 946X2 and from 14 minutes to 12 minutes for CPT code 94621. For CPT code 94621, CMS considered maintaining the current value of 12 minutes due to a lack of justification for increasing the time to 14 minutes. ***CMS seeks comment on whether the alternative clinical labor times would better reflect the work and times for these services.***
Percutaneous Allergy Skin Tests (CPT code 95004)	For CY 2018, ***CMS proposes the RUC-recommended work RVU of 0.01 for CPT code 95004.***	Regarding direct PE inputs, ***CMS proposes to refine the equipment times for exam table (EF023) and mayo stand (EF015) to 79 minutes each to account for clinical 1:4 patient monitoring time. CMS also proposes a price of $0.03 per test for supply item SH101 and a price of $0.13 per test for supply item SH102.***
Patient, Caregiver-Focused Health Risk Assessment (CPT		***The RUC recommended 7 total minutes of clinical staff time, and CMS proposes to adopt this number of minutes in valuing the services.*** The PE worksheet included several distinct tasks with

codes 96160 and 96161)		minutes for each; however, in keeping with the standardization of clinical labor tasks, ***CMS proposes to designate all 7 minutes under "administration, scoring, and documenting results of completed standardized instrument" rather than dividing the minutes into the four categories as shown in the RUC recommendations.***
Chemotherapy Administration (CPT codes 96401, 96402, 96409, and 96411)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT code 96401 (a work RVU of 0.21), CPT code 96402 (a work RVU of 0.19), CPT code 96409 (a work RVU of 0.24) and CPT code 96411 (a work RVU of 0.20).***	***For CPT code 96402, CMS proposes the RUC-recommended equipment times with refinements for the biohazard hood (EP016) and exam table (EF023) from 31 minutes to 34 minutes to reflect the service period time associated with this code. CMS proposes the RUC-recommended direct PE inputs for CPT codes 96401, 96409, and 96411 without refinements.***
Photochemotherapy (CPT code 96910)		***CMS proposes to refine the clinical labor time for the "Provide preservice education/obtain consent" from 3 minutes to 1 minute for CPT code 96910. CMS proposes to remove the 2 minutes of clinical labor for the "Complete diagnostic forms, lab & X-ray requisitions" activity, as this item is considered indirect PE consistent with its established methodology. CMS proposes to create a new supply code (SB054) for the sauna suit, and proposing to price at $9.99 based on the submitted invoice. CMS proposes to adjust the equipment times to reflect changes in the clinical labor for CPT code 96910.*** ***CMS proposes the RUC-recommended clinical labor time of 15 minutes for the "Prepare and position patient/monitor patient/set up IV" activity, the RUC-recommended clinical labor time of 16 minutes for the "Monitor patient during procedure" activity, and the RUC-recommended clinical labor time of 15 minutes for the "Clean room/equipment by physician staff" activity, but seeking additional information regarding the rationale for these values.*** Given the lack of explanation, CMS considered using the current clinical labor time of 7 minutes for the "Prepare and position patient/monitor patient/set up IV" activity, the current clinical labor time of 4 minutes for the "Monitor patient during procedure" activity, and the current clinical labor time of 10 minutes for the "Clean room/equipment by physician staff" activity. ***CMS seeks comment on whether maintaining the current values would improve relativity.*** CMS considered removing the "Single Patient Discard Bag, 400 ml" (SD236) supply and replacing it with the "biohazard specimen

		transport bag" (SM008). ***CMS seeks comments on its proposed and alternative values for these direct PE inputs.***
Photodynamic Therapy (CPT codes 96567, 96X73, and 96X74)	For CY 2018, ***CMS proposes the RUC-recommended work RVUs for CPT code 96X73 (a work RVU of 0.48) and CPT code 96X74 (a work RVU of 1.01).***	***CMS proposes the RUC-recommended PE inputs with refinements. First, CMS proposes to add assist physician clinical staff time to CPT codes 96X73 (10 minutes) and 96X74 (16 minutes). For both CPT codes 96X73 and 96X74, CMS proposes a reduction from 35 minutes to 17 minutes for clinical activity in the postservice time. For CPT codes 96X73 and 96X74, CMS proposes to refine equipment formulas for two items: power table (EF031) and LumaCare external light with probe set (EQ169), consistent with standards for nonhighly technical equipment.*** ***CMS proposes to set the price of supply item SH092 to $0.78 per gram.*** Other CPT codes affected by the proposed change in the price of supply item LMX 4 percent cream (SH092) are: CPT code 46607 (Anoscopy; with high-resolution magnification (HRA) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple), CPT code 17000 (Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion), CPT code 17003 (Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)), and CPT code 17004 (Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions)). ***CMS proposes a price of $4.10 for supply item SJ027 (the average of the two prices for this supply item ($2.30 + $6.00)/2=$4.10)).*** Other CPT codes affected by the proposed change in the price of supply item UV-blocking goggles (SJ027) are: CPT code 36522 (Photopheresis, extracorporeal), CPT code 96910 (Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B), CPT code 96912 (Photochemotherapy; psoralens and ultraviolet A (PUVA)), and CPT code 96913 (Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at

		least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)), CPT code 96920 (Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm), CPT code 96921 (Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm), and CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm). ***CMS seeks comments on its proposed PE refinements, including its proposed supply item prices.***
Physical Medicine and Rehabilitation (PM&R) (CPT codes 97012, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and HCPCS code G0283)	For CY 2018, ***CMS proposes the HCPAC recommendations for CPT code 97014, HCPCS code G0283, and HCPCS code G0281.*** For CY 2018, ***CMS proposes the HCPAC's recommended work RVUs for CPT codes 97012, 97016, 97018, 97022, 97032, 97033, 97533, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and G0283 (97014).*** For supervised modality services reported with CPT codes 97012, 97016, 97018, and 97022, and HCPCS code G0283 (97014), CMS considered maintaining the current values for these codes rather than the HCPAC recommendations. ***CMS seeks comments on whether maintaining the current times would better reflect the work times for these services.***	***CMS proposes to maintain the existing CY 2017 PE inputs for all 19 codes and seeks comments on whether there is an alternative approach that would avoid duplicative downward payment adjustments while still allowing for the direct PE inputs to be updated to better reflect current practice.***
Management and/or Training: Orthotics and Prosthetics (CPT codes 97760, 97761, and 977X1)	For CY 2018, ***CMS proposes the HCPAC recommended work RVU of 0.5 for CPT code 97760, a work RVU of 0.5 for CPT code 97761, and a work RVU of 0.48 for CPT code 977X1.*** For CPT code 977X1, CMS considered a work RVU of 0.33, crosswalking to CPT code 92508 (Speech/hearing therapy). ***CMS seeks comments on the HCPAC one-to-one utilization crosswalk recommendations for all three codes in this family since the utilization assumptions are potentially flawed when viewed in the context of the new CPT code descriptors. CMS seeks comments on its proposed and alternative values for CPT code 977X1. CMS is also interested in receiving comments from stakeholders and clinicians with expertise in furnishing these orthotic management***	***CMS proposes to maintain the current PE inputs for CPT codes 97760, 97761, and 977X1. CMS proposes the current direct PE inputs for CPT code 97762 and for new CPT code 977X1, and seeks comment as to whether or not a different crosswalk or other adjustment would be appropriate given the change in code descriptor.***

	and/or prosthetics training services about the utilization and types of services that would be furnished under the new CPT coding structure, particularly those of the newly created CPT code 977X1 and how these services differ from the services reported with the predecessor CPT code 97762.	
Physician Coding for Insertion and Removal of Subdermal Drug Implants for the Treatment of Opioid Addiction (HCPCS codes GDDD1, GDDD2, and GDDD3)	For CY 2018, ***CMS proposes to make separate payment for the insertion, removal, and removal with reinsertion of Buprenorphine subdermal implants using HCPCS G codes:*** • HCPCS code GDDD1: Insertion, non-biodegradable drug delivery implants, 4 or more. • HCPCS code GDDD2: Removal, non-biodegradable drug delivery implants, 4 or more. • HCPCS code GDDD3: Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more. ***CMS proposes a work RVU of 1.82 for HCPCS code GDDD1, which is supported by a direct crosswalk to CPT code 64644 (Chemodenervation of one extremity; 5 or more muscles).*** ***For HCPCS code GDDD2, CMS proposes a work RVU of 2.10, which is supported by a direct crosswalk to CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm).*** ***For HCPCS code GDDD3, CMS proposes a work RVU of 3.55, which is supported by a direct crosswalk to CPT code 31628 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe).***	***CMS proposes to use the direct PE inputs for HCPCS codes GDDD1, GDDD2, and GDDD3, which are reflected in the Direct PE Inputs public use files for clinical labor, supplies, and equipment, available on the CMS website.*** ***In addition to seeking comment on the proposal to make separate payment for these services using HCPCS G codes, CMS also seeks comment on the appropriateness and accuracy of its proposed work RVUs and direct PE inputs.***
Superficial Radiation Treatment Planning and Management (HCPCS code GRRR1)	***CMS proposes to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1*** (Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical treatment planning (for example, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (for example, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (for example, 77300), treatment devices (for example, 77332,	To develop the proposed direct PE inputs for this code, ***CMS proposes to use the RUC-recommended direct PE inputs from the aforementioned codes with several adjustments. CMS proposes to apply the staff type "RN/LPN/MTA" for all of the clinical labor inputs for this code and seeks comments as to the appropriateness of the staff type "RN/LPN/MTA" for this SRT-related service.*** ***CMS proposes to remove the supply items "gown, patient" and***

	77333, 77334), isodose planning (for example, 77306, 77307, 77316, 77317, 77318), radiation treatment management (for example, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated evaluation and management per course of treatment). For CY 2018, ***CMS proposes a work RVU of 7.93 for HCPCS code GRRR1.***	***"pillow case" that are associated with CPT code 77280. CMS does not propose to include the equipment items "radiation virtual simulation system," "room, CT" and "PACS Workstation Proxy" that are associated with CPT code 77280. Instead, CMS includes additional time for the capital equipment used in delivering SRT in the proposed direct PE inputs. For "radiation dose therapy plan," CMS proposes to apply the clinical labor time that is associated with CPT code 77300 to HCPCS code GRRR1 for purposes of developing a proposed value, but seeks comments as to whether the clinical staff would typically perform the radiation dose therapy planning for this service, or if the physician would perform this and/or other tasks, and, in the case of the latter, what the appropriate physician time would be. Likewise, CMS seeks comment as to whether the clinical labor associated with the teletherapy isodose plan would be performed by the physician. CMS proposes to assign 14 minutes each to the equipment items "radiation therapy dosimetry software (Argus QC)", "computer workstation", and "3D teletherapy treatment planning".*** ***CMS does not propose to include inputs related to radiation physics consultation, and seeks comment as to whether inputs associated with this code or other inputs used in furnishing analogous services should be included. CMS does not propose to include the post-operative office visits included in the valuation of CPT code 77427, but seeks comment regarding the amount of face-to-face time typically spent by the practitioner with the patient for radiation treatment management associated with SRT.*** ***CMS proposes to exclude HCPCS code GRRR1 from the misvalued code target.***
Payment Accuracy for Prolonged Preventive Services (HCPCS codes GYYY1 and GYYY2)	***CMS proposes to make payment for prolonged preventive services using two new HCPCS G codes that could be billed along with the Medicare-covered preventive service codes, when a clinician provides a prolonged Medicare-covered preventive service.*** • GYYY1: Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or	***CMS proposes to use one half of the direct PE inputs for CPT code 99354, which results in a proposal of 7 minutes of clinical labor type L037D (RN/LPN/MTA) and 15 minutes for equipment type EF031 (table, power) for HCPCS code GYYY1 and HCPCS code GYYY2.***

	other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (List separately in addition to code for preventive service)), and • GYYY2: Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for preventive service)). ***CMS proposes a work RVU of 1.17 and 30 minutes of total work time for HCPCS codes GYYY1 and GYYY2.***	

Evaluation and Management (E/M) Guidelines and Care Management Services (p. 373)

CMS has sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients. This includes the development and valuation of several new codes, such as Transitional care management (TCM) services (2013) and Chronic care management services (CCM) (2015, 2017), among others. ***CMS solicits public comments on ways it might further reduce administrative burden for these and similar services under the PFS.***

E/M Guidelines (p. 374)

There are two versions of the E/M documentation guidelines, commonly referenced based on the year of their release (the "1995" and "1997" guidelines). The most substantial differences between the two sets of guidelines pertain to requirements for the physical exam. The two versions have a slight difference in requirements for documenting the history, and no difference in requirements for medical decision making. Table 15 outlines key documentation requirements for Level 2 and 3 E/M visits across the two sets.

Stakeholders have long maintained that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, stating that they are too complex, ambiguous, and that they fail to distinguish meaningful differences among code levels. CMS agrees that there may be unnecessary burden with these guidelines and that they are potentially outdated, especially regarding the requirements for the history and the physical exam. The guidelines have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity and potential upcoding given the frequently automated selection of code level.

While CMS conducts few audits on E/M visits relative to the volume of PFS services they comprise, CMS has repeatedly heard from practitioners that compliance with the guidelines is a source of significant audit vulnerability and administrative burden.

CMS seeks input from a broad array of stakeholders, including patient advocates, on the specific changes CMS should undertake to reform the guidelines, reduce the associated burden, and better align E/M coding and documentation with the current practice of medicine. CMS specifically seeks comment on how it might focus on initial changes to the guidelines for the history and physical exam, including whether it would be appropriate to remove its documentation requirements for the history and physical exam for all E/M visits at all levels. In addition, an increase in the utilization of EHRs, and to some extent, shared health information via EHRs, may have changed the character of extended patient histories since the guidelines were established. As long as a history and physical exam are documented and generally consistent with complexity of medical decision making (MDM), there may no longer be a need for CMS to maintain such detailed specifications for what must be performed and documented for the history and physical exam.

CMS also seeks comment on how such reforms may differentially affect physicians and practitioners of different specialties, including primary care clinicians, and how CMS could or should account for such effects as it examines this issue. There may still be clinical or legal reasons for individual practitioners to document an extended history or physical exam. ***CMS seeks comment on whether it should leave it largely to the discretion of individual practitioners to what degree they should perform and document the history and physical exam. CMS also welcomes comments on specific ideas that stakeholders may have on how to update medical decision-making guidelines to foster appropriate documentation for patient care commensurate with the level of patient complexity, while avoiding burdensome documentation requirements and/or inappropriate upcoding.***

CMS also notes that it has heard from many stakeholders that the E/M code set itself is outdated and needs to be revised (e.g., some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially physician work inputs). CMS previously acknowledged the limitations of the current E/M code set and agrees that the structure of the underlying code set and its valuation relative to other PFS services are also important issues that it expects to continue to explore, though the agency is immediately focused on revision of the current E/M guidelines in order to reduce unnecessary administrative burden.

Care Management Public Comment Solicitation (p. 378)

CMS continues to be interested in the ongoing work of the medical community and other stakeholders to refine the set of codes used to describe care management services. ***CMS seeks comment on ways it might further reduce burden on reporting practitioners for care management services, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes.***

Other Provisions of the Proposed Rule (p. 380)

New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (p. 380)

CMS previously established in the PFS separate payment for complex Chronic Care Management (CCM) services, and temporary codes to make separate payment for general behavioral health integration (BHI) services and a psychiatric collaborative care model (CoCM). CMS established four G codes to describe BHI and psychiatric CoCM services and stated that it would consider whether to adopt and establish values for any associated new CPT codes being developed under its standard process once those codes are active. The separate payment for complex CCM services, general BHI, and psychiatric CoCM services were finalized in the CY 2017 PFS final rule (81 FR 80225) beginning January 1, 2017, for practitioners billing under the PFS. Based on these payments and codes, CMS proposes revisions to the CCM payment for RHCs and FQHCs, and proposes requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018.

Starting on p. 381, CMS provides background on the RHC and FQHC payment methodologies, including current CCM requirements and payment for RHCs and FQHCs. Additional information on CCM requirements is available on the CMS Care Management webpage and on the CMS RHC webpage and FQHC webpage.

Starting on p. 385, CMS provides background on payment for CCM Services (CPT code 99487 and CPT code 99489).

Starting on p. 386, CMS provides background on payment for General BHI Services (HCPCS Code G0507).

Starting at the bottom of p. 386, CMS also provides background on payment for Psychiatric CoCM Services (HCPCS codes G0502, G0503, and G0504).

Proposed Care Management Requirements and Payment for RHCs and FQHCs (p. 388)

To ensure that RHC and FQHC patients have access to new care management services in a manner consistent with the RHC and FQHC per diem payment methodologies, CMS proposes to establish two new G codes for use by RHCs and FQHCs, discussed below.

Proposed Establishment of a General Care Management Code for RHCs and FQHCs (p. 389)

To ensure that RHC and FQHC patients have access to new care management services in a manner consistent with the RHC and FQHC per diem payment methodologies, CMS proposes to establish two new G codes for use by RHCs and FQHCs. More specifically, effective for services furnished on or after January 1, 2018, CMS proposes to create General Care Management code GCCC1 for RHCs and FQHCs, with the payment amount set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are:

- CPT 99490 - 20 minutes or more of CCM services
- CPT 99487 - at least 60 minutes of complex CCM services
- HCPCS G0507 - 20 minutes or more of BHI services

RHCs and FQHCs could bill the new General Care Management code when the requirements for any of these 3 codes are met. The General Care Management code would be billed alone or in addition to other services furnished during the RHC or FQHC visit. This code could only be billed once per month per beneficiary, and could not be billed if other care management services (such as TCM or home health care supervision) are billed for the same time period. CMS notes that CPT 99489 is an addon code when CPT 99487 is furnished, and is therefore not included as RHCs and FQHCs are not paid for additional time once the minimum requirements have been met.

CMS proposes the following requirements for RHCs and FQHCs furnishing BHI services:

- ***Initiating Visit: An E/M, AWV, or IPPE visit with an RHC or FQHC primary care practitioner (physician, NP, PA, or CNM) occurring no more than one-year prior to commencing BHI services. This could be the same initiating visit that is used for initiating CCM services, and would be billed separately as an RHC or FQHC visit (if the RHC or FQHC has not already billed for this visit).***
- ***Beneficiary Consent: Documentation in the medical record that the beneficiary has consented to receive BHI services, given permission to consult with relevant specialists as needed, and been informed that there may be beneficiary cost-sharing, including deductible and coinsurance amounts as applicable, for both in-person and non-face-to-face services that are provided. The beneficiary consent process would also include informing the patient that only one practitioner/facility can furnish and be paid for these services during a calendar month, and that the patient can stop care coordination services at any time (effective at the end of the calendar month). This could be obtained at the same time that beneficiary consent is obtained for CCM services.***
- ***Billing Requirements: At least 20 minutes of care management services per calendar month, furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM, and furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision. These are the same billing requirements as for CCM services. If both CCM and BHI services are furnished in the same month, the time would be combined and billed as one under the new care coordination code.***
- ***Patient Eligibility: One or more new or pre-existing behavioral health or psychiatric conditions being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC primary care practitioner, warrants BHI services.***
- ***Required Service Elements: An initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.***

Table 16 compares the requirements for CCM and general BHI services. CMS believes that even though there are some differences in the requirements of CCM and general BHI, bundling them together will help to promote

integrated care management services for Medicare beneficiaries who have either or both primary care and behavioral health needs. It will also result in the least amount of reporting burden for RHCs and FQHCs because once the 20-minute threshold is met for either CCM or general BHI, reporting and tracking of additional time increments is not required.

If this policy had been adopted for CY 2017, the payment amount for General Care Management for RHCs and FQHCs would have been approximately $61 (CPT 99490 at $42.71, + CPT 99487 at $93.67, + G0507 at $47.73 = $184.11/3 = $61.37). This is more than is the CY 2017 PFS national non-facility rates for CPT code 99490 and HCPCS code G0507, and less than the PFS national non-facility rate for CPT code 99487. CMS believes that this bundling methodology is consistent with the RHC and FQHC payment methodology of averaging costs to determine a payment rate rather than paying for each individual service.

Proposed Establishment of a Psychiatric CoCM Code for RHCs and FQHCs (p. 397)

Effective for services furnished on or after January 1, 2018, CMS proposes to create a psychiatric CoCM code for RHCs and FQHCs, GCCC2, with the payment amount set at the average of the 2 national non-facility PFS payment rates for CoCM codes, to be updated annually based on the PFS amounts. The 2 codes are:

- G0502 - 70 minutes or more of initial psychiatric CoCM services
- G0503 - 60 minutes or more of subsequent psychiatric CoCM services

RHCs and FQHCs could bill the new psychiatric CoCM code when the requirements for any of these 2 codes are met. The psychiatric CoCM code would be billed alone or in addition to other services furnished during the RHC or FQHC visit. To prevent duplication of payment, this code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the proposed General Care Management code, are billed for the same time period. CMS notes that G0504 is an add-on code when G0503 is furnished and is therefore not included as RHCs and FQHCs are not paid for additional time once the minimum requirements have been met.

If this policy had been adopted for CY 2017, the payment amount for psychiatric CoCM for RHCs and FQHCs would have been approximately $134.58 (G0502 at $142.84 + G0503 at $126.33 = $269.17/2 = $134.58).

The psychiatric CoCM team must include the RHC or FQHC practitioner, a behavioral health manager, and a psychiatric consultant. Proposed specific requirements of the psychiatric CoCM team are discussed starting on p. 399.

Table 17 compares the requirements for general BHI, which would be billed using the proposed General Care Management code GCCC1, and psychiatric CoCM services, which would be billed using the proposed psychiatric CoCM code, GCCC2.

Other Options Considered (p. 404)

In this section, CMS discusses two alternative options that it considered, but is not proposing:

- Allowing RHCs and FQHCs to bill for the complex CCM codes, the BHI code, and the psychiatric CoCM codes by allowing the individual CPT or HCPCS codes to be added to an RHC or FQHC claim, in the same manner as it currently allows CPT code 99490 to be added to a claim.
- Bundling all 5 codes together into one G code, or developing 3 G codes – one for the CCM codes, one for the BHI code, and one for the psychiatric CoCM codes.

Implementation (p. 405)

RHCs and FQHCs are familiar with billing G codes. If this proposal is finalized as proposed, RHCs and FQHCs would continue to receive payment for CCM when CPT code 99490 is billed alone or with other payable services

on an RHC or FQHC claim until December 31, 2017. Beginning on January 1, 2018, CMS proposes that RHCs and FQHCs would use the new General Care Management G code GCCC1 when billing for CCM or general BHI services, and the new psychiatric CoCM G code GCCC2 when billing for psychiatric CoCM services, either alone or with other payable services on an RHC or FQHC claim. Claims submitted using CPT 99490 on January 1, 2018, or after, will not be paid.

Part B Drug Payment: Infusion Drugs Furnished through an Item of Durable Medical Equipment (DME) (p. 408)

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003) revised the payment methodology for most Medicare-covered Part B drugs and biologicals by adding section 1847A to the Act, which established a new average sales price (ASP) drug payment methodology beginning January 1, 2005. However, section 303(b) of the MMA specified payments for certain drugs using methodologies other than the ASP pricing methodology. Specifically, section 303(b) of the MMA added section 1842(o)(1)(D)(i) of the Act that required that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95% of the average wholesale price (AWP) for that drug in effect on October 1, 2003.

Section 5004(a) of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255, enacted on December 13, 2016) revised sections 1842(o)(1)(C) and (D) of the Act, changing the payment methodology for DME infusion drugs from being based on AWP to the methodologies in sections 1847, 1847A, 1847B, or 1881(b)(13) of the Act, as the case may be for the drug or biological. To implement the pricing changes required by the Cures Act, which modifies the payment for DME infusion drugs to the amount under section 1847A of the Act (ASP payment methodology), by the statutorily mandated effective date of January 1, 2017, CMS incorporated the ASP-based infusion drug payment amounts into the January 2017 quarterly ASP drug pricing files and instructed claims processing contractors to use the updated payment limits for DME infusion drugs.

Here, CMS proposes to revise §414.904(e)(2) to ensure the regulations conform with the new payment requirements of the Cures Act.

Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule (p. 410)

In the final rule published in the June 23, 2016 Federal Register (81 FR 41036) entitled, "Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System," CMS implemented the requirements of section 1834A of the Act, which requires extensive revisions to the Medicare payment, coding, and coverage for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS). Under that rule, reporting entities are required to report to CMS certain applicable information for their component applicable laboratories. The applicable information includes, for each CDLT furnished during a data collection period, the specific HCPCS code associated with the test, each private payor rate for which final payment has been made, and the associated volume of tests performed corresponding to each private payor rate. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to CMS during a data reporting period.

In the CLFS final rule, CMS established the data collection and data reporting periods. The first data collection period was January 1, 2016 through June 30, 2016, with reporting through March 31, 2017. In light of industry feedback regarding the inability to meet the reporting deadline, CMS decided to exercise enforcement discretion until May 30, 2017, with respect to the data reporting period and the application of the Secretary's

potential assessment of civil monetary penalties for failure to report applicable information. Over the coming months, CMS will be analyzing the applicable information we received, holding its Annual Laboratory Public Meeting, meeting with the Advisory Panel for Clinical Diagnostic Laboratory tests, and posting preliminary payment rates.

To better understand the applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods, CMS is interested in public comments from applicable laboratories and reporting entities on the following questions:

- ***Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity and/or any problems the reporting entity experienced with submitting applicable information to us.***
- ***Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.***
- ***Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.***
- ***Did the applicable laboratory (or its reporting entity) use the subregulatory guidance on data reporting provided on the CMS CLFS website?2 If so, was the information presented useful?***
- ***Was the information that the applicable laboratory was required to report readily available in the applicable laboratory's record systems?***
- ***Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?***
- ***If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?***
- ***How much time (hours) was required to assemble and report applicable information to CMS?***
- ***Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?***

Payment for Biosimilar Biological Products under Section 1847A of the Act (p. 414)

In the CY 2016 Physician Fee Schedule (PFS) final rule with comment period, CMS finalized a proposal to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code (80 FR 71096 through 71101, November 16, 2015 Federal Register). In general, this means that products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products. The regulation went into effect on January 1, 2016. CMS discusses here the varying feedback it received from stakeholders regarding CMS's finalized payment policies for biosimilar biological products under Part B.

CMS expects the biosimilar product marketplace to continue to grow and anticipates that biological products will continue to be heavily utilized in Part B. At the same time, CMS is aware of concerns that current policy may discourage development of new biosimilars and other innovation in this area potentially resulting in higher costs over time due to a lack of competition in the market place. As such, CMS is interested in assessing the effects of Medicare payment policy on this important portion of the Part B drug marketplace. In doing so, CMS aims to further investigate a solution that allows market forces to provide a robust and comprehensive selection of choices for patients at a fair price. CMS also is interested in better understanding if and how the innate

differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars, particularly as it relates to biosimilars that are licensed for fewer than all indications for which the reference product is licensed or situations where different biosimilars may be licensed for different subsets of indications for which the reference product is licensed.

Although CMS is not making any proposed changes to existing policies in this space, it requests comments regarding:

- ***Its Medicare Part B biosimilar biological product payment policy; specifically new or updated information on the effects of the current biosimilar payment policy that is based on experience with the U.S. marketplace***. CMS is particularly interested in obtaining material, such as market analyses or research articles that provide data and insight into the current economics of the biosimilar market place. This includes patient, plan, and manufacturer data both domestic and, where applicable, from European markets that may be more established than, and provide insight for, the current United States' market.
- ***Data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending***.
- ***Other novel payment policies that would foster competition, increase access, and drive cost savings in the biological product marketplace. These solutions may include legislation, demonstrations, and administrative options.***

Note that this is a solicitation for comments on this issue for future consideration.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services (p. 418)

Section 218(b) of the Protecting Access to Medicare Act (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[8] in applicable settings. In this rule, CMS offers proposals to continue implementation of this program.

In the 2017 MPFS final rule, CMS, per the statute, defined applicable payment systems for the AUC consultation and reporting requirements as:

- The physician fee schedule;
- The prospective payment system for hospital outpatient department services; and
- The ambulatory surgical center payment system

Consultation by Ordering Professional and Reporting by Furnishing Professional (p. 426)

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date:

1) **Establishment of AUC by November 15, 2015** (section 1834(q)(2) of the Act): In the 2016 MPFS final rule, CMS established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified provider-led entities (PLEs) was published here. Once a PLE is qualified by CMS, the library of AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC the program. CMS previously defined the term PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities

[8] Defined as diagnostic MRI, CT, and nuclear medicine, but not X-ray, fluoroscopy or ultrasound

such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC so long as it is transparent.

2) **Identification of Clinical Decision Support Mechanisms (CDSMs) for consultation with AUC by April 1, 2016** (section 1834(q)(3) of the Act). In the 2017 MPFS final rule, CMS defined CDSM, identified the requirements CDSMs must meet for qualification including an opportunity for preliminary qualification for mechanisms still working toward full adherence, and established a process by which CDSMs may become qualified for use under this program. CMS previously 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 clinical condition. Tools may be modules within or available through certified EHR technology (CEHRT) or private sector mechanisms independent from CEHRT or established by the Secretary. Note that qualified CDSMs must only make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all priority clinical areas (see below). The first list of qualified CDSMs will be posted on the CMS website in conjunction with this proposed rule.

3) **AUC consultation by ordering professionals of applicable imaging services, and reporting on the Medicare claim by furnishing professionals information about the ordering professional's AUC consultation by January 1, 2017**. The proposals in this rule focus on implementation of this third component of the AUC program. Since CMS did not meet the April 2016 deadline to identify CDSMs, it did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date. ***However, in this rule, CMS proposes that ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services ordered on or after January 1, 2019***. CMS believes this delayed timeline will ensure all impacted parties have sufficient time to prepare to meet the requirements of this program.

CMS also proposes to make this first year an educational and operations "testing period" rather than further delay the start date of the program. Nevertheless, CMS recognizes the complexity of these new consultation and reporting requirements for professionals, facilities and for CMS's own claims processing system, as well as the potential for error. ***As such, during the "testing period," ordering professionals would consult AUC and furnishing professionals would report AUC consultation information on the claim, but CMS would continue to pay claims whether or not they correctly include such information.***

CMS does not expect to continue this testing period beyond the first year of the AUC program. ***Still, the agency recognizes the complexity of this program and seeks additional comments related to whether the program should be delayed beyond the proposed start date of January 1, 2019 and/or whether the testing period should be longer than a year***.

CMS also proposes to offer a voluntary reporting period to be available ahead of January 1, 2019, which is anticipated to begin July 2018 depending on CMS's readiness. This would be separate from the proposed testing period beginning January 1, 2019. During the voluntary reporting period, AUC consultation and reporting are not required. However, for applicable imaging services ordered on and after January 1, 2019, consulting specified applicable AUC and reporting consultation information on the Medicare claim would be required for all ordering and furnishing professionals, respectively.

Consistent with the statute, CMS also proposes that furnishing professionals report the following information on Medicare claims for applicable imaging services ordered on or after January 1, 2019:

- ***Which qualified CDSM was consulted by the ordering professional;***
- ***Whether the service ordered would adhere to specified applicable AUC, would not adhere to specified***

applicable AUC, or whether specified applicable AUC were not applicable to the service ordered; and

- ***The NPI of the ordering professional (if different from the furnishing professional)***

Unless an exception applies, an AUC consultation must take place for every order for an applicable imaging service. In cases where relevant AUC are not available in a particular qualified CDSM, the furnishing professional must indicate that AUC is "not applicable" to the service ordered. CMS expects these situations to be limited in scope and number and to decrease over time.

Per the statute, payment may only be made if the claim for the service includes the specific information discussed in this proposed rule. This information, to the extent feasible, is required across claim types (including both the furnishing professional and facility claims) and across all three applicable payment systems (PFS, hospital outpatient prospective payment system and ASC payment system). In other words, CMS would expect this information to be included on the practitioner claim that includes the professional component of the imaging service and on the hospital outpatient claim for the technical component of the imaging service.

To implement this reporting requirement, CMS proposes to establish a series of HCPCS level 3 codes. These G-codes would describe the specific CDSM that was used by the ordering professional. Ultimately there would be one G-code for every qualified CDSM with the code description including the name of the CDSM. However, because the claims processing system can only recognize new codes quarterly, CMS may not be able to update the G-code descriptors simultaneously with the announcement of any new qualified CDSMs, which is expected to occur in June of each year. To ensure that there is a code available to immediately describe newly qualified CDSMs, CMS proposes to establish a generic G-code that could be used temporarily to report that a qualified CDSM was consulted, but would not identify a specific qualified CDSM. CMS also proposes to establish a G-code to indicate circumstances where a qualified CDSM was ***not*** consulted by the ordering professional. G-codes would be a line-item on both practitioner claims and facility claims.

CMS expects that one AUC consulatation G-code would be reported for every advanced diagnostic imaging service on the claim. If there are two codes billed for advanced imaging services on the claim, CMS would expect two G-codes. Each G-code would be expected, on the same claim line, to contain at least one new HCPCS modifier.

CMS also proposes to develop a series of modifiers to provide necessary information as to whether:

- ***The imaging service would adhere to the applicable appropriate use criteria;***
- ***The imaging service would not adhere to such criteria; or***
- ***Such criteria were not applicable to the imaging service ordered***

CMS proposes to create additional modifiers to describe situations where an exception applies and a qualified CDSM was not used to consult AUC:

- ***Imaging service was ordered for a patient with an emergency medical condition; or***
- ***The ordering professional has a significant hardship exception***

CMS seeks comments on any additional HCPCS modifiers that might be needed to separately identify allowable scenarios for which a qualified CDSM was not consulted by the ordering professional.

4) Annual identification of outlier ordering professionals for services related to specific clinical priority areas furnished after January 1, 2017 (section 1834(q)(5) of the Act). Outlier professionals would be subject to prior authorization requirements beginning January 1, 2020. In the 2017 MPFS final rule, CMS defined these initial clinical priorty areas, which represents about 40% of advanced diagnostic imaging services paid for by Medicare in 2014:

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Cervical or neck pain.

By starting to identify these areas now, CMS believes that ordering professionals will have the opportunity to become familiar with AUC within identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

Since CMS proposes in this rule for the program to start January 1, 2019, it anticipates that implementation of the prior authorization component will be delayed. CMS expects to discuss details around outlier calculations and prior authorization in the CY 2019 PFS proposed rule.

Alignment with Other Medicare Quality Programs (p. 432)

CMS recently proposed in the 2018 Quality Payment Program (QPP) proposed rule to develop a direct tie between MIPS and the AUC program by giving MIPS credit to ordering professionals for consulting AUC using a qualified CDSM as a high-weight improvement activity for the performance period beginning January 1, 2018 (82 FR 30484). CMS believe this will incentivize early use of qualified CDSMs to consult AUC by motivated eligible clinicians looking to improve patient care and to better prepare themselves for the AUC program.

CMS is also considering how the AUC program could serve to support a quality measure under the MIPS quality performance category and seeks feedback from the public regarding feasibility and value of pursuing this idea.

Significant Hardship Exceptions to Consulting and Reporting Requirements (p. 434)

In accordance with the statute, CMS previously finalized 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 are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment. In this rule, CMS proposes changes to the significant hardship exception to better align with those used under existing quality programs. ***CMS clarifies here that the statute only allows the ordering professional to seek a significant hardship exception, not the furnishing professional.***

In its 2017 PFS final rule, CMS finalized the following hardship exceptions for the AUC program:

- Insufficient Internet Connectivity (as specified in §495.102(d)(4)(i))
- Practicing for less than 2 years (as specified in §495.102(d)(4)(ii))
- Extreme and Uncontrollable Circumstances (as specified in §495.102(d)(4)(iii))
- Lack of Control over the Availability of CEHRT (as specified in §495.102(d)(4)(iv)(A))
- Lack of Face-to-Face Patient Interaction (as specified in §495.102(d)(4)(iv)(B))

CMS proposes to remove the "practicing for less than 2 years" exception, but to maintain the remaining exceptions. This will ensure this list is consistent with the categories used under the 2017 QPP to determine which MIPS eligible clinicians qualify for a reweighting of the advancing care information (ACI) performance category to zero in the MIPS final score. MIPS does not include this exception since clinicians who are new to Medicare are excluded from MIPS (i.e., are not considered MIPS eligible clinicians).

CMS also proposes to amend the AUC significant hardship exception regulation to specify that ordering professionals who are granted re-weighting of the ACI performance category to zero percent under MIPS due to the circumstances listed earlier (except for "practicing less than 2 years") would also be excepted from the AUC consultation requirement during the same year that the re-weighting applies for purposes of the MIPS payment adjustment.

Recognizing that there are timing differences between the MIPS and the AUC program, as well as situations where a clinician might need a significant hardship exception to the Medicare AUC program that is outside the MIPS re-weighting process, ***CMS also proposes that ordering professionals who have not received a reweighting to zero for the MIPS ACI performance category for the year, but experience one of the circumstances listed above (except for "practicing less than 2 years") may be granted an AUC significant hardship exception***.[9] CMS expects to provide further information on this exception process in future rulemaking.

These significant hardship exceptions would be granted for no longer than 12 months, and CMS could establish an exception for a shorter period where warranted by the circumstances.

CMS invites the public to comment on additional circumstances for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program.

Regarding the AUC program in general, CMS recognizes that the impact of the program will be extensive. ***To ensure it is implementing the program effectively, CMS seeks public comment on potential unintended consequences. CMS also seeks feedback on how it can continue to engage interested participants in developing AUC in a transparent and scientifically robust manner, and in particular, how qualified PLEs develop or modify AUC in collaboration with non-PLE entities and what additional challenges such entities might face.***

Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment (p. 439)

Currently, individual EPs and group practices who did not satisfactorily report data on quality measures for the 2016 Physician Quality Reporting System (PQRS) reporting period are subject to a downward payment adjustment of 2.0% to the PFS payment amount for covered professional services they furnish in 2018. 2016 is the final reporting period for the PQRS.

Table 18 summarizes previously finalized requirements to avoid the 2018 PQRS payment adjustment if reporting as an individual via claims, qualified registry, electronic health record (EHR) and qualified clinical data registries (QCDRs).

Table 19 summarizes the previously finalized satisfactory reporting criteria for group practices via the group practice reporting option (GPRO).

Proposed Modifications to the Satisfactory Reporting Criteria for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment (p. 443)

Responding to the clinician community's concerns that the 2016 PQRS requirements are too complex and need to better align with the Merit-Based Incentive Payment System (MIPS), CMS makes multiple proposed changes

[9] Note that CMS does *not* include in this hardship exception proposal ordering professionals who receive an ACI category weight of zero because they have met the definition of "hospital-based." CMS also does *not* categorically provide an exception for those who receive an ACI category score of zero because their primary specialty, as listed in PECOS, is anesthesiology, radiology or pathology.

to these requirements to ensure that clinicians can be assessed for purposes of the 2018 payment adjustment based on satisfactory reporting criteria that are simpler, more understandable, and more consistent with the beginning of MIPS:

- To revise the previously finalized satisfactory reporting criteria for the 2016 reporting period to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain requirement. For individual EPs, this would apply to the following reporting mechanisms: claims, qualified registry (except for measures groups), QCDR, direct EHR product and EHR data submissions vendor product. This proposal would not affect the criteria used to determine whether an individual EP or group practice has satisfactorily reported for purposes of avoiding the 2017 PQRS payment adjustment, with the exception of the ACO Secondary Reporting Period related to the 2017 PQRS payment adjustment.
- Individual EPs and group practices reporting via claims or qualified registry would no longer be required to report a cross-cutting measure and individual EPs and group practices reporting via QCDR would no longer be required to report an outcome or "high priority" measure (i.e., for purposes of PQRS, a resource use, patient experience of care, efficiency/appropriate use, or patient safety measure).[10]
- If less than 6 measures apply to the individual EP or group practice, each measure that is applicable would need to have been reported. CMS defines "applicable" to mean measures relevant to a particular individual EP's or group practice's services or care rendered. As previously finalized, individual EPs and group practices would continue to be subject to the measure application validity (MAV) process. CMS would maintain the requirement that each required measure be reported for at least 50% of the individual EP's or group practice's patients to which the measure applies.
- Group practices may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected, but are not required to do so (currently, group practices comprised of 100 or more eligible professionals that register for GPRO are required to administer the CAHPS for PQRS survey).
- No changes are proposed for the measures groups criteria.
- No changes are being proposed for the Web Interface criteria.

CMS believes these proposals will result in fewer individual EPs being subject to the 2018 PQRS payment adjustment, and will impose no additional burden on individual EPs because these data have already been submitted to CMS.

These proposed changes are summarized below:

TABLE 20: Summary of Proposed Modifications to the Requirements for the 2018 PQRS Payment Adjustment: Individual Reporting Criteria for the Satisfactory Reporting of Quality Measures Data via Claims, Qualified Registry, and EHRs and Satisfactory Participation Criterion in QCDRs

Reporting Period	Measure Type	Reporting Mechanism	Proposed Satisfactory Reporting Criteria
12-month (Jan 1–Dec 31, 2016)	Individual Measures	Claims	Report at least 6 measures, AND report each measure for at least 50% of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50% of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted.

[10] CMS notes that what is considered to be a "high-priority" measure in PQRS is different from what is considered a "high-priority" measure in MIPS, and it is not proposing to align this requirement with MIPS for the last year of PQRS to minimize complexity and confusion.

12-month (Jan 1–Dec 31, 2016)	Individual Measures	Qualified Registry	Report at least 6 measures, AND report each measure for at least 50% of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50% of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted.
12-month (Jan 1–Dec 31, 2016)	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product	Report at least 6 measures. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the EP must report all of the measures for which there is Medicare patient data. An EP must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016)	Measures Groups	Qualified Registry	No proposed changes
12-month (Jan 1–Dec 31, 2016)	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR	QCDR	Report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50% of the EP's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the EP, the EP must report on each measure that is applicable, AND report each measure for at least 50% of the EP's patients.

TABLE 21: Summary of Proposed Modifications to the Requirements for the 2018 PQRS Payment Adjustment: Group Practice Reporting Criteria for Satisfactory Reporting of Quality Measures Data via the GPRO

Reporting Period	Group Practice Size	Measure Type	Reporting Mechanism	Proposed Satisfactory Reporting Criteria
12-month (Jan 1–Dec 31, 2016)	25+ EPs	Individual GPRO measures in the Web Interface	Web Interface	No proposed changes
12-month (Jan 1–Dec 31, 2016)	25+ EPs that elect CAHPS for PQRS	Individual GPRO Measures in the Web Interface + CAHPS for PQRS	Web Interface + CMS-Certified Survey Vendor	No proposed changes
12-month (Jan 1–Dec 31, 2016)	2+ EPs	Individual measures	Qualified Registry	Report at least 6 measures, AND report each measure for at least 50% of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group, the group must report on each measure that is applicable, AND report each measure for at least 50% of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted.
12-month (Jan 1–Dec 31, 2016)	2+ EPs that elect CAHPS for PQRS	Individual measures + CAHPS for PQRS	Qualified Registry + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry AND report each measure for at least 50% of the group's Medicare Part B FFS patients seen during the reporting period to which the measure

				applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50% of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0% performance rate will not be counted.
12-month (Jan 1–Dec 31, 2016)	2+ EPs	Individual measures	Direct EHR Product or EHR Data Submission Vendor Product	Report 6 measures. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016)	2+ EPs that elect CAHPS for PQRS	Individual measures + CAHPS for PQRS	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare pat ient data.
12-month (Jan 1–Dec 31, 2016)	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR	QCDR	Report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50% of the group practice's patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50% of the group practice's patients.

Accountable Care Organization (ACO) Participants Who Report PQRS Quality Measures Separately During the Secondary Reporting Period (p. 454)

As discussed in the 2017 PFS final rule (81 FR 80441 through 80445), individual EPs and group practices who bill under the TIN of an ACO participant may report separately from the ACO, if the ACO failed to report on behalf of such individual EPs or group practices for the applicable reporting period, during the CY 2016 reporting period for purposes of the 2017 and 2018 PQRS payment adjustments, as applicable. ***In accordance with previously established policies related to this ACO Secondary Reporting Period, CMS's proposed modifications to the satisfactory reporting criteria for individual EPs and group practices for the 2016 reporting period would apply to such individual EPs and group practices for purposes of the 2017 PQRS payment adjustment***. However, this proposal would not affect the 2017 PQRS payment adjustment for any other individual EP or group practice.

Physician Compare Downloadable Database - Addition of Value Modifier (VM) Data (p. 454)

CMS previously finalized in the 2016 PFS final rule (80 FR 71129 through 71130) the decision to publicly report three data points for the 2018 VM based on 2016 data in the Physician Compare downloadable file in late 2017:

- 2018 VM quality tiers for cost and quality, based on the 2016 data, noting if the EP or group is high, low,

or average on cost and quality per the VM.
- A notation of the payment adjustment received based on the cost and quality tiers –upward, downward, or neutral – for each EP or group.
- An indication if the EP or group was eligible to, but did not report quality measures to CMS for 2016 under PQRS.

Given the fact that VM data would be available for posting in the Physician Compare downloadable database for only one year (prior to the program ending) and that VM data may not reflect an EP or group's actual performance or payment adjustment given the proposed changes in this rule, CMS proposes to not move forward with publicly reporting VM data in 2017. All other previously finalized policies related to 2016 PQRS data available for public reporting on Physician Compare in late 2017 remain unchanged (80 FR 71116 through 71132). ***CMS requests comment on this proposal and specifically, if it were to release these data, how it could be used by the public.***

CMS clarifies that it has created other VM data files intended to promote transparency. For each VM performance year, it will publish a Public Use File (PUF) that contains VM performance results of de-identified practices. Supporting documentation for each PUF contains the field name, length, type, label, description, and notes for each variable included in the PUF. The VM program years 2015 and 2016 (performance year 2013 and 2014) are currently available here. In addition, three Research Identifiable Files (RIFs) for Value Modifier program years 2015 and 2016 (performance year 2013 and 2014) are available through the Research Data Assistance Center (ResDAC) and will be made available for each program year. These files include a practice-level, an NPI-practice level, and a beneficiary- level file, as described here.

Clinical Quality Measurement for Eligible Professionals Participating in the Electronic Health Record (EHR) Incentive Program for 2016 (p. 457)

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act and the definition of "meaningful EHR user" at §495.4, EPs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs. In the final rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017," CMS finalized the options for CQM submission for EPs in the Medicare EHR Incentive Program in 2016 as follows (80 FR 62888 through 62889):

- EP Options for Medicare EHR Incentive Program Participation (single program Participation—EHR Incentive Program only):
    - Option 1: Attest to CQMs through the EHR Registration & Attestation System
    - Option 2: Electronically report CQMs through PQRS Portal
- EP Options for Electronic Reporting for Multiple Programs (for example: EHR Incentive Program plus PQRS participation):
    - Option 1: Report individual EP's CQMs through PQRS Portal
    - Option 2: Report group's CQMs through PQRS Portal
      (NOTE: Under option 2, this may include an EP reporting using the group reporting option, either electronically using QRDA, or via the GPRO Web Interface.)

In the Stage 3 rule, CMS also maintained a requirement that EPs report 9 CQMs covering at least 3 NQS domains (this requirement was originally established in the final rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2" (77 FR 54058)).

In this rule, CMS proposes to change the reporting criteria from 9 CQMs covering at least 3 NQS domains to 6 CQMs with no domain requirement for EPs and groups who, in 2016, chose to electronically report CQMs

through the PQRS Portal for purposes of the Medicare EHR Incentive Program. EPs or groups who satisfy the proposed reporting criteria may qualify for the 2016 incentive and may avoid the downward payment adjustment in 2017 and/or 2018, depending on the EP or group's applicable EHR reporting period for the payment adjustment year. This proposal responds to stakeholder feedback about the complexity of these requirements and the lack of alignment with MIPS, and aligns with changes proposed for the PQRS earlier in this rule. Similar to the proposed changes to the PQRS, CMS is not proposing to collect any additional data for 2016.

Note that CMS does not propose any changes to the previously finalized requirements for CQM reporting in 2016 for eligible hospitals and CAHs or the previously finalized requirements for EPs who chose to report CQMs through attestation in 2016 for the Medicare EHR Incentive Program (80 FR 62888). The reasoning for the former policy is that the changes proposed for PQRS in this rule and the policies established for the transition year of the QPP would only affect clinicians and groups. The reasoning for the latter policy is that those who attested were already successful, thus, there is no need to change the requirement. Also, the Registration and Attestation portal is scheduled to sunset as of October 1, 2017 before this final rule is published.

CMS also does not propose to change the previously finalized requirements for 2016 for EPs participating in the Medicaid EHR Incentive Program. CMS has already proposed in the Hospital Inpatient PPS proposed rule that, for 2017, Medicaid EPs would be required to report on any six CQMs that are relevant to the EP's scope of practice (82 FR 20135). However, CMS believes that due to the timing of when any changes it might propose for 2016 through this rulemaking would take effect, the benefits of proposing to extend the policy proposed for Medicare EPs for 2016 to Medicaid EPs for 2016 would not be realized, and the burden on states to implement such a policy would be significant since most states will have completed processing and paying 2016 Medicaid EHR incentive payments by the time such a proposal would take effect. ***CMS seeks comment on its assessment of the difficulty states might face implementing this policy for 2016 for Medicaid EPs, and on the number of Medicaid EPs who might benefit if CMS instead decides to apply this policy in the Medicaid EHR Incentive Program for 2016, to the extent that doing so would be legally permissible.***

Medicare Shared Savings Program (MSSP) (p. 463)

As CMS has done in the past, it proposes changes to the Medicare Shared Savings ACO program as part of the Medicare Physician Fee Schedule.

Beneficiary Assignment Methodology (p. 465)

CMS reviewed the ACA requirement that CMS assign fee-for-service (FFS) beneficiaries to an MSSP ACO "based on the beneficiary's utilization of primary care services rendered by physicians participating in the ACO."[11] The assignment methodology is broken into several steps (p. 466):

- **Pre-step.** Beneficiaries are *eligible* for assignment to an MSSP ACO if the beneficiary had "at least one primary care service" furnished by a primary care physician who is an ACO professional in the ACO.
- **First step.** A beneficiary eligible for assignment will be assigned if the *allowed charges for primary care services furnished to the beneficiary during the assignment window by all primary care physicians who are ACO professionals* (and non-physician ACO professionals) in the ACO are *greater than the allowed charges by non-ACO (or other ACO) primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists*.
- **Second step.** For those beneficiaries who have received "at least one primary care service" from an ACO professional that is an ACO primary care physician or an ACO physician from a designated specialty[12] and

[11] Current regulations on the MSSP assignment methodology are included in C.F.R. Part 425, Subpart E.

no other primary care services from from a primary care physician nurse practitioner, physician assistant, or clinical nurse specialist (either inside or outside the ACO), the beneficiaries will be assigned to the ACO if *the allowed charges for primary care services by ACO professionals with one of the specialty designation* are *greater than the allowed charges for primary care services furnished by physicians with such specialty designations that are non- or other ACO professionals*.

Track 1 and Track 2. CMS currently uses a "preliminary prospective assignment with retrospective reconciliation" attribution process for Track 1 and Track 2 MSSP ACOs. This involved a process whereby beneficiaries are "preliminarily assigned to an ACO at the beginning of a performance year and quarterly thereafter during the performance year, but the final beneficiary assignment is determined after each performance year based on where beneficiaries chose to receive a plurality of their primary care services during the performance year." (p. 467).

Track 3. For Track 3 MSSP ACOs beneficiaries are prospectively assigned to the ACO "based on where the beneficiaries have chosen to receive a plurality of their primary care services during a 12-month assignment window offset from the calendar year that reflects the most recent 12 months for which data are available prior to the start of the performance year." (p. 468). This methodology is also subject to exclusionary rules.

"Main Doctor" Designation. In CY 2017, CMS created a process whereby the beneficiary may choose the provider or supplier they believe "to be responsible for coordinating their overall care." This will result in prospective attribution of that patient regardless of the otherwise implemented assignment methodology (as long as the beneficiary otherwise meets the eligibility criteria).

Special Assignment Conditions for RHCs an FQHCs. The 21st Centery Cures Act requires the Secretary to assign beneficiaries to MSSP ACOs basednot only on utilization of primary care services by physicians but also by utilization of services furnished by RHCs and FQHCs beginning on or after January 1, 2019. MSSP ACO methodology already includes some methods for incorporating RHC and FQHC services into attribution, but CMS believes that the 21st Century Cures Act provides the Secretary with broad discretion to to incorporate RHC and FQHC services into the MSSP beneficiary assignment methodology (p. 474).

- *RHC and FQHC Payment Methodology*: Rural health clinics (RHCs) and Federally-Qualified Health Centers (FQHCs) have recently undergone changes in the methods by which they submit claims for Medicare services which are relevant to applies the MSSP attribution methodology in the cases of services delivered at RHCs and FQHCs. The recent requirements entail (p. 470):
    - *FQHCs*: FQHCs are now paid under an FQHC prospective payment system (PPS). In the submission of claims, FQHCs must now use HCPCS codes on all claims under the FQHC PPS.
    - *RHCs*: RHCs are required to submit HCPCS codes for each service as well as an appropriate revenue code.
- *Current RHC and FQHC MSSP Attribution Mechanisms*: FQHC and RHC claims are institutional claims and do not include information regarding the individual practitioner who delivered a service (and, as such, CMS does not know if the service was delivered by a physician). Therefore, in order to implement the attribution methodology in situations where an RHC or FQHC is an ACO participant, CMS requires that ACOs that include RHCs or FQHCs attest the physicians that directly provide patient primary care services (p. 471). This attestation may only be updated annually (p. 473). A claim will be treated as a

[12] Cardiology, osteopathic manipulative medicine, neurology, obstetrics/gynecology, sports medicine, physical medicine and rehabilitation, psychiatry, geriatric psychiatry, pulmonary disease, nephrology, endocrinology, multispecialty clinic or group practice, addiction medicine, hematology, hematology/oncology, preventive medicine, neuropsychiatry, medical oncology, and gynecology/oncology.

"primary care service performed by a primary care physician" if the claim includes a HCPCS or revenue center code included in the CMS definition of a primary care service (p. 472).

- *Stakeholder* Concerns: CMS notes, however, that some stakeholders are concerned that the special assignment procedures, and in particular the physician attestation mechanism, used for RHCs and FQHCs are burdensome and discourage ACOs from including these entities as MSSP ACO participants (p. 473).
- *Proposed Changes*:
    - ***Beginning in CY 2019, CMS proposes to remove the RHC and FQHC physician attestation requirement. CMS proposes to instead treat a service reported by on an RHC or FQHC institutional claim as "a primary care service furnished by a primary care physician."*** (p. 475). Of particular note, in practice, this means that a beneficiary could receive care in an RHC or FQHC by a nurse practitioner, physician assistant, clinical nurse specialist, or any other practitioner in an RHC and FQHC and still be eligible for assignment to the ACO.
    - ***CMS proposes to adjust all ACO benchmarks at the start of the first performance year in which the new assignment rules are applied so that the ACO benchmarks reflect the use of the assignment rules as will apply in the performance year*** (p. 476).

Definition of "Primary Care Services." As previously discussed, eligibility for attribution (and the attribution methodology) rely on the receipt of "primary care services." CMS currently defines "primary care services" for these purposes as the following codes (p. 478):

- CPT 99201 through 99215
- CPT 99304 through 99318 (excluding claims including the POS 31 modifier)
- CPT 99319 through 99340
- CPT 99341 through 99350
- CPT 99495 – 99496
- Chronic Care Management: CPT 99490
- Welcome to Medicare Visit: G0402
- Annual Wellness Visits: G0438 and G0439
- Services furnished in electing teaching amendment (ETA) hospitals: G0463
- Cross-walk for listed codes to certain revenue center codes used by FQHCs (for services furnished prior to January 1, 2011) and RHCs (aforementioned FQHC and RHC CY 2019 proposals notwithstanding)

CMS proposes the addition of the following codes to the definition of "primary care services" beginning in the 2018 for performance year 2019 and subsequent years:

- Complex Chronic Care Management Codes: CPT 99487 and 99489; and add-on code G0506 (p. 481)
- Behavioral Health Integration (BHI) Codes: G0502, G0503, G0504, and G0507 (p. 482)

CMS seeks input on whether there are additional existing HCPCS/CPT codes that it should add to the definition of "primary care services" for purposes of MSSP ACO beneficiary attribution in future rulemaking (p. 482).

ACO Quality Reporting (p. 483)

CMS Web Interface Measures

Quality measures are submitted by an MSSP ACO through the CMS Web Interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey. CMS previously finalized that changes to the CMS Web Interface measure will be made through rulemaking for the Quality Payment Program (QPP) and will be applicable to MSSP ACO quality reporting (p. 485). CMS highlights several of the

changes it discussed in the CY 2018 QPP proposed rule to measures included in the CMS Web Interface.[13] CMS reviewed that CY 2018 QPP CMS Web Interface-related proposals to determine whether the changes (if finalized) affect how the measures are used to assess ACO performance in the MSSP. After CMS review, ***CMS has determined that the proposed QPP changes to the CMS Web Interface measures do not require that CMS revert the measures to "pay-for-reporting" measures for the 2018 performance year for purposes of the MSSP*** (p. 489). CMS will instead update the measures through subregulatory guidance and maintain the measure phase-in schedule as otherwise dictated under the MSSP (p. 490).[14]

Validation of ACO Quality Data Reporting

CMS refers to the validation process for MSSP ACO quality reporting as the "Quality Measures Validation audit." CMS had previously expressed its intent to align the Quality Measures Validation audit with other CMS quality program audits (e.g. those used in PQRS, the Hospital IQR, and the Hospital OQR) (p. 494).

- CMS previously finalized changes to its Quality Measures Validation audit policies including that the policies would apply to audited ACOs that result in an audit match rate[15] that falls below 90 percent. Because CMS believes that a 90 percent threshold could inappropriately penalize ACOs that make quality data reporting errors that are unrelated to the actual care quality delivered, ***CMS proposes that it would adjust the ACO's overall quality score proportional to the ACO's audit performance only if the ACO has an audit match rate below 80 percent*** (p. 497). ***CMS proposes that it would also adjust the threshold at which a Corrective Action Plan (CAP) must be submitted to a match rate of less than 80 percent*** (p. 498). CMS notes that it might seek to increase the audit match rate threshold over time and that it might consider requiring a higher match rate for ACOs that have been in the program longer (p. 498).
- For those ACO's subjected to quality adjustments based on ACO audit performance, CMS currently multiplies the ACO's overall quality score by the ACO's audit match rate. ***CMS proposes that for each percentage point difference between the ACO's match rate the match rate considered "passing the audit", the ACO's overall quality score would be adjusted downward by 1 percent*** (p. 497).

Reducing MSSP Application Burden (**p. 499**)

SNF 3-Day Rule: Waiver Application Requirements

The Medicare skilled nursing facility (SNF) benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing, or skilled rehabilitation care, or both. Statue requires that beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days in order to be eligible for Medicare coverage of inpatient SNF care (p. 499).

CMS previously provided ACOs participating in Track 3 with additional flexibility to attempt to increase quality and decrease costs by allowing these ACOs to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries when they are admitted to certain "SNF affiliates."[16,17] In order to qualify, ACOs submit

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[13] These include the CY 2018 QPP proposals directed at ACO-14: Influenza Immunization; ACO-16: Body Mass Index Screening and Follow-up Plan; and ACO-17: Tobacco Use: Screening and Cessation (pp. 488-489).

[14] CMS recognized after this exercise that it might need additional flexibility in the future to address changes made to the CMS Web Interface via the QPP proposed rule so that the measures continue to align with other CMS programs (e.g. the MSSP). Therefore, CMS proposes to amend regulations to include "the right for CMS to redesignate a measure as pay-for-reporting when a substantive change to a CMS web interface measure is made under the Quality Payment Program." (p. 491). This supplements CMS' existing authority to do the same when the measure "no longer aligns with clinical practice or causes patient harm." (p. 492)

[15] CMS defines the audit match rate as the discrepancy between quality data reported and the medical records provided during the audit.

[16] A SNF affiliate is a SNF, meeting certain eligibility requirements, with which the ACO has executed a "SNF affiliate agreement" (p. 499).

[17] CMS notes that it began accepting waiver applications in the summer of 2016 and approved 26 Track 3 ACOs to use the SNF 3-Day waiver beginning January 1, 2017 (p. 503).

SNF 3-Day Rule Waiver applications with "supplemental information sufficient to demonstrate that the ACO has the capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days." (p. 501).

While CMS believes the current waiver requirements are generally reasonable, there are two requirements that it believes can create an unnecessary burden on applicants:

- CMS current requires that applicants include "a narrative describing any financial relationships that exist between the ACO, SNF affiliates, and acute care hospitals" (p. 504). CMS believes that this is overly burdensome, and ***CMS proposes to remove the requirement where the ACO applicants must submit a narrative describing any financial relationships between the ACO, SNF affiliate, and acute care hospitals*** (p. 504).
- CMS currently requires that ACOs submit documentation "demonstrating that each SNF included on their list of SNF affiliates has an overall rating of 3 or higher under the CMS 5-Star Quality Rating System." (p. 505). Because CMS is able to obtain this directly from its own website during the application review process, ***CMS proposes to eliminate the documentation requirement regarding the SNF 3 star or higher rating*** (p. 506). CMS notes that it is *not* modifying the requirement that SNF affiliates must maintain a rating of 3 or higher, but that the ACO applicant need not submit documentation to demonstrate the SNF affiliate's rating.

MSSP Initial Application

As part of its initial application, ACO applicants to the MSSP must meet statutory requirements to define processes to promote evidence-based medicine and patient engagement as well as demonstrate that it meets the patient-centeredness criteria as articulated by the Secretary (p. 507). CMS has outlined the supporting documents and materials that ACOs must submit to demonstrate that it meets the requirements to participate in the program (p. 508). Because CMS believes that the document submission requirements add application and review burden without adding value to the review process, ***CMS proposes to remove the requirement to submit supporting documents or narratives and instead will add that CMS can request these materials as needed in order to "fully assess the ACO's application" before a decision is made to approve or deny the application*** (p. 510; p. 516).

CMS goes on to state that it does not believe it is necessary for ACO applicants to submit narratives describing how they would distribute shared savings payments; CMS instead states that it would be more useful for the ACO to state "that it has a method and plan to receive shared savings payments and to distribute those payments to its ACO participants and ACO providers/suppliers, as required by statute." (p. 515; p. 517). CMS understands that it is useful for stakeholders to know how ACOs use or distribute shared savings and therefore, ***CMS will continue to require ACOs to publicly report information on their dedicated Web pages about their shared savings and losses (including information about proportion of shared savings investing in infrastructure, redesigned care processes, and other resources) including the proportion distributed among ACO participants*** (p. 516)***.***

ACO Participant TIN Exclusivity Requirement (**p. 519**)

MSSP ACO participant TINs are not required to be exclusive to one MSSP ACO unless the TIN submits claims for "primary care services" under the assignment methodology (p. 519). From a process standpoint, when an ACO requests the addition of an ACO participant TIN, CMS will verify whether the TIN already appears on another ACO participant list. If it does, the TIN is considered "overlapping." The overlap is permissible if the TIN does not have a history of billing for "primary care services"; it is not permissible if the TIN has a history of billing for "primary care services."

CMS has found that some ACO participant TINs approved to participate in multiple ACOs (i.e. permissible overlap) began billing for "primary care services" during a benchmark or performance year (p. 520). CMS did not previously have rules to address these scenarios. In 2016, the ACO participant TINs that began billing "primary care services" were notified and were required to terminate their participation in the ACO of their choice (and the ACO was required to then recertify its participant list) (p. 521). Depending on the timing, this could require that CMS recalculate beneficiary assignment and financial benchmarks for the performance year. CMS notes that this creates uncertainty, the implications of which could be magnified by the Advanced APM Incentive Payment rules and participation in Track 2 and Track 3 MSSP ACOs (p. 522).

In order to create more certainty around ACO participant lists in situations where ACO participant TINs fall out of compliance *during* the performance year, ***CMS proposes (p. 524) that if during a benchmark or performance year (including the 3 month claims run out period) an ACO participant TIN that participates in more than one ACO begins billing for services that would be used in assignment:***

- ***CMS would not consider any services billed through that TIN when performing beneficiary assignment for the applicable benchmark or performance year***
- ***The ACOs in which the overlapping TIN is an ACO participant may be subject to compliance action (including requiring that each ACO that includes the TIN as an ACO participant to submit a corrective action plan explaining how the ACO plans to work with the overlapping ACO participant to resolve the overlap)***
- ***If the overlap remains unresolved (by the date specified by CMS), CMS would remove the overlapping ACO participant TIN from the ACO participant list of each ACO for the subsequent performance year.***

Individually Beneficiary Identifiable Payments Made Under a Demo, Pilot, or Time Limited Program (p. 526)

The MSSP holds ACOs accountable for total Parts A and B spending under Medicare, including "individually beneficiary identifiable non-claims based payments made under a demonstration, pilot or time limited program" (i.e. payments made outside the Medicare fee-for-service claims system).[18] CMS tracks these payments through "a separate CMS system that receives and stores these non-claims based payments made from the Medicare Trust Funds under a demonstration, pilot or time limited program." (p. 528). However, because of the different rules and processes used for each various program, CMS has included interim payments under these programs that will "undergo subsequent reconciliation to determine the final payment amount" and this might or might not occur on the same operational schedule as the MSSP (p. 529). CMS and stakeholders are concerned about the fluctuation in interim payments, and therefore, ***CMS proposes that it would only include "final individually beneficiary identifiable payments made under a demonstration, pilot or time limited program" in financial calculations for establishing and updating MSSP benchmarks and for determining MSSP performance year expenditures for the 2018 performance year and subsequent performance years*** (p. 531). ***CMS also makes a proposal to address this issue for ACOs who are in the middle of an agreement period when this policy takes effect*** (p. 532). CMS notes that the final payments (not subject to further reconciliation) must be available and in the CMS system by the end of the 3 month claims run out period to be included (p. 533).

Value-Based Payment Modifier and Physician Feedback Program (p. 534)

CMS reminds readers that under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. CMS provides an overview of existing VM policies starting on p. 534. Note that section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the VM; however, section 1848(p)(4)(C) of the Act requires the VM be implemented in a budget neutral manner.

[18] CMS points to payments made under the Bundled Payments for Care Improvement (BPCI) initiative as an illustrative example (p. 528).

In the interest of program alignment and providing a smooth transition between the VM and MIPS, as well as aligning with the proposed changes to the PQRS in this rule, CMS proposes the following modifications to the VM policies for the CY 2018 payment adjustment period:

- ***Reduce the automatic downward adjustment for groups and solo practitioners in Category 2 (those who do not meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50% of the group's EPs meet the criteria as individuals) to 2.0% for groups with 10 or more EPs and at least one physician, and -1.0% for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs.*** Under existing policy, the total maximum downward adjustment in 2018 under the PQRS and VM programs combined is 6.0%, while the maximum downward adjustment under MIPS in 2019 is -4.0%. CMS believes this proposed reduction in payment adjustments will result in a smoother transition to the payment adjustments under MIPS.
- ***Hold all groups and solo practitioners who are in Category 1 (those who meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50% of the group's EPs meet the criteria as individuals) harmless from downward payment adjustments under quality tiering for the last year of the program.*** CMS proposes this policy, recognizing that some clinicians may have reported differently under PQRS if the modified reporting criteria proposed in this rule had been established prior to the reporting period. For example, it is possible that clinicians may have selected fewer or different PQRS measures to report or may have chosen to report through a different PQRS reporting mechanism, which could have resulted in a higher quality composite score under the VM.
- ***To provide a smoother transition to the MIPS, to align incentives across all groups and solo practitioners, and to account for CMS's proposed reduction in downward adjustments under this budget neutral program, CMS also proposes to reduce the maximum upward adjustment under the quality-tiering methodology to two times an adjustment factor (+2.0x) for groups with 10 or more EPs. This is the same maximum upward adjustment under the quality-tiering methodology that CMS finalized and will maintain for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs.*** Under this proposal, the amount available for upward adjustments for high performers would decrease.

  CMS proposed this change based on its concern that the 2018 VM adjustment factor (the "x" factor used to determine upward adjustments) could potentially be higher than the 2017 VM adjustment factor, which has resulted in payment adjustments for some groups and solo practitioners that are significantly higher than the maximum upward adjustment under MIPS in 2019. The magnitude of the 2017 VM adjustment factor is due in large part to the number of physician practices failing to satisfy the criteria to avoid the PQRS payment adjustment (Category 2). CMS points out that it is likely that many physician practices that fall in Category 2 and are subject to automatic downward adjustments under the 2018 VM will be excluded from MIPS in 2019, due to the low-volume threshold. CMS believes that lowering the maximum upward adjustment in 2018 would mitigate the effect of a high adjustment factor and ensure a smoother transition from the VM adjustment in 2018 to the MIPS adjustment in 2019.

CMS seeks comment on whether it has appropriately balanced the interests of high and low-performing groups and solo practitioners through these proposed changes to policy.

CMS does not propose any change to the existing policy (80 FR 71291) that groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology and have average beneficiary risk score that is in the top 25% of all beneficiary risk scores will earn an additional upward adjustment of one times an adjustment factor (+1x).

CMS also does not propose any changes to the existing policy (81 FR 80520 through 80524) related to clinicians who are in Category 1 as a result of reporting outside of their Shared Savings Program ACO during the ACO Secondary Reporting Period because their ACO failed to successfully report on their behalf to avoid the PQRS payment adjustment for 2017 and/or 2018. Under existing policy, these groups and solo practitioners in Category 1 would be classified as "average quality" and "average cost" for purposes of the 2017 VM.

The tables below illustrate how the proposed policies differ from the existing policies for each group size and composition:

TABLE 22: Current and Proposed 2018 VM Amounts Under the Quality-Tiering Approach for Physicians, NPs, PAs, CNSs, & CRNAs in Groups of Physicians with 10+ EPs

Cost/Quality	Low Quality		Average Quality		High Quality	
VM Payment Adjustment	Current	Proposed	Current	Proposed	Current	Proposed
Low Cost	+0.0%	+0.0%	+2.0x*	+1.0x*	+4.0x*	+2.0x*
Average Cost	-2.0%	+0.0%	+0.0%	+0.0%	+2.0x*	+1.0x*
High Cost	-4.0%	+0.0%	-2.0%	+0.0%	+0.0%	+0.0%

** Under existing policy, these groups are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25% of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.*

TABLE 23: Current and Proposed CY 2018 VM Amounts Under the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, & CRNAs in Groups of Physicians with 2-9 EPs and Physician Solo Practitioners

Cost/Quality	Low Quality		Average Quality		High Quality	
VM Payment Adjustment	Current	Proposed	Current	Proposed	Current	Proposed
Low Cost	+0.0%	+0.0%	+1.0x*	+1.0x*	+2.0x*	+2.0x*
Average Cost	-1.0%	+0.0%	+0.0%	+0.0%	+1.0x*	+1.0x*
High Cost	-2.0%	+0.0%	-1.0%	+0.0%	+0.0%	+0.0%

** Under existing policy, these groups are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25% of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.*

TABLE 24: Current and Proposed 2018 VM Amounts Under the Quality-Tiering Approach for PAs, NPs, CNSs, & CRNAs who are Solo Practitioners or in Groups Consisting of Non-Physician EPs only

Cost/Quality	Low Quality		Average Quality		High Quality	
VM Payment Adjustment	Current	Proposed	Current	Proposed	Current	Proposed
Low Cost	+0.0%	+0.0%	+1.0x*	+1.0x*	+2.0x*	+2.0x*
Average Cost	+0.0%	+0.0%	+0.0%	+0.0%	+1.0x*	+1.0x*
High Cost	+0.0%	+0.0%	+0.0%	+0.0%	+0.0%	+0.0%

** Under existing policy, these groups are eligible for an additional +1.0x if their average beneficiary risk score is in the top 25% of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.*

TABLE 25: Proposed CY 2018 VM Amounts Under the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, and CRNAs Who Are Solo Practitioners and Those in Groups of Any Size. Under the proposed policies, groups of any size and composition would be subject to the same upward adjustments under quality tiering and would be held harmless from any downward adjustments based on performance.

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	+1.0x*	+2.0x*
Average cost	+0.0%	+0.0%	+1.0x*
High cost	+0.0%	+0.0%	+0.0%

MACRA Patient Relationship Categories and Codes (p. 550)

Background (p. 550)

Section 101(f) of MACRA amended section 1848 of the Act to create a new subsection (r) entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement, which requires the development of care episode and patient condition groups, and classification codes for such groups. To facilitate the attribution of patients and episodes to one or more clinicians, it also requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. The categories shall include different relationships of the clinician to the patient and reflect various types of responsibility for and frequency of furnishing care.

Operational List of Patient Relationship Categories (p. 551)

Based on feedback collected through solicitations in April 2016[19] and December 2016,[20] CMS posted an operational list of patient relationship categories on May 17, 2017, which is available here. The patient relationship categories are as follows:

- Continuous/Broad Services
- Continuous/Focused Services
- Episodic/Broad services
- Episodic/Focused Services
- Only as Ordered by Another Clinician

Subsequent Revisions (p. 551)

Section 1848(r)(3)(F) of the Act gives CMS the authority to make revisions to the operational list of categories and codes, not later than November 1 of each year (beginning with 2018). The revisions may be based on experience, new information and input from stakeholders. In preparation for potential subsequent revisions by November 1, 2018, CMS seeks comment on the operational list of patient relationship categories available here.

Reporting of Patient Relationship Codes Using Modifiers (p. 552)

In accordance with Section 1848(r)(4) of the Act, ***CMS proposes that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable HCPCS modifiers listed below, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner).*** Applicable practitioners are defined as a physician assistant, nurse practitioner, and clinical nurse specialist, and a certified registered nurse anesthetist, and beginning January 1, 2019, such other eligible professionals. ***To allow clinicians time to gain familiarity with using these modifiers, CMS proposes that, at least for an initial period, clinicians may voluntarily report these codes on claims. In other words, the selection of the modifiers would not be a condition of payment and claims***

[19] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes.pdf

[20] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes-Posting-FINAL.pdf

would be paid regardless of whether and how the modifiers are included. CMS will work with clinicians to educate them about the proper use of the modifiers.

In December 2016, when CMS previously solicited comments on potential modifications to the patient relationship categories, it also sought comment on the use of Level II HCPCS Modifiers for the patient relationship codes. Public comments indicated that CPT Modifiers would be the best way to operationalize the reporting of patient relationship codes.[21] CMS worked with the AMA's CPT Editorial Panel and submitted an application for the CPT modifiers for reporting of the patient relationship codes. The CPT Editorial Panel, at their June 2017 meeting, determined that AMA would not include the modifiers in the CPT code set, pending future finalization of the modifiers by CMS, whereby CMS publishes the modifiers as Level II HCPCS Modifiers. Thus, ***CMS proposes in this rule Level II HCPCS Modifiers as the patient relationship codes, which CMS would add to the operational list if it adopts them in the final rule.***

TABLE 26: Proposed Patient Relationship HCPCS Modifiers and Categories

No.	Proposed HCPCS Modifier	Patient Relationship Categories
1x	X1	Continuous/broad services
2x	X2	Continuous/focused services
3x	X3	Episodic/broad services
4x	X4	Episodic/focused services
5x	X5	Only as ordered by another clinician

The use of modifiers to report patient relationships would not change the meaning of the procedure codes used to report items and services and guidelines associated with use of such procedure codes. The modifiers would also not be tied or related to intensity of services (evaluation and management services). Also, while CMS may work with clinicians to explore incorporating these codes into the QPP in future years, the measures it has proposed and finalized to date, those it has proposed for 2018, and those it is currently developing for future rulemaking for the MIPS performance categories do not require patient relationship codes to properly measure clinicians' quality and resource use in the Medicare program.

CMS seeks comments on this proposal and its intention to resubmit these patient relationship modifiers to AMA for future consideration into the CPT modifier code set.

Medicare Diabetes Prevention Program (p. 555)

In the CY 2017 PFS final rule, CMS implemented aspects of the Medicare Diabetes Prevention Program (MDPP) expanded model, which has the aim of continuing to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes. Services available through the MDPP expanded model are MDPP services furnished in community and health care settings by coaches, such as trained community health workers or health professionals. In last year's rule, CMS specified that the MDPP expanded model would be implemented through at least two rounds of rulemaking. In this year's rule, CMS refines policies finalized last year, addresses a number of issues raised by the public in response to the MDPP proposed rule, and make additional proposals to implement the MDPP expanded model. CMS also discusses its intent to evaluate the MDPP expanded model to determine if the model continues to meet quality and cost criteria (p. 707).

[21] The CMS Level II HCPCS Coding Workgroup meets regularly (generally monthly) to consider requests for new HCPCS codes and modifiers. Information on the code request and approval process is available here.

CMS does not propose to include virtual DPP services, except for a limited number of virtual make-up sessions. Instead, CMS notes that it is considering a separate model under CMS' Innovation Center authority to test and evaluate virtual DPP services, and intends that any separate model of virtual DPP services would run in parallel with the MDPP expanded model (p. 706).

Proposed Changes to Effective Date of MDPP Services (p. 559)

CMS is proposing that MDPP services would be available on April 1, 2018, rather than January 1, 2018, as previously finalized. CMS is proposing this change because CMS wants to ensure that MDPP suppliers have sufficient time to enroll in Medicare after the effective date of the CY 2018 PFS final rule. Provisions related payment and beneficiary engagement incentives would likewise be effective on April 1, but other provisions (for example related to supplier enrollment and compliance) would be effective January 1, 2018.

Proposed Changes to the Set of MDPP Services (p. 560)

CMS proposes to clarify, build on, and at times change previously finalized policies related to the parameters of MDPP services, which refer to structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

Specifically, CMS proposes to define a "set of MDPP services" as the series of MDPP sessions, composed of the following services offered over the course of the MDPP services period: core sessions; core maintenance sessions, and ongoing maintenance sessions. CMS proposes a total MDPP services period of up to 3 years, consisting of 6 months of core sessions, 6 months of core maintenance sessions, and up to 2 years of ongoing maintenance sessions (p. 562) but solicits comment on alternatives considered. CMS also provides refinements to terminology used in describing the set of MDPP services.

Proposed Changes Related to Beneficiary Eligibility (p. 565)

CMS proposes clarifications and changes to eligibility criteria previously finalized in the CY 2017 PFS for Medicare beneficiaries to have coverage of the set of MDPP services. For example, CMS proposes that:

- Prior diagnosis of gestational diabetes or diagnosis of type 2 diabetes after the start of MDPP services would not disqualify a beneficiary from receipt of MDPP services, but diagnosis of ESRD after the start of MDPP services would disqualify a beneficiary.
- Performance and attendance requirements would apply for beneficiaries to be eligible for ongoing maintenance sessions.
- Beneficiaries may change MDPP suppliers at any time during their MDPP services period, subject to beneficiary eligibility requirements.
- Suppliers may offer make-up sessions, including virtual make-up sessions subject to specific requirements.

Proposed Changes Related to Payment for MDPP Services (p. 584)

CMS proposes to pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. ***CMS proposes a maximum total performance payment amount per beneficiary for the set of MDPP services of $810.*** Performance payments would be made to MDPP suppliers periodically during the course of a beneficiary's MDPP services period based upon a number of factors, including the beneficiary's completion of a specified number of MDPP sessions and the achievement of the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes.

CMS details proposals related to payment for:

- core sessions, which are capped at $105 and based on attendance only (p. 598)
- core maintenance session intervals, which are capped at $120 and based on attendance alone, or attendance and weight loss achievement (p. 604),
- ongoing maintenance session intervals, which are capped at $400 and based on attendance and weight loss achievement (p. 609), and
- one-time performance payments capped at $185 for achieving specified levels of weight loss (p. 613).

Table 32 summarizes proposed performance payments for the set of MDPP services noted above. ***CMS proposes to update payment amounts each year based on the CPI-U (p. 618). CMS also proposes requirements for billing and payment for MDPP services (p. 620), including requirements to accept payment on an assignment-related basis, requirements to include the National Provider Identifier of the MDPP coach on a claim, and expectations around billing instructions. CMS also proposes to establish 19 G-codes to submit claims for payment (see Table 33). Additionally, CMS proposes payment policies when a beneficiary changes MDPP suppliers (p. 639), including a proposal to provide a one-time $25 bridge payment to an MDPP supplier for furnishing its first MDPP services session to an MDPP beneficiary who has previously received services from a different supplier and proposals around transferring MDPP records.***

Supplier Enrollment and Compliance (p. 646)

In the CY 2017 PFS final rule, CMS specified that any organization that meets full recognition under the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) would be eligible to enroll as an MDPP supplier. To address the time required to achieve full DPRP recognition, ***CMS proposes an MDPP interim preliminary recognition standard for organizations with pending CDC recognition (p. 649), and that organizations that meet this standard would also be eligible to enroll as an MDPP supplier if it also meets all other conditions for enrollment (p. 650). CMS also includes specific proposals related to the enrollment application and application requirements, as well to the effective date of MDPP suppliers' billing privileges.***

CMS also proposes supplier standards (p. 661) that build on conditions for enrollment, as well as existing requirements that apply to all Medicare suppliers and providers. CMS also proposes additional standards specific to MDPP suppliers, including standards related to suppliers' individual coaches, to establish program integrity safeguards, as well as to support program evaluation. In addition, CMS proposes a new revocation authority to revoke an MDPP supplier for knowingly using an ineligible coach to furnish MDPP services.

CMS finalized that newly enrolling MDPP suppliers would be identified as high categorical risk in the CY 2017 PFS final rule. ***CMS is proposing that MDPP suppliers would revalidate, however, under a moderate risk level every three years (p. 684). CMS also proposes documentation and record retention requirements for MDPP suppliers (p. 685).***

Beneficiary Engagement Incentives under the MDPP Expanded Model (p. 688)

CMS proposes to establish rules governing the furnishing of beneficiary engagement incentives to MDPP beneficiaries under the MDPP expanded model. These rules cover timing of potential incentives, types and value limits of incentives, conditions for financing and furnishing incentives, prohibition on advertising, and documentation requirements. CMS also notes that the Secretary will consider whether waivers of fraud and abuse laws are necessary to allow for such incentives following determination of the requirements in the final rule, and may take into account comments submitted in response to the proposed rule.

Request for Information on CMS Flexibilities and Efficiencies (p. 709)

CMS seeks ideas from the public on regulatory, subregulatory, policy, practice, and procedural changes to better accomplish the agency's goals of reducing burden for hospitals, physicians and patients; increasing quality of care; lowering costs; improving program integrity; and making the health care system more effective, simple and accessible. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this RFI could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS's authority is welcome for CMS's consideration.

CMS is particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. CMS requests commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

CMS will not respond to comments or questions related to the issues raised in this RFI in the 2018 PFS final rule. Rather, CMS will actively consider all input as it develops future regulatory proposals or subregulatory guidance.

Collection of Information Requirements (p. 711)

The Paperwork Reduction Act of 1995 (PRA) requires CMS to solicit public comment on the need for information collection and its usefulness in carrying out the proper functions of the agency; the accuracy of CMS's burden estimates; the quality, utility, and clarity of the information to be collected; and CMS's effort to minimize the information collection burden on the affected public,
including the use of automated collection techniques. In this section, CMS discussed each of the following information collection requirements (ICRs):

- **Medicare Diabetes Prevention Program (MDPP) Expanded Model.** Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the Paperwork Reduction Act (PRA).
- **PQRS.** Since CMS does not propose to accept any additional data for the 2016 reporting period, this rule does not set out any new or revised burden or requirements that would trigger the requirements of the PRA.
- **Medicare Shared Savings Program.** Section 1899(e) of the Act provides that the PRA shall not apply to the Shared Savings Program.
- **Appropriate Use Criteria for Advanced Diagnostic Imaging Services.** CMS's proposed revision of the hardship exception imposes no burden beyond the provision of identifying information and attesting to the applicable information, and is thus exempt from requirements of the PRA. In regards to requiring that ordering professionals consult specified applicable AUC through a qualified CDSM for applicable imaging services ordered on or after January 1, 2019, CMS proposes a one-time burden associated with a possible 6-month voluntary consulting period beginning sometime in 2018, as well as a mandatory annual burden beginning January 1, 2019. Because general practitioners are the largest group of practitioners who order applicable imaging services and would be required to consult AUC under this

program, CMS uses "family and general practitioner" for its estimates. During the 6-month voluntary participation period, CMS estimates 3,410,000 CDSM consultations, estimated to take 2 minutes at a cost of $6.37. In the aggregate, this would result in a cost of $7,242,430.80 annually. Beginning January 1, 2019, CMS anticipate 43,181,818 CDSM consultations. Using the same assumptions, CMS estimates an aggregate annual burden of $275,139,000.

CMS also proposes to require that furnishing professionals report on the Medicare claims for advanced diagnostic imaging services ordered on or after January 1, 2019, information regarding the AUC consultation, including the CDSM used. CMS states here that this proposed reporting requirement would not have any impact on any Medicare claim forms because the forms' currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review under the authority of the PRA.

Regulatory Impact Analysis (p. 719)

CMS estimates that the PFS provisions included in this proposed rule would redistribute more than $100 million in one year, thus making this rulemaking "economically significant" and a major rule under the Congressional Review Act.

Physician Fee Schedule Impacts

Changes in Relative Value Unit (RVU) Impacts (p. 722)

CMS estimates the CY 2018 PFS conversion factor to be 35.9903, which reflects the budget neutrality adjustment, the 0.5% update adjustment factor specified under section 1848(d)(18) of the Act, and the -0.31% target recapture amount required under section 1848(c)(2)(O)(iv) of the Act. CMS estimates the CY 2018 anesthesia conversion factor to be 22.0353, which reflects the same overall PFS adjustments, as well as an additional adjustment due to an update to the malpractice risk factor for the anesthesia specialty. Table 38 and Table 39 present how CMS calculated the proposed PFS and Anesthesia conversion factors for 2018.

Table 40 shows the payment impact on PFS services, by specialty, of the proposals contained in this proposed rule. The most widespread specialty impacts of the final RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including finalized RVUs for new and revised codes. ***Some specialties, including behavioral health specialists, infectious disease, physical medicine, physical and occupational therapists, and radiation oncology, are estimated to experience increases relative to other physician specialties***. These increases can largely be attributed to proposed increases in value for particular services following the RUC and CMS review, the proposed change in allocation of indirect practice expense RVUs for office-based, face-to-face behavioral health services, and proposed changes based on updated professional liability premium data. ***Other specialties, including diagnostic testing facilities, allergy/immunology, cardiac surgery, colon/rectal surgery, general surgery, gastroenterology, emergency medicine, pathology, neurosurgery, thoracic surgery, urology, and independent laboratories are estimated to experience decreases in payments relative to payment to other physician specialties***. These decreases are largely a result of proposed revaluation of individual procedures reviewed by the RUC and CMS, proposed changes based on updated professional liability premium data, proposed decreases in relative payment as a result of proposed updates to prices for particular medical supplies, and continued implementation of previously finalized code-level reductions that are being phased-in over several years. CMS notes that since independent laboratories receive approximately 83% of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule, the estimated 2% reduction for CY 2018 is only applicable to approximately 17% of the Medicare payment to these entities.

Column F of Table 40 displays the estimated CY 2018 impact on total allowed charges, by specialty, of all the RVU changes. However, a table showing the estimated impact on total payments for selected high volume procedures of all of the changes is available under "downloads" on the 2018 PFS proposed rule website.

Effect of Changes in Telehealth List (p. 730)

CMS estimates no significant impact on PFS expenditures from these proposals.

Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid under the PFS (p. 730)

CMS estimates that this change will result in total Medicare Part B savings of $25 million for CY 2018 relative to maintaining the CY 2017 PFS Relativity Adjuster for CY 2018.

Other Provisions of the Proposed Regulation (p. 731)

New Care Coordination Services and Payment for RHCs and FQHCs (p. 731)

Establishment of the RHC and FQHC General Care Management code, which includes all levels of CCM and general BHI services, is projected to increase Medicare spending by $600,000 in CY 2018 and by $7.4 million over 10 years.

Establishment of the RHC and FQHC Psychiatric CoCM code, which includes all levels of psychiatric CoCM services, is projected to increase Medicare spending by approximately $100,000 in CY2018 and $3.7 million over 10 years.

The combined increase in Medicare spending for both new G codes is estimated to be approximately $600,000 in 2018, and approximately $11.1 million over 10 years. While these services are expected to increase quality and improve efficiency over time, the programs are still new and the data is not available yet to demonstrate any cost savings.

Payment for DME Infusion Drugs (p. 733)

Table 43 shows the effect of changes in drug payments to DME suppliers, as a result of transitioning payment for DME infusion drugs from AWP-based pricing to the ASP-pricing methodology on January 1, 2017. CMS estimates adoption of the ASP+6 pricing methodology will result in total Medicare Part B savings ranging over the 10-year period from $40 million in FY 2017 to $110 million in FY 2026 with a 10-year total Medicare Part B savings of $960 million.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services (p. 733)

CMS estimates the proposed consulting requirement to result in an annual burden of 1,425,000 hours at a cost of $275,139,000. Since claims for advanced diagnostic imaging services would not be denied in 2018 as a result of these proposals, they would not impact 2018 physician payments under the PFS.

The Congressional Budget Office estimates that section 218 of the PAMA would save approximately $200 million over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals. Because CMS has not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, it is unable to quantify that impact at this time.

Physician Quality Reporting System Criteria for Satisfactory Reporting for Individual EPs (p. 734)

Based on 2015 data, CMS estimates that approximately 4.5% (or 23,625) of EPs that received a downward payment adjustment would be found successful and therefore would avoid the 2018 payment penalty under the changes proposed in this rule to reduce the reporting requirements.

Medicare Shared Savings Program (p. 735)

The policies proposed in this rule are expected to have a minimal impact on affected ACOs. CMS notes that potential individual ACO impacts are more likely to offset one another rather than build to a substantial total in terms of costs or savings.

Value-Based Payment Modifier and the Physician Feedback Program (p. 736)

CMS has not yet completed the analysis of the impact of the VM in CY 2018 on physicians and non-physicians in groups of 2 or more EPs and physician and non-physician solo practitioners based on performance in 2016. However, preliminary estimates indicate that the implementation of the policies proposed in this rule would reduce the adjustment factor to below 10%. In the 2018 PFS final rule, CMS present the number of groups and solo practitioners that will be subject to the VM in 2018.

MACRA Patient Relationship Categories and Codes (p. 740)

Since CMS intends is to collect HCPCS codes beginning January 2018, and not to tie the collection of the codes with payment until it is sure clinicians have gained ample experience and education in using these modifiers, this policy will have no impact to 2018 physician payments under the PFS. However, there may be a burden associated with clinicians and their administrative staff having to learn which codes to use and how to submit them properly.

Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model (p. 740)

Table 46 shows the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other model costs, based on CMS's expected enrollment per year. The 10-year impact is a savings to Medicare of $186 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.