Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program Model
[CMS-1676-F]

Summary of Final Rule

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I. Introduction and Background

On November 2, 2017, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2018[1] and other revisions to Medicare Part B policies. The final rule is scheduled to be published in the November 15, 2017 issue of the *Federal Register*. Policies in the final rule generally will take effect on January 1, 2018. CMS finalizes that the Medicare Diabetes Prevention Program (MDPP) expanded model will be implemented April 1, 2018.

The final rule updates the PFS payment policies that apply to services furnished by physicians and other practitioners in all sites of services. In addition to physicians, the PFS pays a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities. The final rule includes payment policies for its methodology for work RVUs; the Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging services; for biosimilar biological products; for nonexcepted items and services furnished by nonexcepted off-campus provider based departments of hospitals (Section 603 of the Bipartisan Budget Act of 2015); and Patient Relationship codes. The rule also includes policies related to the Medicare Shared Savings Program and changes to the previously finalized 2018 Value Modifier (VM). The rule also finalizes the Medicare Diabetes Prevention Program (MDPP) expanded model will begin April 1, 2018; HPA will summarize this program in a separate summary.

The **Conversion Factor (CF) for 2018 is $35.9996**. For 2018, the specified update is 0.5 percent, before applying other adjustments. In addition to the update, the CF calculation for 2018 takes into account two other factors: the RVU budget neutrality adjustment and the target recapture amount (the proposed CMS estimate of the net reduction in expenditures resulting from proposed adjustments to relative values of misvalued codes as compared to the 2018 statutory target of 0.5 percent net reductions in expenditures). The 2018 anesthesia CF is $22.1887, which in addition to the adjustments for budget neutrality and target recapture amount includes an update to the practice expense and malpractice risk adjustment of -0.34 percent. Table 48 from the final rule, is reproduced below.

TABLE 48: Calculation of the 2018 PFS Conversion Factor

2017 Conversion Factor		**$35.8887**
Update Factor	0.50 percent (1.0050)	
2018 RVU Budget Neutrality Adjustment	-0.10 percent (0.9990)	
2018 Target Recapture Amount	-0.09 percent (0.9991)	
2018 Conversion Factor		**$35.9996**

[1]Henceforth in this document, a year is a calendar year unless otherwise indicated

Specialty specific impacts of the final rule, as projected by CMS in the final rule economic analysis are available in the last section of this summary starting on page 43.

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

II. Provisions of the Final Rule for PFS

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

1. Practice Expense Methodology

For 2018, CMS finalizes a list of service-level overrides with modifications that was developed based on its medical review of the RUC list and its own historical treatment of certain other low-volume codes. CMS expanded the list to include 28 additional codes and changed the override specialty for 15 codes based on feedback from one commenter who provided newer information about the typical practice of these CPT codes than CMS possessed when it first reviewed this issue in 2016. The list is available on its website at http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

CMS also finalizes its proposal to apply these service-level overrides for both PE and MP, rather than one or the other category. CMS believes this will simplify the implementation of service-level overrides and address stakeholder concerns about the year-to-year variability for low-volume services. Also with respect to MP, CMS finalizes its proposal to remove service-level MP RVU crosswalks for new or revised codes, and will instead derive the specialty mix assumption for the first year from the specialty mix used for purposes of rate setting.

CMS notes that services for which the specialty is automatically assigned based on previously finalized policies under its established methodology (for example, “always therapy” services) would be unaffected by this proposal.

With respect to the formula for calculating equipment cost per minute, CMS notes that it currently uses an equipment utilization rate assumption of 50 percent for most equipment (90 percent for expensive diagnostic imaging equipment as required by statute).

2. Changes to Direct PE Inputs for Specific Services

a. PE Inputs for Digital Imaging Services

CMS sought comment in the proposed rule regarding whether or not the use of the professional PACS workstation would be typical in the following list of vascular ultrasound CPT and HCPCS 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 would use this information to determine whether the professional PACS workstation should be included as a direct PE input for these codes.

Many commenters stated that the use of a professional PACS workstation would be typical in the list of 26 codes CMS sought comment. They explained that in light of the transition from film to digital imaging, the use of both a technical and professional PACS workstations has become typical for many diagnostic imaging services, including vascular ultrasound and digital pathology services. In response, CMS agrees with the commenters that the use of the professional PACS workstation would be typical in 21 of the 26 codes listed in the proposed rule. CMS did not include CPT code 93965, as it has already been deleted, and code G0365 already includes a PACS workstation. CMS also disagrees with adding CPT codes 93922, 93923, and 93924 because these codes do not include a technical PACS workstation and thus would not require a professional workstation. CMS displays the equipment time for these codes in Table 4 of the final rule using the equipment time formula finalized in 2017.

b. Standardization of Clinical Labor Tasks

CMS finalizes its proposal to assign 5 minutes of clinical labor time for all codes that include the "Obtain vital signs" task for 2018. This includes all codes that include at least 1 minute previously assigned to this task. CMS did not finalize its proposal to establish 5 minutes as the new standard for future rulemaking deferring to code-level recommendations that will help distinguish services that may require fewer or greater than 5 minutes for this activity.

CMS also finalizes its proposal to update the equipment times to match the changes in clinical labor time. For codes that have not been recently reviewed and lack a breakdown of how the equipment time was derived from the clinical labor tasks, CMS will 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 list of all codes (about 1,000) affected by these vital signs changes to direct PE inputs is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

c. Equipment Recommendations for Scope Systems

CMS did not finalize its proposal to create and price 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 agreed with commenters that there could be significant differences in the scopes used by different specialties and a single scope for each category may not sufficiently capture variations across specialties in terms of typical scopes and costs.

For 2018, CMS also proposed two minor changes to PE inputs related to scopes. CMS did not finalize its proposal to add an LED light source into the cost of the scope video system (ES031), and thus remove the need to account for a separate light source in these procedures. In addition, CMS also did not finalize its proposal to increase the price of the scope video system by $1,000 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.) While many commenters supported these CMS proposals, CMS decided not to move forward, as it intends to update the price of the scope video system with these changes for 2019 as part of the scope reorganization project.

d. Clarivein Kit for Mechanochemical Vein Ablation

In the 2017 PFS final rule, CMS finalized work RVUs and direct PE inputs for two new codes related to mechanochemical vein ablation, CPT codes 36473 and 36474. After publication of the final rule, stakeholders requested that the 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. Based on comments received, CMS is not finalizing the addition of the Clarivein kit to CPT code 36474 at this time and believes that any changes should be made as part of a broader review of the direct PE inputs that are typically required to furnish the procedure.

e. Removal of Oxygen from Non-Moderate Sedation Post-Procedure Monitoring

CMS finalizes its proposal to remove the oxygen gas from 15 CPT codes: 31622, 31625, 31626, 31627, 31628, 31629, 31632, 31633, 31645, 31652, 31653, 31654, 52647 52648, and 90870. Table 5 in the final rule shows the codes, the amount of oxygen assumed and the cost impact (ranges from 3 cents to 68 cents).

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

For 2018, CMS finalizes its proposal to correct several clerical inconsistencies and make some technical corrections to the direct PE input database:

- CMS will make several direct PE changes 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, in response to a stakeholder inquiry regarding the use of the ambulatory IV pump equipment for this service. Among other changes, CMS adds 6 minutes of RN/OCN clinical labor, and 1800 minutes for the new ambulatory IV pump equipment.

- CMS corrects an anomaly in the postservice work time for CPT code 91200 (Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report) by changing it from 5 minutes to 3 minutes. This also reduces the total work time for the code from 18 minutes to 16 minutes.

- CMS will make updates to its direct PE database where it discovered discrepancies between the finalized direct PE inputs and the values entered into the database. Table 6 in the final rule details the 42 items CMS will update in its direct PE input database.

CMS also received a comment detailing a series of similar technical corrections in the Physician Work Time file. Specifically, the commenter stated there was an issue with 108 codes that had incorrect immediate post-service times and total times that had been previously identified in the 2014 final rule as incorrect by CMS, but not corrected. CMS agrees that these codes contained

an erroneous amount of total time and is finalizing technical correction to the physician work time (as detailed in Table 7). CMS also made similar corrections for six other codes: 28122, 46900, 47562, 77767, 93668, and 96904. CMS notes that these time corrections will not have a direct effect on the calculation of the individual code RVUs.

g. Updates to Prices for Existing Direct PE Inputs

For 2018, CMS finalizes updates to the prices of supplies and equipment item in response to public submission of invoices, with modifications. An extract of Table 16 (shown below) shows the price updates.

Table 16: 2018 Final Rule – Invoices Received for Existing Direct PE Inputs

CPT/HCPCS Codes	Item Name	CMS Code	Current Price	Updated Price	Number of Invoices
17000, 17003, 17004, 46607, 96567, 96X73, 96X74	LMX 4% anesthetic cream	SH092	1.60	$1.36	3*
20982, 32998, 50592	probe, radiofrequency, 3 array (StarBurstSDE)	SD109	353.64	2233.00	1
30140, 30901, 30903, 30905, 30906, 31231, 31237, 31238, 43197, 43198	Atomizer tips (disposable)	SL464	0.00	2.66	1
36514	Cell separator system	EQ084	59,320.00	80,000.00	1
36514	tubing set, plasma exchange	SC085	173.33	273.66	1
36514, 36516	ACD-A anticoagulant	SJ071	6.58	7.10	1
none (formerly in deleted code 36515)	kit, apheresis treatment	SA072	140.00	243.33	1
36522	kit, photopheresis procedure	SA024	858.00	1598.00	1
36522	Photopheresor system	EQ206	65,000.00	70,000.00	1
36522, 96567, 96910, 96912, 96913, 96920, 96921, 96922,	goggles, uv-blocking	SJ027	2.30	7.95	1
50200, 88108, 88120,88121,88173	Cytology, preservative and vial	SL040	0.80	1.19	1
88358, 88361	DNA/digital image analyzer	EP001	195,000.00	248,946.30	1
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	14.00	14.47	3
95004, 95017, 95018	negative control, allergy test	SH101	5.08	5.17	2
95004, 95017, 95018	positive control, allergy test	SH102	17.28	26.12	6

Table 16: 2018 Final Rule – Invoices Received for Existing Direct PE Inputs					
CPT/HCPCS Codes	**Item Name**	**CMS Code**	**Current Price**	**Updated Price**	**Number of Invoices**
95250	sensor, glucose monitoring (interstitial)	SD114	29.50	53.08	19
95250	glucose continuous monitoring system	EQ125	2465.00	1170.54	5
93972, G0249	test strip, INR	SJ055	21.88	5.66	2

*Text in the 2018 final rule indicates that 3 invoices were submitted instead of the one that was indicated in the table.

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

CMS selected among codes with the lowest ratio between nonfacility PE RVUs and work RVUs.[2] CMS selected 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. Using this criterion, CMS identified fewer than 50 codes, most of which are primarily furnished by behavioral health professionals. CMS looked at the relationship between indirect PE and work RVUs for CPT code 99213 as a marker because that is the most commonly and broadly reported PFS code that describes face-to-face office-based services. CMS believes the 0.4 nonfacility PE RVUs for each work RVU can serve as an appropriate marker that appropriately reflects the relative resources involved in furnishing these services.

CMS finalizes its proposal to set the nonfacility indirect PE RVUs for the 50 or fewer codes it identified 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 will 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. CMS 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.

In developing the PE RVUs for 2018, CMS finalizes its proposal to implement only one quarter of this minimum value for non-facility indirect PE for the outlier codes. Under this approach, CMS estimates 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 4-year transition, including for 2018. CMS finalizes its proposal to exclude the codes directly subject to this change from the mis-valued code target calculation because CMS states that the change is a methodological change and not related to mis-valued codes. CMS notes that the PE RVUs displayed in Addendum B were calculated with the one quarter of the indirect PE adjustment factor implemented.

[2] 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.

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

1. Overview

CMS did not finalize its proposal to use the most recent data for the MP RVUs for 2018 and to align the update of MP premium data and MP GPCIs to once every 3 years. Similar to 2017, the 2018 MP RVUs will continue to be based on the premium data collected for the 2015 MP RVU update and the existing specialty risk factors (same risk factors used to calculate the 2017 MP RVUs).

2. Methodology for the Revision of Resource-Based RVUs

CMS will continue to use the same methodology for 2018 that it has largely used since the 2015 update, and the same approach as in 2017. The approach CMS proposed, which CMS did not finalize, would have used updated malpractice premium data and new specialty risk factors. This approach is described in detail in its 2018 Medicare PFS proposed rule (82 FR 33967-33970). CMS notes that the next MP update must occur by 2020, which is consistent with its typical 5-year review process.

C. Medicare Telehealth Services

CMS finalizes its proposal to add seven services to the Medicare telehealth list. In response to requests received in 2016, CMS added three codes because it believe these services are sufficiently similar to services currently on the telehealth services list (this is known as qualifying on a category 1 basis):

- HCPCS code G0296: Counseling visit to discuss the need for lung cancer screening using low dose computed tomography (LDCT).

- CPT codes 90839 and 90840: Psychotherapy for crisis; first 60 min.
    - CMS adds the code with the explicit condition that for payment the distant site practitioner must be able to mobilize resources at the originating site to diffuse the crisis and restore safety, when applicable, when the codes are furnished by telehealth. CMS states this requirement is consistent with the CPT prefatory language that the treatment described by these codes requires, "mobilization of resources to defuse the crisis and restore safety." CMS states it believes "mobilizing resources" is the ability to communicate with and inform staff at the originating site to the extent necessary to restore safety.

CMS also adds four add-on CPT and HCPCS codes to the telehealth list. CMS notes that these add-on codes describe additional elements for services currently on the telehealth list and would only be considered telehealth services when billed as add-on to codes on the telehealth list.

- CPT code 90875: Interactive complexity.
- CPT codes 96160 and 96161: Administration of patient-focused health risk assessment instrument and Administration of caregiver-focused health risk assessment instrument.

- HCPCS code G0506: Comprehensive assessment or/and care planning for patients requiring chronic care management services.

1. Elimination of the Required Use of the GT Modifier on Professional Claims

Effective January 1, 2017, Place of Service (POS) code 02 Telehealth is required on professional claims for telehealth services. With this new POS code, CMS finalizes its proposal to eliminate the required use of the GT modifier on professional claims.

Because institutional claims do not use a POS code, distant site practitioners billing under CAH Method II need to continue to use the GT modifier on institutional claims. In addition, federal telemedicine programs in Alaska or Hawaii will need to retain the GQ modifier as required.

2. Specific Requests for Comments

a. Remote Patient Monitoring

CMS also sought comment in the proposed rule on whether to make separate payment for CPT codes that describe remote patient monitoring. It was particularly interested in comments regarding CPT code 99091. In particular, CMS sought comments on other existing codes that describe extensive use of communications technology including CPT code 99090 (Analysis of clinical data stored in computers) which is also considered a bundled code (procedure status of B).

CMS acknowledges that these two codes may not describe the services as currently furnished, but that activating separate payment for CPT code 99091 in 2018 will serve to facilitate appropriate payment in the short term. Thus, CMS is changing the status of CPT code 99091 from "bundled" to "active" for 2018. CMS did not receive specific comments to suggest reasons for changing CPT code 99090 to "active" status and thus CMS retains the "bundled" status for this code.

To address some of the concerns raised by commenters regarding the broad nature of CPT code 99091, CMS will apply certain requirements (similar to those for reporting chronic care management services) for billing this service in 2018 as follows:

- Practitioner must obtain beneficiary consent for the service and document this in the patient's record
- For new patients or patient not seen by the billing practitioner within 1 year of billing this code, CMS will require initiation of this service during a face-to-face visit with the billing practitioner. Levels 2 through 5 E/M visits (CPT codes 99212 through 99215) and the face-to-face visit included in transitional care management services (CPT codes 99495 and 99496) would qualify
- Should not be reported more than once in a 30-day period
- Code can be billed once per patient during the same service period as chronic care management, transitional care management, and behavioral health integration codes.

3. Telehealth Originating Site Facility Fee Payment Amount Update

For 2018, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) **is $25.76 or 80 percent of the actual charge, whichever is lesser**.

D. Potentially Misvalued Services Under the Physician Fee Schedule

CMS finalizes its list of potentially misvalued codes in the final rule.

- CPT code 27279. CMS received a request to consider CPT code 27279 (Arthrodesis, sacroiliac joint with image guidance, including obtaining bone graft when performed and placement of transfixing device) as a potentially misvalued code because the current work RVU is potentially misvalued. Stakeholders recommended an increase of RVUs to 14.23. CMS agree that the code is potentially misvalued and will wait for the code to be reviewed by the RUC, and would consider it for next year's rule should the RUC expedite their review process.

- CPT codes 36901 – 36909. Based on feedback from stakeholders regarding the work for the newly created dialysis access vascular codes (CPT codes 36901 – 36909), CMS sought additional comments and data regarding the potentially misvalued work RVUs for these codes.

  The overwhelming majority of commenters suggested CMS finalize the 2017 RUC-recommended work RVUs for CPT codes 36901-36909, as many were concerned that the current valuation could compromise patient access to vascular access services. CMS responds, that upon further reflection, it agrees with commenters that these services are currently misvalued. Thus, CMS finalizes the 2017 RUC-recommended work RVUs for CPT codes 36901-36909, consistent with public comments.

- CPT codes 88184 and 88185. CMS discusses the conflicting information it received about the direct PE inputs for CPT codes 88184 and 88185 for flow cytometry. CMS proposed these codes as potentially misvalued which would allow review of the clinical labor and supplies for these codes.

  CMS received several comments that wanted CMS to use the RUC recommendations for 2017 in developing final PE RVUs for these services instead of recommending additional review of these codes under the misvalued code initiation. In response, CMS reexamined the RUC recommended direct inputs and incorporated changes to direct inputs.

- CPT codes 99281 – 99385. CMS discusses stakeholders' concerns that the work RVUs for emergency department visits (CPT codes 99281 – 99385) are undervalued given the increased acuity of the patient population and the various sites for receiving care (e.g. freestanding and off-campus emergency departments).

  CMS agreed with the majority of commenters that these ED services might be potential misvalued citing the increased acuity of the patient population and the heterogeneity of

the sites where emergency department visits are furnished. CMS will address this issue in future rulemaking after review of the RUC's recommendations.

E. Payment Incentive for the Transition from Traditional X-Ray Imaging to Digital Radiology and Other Imaging Services

Section 1848(b)(9)(B) of the Act provides for a 7 percent reduction in payments for the technical component (TC) for imaging services made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using *computed radiology* furnished during 2018 through 2022 and for a 10 percent reduction for the TC during 2023 or a subsequent year. Computed radiology technology is defined as cassette-based imaging, which utilizes an imaging plate to create the image involved.

CMS finalizes its proposal, without modification, to establish a new modifier to be used on claims. Beginning January 1, 2018, this modifier will be required on claims for X-rays that are taken using computed radiography technology; the modifier will be required on claims for the technical component of the X-ray service, including when the service is billed globally. The use of this modifier will result in the corresponding percent reduction for the technical component of the X-ray service.

CMS has created modifier "FY" (X-ray taken using computed radiography technology/cassette-based imaging) for purposes of identifying these claims and applying the applicable payment reduction.

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

CMS' finalized payment policies under the PFS for nonexcepted items and services furnished during 2018 are discussed below.

1. Establishment of Payment Rates

For 2018, CMS will continue its 2017 policy and not adopt OPPS payment adjustments for outlier payments, the rural sole community hospital 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.

After consideration of comments, CMS finalizes a PFS Relativity Adjuster of 40 percent for 2018 (instead of the 25 percent purposed).

CMS states that drugs and biological that are unconditionally packaged under the OPPS will continue to be packaged when furnished in a nonexcepted off-campus PBD. Drug administration services subject to conditional packaging (identified by status indicator Q1 under the OPPS) will be packaged under the OPPS if the relevant criteria are met; otherwise they are separately paid. Drugs and biological that are separately payable under the OPPS (identified by status indicator

"G" or "K" under the OPPS) are paid consistent with payment rules in the physician office setting[3]. **In addition, drugs that are acquired under the 340B program and furnished by nonexcepted off-campus PBDs are paid under the PFS and are not subject to the OPPS drug payment policies and will continue to be paid at ASP + 6 percent.**

2. Partial Hospitalization Programs (PHPs)

For 2018, CMS proposed to continue the policies finalized in 2017 for PHPs services furnished by nonexcepted off-campus PBDs. Specifically, CMS proposed to continue to pay PHP services at the CMHC rate for APC 5853, for providing 3 or more PHP services per day. CMS believes that adopting the CMHC rate is appropriate since CMHCs are freestanding entities that are not part of a hospital but provide the same services as hospital-based PHPs. CMS reiterates that an off-campus PBD may still enroll as a CMHC if it chooses to do so and meets the relevant requirements.

After consideration of public comments, CMS finalizes its proposal and sets the PFS payment rate for these PHP services as the per diem rate that would be paid to a CMHC in 2018. The final 2018 CMHC per diem rate is 68.8 percent of the final 2018 hospital-based per diem rate under the OPPS. (The final 2018 PHP APC geometric mean per diem costs for hospital-based PHP APC 5863 is $208.09.)

3. Supervision Rules

CMS notes that the amendments made by section 603 did not change the status of off-campus PBDs as provider-based departments; the amendments only changed the manner in which these provider-based departments are reimbursed for their nonexcepted items and services. Thus, the supervision rules under 42 CFR 410.27 continue to apply to off-campus PBDs that furnish nonexcepted items and services.

4. Beneficiary Cost-Sharing

CMS specifies that all beneficiary cost-sharing rules that apply under the PFS pursuant to sections 1848(g) and 1866(a)(2)(A) of the Act will continue to apply for all nonexcepted items and services furnished by off-campus OPDs, regardless of the cost-sharing obligation under the OPPS.

Regulatory Impact

For 2018, nonexcepted items and services furnished by nonexcepted off-campus PBDs will be paid under the PFS at a rate that is 40 percent of the OPPS rate. CMS estimates that this change will result in total Medicare Part B savings of $12 million for 2018 relative to maintaining the 2017 PFS Relativity Adjuster of 50 percent for 2018.

[3] The file "Nonexcepted Items and Services Payment by OPPS Status Indicator" provides information about the services by OPPS status indicator subject to the PFS Relativity Adjuster. The file is available on the CMS website under down loads for the 2018 PFS final rule at http:/www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

G. Valuation of Specific Codes

1. Methodology for Proposing Work Relative Value Units (RVUs)

For 2018, CMS first adopted the RUC-recommended work values as the CMS-proposed values for almost all services. Second, CMS provided "alternative" valuation approaches and values for selected services about whose RUC-recommended values CMS had work/time concerns. However, unlike prior years, CMS did not formally propose the alternative values in place of the RUC-recommended values. CMS solicited comments upon the alternative values presented as well as the RUC recommendations.

2. Methodology for Proposing Direct Practice Expense (PE) Inputs

CMS describes its methodology for proposing direct PE inputs, namely clinical labor, disposable medical supplies, and medical equipment. The RUC annually recommends PE inputs to CMS for new, revised, and potentially misvalued codes. CMS evaluates the methodology, data, and decision-making rationales accompanying the RUC recommendations. CMS also determines whether facility and/or non-facility direct PE inputs are appropriate for each service, and makes adjustments based upon application of the Multiple Procedure Payment Reduction (MPPR) policy and the OPPS Cap. CMS makes no strategic changes to their PE input process for 2018.

3. Valuation of Specific Codes for 2018

a. General Considerations

CMS reviewed RUC work value recommendations for 252 codes and direct PE input recommendations for 241 codes. Extensive work, time, and PE input data tables are available for download on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1676-F.html . CMS includes five more limited tables in the rule (Tables 12-16), described briefly below.

Table 12 lists the 2018 final work RVUs; entries include 73 new codes, one existing CPT code for which Medicare coverage is new, and one existing CPT code formerly bundled but newly eligible for separate payment.[4] CMS finalizes their proposed (and RUC-recommended) values for all 252 codes; no CMS alternative values are being adopted.[5] Table 13 lists 2018 final direct PE inputs; these are based upon RUC recommendations and CMS refinements. Many of the codes have two or more PE input adjustments. While almost half of the adjustments each alter payment by less than the $0.30 threshold for producing a PE RVU change, multiple PE adjustments to a code may impact its PE RVU.
Refinements most often reflect the following:

[4] Newly covered is supervision of peripheral arterial disease rehabilitation (CPT 93668) and newly unbundled is physician interpretation of remotely monitored physiologic data (CPT 99091).
[5] The RUC submitted a revised recommendation for screening colonoscopy anesthesia (CPT 00812) in comments on the proposed rule; the RUC revised value matched the CMS alternative value outlined in the proposed rule.

- Equipment time adjustments to match changed clinical labor times or to conform to relevant CMS policies (e.g., for use of highly-technical equipment, surgical instruments, scopes/scope accessories, and PACS workstations);
- Clinical labor times adjusted to match CMS direct PE database "standard" task times; and
- Changes in supply items used during a service or in supply item prices.

Table 14 lists the 2018 final direct PE inputs for 136 codes for which RUC recommendations were finalized by CMS without refinements. Tables 15 and 16 list the finalized prices, along with the supply and equipment invoices received and reviewed by CMS in setting prices, for new (n = 16) or existing (n = 19) direct PE inputs, respectively.

b. Code-specific Considerations

In Section II.H.4 CMS discusses at a code-specific level the comments received on their proposed work RVUs and direct PE inputs, and states their final decisions. Codes are grouped into 61 families for discussion (Sections II.H.4 (1) through (61) of the rule). A comprehensive review of this lengthy discussion is beyond the scope of this summary. Highlights for selected code groups are provided below using their group numbers from the final rule. A complete code family group list is provided at the end of this summary section; readers particularly interested in any of the 61 groups are referred to the rule for complete details.

(1) Anesthesia for GI Procedures (CPT codes 00731-00732, 00811-00813)
CMS observed a shift of colonoscopy procedures from performance under moderate sedation to separately billed anesthesia services, and flagged endoscopy anesthesia CPT codes as potentially misvalued. New CPT codes were created, for all of which CMS proposed the RUC-recommended work values, but also described an alternative value of 4.00 base units instead of the RUC-recommended 3.00 units for 00812 (screening colonoscopy anesthesia). While some commenters supported the original RUC-recommended value, the RUC submitted comments recommending a revised work value of 3.00 base units. This revision was based upon new RUC survey data, as responses to the initial survey of this code fell below the RUC minimum standard. CMS now finalizes the revised RUC recommendation for 00812 along with the original RUC-recommended, CMS-proposed values for the four remaining codes. CMS also notes its continued commitment to physician clinical autonomy (e.g., selecting appropriate anesthesia method) and to identifying potentially misvalued services.

(8) Nasal Sinus Endoscopy (CPT codes 31254, 31255, 31256, 31267, 31276, 31287, 31288, 31295, 31296, 31297, 31241, 31253, 31257, 31259, and 31298)
The CPT Editorial Panel created new and revised codes in response to professional society requests, including four codes (31253, 31257, 31259, and 31298) that each describe bundles of services frequently performed together (31253, 31257, 31259, 31298). CMS proposed the RUC-recommended work values for all 15 codes but also offered alternatives for 11 codes. The proposed rather than the alternative values were supported by most commenters and CMS is finalizing the proposed work values for the entire code family.

Finally, CMS sought comment on the number of sinus surgery balloons used for each service; commenters agreed that one balloon (0.5 of balloon kit SA106) was required for each sinus

treated. CMS finalizes its proposed input of 0.5 kit per sinus treated and all other proposed direct PE inputs for this family.

(10) Bronchial Aspiration of Tracheobronchial Tree (CPT codes 31645 and 31646)
Therapeutic initial tracheobronchial aspiration (31645) was flagged as potentially misvalued, having not been reviewed since initial Harvard valuation; review of the related subsequent aspiration code (31646) was added. CMS proposed the RUC-recommended work values but also offered alternatives for both services based upon analysis of work/time ratios and the removal of moderate sedations as an inherent part of 31645. Moderate sedation removal led CMS to propose removing direct PE inputs from 31645 for oxygen gas (SD084), CO2 monitor equipment time (EQ004), and mobile instrument table time ((EF027). CMS proposed increases to the equipment times for the flexible bronchoscopy fiberscope (ES017), Gomco suction machine (EQ235), and power table (EF031).

CMS finalizes the work values as proposed. A commenter observed that the oxygen volume to be removed (formerly included for moderate sedation) was less than the total required during performance of 31645, and that the proposed gas removal would present a safety risk to patients. Further risk would be added by removal of CO2 monitoring equipment. CMS is not finalizing deletion of the oxygen gas and CO2 monitor PE inputs but is finalizing the proposed Gomco suction and power table equipment time increases.

(12) Artificial Heart System Procedures (CPT codes 33927-33929)
The CPT Editorial Panel created three new Category I codes to replace predecessor Category III codes for implantation, removal, and removal plus placement of artificial heart system components. CMS proposed the RUC-recommended work RVU for 33927 and contractor pricing for the remaining codes, along with the alternative of contractor-pricing for all three services. Commenters supported the proposed value for 33927 rather than contractor-pricing. CMS finalizes its proposal for valuing 33927 and contractor-pricing for 33928-33929. No direct PE inputs were proposed or finalized.

(13) Endovascular Repair Procedures (CPT codes 34X01-34X13, 34812, 34X15, 34820, 34833, 34834, 34X19, and 34X20)
Multiple codes were deleted, and new codes added to bundle radiologic supervision and interpretation codes with their corresponding endovascular aortic aneurysm repair procedure codes. Related arterial access procedures for delivery of graft modules were simultaneously reviewed for work and direct PE inputs. While proposing RUC-recommended values for all services, CMS offered alternative values for several codes based upon 25th percentile RUC survey data. CMS also sought comments about retaining 0-day global status for the arterial access codes rather than the RUC-suggested ZZZ status. Zero-day global services are subject to MPPR discounting while ZZZ codes are not, so that the aggregate RVUs of the multiple codes submitted in a typical case would increase due to the change to ZZZ status and not because of added work being performed. Commenters supported the CMS-proposed, RUC-recommended work values for all codes along with ZZZ status for the arterial access codes. CMS finalizes all of the proposed work values and ZZZ status for the access codes.

(17) Vascular Catheter Insertion (CPT codes 36555, 36556, 36620, and 93503)

Review of this code family was triggered by the identification of non-tunneled central venous catheter placement codes 36555 (under age 5) and 36556 (age 5 or older) as potentially misvalued. These procedures are frequently performed in emergency and critical care areas, operating rooms, and other invasive procedural suites. CMS proposed the RUC-recommended work values and offered no alternatives. CMS proposed removing direct PE inputs related to previously bundled moderate sedation from 36555 and to refine clinical labor and equipment times. CMS finalizes the work and PE inputs as proposed.

(28) Magnetic resonance angiography, head (CPT codes 70544, 70545, and 70546),
(29) Magnetic resonance angiography, neck (CPT codes 70547, 70548, and 70549),
(31) Magnetic resonance imaging, abdomen and pelvis (CPT codes 72195, 72196, 72197, 74181, 74182, and 74183), and
(32) Magnetic resonance imaging, lower extremity (CPT codes 73718, 73719, and 73720). These four magnetic resonance imaging code families were reviewed, as each contained one or more potentially misvalued services. CMS proposed the RUC-recommended work RVUs for all of the codes without considering any alternative values. CMS also proposed various PE clinical labor refinements (i.e., decreases to "standard" CMS direct PE database clinical task times for pre-service education and obtaining consent, for image acquisition, and for QC of images by tech, and deletion of clinical labor time for procedure room, equipment, and supply preparation). Commenters supported the proposed work values and objected to several of the PE refinements. CMS is finalizing the RUC-recommended, CMS-proposed work values along with clinical labor time decreases for the education/consent and QC images tasks. CMS is not finalizing changes to the clinical labor times for image acquisition and procedure room preparation.

(39) Radiation therapy planning (CPT codes 77261, 77262, and 77263)
Code 77263 and its code family met screening criteria as potentially misvalued. CMS proposed the RUC-recommended work values while considering alternative values to address time decreases that are disproportionate to proposed work reductions. No PE input refinements were proposed. Commenters supported the RUC-recommended work values, which CMS finalizes.

(41) Cardiac Electrophysiology Device Monitoring (CPT codes 93279, 93281-93299)[6]
Multiple services in this family were identified as potentially misvalued. CMS proposed the RUC-recommended work values for 19 of the 21 services; 93296 and 93299 have no physician work (only PE RVUs are assigned). CMS is finalizing the RUC-recommended work values for the 19 codes.

CMS proposed PE input refinements to clinical labor and to equipment time for codes 93279 and 93281-93292; comments were few and CMS finalizes the refined PE inputs. CMS proposed the RUC-recommended PE input for 93299 rather than the existing contractor-pricing. However, CMS does not finalize the proposed PE rate and instead finalizes retention of contractor-pricing for 93299.

(48) Continuous Glucose Monitoring (CPT codes 95250, 95251, and 95249)

[6] In this section CMS appears to incorrectly refer to code numbers 99392, 99294, 99295, 99297, and 99298 when discussing codes 93293, 93294, 93295, 93297, and 93298, respectively. Descriptors and values remain correct.

The technical (95250) and professional (95251) components of continuous glucose monitoring were reviewed by the RUC after 95251 was identified as potentially misvalued. Commenters supported the CMS-proposed RUC-recommended time and CMS finalizes the work value proposed for 95251. CMS finalizes the RUC-recommended PE inputs for 95249.

(53) Physical Medicine and Rehabilitation (PM&R) (CPT codes 97012, 97016, 97018, 97022, 97032-97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, 97542, and HCPCS code G0283) Ten "always therapy"[7] codes met criteria as potentially misvalued and were combined with nine additional codes for comprehensive code family review by the HCPAC, sponsored by physical therapy (PT) and occupational therapy (OT) professional societies. CMS proposed the HCPAC-recommended work values and work times for all 19 codes. CMS finalizes the HCPAC-recommended, CMS-proposed work values for all 19 codes reviewed.

CMS proposed to maintain the 2017 direct PE inputs for all 19 codes for 2018, rather than adopting HCPAC-recommended changes that incorporated reductions for efficiencies achieved when multiple services are typically provided together. CMS expressed concern that the proposed, embedded efficiency discounts would later be improperly and unfairly duplicated when the mandatory MPPR policy for always therapy PE RVUs was applied to these codes. Many commenters supported the CMS proposal to maintain the 2017 PE inputs, but others -- including the HCPAC -- strongly supported the HCPAC PE recommendations. The HCPAC's comment letter clarified that their PE recommendations were intended to apply to all 19 MPPR-eligible codes. CMS accepted the HCPAC's reassurance that the combined effects on PE RVUs, of the efficiency discounts and MPPR adjustments were considered by the HCPAC while deriving PE RVUs. CMS, therefore, does not finalize their proposal to maintain the 2017 PE direct inputs and instead finalizes the HCPAC's PE recommendations for all 19 codes.

(54) Cognitive Function Intervention (CPT code 97127)

The HCPAC made work and PE recommendations to CMS for 97127, a new code replacing the deleted 97532. Valuing 97127 presents multiple challenges including a) 97532 was reported in 15-minute increments while 97127 is untimed (reported once per day); b) the service described is furnished by a wide range of healthcare professionals; c) the service is provided in a variety of settings; d) the service is payable both under and separately from the outpatient therapy benefit (OPT); and e) under the OPT, this service can be billed by both institution-based and independent providers. Service utilization patterns vary between the dominant providers of this service (<4 units/claim for therapists and ≥ 4 units/claim for psychologists) and vary by site-of-service (outpatient therapy professionals report shorter times with patients in institutional settings). CMS analysis suggested that the HCPAC-recommended work value could produce significant reimbursement shifts based simply upon the code descriptor changes (97532 to 97127), with increases for therapists and decreases for clinical psychologists). CMS, therefore, proposed creating G0515 to mirror the coding and valuation of 97532 while marking 97127 as invalid for payment by Medicare until a satisfactory, more permanent coding solution can be developed.

[7] The "always therapy" designation means: a service will always be considered "therapy" regardless of the furnishing clinician type; for reporting, the GP or GO modifier must be added (for PT and OT respectively); attesting to a PT or OT care plan; payment counts towards the statutory therapy cap and is subject to the MPPR.

CMS finalizes their proposal to create G0515 to describe the service of deleted 97532 and to assign the work values and PE inputs of 97532 to G0515 for 2018. Code G0515 will be designated as "sometimes therapy"[8] and 97127 will be marked invalid for Medicare payment.

(55) Orthotics and Prosthetics Management and Training (CPT codes 97760, 97761, and 97763)

CMS proposed the HCPAC-recommended work values though it considered alternative values for 97761 and 97763 due to crosswalk-utilization projection concerns about 97763. CMS now finalizes the proposed, HCPAC-recommended work values for all codes. Instead of proposing the HCPAC-recommended PE inputs, CMS proposed to maintain the 2017 PE inputs for 97760 and 97761 and to assign the PE inputs of (deleted) 97762 to new code 97763, based upon the same overlapping efficiency and MPPR discounts concerns described for 19 other rehabilitation codes (see item 53 above). Some commenters supported the proposal to maintain the 2017 PE inputs. The HCPAC and others instead supported the HCPAC-recommended inputs. CMS, reassured by HCPAC's reassurances that the overlapping discounts were taken into consideration during PE input deliberations, finalizes the HCPAC-recommended direct PE inputs for the entire code family for 2018 rather than maintaining the 2017 values. Finally, CMS notes that this code family is designated as "always therapy".

(59) Prolonged Preventive Services (G0513 and G0514)

CMS proposed to create Level II HCPCS codes to provide a mechanism for reporting medically necessary, prolonged, face-to-face physician time required for the provision of preventive services. CMS proposed that prolonged preventive service time be defined in comparison to the intraservice times of preventive services with physician work and to the clinical staff times of services without face-to-face physician work. Work values and PE inputs were proposed at one-half of those assigned to the prolonged outpatient/office E/M or psychotherapy service (99354). CMS also proposed that G0513 and G0514 be restricted to billing only with Medicare-covered preventive services with no beneficiary cost-sharing. In response to commenters, CMS clarifies that G0513 and G0514 cannot be added to timed Medicare preventive services (e.g., G0447 behavioral counseling for obesity). CMS also responds that the additional time described by G0513 and G0514 could be the sum of excess time distributed across multiple, untimed, preventive services performed in a single encounter. CMS finalizes the G-code descriptors, work values, and direct PE inputs as proposed. (The relevant comparison base preventive services times are available in the file "CY 2018 Preventive Services Billed with Prolonged Preventives Code", available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html after filtering on CMS-1676-F.)

(60) Physician Coding for Insertion and Removal of Subdermal Drug Implants for the Treatment of Opioid Addiction (HCPCS codes G0516, G0517, and G0518)

Service times were provided by ASAM (based upon compliance with provisions of the FDA Risk Evaluation and Mitigation Strategies program), and CMS linked the times to suitable crosswalk codes to derive work RVU assignments for the new G-codes. CMS also proposed to

[8] The relevant therapy modifier is required when G0515 is furnished under a therapy plan of care. G0515 is never considered therapy when furnished by a clinical psychologist.

adopt direct PE inputs as requested by ASAM. CMS finalizes all of the proposed work values and direct PE inputs for the new G-codes.

(61) Superficial Radiation Treatment Planning and Management (GRRR1)[9]

CMS notes that CPT prefatory language limits the codes that can be reported with superficial radiation treatment (SRT) delivery code 77401, and that some Medicare contractors have continued to apply a deleted edit barring E/M billing in conjunction with radiation oncology services including SRT. To simplify reporting of services associated with SRT delivery (e.g., clinical treatment planning, basic radiation dosimetry calculation), CMS proposed creating GRRR1 for those services typically performed in conjunction with SRT. Based upon those typical services, CMS derived and proposed a work value and direct PE inputs for GRRR1; a very detailed description of service inclusions and exclusions for GRRR1 is provided in the rule. Commenters generally were not supportive of the GRRR1 proposal, citing concerns such as payment reductions from current levels, included service bundle variability, insufficient code granularity, typical staff type identification, and variable collaboration with medical physicists. Given the number and range of commenter concerns, CMS is not finalizing the creation of GRRR1 at this time but will consider other options in future rulemaking.

Code family groups for which work value or direct PE input changes for 2018 are reviewed			
	Code Group Number and Name		**Code Group Number and Name**
1	Anesthesia for GI Endoscopy	32	MRI Lower Extremity
2	Acne Surgery	33	X-ray Abdomen
3	Muscle Flaps	34	Extremity Angiography
4	Application Rigid Leg Cast	35	Ophthalmic Biometry
5	Multilayer Compression Strapping	36	Extremity Ultrasound
6	Resection Inferior Turbinate	37	Flow Cytometry
7	Control Nasal Hemorrhage	38	Surgical Pathology Consultation
8	Nasal Sinus Endoscopy	39	Radiation Therapy Planning
9	Tracheostomy	40	Tumor Immunohistochemistry
10	Bronchoscopy w/Therapeutic Aspiration	41	Cardiac EP Device Monitoring
11	Cryoablation Pulmonary Tumor	42	Transthoracic Echocardiography
12	Artificial Heart System	43	Stress TTE
13	Endovascular Repairs	44	Peripheral Arterial Disease Rehabilitation
14	Selective Arterial Catheter Placement	45	INR Monitoring
15	Treatment Incompetent Veins	46	Pulmonary Diagnostic Tests
16	Therapeutic Apheresis	47	Percutaneous Allergy Skin Tests
17	Vascular Catheter Insertion	48	Continuous Glucose Monitoring
18	PICC Catheter Insertion	49	Parent/Caregiver Health Risk Assessment
19	Bone Marrow Aspiration	50	Chemotherapy Administration
20	Esophagectomy	51	Photochemotherapy
21	TURP Electrosurgical	52	Photodynamic Therapy
22	Peri-Prostatic Implant Insertion	53	Physical Medicine & Rehabilitation
23	Colporrhaphy w/ Cystourethroscopy	54	Cognitive Function Intervention
24	Injection Anesthetic agent	55	Orthotics & Prosthetic Mgmt & Training
25	Nerve Repair w/Allograft	56	Care Planning Cognitive Impairment
26	Correction of Trichiasis	57	Psychiatric Collaborative Care

[9] This item is incorrectly labeled as section (60) in the preamble of the final rule.

Code family groups for which work value or direct PE input changes for 2018 are reviewed			
	Code Group Number and Name	**Code Group Number and Name**	
27	Soft Tissue Neck	58	Hyperbaric Oxygen Therapy
28	MRA Head	59	Prolonged Preventive Services
29	MRA Neck	60	Implanted Buprenorphine
30	CT Chest	61	Superficial Radiation Treatment/Planning
31	MRI Abdomen/Pelvis		

H. Therapy Caps

The therapy caps are updated each year based on the MEI. Increasing the 2017 therapy cap of $1,980 by the 2018 MEI of 1.4 percent and rounding to the nearest $10.00 results in a **2018 therapy cap of $2,010.**

An exceptions process for the therapy caps has been in effect since January 1, 2006. CMS notes that both the existing exceptions process for therapy caps and the manual medical review process for claims exceeding a threshold amount of $3,700 expires December 31, 2017 under current law. Under current law, the therapy caps will be applicable in accordance with the statute to all outpatient therapy settings, except for services furnished by outpatient hospitals under section 1833(a)(8)(B) of the Act. Without a therapy caps exceptions process, the beneficiary becomes financially liable for 100 percent of expenses they incur for services that exceed the therapy caps.

III. Other Provisions of the Final Rule

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

a. Proposed Establishment of a General Care Management Code for RHCs and FQHCs

CMS proposed to create General Care Management Code (GCCC1) with the payment rate set at the average of the national non-facility PPS payment rates for the CCM and general BHI codes:

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

CMS proposed the General Care Management code could be billed when the requirements for any of these 3 codes are met and could be billed alone or in addition to other services furnished during the visit. The code could only be billed once per month per beneficiary, and could not be billed if other care management services are billed for the same time period.

CMS did not propose any changes to the requirements for CCM services. BHI refers to care management services that integrate behavioral health services with primary care and other clinical services. To bill for this service with the General Care Management code requires 20 minutes or more of clinical staff time, directed by an RHC or FQHC practitioner, and must be furnished per calendar month. As discussed in greater detail in the final rule, CMS proposed the requirements for BHI services include an initiating visit and beneficiary consent. The billing requirements are the same as for CCM services. CMS proposed if both CCM and BHI services

were furnished in the same month, the time would be combined and billed as one service under the new care coordination code. Table 18 in the final rule compares the proposed requirements for CCM (CPT codes 99490 and 99487) and general BHI services (proposed HCPCS code G0507) for RHCs and FQHCs.

TABLE 18—COMPARISON OF PROPOSED CCM AND GENERAL BHI REQUIREMENTS AND PAYMENT FOR RHCS AND FQHCS

Requirements	CCM (CPT codes 99490 and 99487)	General BHI (proposed) (HCPCS code G0507)
Initiating Visit	An E/M, AWV, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same.
	Furnished by a primary care physician, NP, PA, or CNM.	Same.
	Billed as an RHC/FQHC visit	Same.
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same.
	Written or verbal, documented in the medical record	Same.
	Includes information: • On the availability of care coordination services and applicable cost-sharing; • That only one practitioner can furnish and be paid for care coordination services during a calendar month; • That the patient has right to stop care coordination services at any time (effective at the end of the calendar month); and	
	• That the patient has given permission to consult with relevant specialists.	Same.
Billing Requirements	At least 20 minutes of care coordination services per calendar month that is: • 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.	Same.
Patient Eligibility	Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, and place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.	Any behavioral health or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC practitioner, warrants BHI services.
Requirement Service Elements.	Includes: • Structured recording of patient health information using Certified EHR Technology and includes demographics, problems, medications, and medication allergies that inform the care plan, care coordination, and ongoing clinical care; • 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week, and continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; • Comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications;	Includes: • 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.

	• Comprehensive care plan including the creation, revision, and/or monitoring of an electronic care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed; • Care plan information made available electronically (including fax) in a timely manner within and outside the RHC or FQHC as appropriate and a copy of the plan of care given to the patient and/or caregiver; • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities; timely creation and exchange/transmit continuity of care document(s) with other practitioners and providers; • Coordination with home- and community-based clinical service providers, and documentation of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits in the patient's medical record; and • Enhanced opportunities for the patient and any caregiver to communicate with the practitioner regarding the patient's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.	
CY 2017 PFS Non-Facility Payment.	CPT 99490—$42.71, CPT 99487—$93.67	G0507—$47.73.
RHC/FQHC Payment for new General Care Management G code.	Current: $42.71 ..... Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).	Current: N/A. Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).

b. Proposed Establishment of a Psychiatric CoCM Code for RHCs and FQHCs

The psychiatric Collaborative Care Model (CoCM) is a model consisting of a primary care provider and a care manager who work in collaboration with a psychiatric consultant. Services in the psychiatric CoCM are provided under the direction of a treating physician or other qualified health care professional during a calendar month.

CMS proposed a psychiatric CoCM code (GCCC2) with the payment rate set at average of the national non-facility PPS payment rates for the CoCM codes:

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

CMS proposed the psychiatric CoCM code could be billed when the requirements for any of the 2 codes are met and could be billed alone or in addition to other services furnished during the visit. The code could only be billed once per month per beneficiary, and could not be billed if other care management services are billed for the same time period.

As discussed in greater detail in the final rule, the psychiatric CoCM team must include a RHC or a FQHC practitioner, a behavioral health manager, and a psychiatric consultant. Table 19 in the final rule compares the proposed requirements for general BHI services and proposed psychiatric CoCM code.

TABLE 19—COMPARISON OF PROPOSED GENERAL BHI AND PSYCHIATRIC COCM REQUIREMENTS AND PAYMENT FOR RHCS AND FQHCS

Requirements	General BHI (proposed) (HCPCS code G0507)	Psychiatric CoCM (proposed) (HCPCS code G0502 and G0503)
Initiating Visit	An E/M, AWV, or IPPE visit occurring no more than one-year prior to commencing care coordination services.	Same.
	Furnished by a primary care physician, NP, PA, or CNM.	Same.
	Billed as an RHC or FQHC visit	Same.
Beneficiary Consent	Obtained during or after initiating visit and before provision of care coordination services by RHC or FQHC practitioner or clinical staff.	Same.
	Written or verbal, documented in the medical record	Same.
	Includes information: • On the availability of care coordination services and applicable cost-sharing; • That only one entity can furnish and be paid for care coordination services during a calendar month; • That the patient has the right to stop care coordination services at any time (effective at the end of the calendar month); and • That the patient has given permission to consult with relevant specialists.	Same.
Billing Requirements	At least 20 minutes of care management services per calendar month that is: • 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.	At least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services that is: • Furnished under the direction of the RHC or FQHC primary care practitioner; and • Furnished by an RHC or FQHC practitioner or behavioral health care manager under general supervision.
Patient Eligibility	Any mental, behavioral health, or psychiatric condition being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC practitioner, warrants BHI services.	Same.
Requirement Elements	Includes: • 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). Continuity of care with a designated member of the care team.	Includes: RHC or FQHC primary care practitioner: • Direct the behavioral health care manager or clinical staff; • Oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed; and • Remain involved through ongoing oversight, management, collaboration and reassessment. Behavioral Health Care Manager: • Provide assessment and care management services, including the administration of 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; provision of brief psychosocial interventions; ongoing collaboration with the RHC or FQHC practitioner; maintenance of the registry; acting in consultation with the psychiatric consultant;

		• Be available to provide services face-to-face with the beneficiary; having a continuous relationship with the patient and a collaborative, integrated relationship with the rest of the care team; and • Be available to contact the patient outside of regular RHC or FQHC hours as necessary to conduct the behavioral health care manager's duties. Psychiatric Consultant: • Participate in regular reviews of the clinical status of patients receiving CoCM services; • Advise the RHC or FQHC practitioner regarding diagnosis, options for resolving issues with beneficiary adherence and tolerance of behavioral health treatment; making adjustments to behavioral health treatment for beneficiaries who are not progressing; managing any negative interactions between beneficiaries' behavioral health and medical treatments; and • Facilitate referral for direct provision of psychiatric care when clinically indicated.
Cy 2017 PFS Non-Facility Payment.	G0507—$47.73	G0502—$142.84, G0503—$126.33.
RHC/FQHC Payment for New Psychiatric CoCM G Code.	Current: N/A Proposed: Average of CPT codes 99490, 99487, and G0507. (If using the 2017 payment amounts, this would be $61.37).	Current: N/A. Proposed: Average of HCPCS codes G0502 and G0503. (If using the 2017 payment amounts, this would be $134.58).

c. Finalized Policies

In response to public comments, CMS finalizes the proposed revisions to CCM payment for RHCs and FQHCs beginning January 1, 2018. CMS finalizes with a modification the proposed revisions for the requirements and payments for general BHI and psychiatric CoCM beginning January 1, 2018. CMS finalizes the proposed requirements except it removes the requirement that the behavioral health care manager is available to contact the patient outside of regular RHC or FQHC business hours as necessary to conduct the behavioral health care manager's duties.

Table 20 in the final rule, reproduced below, compares the proposed and final codes.

Table 20: Comparison of Proposed and Final HCPCS/CPT Codes		
Description of Code	**Proposed or Current Code**	**Final Code (Effective January 1, 2018)**
General Care Management for RHCs and FQHCs only	GCCC1	G0511
Psychiatric CoCM for RHCs and FQHCs only	GCCC2	G0512
Psychiatric CoCM Services (first 70 minutes)	G0502	99492
Psychiatric CoCM Services (subsequent 60 minutes)	G0503	99493
Psychiatric CoCM Services (add on)	G0504	99494
General BHI Services	G0507	99484

CMS discusses the implementation of these policies. RHCs and FQHCs will continue to receive payment for CCM services when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim for dates of services on or before December 31, 2017. Beginning on January 1, 2018, RHCs and FQHCs must use the General Care Management code when billing CCM or General BHI Services code, and the Psychiatric CoCM code when billing for psychiatric CoCM services either alone or with other payable services on a RHC or FQHC claim. Service lines submitted using CPT code 99490 for dates of services on or after January 1, 2018 will be denied.

Payment rates will be based on the PFS national non-facility rates and will be updated annually when the PFS are finalized for the year. No geographic adjustment will be applied to the General Care Management or Psychiatric CoCM codes. RHCs and FQHCs are required to submit claims for care management services on an institutional claim and are not authorized to bill care management services separately to the PFS. CMS will provide additional information on its website for RHCs and FQHCs.

Several commenters requested clarification of the qualifications for the behavioral health manager. CMS notes that the behavioral health manager is a designated individual with formal education or specialized training in behavioral health such as social work, nursing, or psychology. A behavioral health care manager would be expected to have a minimum of a bachelor's degree in a behavioral health field or be a clinician with behavioral health training, including RNs and LPNs. A clinical social worker is not required to have a master's degree to serve as the psychiatric CoCM health manager.

Regulatory Impact

The combined increase in Medicare spending for these new policies is estimated to be approximately $2.2 million in 2018 and approximately $29.5 million over 10 years. CMS notes that although 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.

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

Section 5004(a) of the 21st Century Cures Act (Cures Act) modified the payment for DME infusion drugs to the amount under section 1847A of the Act (ASP payment methodology). To meet the statutorily mandated effective date of January 1, 2017, CMS incorporated the ASP-based infusion payment amounts into the January 2017 quarterly ASP drug pricing files and instructed claims processing contractors to use the updated payment limits for the DME infusion drugs.

To conform regulations to the new payment requirements in section 5004(a) of the Cures Act, CMS finalizes its proposal to revise 414.904(e)(2). Currently, this describes an exception to the ASP-based payments and requires pricing DME infusion drugs at 95 percent of the 2003 AWP. Consistent with the Cures Act, the revision limits the exception to infusion drugs furnished before January 1, 2017. Effective January 1, 2017, payment limits for these drugs are determined under section 1847A of the Act.

Regulatory Impact

CMS estimates adoption of the ASP+6 pricing methodology will result in total Medicare 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 B savings of $960 million.

C. Payment for Biosimilar Biological Products

CMS is changing its policy and effective January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same HCPCS code and CMS will separately code and pay for biological biosimilar products under Part B. CMS will issue detailed guidance on coding, including instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers. CMS notes that completion of these changes will require changes to the claims processing system which will occur as soon as possible, but might not be completed until mid-2018. CMS will issue instructions using subregulatory means. CMS plans to continue to monitor Part B biosimilar payment and utilization.

CMS is not proposing any regulatory change because as it stated in the 2016 PFS final rule (80 FR 71098), it believes that the current regulation text at §414.904(j) would not preclude separation of a group of biosimilars for payment (and the creation of one or more separate HCPCS codes) should a program need arise.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

1. Implementation

As discussed below, CMS finalizes with modifications its proposals to amend §414.94, "Appropriate Use Criteria for Certain Imaging Services". The finalized policies include:

- Making the AUC consultation and reporting requirements effective for an educational and operational testing period beginning on January 1, 2020 instead of the proposed start date of January 1, 2019; and
- Extending the voluntary reporting to 18 months starting July 2018 and continuing through 2019.

CMS is not finalizing changes to the significant hardship exceptions and intends to address this issue in 2019 rulemaking.

a. Consultation by Ordering Professional and Reporting by Furnishing Professional

Ordering Professional. CMS proposed that ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019. The proposed date lags the statutory requirement of January 1, 2017 but CMS stated this delay was necessary to maximize the opportunity for public comment and stakeholder engagement, also a statutory requirement, and allowed for adequate advance notice for all stakeholders.

In response to public comments, CMS is delaying the effective date for the AUC consultation and reporting requirements to January 1, 2020. On January 1, 2020, the program will begin with an educational and operations testing period. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020.

Furnishing professionals must report the AUC information on the Medicare claim for these services ordered on or after January 1, 2020. CMS will continue to pay claims whether or not they correctly include the appropriate information.

CMS also finalized a voluntary period during which early adopters can begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation.

In response to commenters requesting whether the furnishing professional can update the order as necessary or do they need to consult with the ordering professional or AUC, CMS expects furnishing professionals and facilities to continue to adhere to the relevant rules discussed in the Benefit Policy Manual (Chapter 15, sections 80.6.2-4). Specifically, when the furnishing professional must update or modify the order for an advanced diagnostic imaging service, the AUC consultation information provided by the ordering professional with the original order should be included on the Medicare claim. In future rulemaking, CMS expects to establish a means to account for instances when the order must be updated or modified and to develop policies relating to the identification of outlier ordering professionals.

Furnishing Professional. CMS finalizes with modifications that furnishing professionals report the following information on Medicare claims for applicable imaging service, furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2020, instead of the proposed beginning date of 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).

CMS states that unless a statutory exception applies, an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system. CMS notes that qualified CDSMs must make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all clinical areas and that the current list of priority clinical areas represent about 40 percent of advanced diagnostic imaging services paid for by Medicare in 2014. CMS expects CDSMs to have limited situations where the CDSM does not have specified applicable AUC for the service ordered and expects these responses to decrease with time.

Section 1834(q)(4)(B) requires that payment may only be made if the claim for the service includes the proposed information required by furnishing professionals. This information is required across claims types (both the furnishing and facility claims) and across all three applicable payment systems (PFS, hospital outpatient, and ambulatory surgery center). CMS states this information would need to be included on the practitioner claim that includes the PC of the imaging service and on the hospital outpatient claim for the TC of the imaging service. Claims not paid under the PFS, hospital outpatient or ambulatory surgery center payment system would not need to include the information.

CMS proposed to establish a series of G-codes and HCPCS modifiers to capture AUC consultation information on Medicare claims. CMS also proposed to create additional modifiers to describe situations where an exception applies and a qualified CDSM was not used. A modifier would indicate the imaging service was ordered for a patient with an emergency medical condition and another modifier would indicate the ordering professional has a significant hardship exception.

CMS finalizes voluntary reporting starting July 2018 and continuing through 2019. During the voluntary reporting period, ordering professionals are not required to consult AUC and furnishing professionals are not required to report consultation information on their Medicare claims. Furnishing professionals and facilities reporting AUC consultation information during the voluntary reporting period will have one HCPCS modifier to report on the line level with the CPT code for the advanced diagnostic imaging service. CMS expects this type of limited reporting will be temporary as it implements the AUC consultation and reporting requirements using the unique AUC consultation identifier.

In response to comments, CMS reiterates that when a patient is in an inpatient setting, the physician's Part B professional claims would not require reporting of an AUC consultation. In addition, any advanced imaging service furnished within a critical access hospital (CAH) would not be furnished in an applicable setting. Applicable settings include physician offices, hospital outpatient departments, and ambulatory surgical centers. CMS notes that CAH patients who are furnished an advanced diagnostic imaging service in an applicable setting but the claim for that imaging service is not paid under one of the applicable payment systems would not require consultation and reporting of the AUC consultation. This requirement may apply in situations when a CAH has elected Method II billing.

b. Significant Hardship Exceptions to Consulting and Reporting Requirements

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements under section 1834(q)(4)(B) of the Act.

First, the statute provides for an exception when an applicable imaging service is ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. CMS discusses that these emergency situations would occur primarily in the emergency department, but they could also arise in other settings and CMS recognizes that most encounters in an emergency department are not for an emergency medical condition. In the 2017 PFS final rule, CMS finalized an exception to the AUC consultation and reporting requirements for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. CMS noted that to meet this exception, the clinician needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part.

The second exception is for an applicable imaging service ordered for an inpatient and for which payment is made under Medicare Part A.

The third exception is for an applicable imaging service ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship. In the 2017 PFS final rule, CMS adopted that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment would also be granted a significant hardship exception for the AUC consultation requirement. The categories for significant hardship were: insufficient internet connectivity; practicing for less than 2 years; extreme and uncontrollable circumstances; lack of control over the availability of CEHRT; and lack of face-to-face patient interaction.

With the payment adjustments under the Medicare EHR Incentive Program sunsetting, CMS proposed to align the significant hardship exception with the significant hardship exception for the MIPS. Specifically, CMS proposed to amend the AUC significant hardship exception regulation to specify that ordering professionals who are granted re-weighting of the advancing care information (ACI) performance category to zero percent of the final score for the year would be exempted from the AUC consultation requirement during the same year that the reweighting applies for purposes of the MIPS payment adjustment. Based on this proposal, Medicare physicians practicing for less than 2 years would no longer have a significant hardship exemption from the AUC program because they are not considered MIPS eligible clinicians.

For those circumstances when a clinician who is not a MIPS eligible clinician needs a significant hardship exception to the AUC program, CMS proposed that ordering professionals who have not received a reweighting to zero for the year but meet one of the criteria described under the exemptions for the Medicare EHR Incentive Program (§495.102(d)(4)(i),(ii,)(iii),(iv)(A) and (iv)(B)) may be granted an AUC significant hardship exception. A significant hardship exemption would be granted for no longer than 12 months.

In the final rule, CMS has decided further evaluation is needed before making changes to the significant hardship exception regulatory language and intends to address this issue in 2019 rulemaking. CMS will continue to explore opportunities to use a more automated process for providing additional information to ordering and furnishing professionals in a timely manner and to make the information readily accessible.

E. Criteria for 2018 Physician Quality Reporting System Payment Adjustment

In the 2016 PFS Final Rule (80 FR 71140 through 71250), CMS established the criteria for satisfactory eligible professional (EP) and group practice reporting under the Physician Quality Reporting System (PQRS) for 2018, the program's final year. Individual EPs and group practices that do not meet these requirements are subject to a 2 percent reduction to the PFS amount for covered professional services furnished in 2018.

1. Requirements for 2018 PQRS Payment Adjustment

In this rule, CMS modifies the requirements for successful reporting under the 2018 PQRS payment adjustment without collecting any additional data for the 2016 reporting period. CMS makes these changes in response to communications from stakeholders. It wants individual EPs and groups to be assessed for the 2018 PQRS payment adjustment using reporting criteria that are "simpler, more understandable, and more consistent with the beginning of the [Merit-based Incentive Payment System] MIPS." The proposed changes would result in fewer individual EPs and groups being subject to the PQRS payment reduction.

Tables 21 and 22 in the final rule list the modified final requirements for the 2018 PQRS payment adjustment for individual EPs and group practices, respectively. The summary table below combines information from these tables along with material from tables in the proposed rule that describe policies unchanged in this final rule.

The modifications adopted in this final rule are:

- Reduce the number of required measures from 9 measures across 3 National Quality Strategy (NQS) domains to 6 measures with no domain requirement (consistent with the MIPS transition year)
    - For individual EPs, this requirement applies to the following reporting mechanisms: claims, qualified registry (except for measures groups), Quality Clinical Data Registry (QCDR), direct Electronic Health Record (EHR) product, and EHR data submissions vendor project.
    - For group practices, this applies to the following reporting mechanisms: qualified registry, QCDR, direct EHR product and EHR data submissions vendor project.
    - If less than 6 measures apply to an individual EP or group, each applicable measure must be reported.
- Eliminate the requirement that individual EPs and group practices reporting via QCDR report an outcome or "high priority" measure.
- Eliminate the requirement that individual EPs and group practices reporting via a claims or qualified registry report a cross-cutting measure.
- Eliminate the requirement that group practices of 100 or more EPs that register to participate in the group practice reporting option (GPRO) must administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS patient survey.

The current requirement that each measure be reported for at least 50 percent of the EP or group's patients to which the measure applies is continued, and the measure application validity (MAV) process continues to apply.

In general, the proposals will not affect the criteria used to determine whether an individual EP or group practice has satisfied quality reporting requirements for purposes of avoiding the 2017 PQRS payment adjustment. However, an exception applies in the case of individual EPs and group practices who bill under the TIN of an Accountable Care Organization (ACO) participant and who report PQRS quality measures separately during a secondary reporting period because the ACO failed to report on their behalf during the 2016 reporting period for purposes of the

2017 and 2018 PQRS payment adjustments. The finalized changes to the 2016 reporting period apply to these individual EPs and group practices for purposes of the 2017 payment adjustment.

Summary of Final Requirements for the 2018 PQRS Payment Adjustment

Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
Individual Reporting for Jan 1, 2016-December 31, 2016			
	Individual Measures	Claims OR Qualified Registry	Report at least 6 measures, AND report each measure for at least 50 percent 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 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
	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 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.
	Measures Groups	Qualified Registry	[No changes made.] Report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
	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 percent 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 percent of the EP's patients.
Group Practice Reporting for Jan 1, 2016-December 31, 2016			
25+ EPs	Individual GPRO Measures in the Web Interface	Web Interface	[No changes made.] Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
25+ EPs that elect CAHPS for PQRS	Individual GPRO Measures in the Web Interface + CAHPS for PQRS	Web Interface + CMS-Certified Survey Vendor	[No changes made. *] 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 on all measures included in the Web Interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data. Please note that, if the CAHPS for PQRS survey is applicable to a group practice that reports quality measures via the Web Interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the Web Interface measures.
2+ EPs	Individual Measures	Qualified Registry	Report at least 6 measures AND report each measure for at least 50 percent 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 practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
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 percent 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 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).
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 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.
2+ EPs that elect CAHPS for PQRS	Individual Measures + CAHPS for PQRS	Direct EHR Product or EHR Data Submission Vendor Product + CMS-	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 the measures for which there is patient data. Of the additional 3

Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
		Certified Survey Vendor	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 patient data.
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 percent 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 percent of the group practice's patients
Source: Material copied from Tables 21 and 22 of the final rule (display copy pages 641 and 645-6) and Tables 18 and 19 of the proposed rule (82 FR 34097-34099 with respect to categories for which the final rule makes no changes. *This final rule eliminates the PQRS requirement that group practices of 100 or more EPs that register to participate in the GPRO must administer the CAHPS for PQRS patient survey. CAHPS is voluntary for all groups.			

2. Physician Compare Downloadable Database

CMS finalizes its proposal not to proceed with public reporting of certain data related to the value-based modifier (VM) that it planned to include in the Physician Compare downloadable file in late 2017. The decision not to proceed with public reporting of these data is made because of modifications to the PQRS reporting requirements and the VM adjustment for 2018. In addition, CMS believes that the data would only ever be available for one year and could be confusing to the public. Other policies related to the public reporting of 2016 PQRS data on Physician Compare in late 2017 (80 FR 7116-71132) remain unchanged.

3. Collection of Information Requirements and Impact Analysis

CMS estimates that the finalized proposal to reduce the number of measures needed to satisfactorily report for 2018 PQRS payment adjustment would result in fewer penalized EPs. It reports that roughly 525,000 eligible professionals failed the PQRS reporting requirements for the 2015 reporting period and as a result received a downward payment adjustment in 2017. It estimates that approximately 4.5 percent of these EPs (23,625) would successfully report under the final rule and therefore would avoid the payment penalty for 2018. The estimated average 2 percent payment reduction for 2015 was -$937.02. Based on that amount, CMS estimates that these EPs would receive an aggregate $22.1 million in 2018 as a result of not receiving the negative PQRS payment adjustment because of the changes in this final rule.

F. Clinical Quality Measurement for Eligible Professionals Participating in the EHR Incentive Program for 2016

The reporting criteria for EPs is reduced from at least 9 CQMs covering 3 domains, to 6 CQMs with no domain requirement. This aligns the reporting requirement for the Medicare EHR Incentive Program with the modified requirement for the 2016 PQRS reporting period (2018 payment), as well as the QPP transition year requirement.

No changes were proposed to the previously-adopted 2016 requirements for CQM reporting for hospitals and critical access hospitals, or for EPs who choose to report for the Medicare EHR Incentive Program in 2016 through attestation. Regarding the former, CMS says the alignment with PQRS is not relevant to hospitals. In the latter case, CMS says that EPs who attest were successful and there is no need to change the requirement. In addition, the registration and attestation portal was phased out on October 1, 2017 and is no longer available for use.

Furthermore, CMS did not propose any changes with respect to requirements for EPs participating in the Medicaid EHR Incentive Program for 2016.

G. Medicare Shared Savings Program

Modifications are adopted, without change from the proposed rule, to the Medicare Shared Savings Program (MSSP). Included are changes to the beneficiary assignment process for beneficiaries using the services of rural health clinics (RHCs) and federally qualified health centers (FQHCs); the definition of primary care services used for the assignment process; quality validation audits; the exclusivity requirement for providers submitting ACO claims; calculations for establishing and updating benchmarks and determining performance year spending; and other changes intended to reduce the application burden for participating providers.

1. Modification to Shared Savings Program Beneficiary Assignment Methodology

a. Assignment of Beneficiaries to ACOs that include RHCs and FQHCs

CMS finalizes its proposal to change the treatment of claims for beneficiaries receiving primary care services from RHCs and FQHCs when assigning beneficiaries to ACOs beginning with performance year 2019 and for subsequent years. The requirements are set forth in 42 CFR 425.

In this final rule CMS is adopting the following:

- Removing the attestation requirement by eliminating §425.204(c)(5)(iii); and instead treating a service reported on an RHC or FQHC claim as a primary care service furnished by a primary care physician.
- Revising §425.404 which lays out the assignment process for beneficiaries treated by RHCs and FQHCs to indicate that, for performance year 2019 and thereafter, beneficiaries assigned to ACOs will be assigned using the general assignment methodology in §425.102 and by treating a service reported on an RHC or FQHC institutional claim in the same way as a primary care service performed by a primary care physician; and
- Making changes to the list of revenue center codes in the definition of primary care to eliminate revenue center codes that are no longer needed.

All benchmarks will be adjusted at the start of the first performance year in which the new rules are in effect (2019), and the new methodology will be used in late 2018 when determining the eligibility of ACOs considering entering into or renewing a participation agreement.

The newly adopted changes are made consistent with Section 17007 of the 21st Century Cures Act, which requires the Secretary to assign beneficiaries to ACOs based not only on their use of primary care services furnished by physicians but also on the use of services furnished by RHCs and FQHCs, beginning with performance years on or after January 1, 2019.

b. Revisions to the Definition of Primary Care Services (§425.400)

Consistent with the changes described above and for making other organizational improvements to the rules, CMS adopts a number of changes to the definition of Primary Care Services in §425.400:

- Instead of listing service codes for primary care services in "Definitions" in §425.20 and cross referencing those codes in §425.400, where primary services for the purposes of assigning beneficiaries to ACOs are addressed, those codes are moved from §425.20 to §425.400.
- Adding, beginning in 2018 for the 2019 performance year, three additional chronic care management (CCM) service codes 99487, 99489, and G0506 to incorporate complex CCM services and which differ on the basis of the amount of clinical staff service time involved; and four behavioral health integration (BHI) service codes G0502, G0503, G0504, and G0507 that CMS says reflect important enhancements in primary care for people receiving behavioral health treatment.
- Reorganizing the list to group HCPCS codes, G codes and revenue center codes together and group by relevant performance year.
- Eliminating paragraph (3) of the definition of primary care services (currently at §425.20) which provides CMS with the authority to modify the list of codes. CMS believes a statement of this authority is unnecessary since it always has the authority and flexibility to make such changes.

2. ACO Quality Reporting

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard

CMS finalizes its proposal to modify §425.502(a)(5) regarding its ability to redesignate a measure as pay for *reporting* instead of pay for *performance*. The underlying rule allows CMS to make a redesignation when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm. The change will allow CMS to also make such a redesignation when there are changes to a measure under the Quality Payment Program (QPP) that represent a substantive change and that could consequently raise sampling problems when measuring performance for ACOs.

b. Further Refining the Process Used to Validate ACO Quality Data Reporting

CMS adopts two changes to the method and process for adjusting an ACO's quality score based on the findings during a Quality Measures Validation audit. Under the existing Quality Measures Validation audit described in §425.500(e), CMS validates the quality measure data reported by participants in the MSSP. The audit measures the quality of the data submitted by the

ACO and if it finds that the ACO quality reporting and the medical records provided during the audit have a match that is below 90%, CMS makes an adjustment to the ACO's quality score.

For calendar year 2016, CMS found that the average match rate was 72% and the median performance was 80%. In the process of implementing the audits, CMS states that it has gained an understanding of the discrepancies in the data. It finds that ACOs continue to experience challenges in understanding certain aspects of the measure specifications, in collecting the required information across all of the different participant providers and practices, and meeting the requirements for supporting documentation. As a result, CMS believes that a portion of the discrepancy is not due to poor quality of care and instead is due to measurement errors in data collection or in understanding the measures.

In response to those concerns, CMS proposed and is now finalizing a reduction in the audit threshold match rate from 90% to 80%. CMS believes the lower rates strikes a balance between the need for accuracy of ACO quality reporting and avoiding penalties to ACOs for reporting errors that are unrelated to quality of care.

In addition, CMS adopts its proposal to amend the method for adjusting the ACO's overall quality score to take into account the results of the ACO's audit. Instead of the methodology described in the 2017 PFS final rule (81 FR 80490) under which the audit-adjusted quality score is calculated by multiplying the ACO's overall quality score by the ACO's audit match rate, CMS finalizes that for each percentage point difference between the ACO's match rate and the match rate considered for passing the audit, the ACO's overall quality score will be adjusted downward by 1 percent. In addition, CMS adopts a conforming change to §425.500(e)(3) ensuring that if the 80% threshold is not reached, CMS may require the ACO to submit a corrective action plan.

3. Reducing Shared Savings Application Burden

a. SNF 3-Day Rule Application Burden (§425.612)(a)(1))

In order to reduce the application burden for ACOs, CMS finalizes its proposal to eliminate certain documentation requirements for ACOs participating in Track 3 that apply for a waiver of the rule requiring that beneficiaries have a prior 3-day hospital stay before they are eligible for Medicare coverage in a SNF. Waiver requirements are set in §425.612. The requirements removed are:

- A requirement that ACOs applying for the waiver provide a narrative describing financial relationships that exist between the ACO, SNF affiliates, and acute care hospitals. CMS states that because all existing Medicare SNF requirements are retained under waivers except for the prior 3-day stay, this rule does not prevent waivers from protecting financial or other arrangements between or among ACOs, their participants and providers.
- The requirement which requires ACOs to submit documentation demonstrating that each SNF on their list of SNF affiliates has an overall rating of 3 or higher under the CMS 5-star Quality Rating System.

b. Modification to the Shared Savings Program Initial Application (425.112 and 425.204)

CMS adopts its proposal to eliminate certain requirements on MSSP applicants for supporting documentation which it believes will reduce the application burden for ACOs as well as the review burden for CMS. CMS retains the ability to request such documentation if additional information is needed to fully assess the ACO's application.

Specifically, CMS makes the following changes:

- Modifies §425.204(c)(1) to require an ACO, as part of its application, to *certify* (instead of submit supporting materials) that it satisfies the MSSP requirements and to submit, *upon CMS request*, materials demonstrating that the ACO satisfies program requirements related to how shared savings will encourage ACO participants to adhere to the quality assurance and improvement program and evidence-based clinical guidelines; how the ACO will implement the required processes and patient-centeredness criteria; and the ACO's organization and management structure and governing body.
- Modifies paragraph §425.204(d) to indicate that the ACO must *certify* (instead of describe), as part of its application to participate in MSSP, that it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers.
- Eliminates §425.204(d)(1) through (3). Those paragraphs further describe components of the narrative required under existing rules related to the ACO's use of shared savings payments. CMS notes that the way that an ACO intends to use or distribute shared savings has not been a relevant consideration during consideration of applications. However, if continues to believe that information on how an ACO uses and distributes its shared savings is useful for the public, and therefore ACOs will continue to be required to publicly report this information under existing §425.308(b)(4)(ii).
- Similar changes are made to requirements in §425.112(a)(3)(i), (a)(3)(ii), and (b)(4)(ii) to remove references to the submission of narratives to explain or describe how the ACO will implement elements of the ACO's care processes and patient centeredness criteria.

4. Addressing Compliance with ACO Participant TIN Exclusivity Requirement

The newly finalized approach will allow the provider to remain on multiple ACO participant lists for the current performance year, but the ACOs involved would need to resolve the overlap prior to recertification of their participant lists for the subsequent performance year. If not resolved for the subsequent year, CMS will remove the TIN from the participant lists for all ACOs seeking to include the TIN.

Conforming changes are made to the general assignment methodology in §425.400(a)(1.

5. Treatment of Individually Beneficiary Identifiable Payment Made Under a Demonstration, Pilot, or Time Limited Program

CMS finalizes its proposed changes to the treatment of non-claims based payments that are individually identifiable to a beneficiary and that are made under a demonstration, pilot or time

limited program when performing financial calculations for the MSSP. Beginning with calculations for the 2018 performance year, CMS will exclude interim payments and include *only final* payments that can be identified to an individual beneficiary under a demonstration, pilot or time limited program in financing calculations related to establishing and updating benchmarks and determining performance year spending amounts under MSSP.

Under the MSSP, ACOs are accountable for total Parts A and B costs for beneficiaries assigned to the ACO. As a result, CMS instituted a practice whereby all Medicare claims and non-claims costs attributable to ACO beneficiaries were included in financial calculations under the program. However, because of the different timing of various demonstrations or programs, sometimes CMS has access to only interim payment amounts rather than final payment amounts to the affected providers under those demonstrations, pilots or programs. (Final payments would be those that incorporate after-the-fact shared savings or that include recoupment payments under bundled payment programs, for example). By incorporating interim payments, CMS has found that some of the financial calculations for ACOs under the MSSP are subject to significant fluctuation and volatility, raising stakeholder concerns. As a result, CMS is modifying the treatment of the claims so that only final amounts are incorporated into financial calculations.

Specifically, CMS modifies regulations at §§425.602(a)(1)(ii) (relating to establishing, adjusting and updating benchmarks), 425.603(c)(1)(ii) (relating to resetting, adjusting and updating the benchmark for 2016), and 425.603(e)(2)(ii) (relating to resetting, adjusting and updating the benchmark for 2017 and subsequent years) to add new provisions to indicate that: (1) when establishing benchmarks for agreement periods before 2018, all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time limited program are included, (2) for agreement periods beginning in 2018 and subsequent years, only *final* individually beneficiary identifiable payments made under a demonstration, pilot or time limited program will be included, and (3) for the 2018 performance year and subsequent years in agreement periods beginning in 2015, 2016 and 2017, the benchmark will be adjusted to reflect only final payments made under a demonstration, pilot or time limited program. Technical changes are made to correct references in the regulatory text as it was proposed.

H. Value-Based Payment Modifier and Physician Feedback Program

1. Changes for 2018

In this rule, CMS adopts modifications to the VM policies for the 2018 payment adjustment. These changes will result in fewer EPs and groups receiving a negative VM adjustment, and because the VM is budget neutral, the size of the positive adjustments made to high performers would therefore also be reduced. CMS believes the revised policies will provide a better transition from the last year of the VM to the first year of MIPS (2019). It notes that due to the number of practices failing to avoid the PQRS adjustment, the 2017 VM adjustment factor has resulted in payment adjustments for some groups and individual practitioners that exceed the maximum upward adjustment that will apply under the MIPS in 2019. In addition, CMS expects that many physician practices failing to meet the PQRS requirements will be excluded from MIPS in 2019 under the low-volume threshold. Finally, CMS expects that the number of groups

and solo practitioners failing to meet PQRS requirements for 2018 could be higher because non-physician EPs newly subject to the VM may be less familiar with quality reporting.

The specific changes follow:

- All groups and solo practitioners in Category 1 (i.e., those that meet the criteria to avoid the 2018 PQRS payment reduction)[10] will be held harmless from downward adjustments under quality tiering for 2018. (Under previously finalized policy, only non-physician solo practitioners and groups consisting of non-physician practitioners would be held harmless in this way.)
- The automatic downward adjustment for groups and solo practitioners in Category 2[3] is reduced from -4% to -2% for groups with 10 or more EPs and at least one physician, and from -2% to -1% for groups with between 2 and 9 EPs, physician solo practitioners, and for groups and solo practitioners consisting only of non-physician EPs.
- For groups with 10 or more EPs, the maximum upward adjustment under quality tiering (for the high quality/low cost classification) is reduced to from +4.0 times the adjustment factor (+4.0x) to two times (+2.0x), and the adjustment for those classified as either average quality/low cost or high quality/average cost would be reduced from 2.0x to 1.0x the adjustment factor. These changes align the upward adjustment for groups of 10 or more with those previously finalized for groups with 2 to 9 EPs and solo practitioners and for non-physician groups and solo practitioners.

Corresponding changes are made to the regulatory text (42 CFR 414.1270 and 414.1275).

Some previously adopted policies continue without change. CMS notes in particular that groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology, and that have an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores, will continue to earn an additional upward adjustment (+1x). In addition, no change is made with respect to existing policies for the 2017 payment adjustment for groups and solo practitioners that would be in Category 1 because of meeting the proposed reduced PQRS reporting criteria (described in section III. F above) outside of their Shared Savings Program ACO during the secondary PQRS reporting period in 2016; or (b) for the 2018 payment adjustment for groups and solo practitioners who would fall in Category 1 because of reporting outside of their Shared Savings Program ACO because their ACO failed to successfully report on their behalf to avoid the PQRS payment adjustment. These groups and solo practitioners in Category 1 are classified as "average quality" and "average cost" for purposes of the CY 2017 VM.

[10] Category 1 includes (1) Groups that meet the criteria to avoid the 2018 PQRS payment adjustment as a group practice participating in the PQRS GPRO; (2) Groups with at least 50 percent of participating EPs who meet the criteria to avoid the 2018 PQRS payment adjustment as individuals; (3) Solo practitioners that meet the criteria to avoid the 2018 PQRS payment adjustment as individuals; and (4) Groups and solo practitioners that meet the criteria to avoid the 2018 PQRS payment adjustment through participation in a Shared Savings Program ACO, if the ACO in which they participate successfully reports quality data as required by the Shared Savings Program. They are subject to an upward, neutral or downward adjustment under quality tiering. Category 2 includes groups and solo practitioners who are subject to the VM in 2018 and not included in Category 1. They are subject to an automatic downward VM adjustment.

Tables 23 through 26 in the final rule, reproduced below, show the final 2018 VM amounts for different categories/sizes of practitioners.

TABLE 23: Final 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

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%

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

TABLE 24: Previous and Final CY 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	Previous	Final	Previous	Final	Previous	Final
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%

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

TABLE 25: Previous and Final 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	Previous	Final	Previous	Final	Previous	Final
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%

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

TABLE 26: Previous and Final CY 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	Previous	Final	Previous	Final	Previous	Final
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%

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

2. Regulatory Impact Analysis

CMS states that there are 180,621 groups and solo practitioners (as identified by their TIN) consisting of 1,121,857 clinicians (i.e., physicians, PAs, NPs, CNSs, and CRNAs) whose payments under the Medicare PFS will be subject to the VM in the CY 2018 payment adjustment period. These counts include both TINs that participated in a Shared Savings Program ACO in CY 2016 and TINs that did not. Approximately 75 percent of clinicians subject to the VM (838,376) are in TINs that met the criteria for inclusion in Category 1 and are subject to the quality-tiering methodology in order to calculate their CY 2018 VM; and approximately 25 percent (283,481) are in TINs that are Category 2.

The percentage of clinicians receiving an automatic downward payment adjustment because their TIN failed to meet the criteria to avoid the PQRS adjustment declined from 33 percent for the 2017 VM to 25 percent for the 2018 VM (based on 2016 performance), despite the expansion of the VM from all physicians to all physicians and NPs, PAs, CNSs, and CRNAs in the 2018 payment year. CMS believes it is likely that many TINs that failed to meet the criteria to avoid the PQRS adjustment and as a result are in Category 2 and are subject to automatic downward payment adjustments under the CY 2018 VM will be excluded from MIPS in CY 2019, due to the low-volume threshold. Furthermore, the lower percent of clinicians who do not meet the criteria to avoid the PQRS adjustment, coupled with lower downward adjustments and upward adjustments based on performance will likely result in payment adjustments that are more in line with MIPS-level adjustments.

Table 55 in the final rule, reproduced below, shows how the 838,376 clinicians that are in Category 1 TINs in CY 2018 are distributed across the various quality and cost tiers.
In total, 19,862 clinicians (in 3,121 TINs) will receive an upward payment adjustment; and 818,514 clinicians (in 74,216 TINs) will receive a neutral payment adjustment under the VM in CY 2018. Out of those receiving a neutral payment adjustment in CY 2018, 7,387 TINs consisting of 88,706 physicians, PAs, NPs, CNSs, and CRNAs were held harmless from downward adjustments.

TABLE 55: Preliminary distribution of Category 1 TINs (and physicians, PAs, NPs, CNSs, and CRNAs in the TINs) under the CY 2018 VM (77,337 TINs; 838,376 physicians, PAs, NPs, CNSs, and CRNAs)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0% (18 TINs; 2,522 clinicians)	+1.0x (57 TINs; 1,017 clinicians) +2.0x* (68 TINs; 4,245 clinicians)	+2.0x (5 TINs; 218 clinicians) +3.0x* (11 TINs; 51 clinicians)
Average Cost	+0.0% (5,721 TINs; 61,628 clinicians)	+0.0% (66,780 TINs; 727,032 clinicians)	+1.0x (2,158 TINs; 10,132 clinicians) +2.0x* (822 TINs; 4,199 clinicians)
High Cost	+0.0% (499 TINs; 7,689 clinicians)	+0.0% (1,167 TINs; 19,389 clinicians)	+0.0% (31 TINs; 254 clinicians)

*These TINs were eligible for an additional +1.0x for reporting measures and having an average beneficiary risk score in the top 25 percent of all beneficiary risk scores. The term 'clinicians' refers to the physicians, PAs, NPs, CNSs, and CRNAs in the TINs.

I. MACRA Patient Relationship Categories and Codes

1. Overview

Section 101(f) of MACRA added a new subsection (r) to section 1848 of the Act, requiring the development of care episode and patient condition groups plus group classification codes, to allow patient and/or episode attribution to one or more clinicians. Subsection (r) further requires that:

- The categories and codes must define and distinguish an applicable practitioner's relationship to and responsibility for each patient when furnishing an item or service.
- The categories shall include different potential practitioner-patient relationship types.
- The categories shall reflect various potential responsibility types.
- The categories shall capture the frequency with which the practitioner delivers care to the patient.

Applicable practitioners include MIPS-eligible clinicians; currently they are physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. More practitioner types may be added by the Secretary on or after January 1, 2019.

CMS finalizes its proposal without modification that voluntary reporting of patient relationship modifiers (as shown in Table 27) will begin on January 1, 2018. Modifier completeness and accuracy will not affect payment during voluntary reporting. The duration of the initial voluntary reporting period remains unspecified.

TABLE 27 Patient Relationship HCPCS Modifiers and Categories

Number	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

Finally, CMS noted that the relationship codes may be incorporated into future QPP measures, but also that measures currently active, proposed for 2018, and presently under development do not require patient relationship code use for successful submission.

J. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

CMS specifies that the entire scope of designated health services (DHS) for purposes of the physician self-referral prohibition is defined in a list of CPT/HCPCS codes (the Code List) which is updated annually to account for both changes in the most recent CPT and HCPCS publications and changes in Medicare coverage policy and payment status. The Code List was last updated in the 2017 PFS final rule (81 FR 80543).

The updated comprehensive Code List effective January 1, 2018 is available on the CMS website at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html. Additions and deletions to the Code List conform to the most recent publications of CPT and HCPCS Level II codes and to changes in Medicare coverage policy and payment status.

Tables 44 and 45 in the rule identify additions and deletions to the list. Additions and deletions involve physical therapy, occupational therapy and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; and preventive screening tests, immunizations and vaccines.

IV. Regulatory Impact Analysis

A. RVU Impacts

2018 PFS Impact Discussion

The specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiatives, including the establishment of RVUs for new and revised codes. Behavioral health specialists, radiation oncology, and cardiology, among others, see increases relative to other physician specialties. CMS attributes these changes to increases in value for particular service and changes in how CMS allocates indirect practice expense RVUs for office-based services. Other specialties, including diagnostic testing facilities, allergy/immunology, physical/occupational therapy, otolaryngology, anesthesiology, and nurse anesthetists, would experience decreases in payments relative to other

specialties for similar reasons as well as changes to prices for particular medical supplies, and continued implementation of code-level reductions being phased-in over several years. Specialty impacts vary from the proposed rule as CMS decided not to finalize updated professional liability premium data, which had negative impacts on certain specialties, such as cardiology.

Column F of Table 50 shows the estimated 2018 combined impact on total allowed charges by specialty of all the final RVU and other changes. These specialty impacts range from an increase of 3 percent for clinical social worker, increase of 2 percent for clinical psychologist, to a decrease of 4 percent for diagnostic testing facility, a decrease of 3 percent for allergy/immunology, and a decrease of 2 percent for nurse anesthetists, otolaryngology, and physical/occupational therapy.

Table 50: 2018 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
TOTAL	$93,149	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	$247	0%	-3%	0%	-3%
ANESTHESIOLOGY	$2,018	-1%	0%	0%	-1%
AUDIOLOGIST	$66	0%	0%	0%	0%
CARDIAC SURGERY	$312	0%	0%	0%	0%
CARDIOLOGY	$6,705	0%	-1%	0%	1%
CHIROPRACTOR	$779	0%	1%	0%	1%
CLINICAL PSYCHOLOGIST	$762	0%	2%	0%	2%
CLINICAL SOCIAL WORKER	$670	0%	3%	0%	3%
COLON AND RECTAL SURGERY	$167	0%	0%	0%	0%
CRITICAL CARE	$334	0%	0%	0%	0%
DERMATOLOGY	$3,485	0%	1%	0%	0%
DIAGNOSTIC TESTING FACILITY	$773	0%	-4%	0%	-4%
EMERGENCY MEDICINE	$3,191	0%	0%	0%	0%
ENDOCRINOLOGY	$480	0%	0%	0%	0%
FAMILY PRACTICE	$6,350	0%	0%	0%	0%
GASTROENTEROLOGY	$1,801	0%	0%	0%	0%
GENERAL PRACTICE	$458	0%	0%	0%	0%
GENERAL SURGERY	$2,170	0%	0%	0%	0%
GERIATRICS	$212	0%	0%	0%	0%
HAND SURGERY	$201	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	$1,809	0%	0%	0%	0%
INDEPENDENT LABORATORY	$690	0%	-1%	0%	-1%
INFECTIOUS DISEASE	$656	0%	0%	1%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
INTERNAL MEDICINE	$11,107	0%	0%	0%	0%
INTERVENTIONAL PAIN MGMT	$834	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$360	0%	0%	0%	0%
MULTISPECIALTY CLINIC/OTHER PHYS	$140	0%	0%	0%	0%
NEPHROLOGY	$2,270	0%	0%	0%	0%
NEUROLOGY	$1,554	0%	0%	0%	0%
NEUROSURGERY	$811	0%	0%	0%	0%
NUCLEAR MEDICINE	$50	0%	0%	0%	0%
NURSE ANES / ANES ASST	$1,243	-2%	0%	0%	-2%
NURSE PRACTITIONER	$3,566	0%	0%	0%	0%
OBSTETRICS/GYNECOLOGY	$662	0%	0%	0%	0%
OPHTHALMOLOGY	$5,498	0%	1%	0%	0%
OPTOMETRY	$1,269	0%	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	$57	0%	-1%	0%	-1%
ORTHOPEDIC SURGERY	$3,801	0%	0%	0%	0%
OTHER	$29	0%	0%	0%	0%
OTOLARNGOLOGY	$1,237	0%	-1%	0%	-2%
PATHOLOGY	$1,154	0%	0%	0%	-1%
PEDIATRICS	$64	0%	0%	0%	0%
PHYSICAL MEDICINE	$1,112	0%	0%	0%	0%
PHYSICAL/OCCUPATIONAL THERAPY	$3,807	1%	-2%	0%	-2%
PHYSICIAN ASSISTANT	$2,242	0%	0%	0%	0%
PLASTIC SURGERY	$384	0%	0%	0%	1%
PODIATRY	$1,994	0%	1%	0%	1%
PORTABLE X-RAY SUPPLIER	$102	0%	1%	0%	1%
PSYCHIATRY	$1,247	0%	1%	0%	1%
PULMONARY DISEASE	$1,761	0%	0%	0%	0%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	$1,745	0%	1%	0%	1%
RADIOLOGY	$4,896	0%	0%	0%	0%
RHEUMATOLOGY	$554	0%	1%	0%	1%
THORACIC SURGERY	$358	0%	0%	0%	0%
UROLOGY	$1,777	0%	0%	0%	-1%
VASCULAR SURGERY	$1,125	0%	-1%	0%	-1%

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

The following is an explanation of the information for Table 50:

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

- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2016 utilization and 2017 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.

- Column C (Impact of Work RVU Changes): This column shows the estimated 2018 impact on total allowed charges of changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

- Column D (Impact of PE RVU Changes): This column shows the estimated 2018 impact on total allowed charges of changes in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2018 impact on total allowed charges of changes in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2018 combined impact on total allowed charges of all the changes in the previous columns