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-P]

Summary of Proposed Rule

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I. Introduction and Background

On July 13, 2017, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2018[1] and other revisions to Medicare Part B policies. The proposed rule was published in the July 21, 2017 issue of the *Federal Register* (82 FR 33950).[2] If finalized, policies in the proposed rule generally would take effect on January 1, 2018. **The 60-day comment period ends at close of business on September 11, 2017.**

The **CF for 2018 is $35.9903**. For 2018, the specified update is 0.5 percent, before applying other adjustments. The 2018 anesthesia CF is $22.0353, which in addition to the adjustments for budget neutrality and target recapture amount includes an update to the malpractice risk adjustment of -0.33 percent. Table 38 from the proposed rule, is reproduced below.

TABLE 38: Calculation of the Proposed 2018 PFS Conversion Factor

Conversion Factor in effect in 2017		**$35.8887**
Update Factor	0.50 percent (1.0050)	
2018 RVU Budget Neutrality Adjustment	-0.03 percent (0.9997)	
2018 Target Recapture Amount	-0.19 percent (0.9981)	
2018 Conversion Factor		**$35.9903**

On a specialty-specific basis, CMS estimates that the combined impact of the proposed rule would have the greatest positive effect on payments to clinical social workers (+3 percent) and clinical psychologist (+2 percent); and the greatest negative effect on diagnostic testing facilities (-6 percent), allergy/immunology (-3 percent), cardiac surgery (-2 percent), cardiology (-2 percent), independent laboratory (-2 percent), oral/maxillofacial surgery (-2 percent), otolaryngology (-2 percent), pathology (-2 percent) and vascular surgery (-2 percent).

The addenda to the proposed 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 Proposed Rule for PFS

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

1. Changes to Direct PE Inputs for Specific Services

a. PE Inputs for Digital Imaging Services

CMS notes that in the 2017 PFS final rule, CMS finalized its proposal to add a professional

[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.
[2] https://www.gpo.gov/fdsys/pkg/FR-2017-07-21/pdf/2017-14639.pdf

PACS workstation (ED053) used for interpretation of digital images to a series of CPT codes and addressed costs related to the use of film that had previously been incorporated into as direct PE inputs for these services. In total, CMS added the professional PACS workstation to 525 codes in its direct PE input database: 94 therapeutic codes and 431 diagnostic codes.

A stakeholder has expressed concern about CMS' decision not to include the professional PACS workstation in a series of vascular ultrasound codes that use technical PACS workstations. The stakeholder believes that to furnish vascular ultrasound services requires both a technical and professional PACS workstation regardless of provider type.

CMS seeks comments 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 states that it will consider this information to determine whether the professional PACS workstation should be included as a direct PE input for these codes.

b. Standardization of Clinical Labor Tasks

CMS states that it continues to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. In addition, CMS notes the advantage that as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

CMS specifically seeks comment on clinical labor time associated with the preservice clinical labor for 0-day and 10-day global periods and the "obtain vital signs" clinical labor activity. CMS also discusses a crosswalk it developed for the new clinical labor activity codes being developed by the RUC.

For 0-day and 10-day global periods the RUC's PE subcommittee concluded that these codes are assumed to have no preservice clinical staff time (standard time of 0 minutes) unless the specialty can provide evidence that the preservice time is appropriate. CMS notes, however, that over three-quarters of the 0-day or 10-day global periods it reviewed as misvalued for 2018 included preservice clinical labor of some kind, suggesting that it is typical for clinical staff to prepare for the procedure prior to the patient's arrival. Overall, CMS found that for the 1,142 total 0-day global codes, 741 of them had preservice clinical labor of some kind (65 percent) in its direct PE inputs database.

CMS seeks comment on whether the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking.

CMS notes that it has traditionally assigned a clinical labor activity of 3 minutes based on the amount of time typically required to check a patient's vitals. However, for many of the reviewed

codes for the 2018 rulemaking cycle the recommended labor time has been 5 minutes based on the measurement of two additional vital signs: the patient's height and weight. CMS states that it has no reason to believe that measuring a patient's height and weight is only typical for services described by recently reviewed codes.

CMS proposes to assign 5 minutes of clinical labor time for all codes that include the "Obtain vital signs" task, regardless of the date of last review. This includes all codes that include at least 1 minute previously assigned to this task. CMS also proposes to update the equipment times to match the changes in clinical labor time.

The proposed list of all codes (about 1,000) affected by these proposed 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 states that it is considering creating a single scope equipment code for each of the five categories detailed in this proposed rule: (1) a rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. CMS believes that the variation between these scopes is not significant enough to warrant maintaining these distinctions within a category, and that creating and pricing a single scope equipment code for each category would help provide additional clarity. **CMS seeks public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories**.

For 2018, CMS also proposes two minor changes to PE inputs related to scopes. CMS proposes to add an LED light source into the cost of the scope video system (ES031), and thus remove the need for a separate light source in these procedures. CMS also proposes to increase to the price of the scope video system of $1,000.00 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.)

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.

CMS solicits comment regarding the use of multiple kits during procedures described by the base and add-on codes to determine whether or not the Clarivein kit supply item (SA122) should be included as a direct PE input for CPT code 36474 for 2018.

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

CMS received additional recommendations after last year's rule to remove the oxygen gas supply item (SD084) from a series of CPT codes that were previously valued with moderate sedation as an inherent part of the procedure. Because oxygen gas is included in the moderate sedation pack contained within the separately billed moderate sedation codes, CMS believes the inclusion of oxygen gas in these codes is duplicative.

CMS proposes 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 14 in the proposed 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 proposes to correct several clerical inconsistencies and makes some technical corrections to the direct PE input database:

- CMS proposes 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 proposes to correct 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 also proposes to 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 5 in the proposed rule details the 42 items CMS proposes to update in its direct PE input database.

g. Updates to Prices for Existing Direct PE Inputs

For 2018, CMS proposes to update the prices of thirteen supplies and one equipment item in response to public submission of invoices. An extract of Table 14 (shown below) shows the proposed price updates.

Table 14: 2018 Proposed 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	0.78	1
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	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, 96567, 96910, 96912, 96913, 96920, 96921, 96922, 96X73, 96X74	goggles, uv-blocking	SJ027	2.30	4.1	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
95250	sensor, glucose monitoring (interstitial)	SD114	29.50	53.08	19
95250	glucose continuous monitoring system	EQ125	2465.00	1170.54	5
993X1, G0249	test strip, INR	SJ055	21.88	5.66	2

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

Some stakeholders have suggested that for codes in which direct PE inputs for services are very low, this allocation methodology does not accurately reflect the indirect costs involved in furnishing services in nonfacility settings. CMS notes that the services most affected by this anomaly are the primary therapy and counseling services available to Medicare beneficiaries for treatment of behavioral health conditions, including substance use disorders. CMS agrees with stakeholders that the site of service differential for these services that is produced by its PE methodology seems unlikely to reflect the relative resource costs for these practitioners

furnishing these services in nonfacilty settings. Thus, CMS believes modifications to its PE methodology is warranted.

CMS selected among codes with the lowest ratio between nonfacility PE RVUs and work RVUs.[3] 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 proposes 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 proposes to compare the ratio between indirect PE RVUs and work RVUs that result from the preliminary application of the standard methodology to the ratio for the marker code, CPT code 99213. CMS proposed change in the methodology would then increase the allocation of indirect PE RVUs to the outlier codes to at least one quarter of the difference between the two ratios.

In developing the proposed PE RVUs for 2018, CMS proposes to implement only one quarter of this proposed minimum value for nonfacility 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 proposed 4-year transition, including for 2018. CMS proposes to exclude the codes directly subject to this proposed change from the misvalued code target calculation because the proposed change is a methodological change and not related to misvalued codes. CMS notes that the PE RVUs displayed in Addendum B were calculated with the one quarter of the indirect PE adjustment factor implemented.

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

1. Overview

CMS proposes to use the most recent data for the proposed MP RVUs for 2018 and to align the update of MP premium data and MP GPCIs to once every 3 years. **CMS seeks comment on its proposals, and comment on methodologies and sources that it might use to improve the next update of MP premium data.**

2. Methodology for the Proposed Revision of Resource-Based RVUs

The methodology CMS used in calculating the proposed 2018 review and update of resource based MP RVUs largely parallels the process used in the 2015 update.

[3] 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.

CMS relies on four data sources to calculate the proposed MP RVUs: 2014 and 2015 malpractice premium data; 2016 and 2017 Medicare payment and utilization data; 2017 GPCIs, and 2018 proposed work and clinical labor RVUs. Similar to prior updates, CMS calculated the proposed MP RVUs using the most recent available specialty-specific malpractice premium data published in the 2014 and 2015 Market Share Reports accessed from the National Association of Insurance Commissioners (NAIC) website. For premiums for which there were not premium data for at least 35 states and specialties for which there were not distinct premium data in rate filing, CMS crosswalked the specialty to a similar specialty. CMS details the specialties that it proposes to use in Table 6 of the proposed rule. For example, the radiation oncology data were only from 23 states, and thus CMS developed the proposed MP RVUs for radiation oncology by using the risk factors for diagnostic radiology. **CMS seeks comments as to the appropriateness of this and the other crosswalks it used in developing MP RVUs.**

CMS details the five steps it uses to calculate Malpractice RVUs and discusses issues of note that were comparable or different from it 2015 approach.

C. Medicare Telehealth Services

In the 2003 PFS final rule (67 FR 79988), CMS established a process for adding or deleting services from the Medicare telehealth list. CMS assigns requests to new categories: Category 1 and Category 2. Category 1 services are similar to services that are currently on the telehealth list. Category 2 services are not similar to services on the telehealth list and CMS requires evidence demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part.

As discussed below, CMS proposes to add seven services to the Medicare telehealth list. In response to requests received in 2016, CMS proposes to add 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).
    - CMS considers this service similar to office visits.

- CPT codes 90839 and 90840: Psychotherapy for crisis; first 60 min.
    - CMS considers these services similar to the psychotherapy services.
    - CMS is proposing to add 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 proposed 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 proposes to add four add-on CPT and HCPCS codes. 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 proposes 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.

D. Potentially Misvalued Services Under the Physician Fee Schedule

CMS proposes the following codes as potentially misvalued:

- 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 is proposing this code as a potentially misvalued code.

- 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 seeks additional comments and data regarding the potentially misvalued work RVUs for these codes. CMS seeks alternative work valuations for these codes.

- 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 proposes these codes as potentially misvalued which would allow review of the clinical labor and supplies for these codes.

- 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 seeks comments on whether these codes should be reviewed under the misvalued code initiative.

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 proposes to establish a new modifier to be used on claims. Beginning January 1, 2017, this modifier would be required on claims for X-rays that are taken using computed radiography technology; the modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally. The use of this proposed modifier would result in the corresponding percent reduction for the technical component of the X-ray service.

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

In the 2017 OPPS interim final rule with comment (81 FR 79720 through 79729), CMS established initial payment policies under the PFS for nonexcepted items and services furnished on or after January 1, 2017. CMS' proposed payment policies under the PFS for nonexcepted items and services furnished during 2018 are discussed below.

1. Payment Mechanisms

For 2017, CMS established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid to off-campus PBDs of a hospital with packaging rules that are significantly different from the current PFS rules. The new payment rates established a means to report the technical aspect of all applicable items and services under the PFS.

For 2018, CMS proposes to maintain the 2017 payment mechanisms.

2. Establishment of Payment Rates

CMS discusses the methodology used for estimating the general relativity between the TC of PFS services furnished in nonexcepted off-campus PBDs and all other PFS services furnished in other settings. CMS analyzed hospital outpatient claims data from January 1, 2016 through August 26, 2016 that contained the "PO" modifier for a limited number of services.[4] CMS adopted (with some exceptions) a set of payment rates for 2017 that are based on a 50-percent reduction to the OPPS payment rates (inclusive of packaging) for nonexcepted items and services furnished by nonexcepted off-campus PBDs. CMS arrived at the 50-percent reduction by comparing (i) the payment differential between the OPPS and the ASC payment rates (where covered surgical procedures in ASCs are paid at 55 percent of the rate under the OPPS) and (ii)

[4] The "PO" modifier is used to indicate services, procedures, and/or surgeries provided at an off-campus PBD.

the weighted average payment differential for overall payment under the OPPS and the MPFS for clinic visits from a list of most frequently billed HCPCS codes reported with the "PO" modifier (45 percent). (See Table 9 in the proposed rule for the list of frequently billed HCPCS codes). CMS refers to this adjustment of the OPPS payment amount as the "PFS Relativity Adjuster."

CMS established several exceptions to the percentage reduction. CMS does not adjust the payment rates for the following:

- Services currently paid under the OPPS based on payment rates from other Medicare fee schedules (including the PFS) on an institutional claim (i.e., items and services assigned status indicator "A" in Addendum B to the 2017 OPPS/ASC final rule) that will continue to be reported on an institutional claim and paid under the PFS, the CLFS, or the Ambulance Fee Schedule without a payment reduction.
- Drugs and biologicals that are separately payable under the OPPS (identified by status indicator "G" or "K" in Addendum B to the 2017 OPPS/ASC final rule) will be paid under section 1847A of the Act (i.e., typically ASP + 6 percent), consistent with payment rules in the physician office setting.
- Drugs and biologicals that are unconditionally packaged under the OPPS and are not separately payable (i.e., those drugs and biologicals assigned status indicator of "N" in Addendum B to the 2017 OPPS/ASC final rule) will be bundled into the MPFS payment and will not be separately paid to hospitals billing for nonexcepted items and services.

The full range of exceptions and adjustments to the otherwise applicable OPPS payment rates that were adopted in the 2017 interim final rule with comment are on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-FC-2017-OPPS-Status-Indicator.zip.

For nonexcepted off-campus PBDs, CMS established a mechanism to permit them to bill for nonexcepted items and services through the institutional claims processing systems to be paid in 2017. Specifically, for 2017 these facilities are billing on the institutional claim which passes through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment under the PFS. Nonexcepted off campus PBD must report modifier "PN" on each UB-04 claim line to indicate a nonexcepted item or service.

a. PFS Relativity Adjuster

For 2018, CMS proposes to revise the PFS relativity adjuster to 25 percent of the OPPS payment rate. CMS believes this change would ensure that payments made to nonexcepted PBDs better align with the services that are most frequently furnished by physicians.

To determine the 2018 PFS relativity adjuster, CMS made a code-level comparison for a clinic visit reporting using HCPCS code G0462, the service most commonly billed in the off-campus PBD setting under the OPPS. CMS compared the 2017 OPPS national payment rate for G0463 ($102.12) to the difference between the nonfacility and facility PFS payment under the PFS using 2017 rates for the weighted average of outpatient visits (CPT codes 99201- 99205 and CPT codes 99211 - 99215) billed by physicians and other professionals in an outpatient hospital place of service.

In addition to stakeholder input about this analysis and proposed rate, CMS requests comments on whether it should adopt a different PFS relativity adjuster. **Specifically, CMS requests comments on whether it should adopt a 2018 PFS relativity adjuster such as 40 percent which would represent a middle ground between the 2017 and the proposed 2018 relativity adjuster.**

b. Geographic Adjustments

For 2017, CMS adopted hospital area wage index areas, as well as the actual hospital wage index values, for nonexcepted off-campus PBDs furnishing nonexcepted items and services to adjust the technical component rates in lieu of the PFS geographic practice cost indices to adjust the special PFS rates paid in these sites. For 2018, CMS proposes to continue these policies.

c. Coding Consistency

CMS notes that the same HCPCS codes are used to describe services paid under both the PFS and the OPPS for most services. For 2018, CMS proposes to maintain the same coding policies finalized in 2017.

- Under the OPPS, E&M services are reported using the single HCPCS code G0463 while 10 CPT codes are used to describe these services under the PFS.

- CMS established HCPCS Level II "G" codes for radiation treatment delivery services furnished in a physician's office; under the OPPS, CPT codes are used to described these services furnished in the hospital outpatient department. CMS will require off-campus PBDs to bill for nonexcepted items and services using the HCPCS "G" codes under the PFS to describe radiation treatment delivery services. The off-campus PBD must append modifier "PN" to each applicable claim line for nonexcepted items and services.

d. OPPS Payment Adjustments

For 2018, CMS proposes to maintain the policies finalized in 2017. Specifically, CMS adopted the packaging payment rates and multiple procedure payment reduction percentage that apply under the OPPS to establish the PFS payment rates for nonexcepted off-campus PBDs furnishing nonexcepted items and services that are billed by hospitals. The claims processing logic that is used for OPPS payment for comprehensive APCs, conditionally and unconditionally packaged items and services, and major procedures is incorporated into the newly established PFS rates.

For 2018, CMS proposes to continue its 2017 policy and not adopt a number of OPPS payment adjustments. These adjustments include 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.

3. Partial Hospitalization Programs (PHPs)

For 2018, CMS proposes to continue the policies finalized in 2017 for PHPs services furnished by nonexcepted off-campus PBDs. Specifically, CMS proposes 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.

4. 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.

5. 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.

6. 2019 and Subsequent Years

CMS states it continues to believe that Section 603 of the Bipartisan Budget Act of 2015 intended to eliminate the payment incentive for hospitals to purchase physicians' offices, convert them to off-campus PBDs, and bill under the OPPS for items and services furnished in these PBDs.

CMS expects to use the 2017 claims data reported using the "PN" modifier for use in PFS rate-setting for 2019. Using the current methodology, CMS expects to use that data to determine the relative resources involved in furnishing non-exempted items and services in nonexcepted off–campus PBDs relative to other PFS services. CMS acknowledges that based on the current methodology, payment rates are not equal on a procedure-by-procedure basis but instead work towards equalizing payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs.

G. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

For 2018, CMS is proposing values for all codes for which CMS received complete Relative Value Update Committee (RUC) recommendations before February 10, 2017. RUC

recommendations contain both service work and time information and they include services provided by physician and non-physician practitioners.

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

CMS concerns about RUC rationales and their underlying practitioner survey data have increased in recent years, most often centering on the incorporation of service times and time changes into specific work RVU proposals. CMS, therefore, has "refined" numerous RUC-recommended work values each year. Many refinements have addressed RUC-recommended decreases in time that appear to be disproportionately larger than the associated reductions in work for revised or potentially misvalued codes. CMS has proposed their refined work values, rather than those from the RUC, for multiple services in each year's proposed rule.

For valuing new, revised, and potentially misvalued codes in the 2018 PFS, CMS is adopting a new, two-part strategy. First, CMS will adopt the RUC-recommended work values as CMS-proposed values for almost all services. Second, CMS will provide code-level descriptions of alternate valuation approaches, rather than proposing actual CMS-refined substitute values for all services about whose RUC-recommended values CMS has work/time concerns.

Table 10 in the proposed rule lists the code descriptors along with RUC-recommended work values (plus the matching CMS proposals) for 2018. CMS' alternative valuation approaches and resulting values are not included in Table 10 but are described separately for multiple specific code groups in section II.H.4. of the proposed rule (items II.H.4.(1) – (57)). Work times and additional payment information for all 2018 proposed Medicare-payable codes are available for download under CMS-1676-P at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html .

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

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes. CMS specifically evaluates the methodology, data, and decision-making rationales that accompany RUC recommendations, and it determines whether establishing facility or non-facility (or both) direct PE inputs are appropriate.

Table 11 in the proposed rule lists the CMS-proposed refinements to RUC-recommended direct PE inputs at the code-specific level;[5] some changes are discussed in the proposed rule as part of items II.H.4.(1)-(57). The 2018 proposed direct PE inputs are provided in a database available for download under CMS-1676-P at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html .

[5] When a projected refinement impact on direct costs is $0.30 or less, the refinement does not change the PE RVUs. Nearly half of the proposed refinements fall under the $0.30 threshold.

4. Proposed Valuation for Specific Codes

There are 57 code groups discussed in section II.H.4. of the proposed rule. The table below lists all the groups and identifies those for which CMS describes alternative work RVU approaches or for which CMS proposes PE RVU refinements. Readers with a particular interest in any of the 57 code groups are referred to the proposed rule for complete details.

CMS Proposals for 2018 Work Values and Direct PE Inputs for Specific Codes			
Code Group Number and Name	**Status N/R/R*/PM[1]**	**CMS Work Alternative?**	**CMS PE Refinement?**
1. Anesthesia for GI Endoscopy	PM(N)	X	
2. Acne Surgery	PM	X	X
3. Muscle Flaps	PM(N)	X	X
4. Application Rigid Leg Cast	PM(R*)		X
5. Multilayer Compression Strapping	PM(R)	X	
6. Resection Inferior Turbinate	PM	X	X
7. Control Nasal Hemorrhage	PM	X	
8. Nasal Sinus Endoscopy	PM(N,R)	X	X
9. Tracheostomy	PM	X	X
10. Bronchoscopy w/ Therapeutic Aspiration	PM(R)	X	X
11. Cryoablation Pulmonary Tumor	N,R	X	X
12. Artificial Heart System	N	X	
13 Endovascular Repairs	N,R	X	
14. Selective Arterial Catheter Placement	PM	X	X
15. Treatment Incompetent Veins	N,R	X	X
16. Therapeutic Apheresis	PM(R)		X
17. Vascular Catheter Insertion	PM(R*)		X
18. PICC Catheter Insertion	PM(R*)		X
19. Bone Marrow Aspiration	PM(N,R)	X	X
20. Esophagectomy	N,R	X	X
21. TURP Electrosurgical	PM	X	
22. Peri-Prostatic Biodegradable Implant Insertion	N	X	X
23. Colporrhaphy w/ Cystourethroscopy	PM(R)	X	
24. Nerve Repair w/Allograft	N,R	X	
25. CT Soft Tissue Neck	PM	X	
26. MRA Head	PM(R*)		X
27. MRA Neck	PM(R*)		X
28. CT Chest	PM	X	
29. MRI Abdomen/Pelvis	PM(R*)		X
30. MRI Lower Extremity	PM(R*)		X
31. X-ray Abdomen	PM(N)	X	
32. Extremity Angiography	PM(R*)		X
33. Ophthalmic Biometry	PM	X	
34. Extremity Ultrasound	PM(R*)		X
35. Radiation Therapy Planning	PM	X	
36. Surgical Pathology Consultation	PM(R*)		X
37. Tumor Immunohistochemistry	PM(R*)		X
38. Cardiac EP Device Monitoring	PM	X	X

CMS Proposals for 2018 Work Values and Direct PE Inputs for Specific Codes			
Code Group Number and Name	**Status N/R/R*/PM[1]**	**CMS Work Alternative?**	**CMS PE Refinement?**
39. Transthoracic Echocardiography	PM	X	
40 Stress TTE	PM(R*)		X
41. Peripheral Arterial Disease Rehabilitation	OTHER[2]		
42. Pulmonary Diagnostic Tests	PM(N)		X
43. Percutaneous Allergy Skin Tests	PM(R*)		X
44. Continuous Glucose Monitoring	PM(R*)	X	X
45. Parent/Caregiver Health Risk Assessment	OTHER[2]		X
46. Chemotherapy Administration	PM(R*)		X
47. Photochemotherapy	PM	X	X
48. Photodynamic Therapy	PM(N)		X
49. Physical Medicine & Rehabilitation	PM	X	X
50. Orthotics & Prosthetic Mgmts. & Training	N,R	X	X
51. Cognitive Function Intervention	N	X	
52. INR Monitoring	N	X	X
53. Psychiatric Collaborative Care	N		X
54. Hyperbaric Oxygen Therapy	R*		X
G-code changes	Status		
55. Implanted Buprenorphine	N		
56. Superficial Radiation Treatment/Planning	N		
57. Prolonged Preventive Services	N		

[1] Status = New (N), Revised (R), or Potentially Misvalued (PM); PM(N) = New codes were developed in this group during review of potentially misvalued predecessor codes. PM(R) = Codes in this group were revised during review of a potentially misvalued code(s) in the group. R* = Revised PE input without CPT code change

[2] OTHER = Newly payable code for the Medicare program

H. Evaluation & Management (E/M) Guidelines and Care Management Services

In this section of the proposed rule, CMS explores issues surrounding the delivery of non-procedural services, sometimes termed "cognitive" services.

1. E/M Documentation Guidelines

E/M services are delivered in very high volumes and by virtually all Medicare clinicians, though with variations in frequency and complexity. Accurately paying for such broad-based, high-volume services led CMS to join with the CPT Editorial Panel to create documentation guidelines. Two guideline sets are available currently for use subject to provider preference, differing primarily in their physical examination structures: one emphasizes exam breadth and the other exam depth. CMS reports receiving frequent and consistent feedback that the current E/M guidelines are badly outdated and not reflective of modern clinical workflows or electronic recordkeeping. CMS **invites comments** on a path forward as follows:

- Approaches to guideline revision that reduce practitioner burden and leverage electronic health technology to achieve better, more relevant clinical recordkeeping that folds seamlessly into clinical workflow

- Revisions that deemphasize history and physical exam performance and unnecessarily voluminous documentation thereof
    - CMS indicates willingness to consider reducing or even eliminating the history and physical exam components at all E/M code levels for Medicare patients
- Extension of practitioner autonomy to determine the volume of E/M service-related documentation, especially for the history and physical exam components
- Guidelines structured to match documentation to patient complexity, especially related to medical decision-making
- Revision design that does not purposefully or inadvertently provide inappropriate performance or payment advantages to subsets of physicians
- Guideline revision process that welcomes all willing participants including patient advocates and that takes into account special needs patient populations

2. Care Management Services

CMS continues to seek innovative approaches to care management and care coordination of beneficiaries with one or more chronic illnesses (e.g., hypertension, asthma, depression). CMS concomitantly has identified and addressed gaps in coding and payment for care management, for example transitional care management for vulnerable patients at the time of hospital discharge.[6] Stakeholder comments have led CMS most recently to prioritize reducing administrative burden during the delivery and documentation of care management services. CMS affirms its continued commitment to recognize and to appropriately pay for effective, efficient, care management services. **CMS invites comments about all aspects of these services including their expansion outside of traditional office visits, refining the code set for reporting the expanded service spectrum, their suitability for addressing health disparities and disabled patients, ensuring appropriate payment, and burden reduction through harmonizing CMS requirements and CPT guidance**.

III. Other Provisions of the Proposed Rule

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

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

Beginning on January 1, 2016, RHCs and FQHCs were eligible to receive additional payment for providing a minimum of 20 minutes of qualifying chronic care management (CCM) services during a calendar month to patients with multiple chronic conditions that would place the patient at significant risk of death, acute exacerbation, or functional decline (CPT code 99490). In the 2017 PFS final rule, CMS finalized revisions to the CCM requirements for RHCs and FQHCs

[6] Other payment and coding frameworks developed by CMS in recent years targeted at care management and coordination gaps include chronic care management, behavioral health integration, assessment and care planning for cognitive impairment, and prolonged, non-face-to-face E/M services.

(81 FR 80256), including allowing CCM services and supplies to be furnished under general supervision when billed under the PFS.[7] The CCM payment rate for RHCs and FQHCs is set annually based on the PFS national non-facility payment rate for CPT code 99490; the 2017 rate is $42.71.

In the 2017 PFS final rule, CMS finalized coding and payment policies designed to improve payment for care management services. These policies included payment for:

- Complex CCM services (CPT codes 99487 and 99489);
- Care management services for general behavioral health issues (BHI) (G0507); and
- Psychiatric collaborative care management (CoCM) services (G0502, G0503, and G0504).

As discussed below, to ensure that RHC and FQHC patients have access to these new care management services, CMS is proposing the establishment of new G codes for use by RHCs and FQHCs:

- GCCC1 would be a General Care Management code
- GCCC2 would be a Psychiatric CoCM code.

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

CMS is proposing to create General Care Management Code GCCC1 with the payment rate set 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

Based on 2017 payment rates, the payment amount for General Care Management would be approximately $61. CMS notes this is more than the 2017 PFS rate for CPT code 99490 and HCPCS code G0507, and less than the national rate for CPT code 99487.

CMS proposes 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 period.

CMS is not proposing 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 proposed rule, CMS is proposing the requirements for BHI services including an initiating visit and beneficiary consent. The billing requirements are the same as for CCM services. CMS proposes if both CCM and BHI services are furnished in the same month, the time would be combined and billed as one service under the new care coordination code. Table 16 in the proposed rule compares the

[7] Additional information about CCM requirements is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.

requirements for CCM (CPT codes 99490 and 99487) and general BHI services (proposed HCPCS code G0507) for RHCs and FQHCs.

TABLE 16—COMPARISON OF PROPOSED CCM AND GENERAL BHI REQUIREMENTS 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; • 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;	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.

	• 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	G0507—$47.73.
	CPT 99487—$93.67	
RHC/FQHC Payment for new General Care Management G code.	Current: $42.71	Current: N/A
	Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).	Proposed: Average of CPT codes 99490, 99487 and G0507 (If using the 2017 payment amounts, this would be $61.37).

2. 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 is proposing to create 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.

Based on 2017 payment rates, the payment amount for psychiatric CoCM would be approximately $134.58.

CMS proposes 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 period.

Prior to commencement of psychiatric CoCM services, the beneficiary must provide consent for this service, including permission to consult with a psychiatric consultant and relevant specialties. Advance consent must also include information on cost sharing for both face-to-face and non-face-to-face services, and acceptance of these requirements must be documented in the medical record. Patients with mental health, behavioral health or psychiatric conditions, including substance use disorders, who are being treated by an RHC or FQHC practitioner, may be eligible for psychiatric CoCM services.

As discussed in greater detail in the proposed rule, the psychiatric CoCM team must include a RHC or a FQHC practitioner, a behavioral health manager, and a psychiatric consultant.

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

TABLE 17—COMPARISON OF PROPOSED GENERAL BHI AND PSYCHIATRIC COCM REQUIREMENTS 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. RHC/FQHC Payment for New Psychiatric CoCM G Code.	G0507—$47.73 ..... Current: N/A ..... Proposed: Average of CPT codes 99490, 99487, and G0507. (If using the 2017 payment amounts, this would be $61.37)	G0502—$142.84. G0503—$126.33. Current: N/A Proposed: Average of HCPCS codes G0502 and G0503. (If using the 2017 payment amounts, this would be $134.58).

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

Section 303(c) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) added section 1847A to the Act, which established a new average sales price (ASP) drug payment methodology. However, section 303(b) of the MMA added section 1842(o)(1)(D)(i) of the Act that required that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price (AWP) for that drug in effect on October 1, 2003.

Section 5004(a) of the 21st Century Cures Act (Cures Act) 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 proposes revising 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 proposed 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.

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

CMS requests feedback on specific questions related to statutorily mandated revisions to the Clinical Laboratory Fee Schedule. Please see Appendix I for background and specific questions CMS poses in the proposed rule.

D. Solicitation of Public Comments on Biosimilars

CMS requests comments regarding the Medicare Part B biosimilar biological product payment policy. Please see Appendix II for background and specific questions.

E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

1. Background

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date:

(1) establishment of AUC by November 15, 2015;
(2) mechanisms for consultation with AUC by April 1, 2016;
(3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and
(4) annual identification of outlier ordering professionals for services furnished after January 1, 2017.

CMS notes it did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified clinical decision support mechanisms (CDSMs) by January 1, 2017; therefore, ordering professionals will not be required to consult CDSMs and furnishing professionals will not be able to report information on the consultation by January 1, 2017.

In the 2016 PFS final rule, CMS primarily addressed the first major component – the process for establishment of AUC. CMS finalized that an "applicable imaging service" must be an advanced imaging service (includes diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services CMS may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services).

CMS defined the term provider-led entities (PLE) to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the National Comprehensive Cancer Network. Qualified PLEs may also collaborate with third parties. In June 2016, CMS identified 11 qualified PLEs.[8]

In the 2017 PFS final rule, CMS primarily addressed the second major component of the AUC program - the identification of qualified CDSMs that could be used by ordering professionals for consultation with applicable AUC. CMS defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the

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

most appropriate treatment decision for a patient's specific condition. In June 2017, CMS identified 6 qualified CDSMs and 9 CDSMs with preliminary qualifications.[9]

The third major component of the AUC program is Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a listed qualified CDS mechanism when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system, and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDS mechanism. The Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to significant hardship. The Act specifies that the applicable payment systems for the AUC consultation and reporting are the PFS, hospital OPPS and ASC payment systems. Since a list of qualified CDSMs will not be available by January 1, 2017, CMS states it will not require ordering professionals to meet this requirement by that date.

The fourth component of the AUC program is Identification of Outlier Ordering Professionals. This section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020. In the 2017 PFS final rule, CMS finalized the first list of priority clinical areas,[10] which may serve as part of the basis for identifying outlier ordering professionals.

2. Proposals for Implementation

CMS proposes to amend §414.94, "Appropriate Use Criteria for Certain Imaging Services" to reflect the following proposals:

a. Consultation by Ordering Professional and Reporting by Furnishing Professional

Ordering Professional. CMS proposes 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. CMS states it is establishing this date through rulemaking this year to allow impacted parties to have sufficient time to prepare to meet all the requirements. In response to commenters' recommendations, CMS believes it is allowing sufficient time for education and outreach efforts, time for practitioners and stakeholders to prepare, and time for CDSMs to continue to evolve and become more "user-friendly and less burdensome." The proposed date lags the statutory requirement of January 1, 2017 but CMS states this delay is necessary to maximize the opportunity for public comment and stakeholder engagement, also a statutory requirement, and allows for adequate advance notice for all stakeholders.

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

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

Furnishing Professional. CMS proposes 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, 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 proposes to establish a series of HCPCS level 3 codes to implement the reporting requirements. CMS eventually intends to have one G-code for every qualified CDSM with the code description including the name of the CDSM. To ensure that there is a code available to immediately describe newly qualified CDSMs, CMS proposes to establish a generic G-code that would indicate a qualified CDSM was consulted, but would not identity a specific qualified CDSM. This generic code would be used until a specific G-code was available. CMS also proposes to establish a G-code that indicates a qualified CDSM was not consulted by the ordering professional. CMS states that G-codes would be a line-item on both practitioner and facility claims. For example, if there are two codes billed for advanced diagnostic imaging on the claim, CMS would expect two G-codes.

CMS also proposes to develop a series of modifiers to provide information as to whether the ordered service adheres to the AUC:

- The imaging service would adhere to the applicable AUC;
- The imaging service would not adhere to the applicable AUC; or
- AUC were not applicable to the imaging service ordered.

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

CMS expects voluntary reporting to be available beginning July 2018. CMS expects the January 1, 2019 proposed start date provides adequate time for it to develop the claims-based procedures and system changes necessary to process claims with the AUC information. It also believes this time will allow development of processes for the transfer of the AUC consultation information from the ordering to the furnishing professional and facility and development of billing system to translate the AUC consultation information into Medicare claims in the form of G codes and HCPCS modifiers. CMS notes that all these issues contribute to the need for an educational and operations testing program during the first year. CMS would continue to pay claims whether or not the claims correctly included the required information during this period but it does not expect to continue the educational and operational testing period beyond the first year of the AUC program.

b. Alignment with Other Medicare Quality Programs

CMS discusses how both the AUC program and the Quality Payment Program (QPP) are both designed to improve care delivery and the opportunities for the AUC program to support the QPP. Specifically, in the 2018 QPP proposed rule (82 FR 30010), CMS proposed a high-weight improvement activity for ordering professionals consulting AUC using a qualified CDSM. **CMS seeks comments regarding the development of a quality measure linked to the AUC program**.

c. Significant Hardship Exceptions to Consulting and Reporting Requirements

First, the statute provides for an exception when an applicable imaging service is ordered for an individual with 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. 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 be also 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 proposes to align the significant hardship exception with the significant hardship exception for the MIPS. Specifically, CMS proposes 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.

CMS notes there will be circumstances when a clinician who is not a MIPS eligible clinician will need to seek a significant hardship exception to the AUC program. CMS proposes 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 may be granted an AUC significant hardship exception. A significant hardship exemption would be granted for no longer than 12 months. CMS anticipates providing additional information about the exception process in future rulemaking.

3. Additional Requests for Public Comment

CMS acknowledges that the impact of the AUC program will be extensive and it requests comments about the following issues:

- The potential unintended consequences form implementing the AUC program.
- Ways to engage a variety of stakeholders for the development of the AUC program.
- The ways qualified PLEs develop or modify AUC in collaboration with non-PLE entities and what additional challenges such entities might face.

F. 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 proposes to modify the requirements for successful reporting under the 2018 PQRS payment adjustment without collecting any additional data for the 2016 reporting period.

CMS offers these proposals 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 18 and 19 in the proposed rule list the previously finalized requirements for the 2018 PQRS payment adjustment for individual EPs and group practices, respectively. The proposed modifications to the requirements are presented in Tables 20 and 21. The summary table below combines information from all these tables to show CMS' proposed requirements for 2018.

The proposed modifications 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 would apply 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 would apply 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 would need to 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 would be continued, and the measure application validity (MAV) process would continue to apply.

In general, the proposals would 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 proposed changes to the 2016 reporting period would apply to these individual EPs and group practices for purposes of the 2017 payment adjustment.

CMS notes that certain MIPS-eligible clinicians are required to report at least one outcome or high priority measure, but the definition of "high priority" differs between PQRS and MIPS. Because CMS believes this could cause confusion and because it is seeking to make the PQRS less complex, it is not proposing to align the 2018 PQRS requirement with the MIPS requirement.

Summary of Proposed 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 proposed] 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 proposed.] 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

Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
			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.
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 proposed]* 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	Individual Measures +	Direct EHR Product or	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey

Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
CAHPS for PQRS	CAHPS for PQRS	EHR Data Submission Vendor Product + CMS-Certified Survey Vendor	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 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 18 through 21 of the proposed rule (display copy pages 440-442; 447-448, and 452-453). *The proposed rule would eliminate 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.			

2. Physician Compare Downloadable Database

CMS proposes 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. Specifically, CMS had planned to report for EPs and groups the VM cost and quality tiers for 2018, noting if the EP or group assignment is high, low or average on cost and quality; reporting the VM payment adjustment received by the EP or group based on the cost and quality tiers; and indicating if the EP or group was eligible to but did not report PQRS quality measures in 2016. Other policies related to the public reporting of 2016 PQRS data on Physician Compare in late 2017 (80 FR 7116-71132) would remain unchanged.

CMS describes public use files with de-identified VM data that it intends to make available for each VM performance year and that it believes will promote transparency. Data for VM program years 2015 and 2016 (performance year 2013 and 2014) are currently available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/VMPUF/Value-Modifier-PUF.html.

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

CMS proposes to modify requirements for EPs and groups who choose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program for the 2016 reporting period. Specifically, instead of reporting at least 9 CQMs covering 3 domains, the requirement would be for reporting 6 CQMs with no domain requirement. This would align the reporting requirement for the Medicare EHR Incentive Program with the proposed modified

requirement for the 2016 PQRS reporting period (2018 payment) as described in III.F above, as well as the QPP transition year requirement.

No changes are 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 is scheduled to sunset on October 1, 2017 before the PFS rule for 2018 will be finalized.

H. Medicare Shared Savings Program

1. Modification to Shared Savings Program Beneficiary Assignment Methodology

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

CMS proposes 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.

To date, using FQHC and RHC primary care visits to as part of the ACO attribution process has required special handling. This has required an attestation process as well a crosswalk to identify primary care services. Providers contend that the process is overly burdensome and discourages ACOs from including RHCs and FQHCs as ACO participants.

Section 17007 of the 21st Century Cures Act [11]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, provides an opportunity to reduce operational burdens for ACOs to include RHCs and FQHCs. CMS proposes to do this by:

- Removing the physician attestation requirement and instead treating a service reported on an RHC or FQHC claim as a primary care service furnished by a primary care physician.
- Revising 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 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.

Consistent with the way CMS has implemented other changes to assignment methodologies, CMS states that all benchmarks would be adjusted at the start of the first performance year in which the new rules are in effect (2019) and the new methodology would be used in late 2018

[11] beginning with performance years on or after January 1, 2019

when determining the eligibility of ACOs considering entering into or renewing a participation agreement.

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 proposes 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 is addressed, moving those codes from §425.20 and place them into §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) 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.

CMS seeks comment on whether there are additional existing HCPCS/CPT codes that it should consider adding to the definition of primary care services for the purpose of beneficiary assignment in future rulemaking.

2. Reducing Shared Savings Application Burden

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

CMS proposes to eliminate certain documentation requirements to reduce the application burden for Track 3 ACOs applying for a waiver of the Skilled Nursing Facility (SNF) 3-day hospital stay rule. The waiver application includes two requirements that CMS believes impose an unnecessary burden on ACOs and are not useful for CMS in determining whether to approve a waiver. CMS proposed to eliminate those two requirements.

The first of those is a requirement at 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 second requirement that CMS proposes to remove 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. CMS says that having ACOs provide a screen shot of information that CMS has direct access to from the CMS Nursing Home Compare website does not add value to the review process. CMS notes that it is not changing the requirement that such affiliates have and maintain an overall rating of 3 or higher under the star rating system, but rather it only proposing to eliminate the documentation requirement from the ACO.

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

CMS proposes to eliminate certain requirements for ACO applicants to provide supporting documentation when applying to participate in the MSSP to reduce the application burden for ACOs and the review burden for CMS. CMS claims that such documentation does not lend significant value to its review of an organization's application. CMS would, however, under the proposal, retain the ability to request such documentation if additional information is needed to fully assess the ACO's application.

Specifically, CMS proposes 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.
- 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.
- Eliminate §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 it does not propose retaining those components upon request because the way that an ACO intends to use or distribute shared savings has not been a relevant consideration during consideration of applications. CMS does, however, continue 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).

3. Addressing Compliance with ACO Participant TIN Exclusivity Requirement

Under the MSSP, the same TIN number cannot be used to submit claims for primary care services for more than one ACO's assigned population – although providers may participate in more than one ACO. The purpose of this rule is to ensure that a unique set of beneficiaries is assigned to each ACO participating in the MSSP. Heretofore, CMS has used an approach at identifying and resolving overlapping TINs, which, in addition to being complex, adds to

uncertainty for ACO providers. As a result, CMS proposes a new process for ensuring that TIN numbers are exclusive for the purpose of beneficiary assignment.

Under the new process, if CMS finds that during a benchmark or performance year, an ACO participant that participates in more than one ACO begins billing for services that would be used in assignment, CMS will not consider *any services* billed through that TIN during the relevant performance year when assigning beneficiaries for the applicable benchmark or performance year. CMS notes that ACOs for which there are overlapping TINs may be subject to compliance action under existing §425.216 or termination under §425.218.

CMS' prior approach was to resolve such discrepancies during the performance year. In doing so, providers with overlapping TINs were required to terminate their participation in one of the overlapping ACOs, triggering that ACO's need to resubmit its participant list and possibly requiring CMS to recalculate that ACO's performance year beneficiary assignment and financial benchmarks. CMS states that the process of recertifying the ACO participant list is burdensome; moreover, the potential for financial benchmarks and beneficiary assignments to be altered during a performance year raises significant uncertainty for ACOs.

CMS states in the preamble that its proposed approach would allow the provider to remain on the 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 would remove the TIN from the participant lists for all ACOs seeking to include the TIN.

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

CMS proposes 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 would exclude interim payments and would 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 proposes to modify regulations 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 would be included, and (3) for the 2018 performance year and subsequent years in agreement periods beginning in 2015, 2016 and 2017, the benchmark would be adjusted to reflect only final payments made under a demonstration, pilot or time limited program.
In addition, CMS proposes to:

- Add new §§425.604(a)(6)(ii)(A) (relating to calculating savings under a one-sided model), 425.606(a)(6)(ii)(A) (relating to calculating shared savings and losses under track 2) and 425.610(a)(6)(ii)(A) (relating to calculating shared savings and losses under Track 3) indicating that when calculating spending for performance years before 2018, all individually beneficiary identifiable payments, including interim payments, made under a demonstration, pilot, or time limited program would be included; and
- Add new §§425.604(a)(6)(ii)(B), 425.606(a)(6)(ii)(B) and 425.610(a)(6)(ii)(B) indicating that when calculating spending for performance year 2018 and subsequent performance years, only final payments would be included.

I. Value-Based Payment Modifier and Physician Feedback Program

1. Background

Beginning January 1, 2015, the Secretary was required to apply a value-based modifier (VM) to specific physicians[12] and groups of physicians, and then expand the VM to all physicians and groups of physicians effective January 1, 2017. On or after January 1, 2017, the Secretary has the discretion to apply the VM to other EPs.[13] Under MACRA, the VM is sunset after 2018. CMS has phased-in the VM in the following sequence:

- Starting January 1, 2015, the VM applied to physicians in groups of 100 or more EPs.
- Starting January 1, 2016, the VM applies to physicians in groups of 10 or more EPs.
- Starting January 1, 2017, the VM applies to physicians in groups of 2 or more EPs and to physician solo practitioners.

In addition, the VM was extended for the 2018 payment adjustment period to include nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs) and certified registered nurse anesthetists (CRNAs) in groups with two of

[12] Physicians are defined in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.
[13] Eligible professionals are defined in section 1848(k)(3)(B) of the Act as any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act: physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse mid-wife, clinical social worker, clinical psychologist, registered dietician, or nutritional professional; (3) a physician or occupational therapist or qualified speech-language pathologist; or (4) a qualified audiologist.

more EPs and to those who are solo practitioners and not to other types of professionals who are nonphysician EPs.

2. Proposed Changes for 2018

In this rule, CMS proposes to modify the VM policies for the 2018 payment adjustment. The proposals would 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 specifically seeks comment on whether the proposals appropriately balance the interests of high and low-performing groups and solo practitioners.**

CMS believes the proposed policies would 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 proposed are as follows:

- All groups and solo practitioners in Category 1 (i.e., those that meet the criteria to avoid the 2018 PQRS payment reduction)[14] would 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] would be reduced from -4 percent to -2 percent for groups with 10 or more EPs and at least one physician, and from -2 percent to -1 percent 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) would be reduced to from +4.0 times the adjustment factor (+4.0x) to two times (+2.0x) and the adjustment for those classified as

[14] 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.

either average quality/low cost or high quality/average cost would be reduced from 2.0x to 1.0x the adjustment factor. These proposed changes would 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.

No changes are proposed to existing policies providing that groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology, and have an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores, will earn an additional upward adjustment (+1x). In addition, no change is proposed with respect to existing policies: (a) 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. Under the existing policy, these groups and solo practitioners in Category 1 would be classified as "average quality" and "average cost" for purposes of the CY 2017 VM.

Tables 22 through 25 in the proposed rule, reproduced below, show the current and proposed 2018 VM amounts for different categories/sizes of practitioners.

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

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

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

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

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

* Under existing policy, these groups and solo practitioners 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: Current and Proposed 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	Current	Proposed	Current	Proposed	Current	Proposed
Low Cost	+0.0%	+0.0%	+1.0x*	+1.0x*	+2.0x*	+2.0x*
Average Cost	+0.0%	+0.0%	+0.0%	+0.0%	+1.0x*	+1.0x*
High Cost	+0.0%	+0.0%	+0.0%	+0.0%	+0.0%	+0.0%

* Under existing policy, these groups and solo practitioners 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 payment adjustment factor.

TABLE 25: Proposed CY 2018 VM Amounts Under the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, and CRNAs Who Are Solo Practitioners and Those in Groups of Any Size

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%

* Under existing policy, these groups and solo practitioners 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 payment adjustment factor.

3. Regulatory Impact Analysis

CMS says it has not completed the analysis of the impact of the VM in CY 2018, but preliminary estimates indicate that the implementation of the proposed policies would reduce the adjustment factor to below 10 percent. The 2017 VM adjustment factor is 15.48 percent. In the 2018 PFS final rule, CMS intends to present estimates of the number of groups and solo practitioners that will be subject to the VM in 2018.

J. MACRA Patient Relationship Categories and Codes

1. Background

Section 101(f) of MACRA added a new subsection (r) to section 1848 of the Act entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. Section 1848(r)(2) requires the development of care episode and patient condition groups plus group classification codes. To satisfy the purpose of 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 an item or service is furnished to the patient by that practitioner.
- 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 physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. Additional practitioner types may be added on or after January 1, 2019, as specified by the Secretary.

2. Patient Relationship Categories Operational List

CMS posted and solicited public comment upon a draft relationship categories list and the list's foundational principles in April, 2016. Potential category modifications were developed based upon comments received. In December, 2016, CMS sought comments about such modifications and about operational approaches for reporting the categories on Medicare claims. After comment review, CMS posted the first operational list of patient relationship categories on May 17, 2017 as follows:

- Continuous/Broad Services,
- Continuous/Focused Services,
- Episodic/Broad Services,
- Episodic/Focused Services, and
- Only as Ordered by Another Clinician.

The list is available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-Relationship-Categories-and-Codes.pdf. Section 1848(r)(3)(F) of the Act provides for list revisions by the Secretary through rulemaking no later than November 1 annually, beginning in 2018. In preparation for the 2018 update, the list is now open for comment.

3. Patient Relationship Reporting Using Modifiers

Section 1848(r)(4) of the Act specifies that claims for services furnished beginning January 1, 2018, shall include, as determined appropriate by the Secretary, the following:

- Any applicable codes for care episode groups,
- Any applicable codes for patient condition groups,
- Any applicable codes for patient relationship categories, and
- The NPI of the ordering physician or applicable practitioner.

CMS describes having planned to use procedure code modifiers for patient relationship code reporting via claims. Commenters in December, 2016 had indicated a preference for CPT modifier codes rather than HCPCS Level II modifiers. CMS submitted a CPT code application that was rejected in June, 2017, as the CPT Editorial Panel preferred to wait until the proposed modifiers were finalized before issuing Category I CPT codes. CMS, therefore, is proposing HCPCS modifiers as shown below in Table 26 reproduced from the proposed rule.

TABLE 26: Proposed 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

CMS proposes that claims for services furnished beginning January 1, 2018, shall include the appropriate modifier selected from Table 26 and the NPI of the ordering practitioner. To support practitioners during their learning curve for category and code selection, CMS proposes that modifier reporting will be voluntary. Modifier use would not be a condition of payment, affect payment, change the meaning of a reported procedure code(s), or be tied to any reported E/M service(s) intensity. The duration of the voluntary HCPCS modifier reporting period is not specified by CMS. Finally, CMS notes that the relationship codes may be incorporated into future QPP measures, but that current, 2018-proposed, and currently under-development measures do not require patient relationship codes for proper QPP measure submission. CMS seeks comment on the proposed modifier list, the plan to resubmit the modifiers for CPT code assignments, and the initial voluntary reporting of the proposed modifiers.

K. Proposed Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model

1. Background

The National Diabetes Prevention Program (DPP) administered by the Centers for Disease Control and Prevention (CDC), is a structured health behavior change program delivered in community and health care settings by trained community health workers or health professionals. The program consists of 16 intensive "core" sessions of a CDC-approved curriculum in a group-based setting that provides practical training for overcoming challenges to sustaining weight loss and a healthy lifestyle. Monthly maintenance sessions help to ensure that the participants maintain healthy behavior. The primary goal of the intervention is at least 5 percent average weight loss among participants during the program.[15]

In the 2017 PFS final rule (81 FR 80459 through 80475), CMS finalized an expanded DPP model test as the Medicare Diabetes Prevention Program (MDPP). The MDPP was to begin January 1, 2018.

The MDPP core benefit was finalized as a 12 consecutive month program that consists of at least 16 weekly core sessions over months 1 through 6 and at least six monthly core maintenance sessions over months 6-12, furnished regardless of weight loss. Beneficiaries have access to ongoing maintenance sessions after the 12-month core benefit if they achieve and maintain the

[15]Additional information about the National DPP is available at http://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html.

required minimum weight loss of 5 percent. CMS also adopted policies that will enable CDC-recognized organizations to prepare for enrollment.

As discussed below, CMS proposes modifications to the MDPP benefit, including limiting the program to 3 years and proposes a new start date of April 1, 2018.

2. Proposed Policy Changes: MDPP Services

CMS proposes to change the date that MDPP services would be available from January 1, 2018 to April 1, 2018.

Table 34 from the proposed rule (partially reproduced below[16]), provides a summary of the proposed set of MDPP services and beneficiary eligibility for coverage for the set of MDPP services. The following sections in this summary discuss these proposals.

***Table 34: Proposed Set of MDPP Services and MDPP Beneficiary Eligibility for Coverage**

MDPP Services	**MDPP Beneficiary Eligibility for Coverage**
Core Sessions (months 1 to 6 of the MDPP services period)	An eligible beneficiary has Medicare coverage of core sessions in the first 6 months of the MDPP core services period, regardless of attendance or weight loss. • To start the MDPP services period, the beneficiary attends the first core session, which begins the beneficiary's MDPP services period timeline of a maximum of 36 months.
Core Maintenance Sessions (months 7 to 12)	Beneficiary has coverage of core maintenance sessions in months 7 to 12 of the MDPP service period, regardless of attendance or weight loss.
Ongoing Maintenance Sessions (months 13 to 36)	Beneficiary has coverage of ongoing maintenances sessions in the first ongoing maintenance session interval (months 13 to 15 of the MDPP service period if the beneficiary: • Attended at least 1 session during the final core maintenance session interval (months 9 to 12 of the MDPP service period) and had weight measured, and • Achieved or maintained the required minimum weight loss at least once during the final core maintenance session interval (months 10 to 12 of the MDPP services period). A beneficiary has coverage of a subsequent ongoing maintenance session interval (for up to 21 months after the end of the first ongoing maintenance session interval), if the beneficiary: • Attended at least 3 sessions and • Maintained the required minimum weight loss from baseline at least once during the previous ongoing maintenance session interval.

[16] The table is an abbreviated display of Table 34. The entire Table 34 in the proposed rule also contains information about services the MDPP supplier must offer and MDPP supplier payments. A complete copy of Table 34 is included in this summary in section K.5.

*The table is an abbreviated display of Table 34. The entire Table 34 in the proposed rule also contains information about services the MDPP supplier must offer and MDPP supplier payments. A complete copy of Table 34 is included in this summary in section K.5.

a. Ongoing Maintenance Session Time Limit

CMS proposes a 2-year limit on coverage for maintenance sessions. CMS notes this proposal is consistent with the CMS Chief Actuary's certification of the expansion of the DPP model that indicated continued participation in a type 2 diabetes DPP after 3 years has been generally untested.

b. MDPP Service Period Clarifications

CMS proposes to remove the existing definition of "maintenance session bundle" and to establish new definitions for "core maintenance session interval" and "ongoing maintenance session interval". CMS proposes the following (proposed §410.79(b)):

- "Core maintenance session interval" is defined as one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period. During this interval, a MDPP supplier offers a beneficiary at least one core maintenance session per month.

- "Ongoing maintenance session interval" is defined as one of the eight consecutive 3-month time periods during the ongoing service period described in §410.79(c)(2)(ii). During this interval, a MDPP supplier offers at least one ongoing maintenance session per month to a MDPP beneficiary.

CMS proposes additional terminology related to the MDPP services (proposed §410.79(b)):

- "Make-up session" is defined as a core session, core maintenance session, or an ongoing maintenance session furnished to a MDPP beneficiary when the beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session.

- "Virtual make-up session" is defined as a make-up session that is not furnished in person and is consistent with the CDC Diabetes Prevention Recognition Program (DPRP) standards for virtual sessions.

CMS also proposes additional terminology to describe aspects of the MDPP:

- "Performance goal" is defined as an attendance or weight loss goal that a beneficiary must achieve during the MDPP service period for a MDPP supplier to be paid a performance payment (proposed §414.84(a)). CMS notes that this proposal more broadly defines the performance goal, and proposes to remove the definition of "maintenance of weight loss".

- "MDPP supplier" is revised to mean an entity that is enrolled in Medicare to furnish MDPP services as proposed in §424.59 (proposed to be redesignated as §424.205).

3. Proposed Policy Changes: Beneficiary Eligibility

CMS proposes to replace the term "MDPP eligible beneficiary" with "MDPP beneficiary". CMS proposes to define a "MDPP beneficiary" as a Medicare beneficiary who meets the criteria specified in paragraph §410.79(c)(1)(i), who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended (as specified in paragraph §410.79(c)(3) (proposed §410.79(b)).

In the 2017 final rule (81 FR 80470) CMS finalized at §410.79(c)(1) that MDPP services would be available for beneficiaries who meet all of the following criteria:

1. Are enrolled in Medicare Part B;
2. Have as of the date of attendance at the first Core Session a body mass index (BMI) of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian;[17]
3. Have within the 12 months prior to attending the first Core session a hemoglobin A1c (HgA1c) test with a value between 5.7 and 6.4 percent, or a fasting plasma glucose of 110-125 mg/dL, or a 2-hour post-glucose challenge of 140-199 mg/dL;
4. Have no previous diagnosis of Type 1 or Type 2 diabetes (a previous diagnosis of gestational diabetes is eligible for MDPP); and
5. Does not have end-stage renal disease (ESRD).

As discussed below, CMS proposes changes to these eligibility criteria.

a. MDPP Eligibility Criteria Related to Diabetes and ESRD

Clarifying MDPP Eligibility Criteria Related to Gestational Diabetes and ESRD. CMS clarifies it is not excluding beneficiaries with a prior history of gestational diabetes from eligibility for MDPP services. Beneficiaries with a prior history of a diagnosis of type 1 or type 2 diabetes are ineligible.

CMS also clarifies that a beneficiary who is diagnosed with ESRD after having begun receiving MDPP services would lose eligibility. Suppliers can use the online HIPPA Eligibility Transaction System (HETS) to verify if a beneficiary has ESRD.

Diabetes Diagnoses during the MDPP Services Period. CMS proposes the diabetes diagnosis exclusion applies only at the time of the first core session. Specifically, CMS proposes to revise the eligibility requirements for MDPP services to state that a beneficiary has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes (proposed §410.79(c)(1)(i)(E)).

[17] The CDC DPRP Standards have defined a lower BMI for self-identified Asian individuals based on data that show Asians develop abnormal glucose levels at a lower BMI.

b. Once-Per-Lifetime Set of Services

In the 2017 PFS final rule, CMS specified that coverage for the set of core MDPP services is available only once per lifetime for each MDPP beneficiary. In this rule, CMS proposes to delete this provision. CMS also proposes to edit this provision to specify that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once per lifetime per Medicare beneficiary. CMS notes this limitation would not apply to beneficiaries who participated in a DPP as part of the DPP model test unless they receive the set of MDPP services.

In the 2017 PFS final rule, CMS stated that beneficiaries could self-report to MDPP suppliers that they had not previously received MDPP services. CMS is now considering ways that MDPP suppliers would be able to verify if a beneficiary has received coverage of MDPP services from another supplier, such as through a standardized tracker (see discussion below in section 5).

c. Eligibility throughout the MDPP Services Period

(1) MDPP Services Period

CMS proposes to revise §410.79(c)(2) to specify that the MDPP services period consists of two service periods: the core services period and the ongoing services period.

Core Services Period. CMS proposes to define the core services period as the first 12 months of the MDPP service period, consisting of core sessions and core maintenance sessions.

- A minimum of sixteen core sessions must be offered at least a week apart in months 1 through 6, beginning on the date of attendance at the first core session.
- The core maintenance sessions are offered at least once per month in months 7 through 12.

CMS notes that some MDPP suppliers may choose to furnish more than the minimum number of sessions and the proposed parameters would allow MDPP suppliers to furnish them.

CMS reiterates the beneficiary must attend at least one session to initiate the MDPP services period. Medicare will pay for the set of core MDPP services, regardless of how many sessions the beneficiary attends and regardless of their weight loss.

Ongoing Services Period. CMS proposes to revise §410.79(c)(2)(ii) to clarify that the ongoing services consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period.

In the 2017 PFS final rule, CMS finalized that for coverage of ongoing maintenance sessions, the beneficiary must have achieved a weight loss of 5 percent from their baseline weight. In this rule, to have coverage of ongoing maintenance services, CMS proposes a beneficiary must attend at least one in-person core maintenance session in months 10 through 12 of the MDPP service period to document the 5 percent weight loss from baseline to have coverage of ongoing maintenance services.

For eligibility for ongoing maintenance session intervals 2 through 8, CMS proposes an attendance-related performance goal. Specifically, for coverage of ongoing maintenance session intervals 2 through 8, a beneficiary must attend at least 3 ongoing maintenance sessions during the previous ongoing maintenance session interval.

Limitations on the Set of MDPP Services. CMS proposes to specify that coverage of the MDPP services period would end upon completion of the core services period for a beneficiary that is not eligible for the first ongoing maintenance session interval (proposed §410.79(c)(1)(ii)).

For any beneficiary who is eligible for at least one ongoing maintenance session interval, but does not meet the requirements for coverage of a subsequent interval (proposed §410.79(c)(2)(iii)), the beneficiary's coverage of the set of MDPP services would end upon completion of their ongoing maintenance session interval.

4. Proposed Policy Changes: Payment for MDPP Services

Payment for MDPP services is based on a performance-based payment methodology that makes periodic payments to MDPP suppliers during the MDPP services period (discussed below in greater detail). The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. CMS is proposing a maximum total performance payment amount per beneficiary for the set of MDPP services of $810.

Performance payments would be made to MDPP suppliers periodically while a MDPP service period based upon a number of factors, including the beneficiary's completion of a specific number of MDPP sessions and the achievement of the required minimum weight loss. The total payment amount for the set of MDPP services includes the payment for core sessions, core maintenance sessions, and ongoing maintenance sessions. Performance payments would be made periodically and the payments would not be evenly distributed across the course of sessions furnished during the MDPP service period. For example, CMS proposes a performance payment rate of $25 that would be relatively high on a per-session basis as compared to other attendance-based performance payments. CMS notes the performance payment for the first core session would make payments for some of the MDPP supplier resources used in furnishing the first session, as well as make a partial prospective payment for furnishing subsequent sessions.

CMS discusses the differences in the performance goals during the MDPP service period. During the core sessions, for coverage of MDPP services, a beneficiary would not be required to achieve attendance and/or weight loss performance goals. A beneficiary would be required to achieve specified performance goals for an MDPP supplier to receive performance payments. In contrast, during the ongoing services period, achieving specified performance goals would be required for both coverage of services and performance payments. Once the required weight loss is achieved and the 12-month services period ends, CMS would make additional 3-month interval performance payments for ongoing maintenance sessions only when the required minimum weight loss is maintained. CMS proposes to make additional performance payments when a beneficiary achieves a weight loss of 5 percent (the required minimum weight loss) or 9 percent.

Table 32 from the proposed rule (reproduced below), provides a summary of the proposed performance payments for the set of MDPP services.

Table 32: Proposed Performance Payments for the Set of MDPP Services

Performance Goal	**Performance Payment Per Beneficiary (*with* the required minimum weight loss)**	**Performance Payment Per Beneficiary (*without* the required minimum weight loss)**
1st core session attended	$25	
4 total core sessions attended	$30	
9 total core sessions attended	$50	
3 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)	*$60	$10
3 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)	*$60	$10
5 percent weight loss achieved	$160	$0
9 per weight loss achieved	$25	$0
3 sessions attended in ongoing maintenance session interval (eight consecutive 3-month intervals over months 13-36 of the MDPP ongoing services period)	*$50	**$0
Total performance payment	**$810**	**$125**

* = The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.
** = To have coverage of the first ongoing maintenance session interval, a beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least during the final core maintenance session 3-month interval. To have coverage of the next ongoing maintenance session interval, a beneficiary must attend at least 3 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval.

a. Overall Approach Performance Payments for MDPP Services

CMS discusses how the proposed performance-based payment methodology for MDPP services differs from the proposed MDPP payment structure discussed in the 2016 PFS proposed rule (81 FR 46415 through 46416). First, the proposed payment structure values beneficiary weight loss more significantly. Second, the proposed payment structure values beneficiary attendance because in the DPP model test, session attendance was associated with greater weight loss.

CMS believes that the proposed payment structure based on individual beneficiary success, rather than the average weight loss across all beneficiaries who receive MDPP services from an MDPP supplier, maximizes the focus of MDPP suppliers on all beneficiaries, including those beneficiaries who experience challenges with achieving attendance and/or weight loss performance goals.

1. Total Amount and Distribution of Performance Payments

CMS proposes a maximum total performance payment per beneficiary for the set of MDPP services of $810. This amount is the aggregate of the maximum performance payments for core sessions, core maintenance sessions and ongoing maintenance sessions furnished to beneficiaries who achieve weight loss of at least 9 percent over the 36 months of the MDPP services period. This performance payment amount would be made for a minimum of 46 MDPP sessions required to be offered to the beneficiary. Table 27 in the proposed rule (reproduced below) summarizes the distribution of performance payments.

Table 27: Proposed Maximum Total Amount and Distribution of Performance Payments for the Set of MDPP Services

Type of Performance Payment	Maximum Performance Payment for Achieving Attendance and/or Weight-Loss Performance Goals	Percentage of Maximum Total Performance Payments
Core sessions	$105	13%
Core maintenance session intervals	$120	15%
Ongoing maintenance session intervals	$400	49%
Weight loss	$185	23%
Total performance period	**$810**	**100%**

CMS notes that, estimated on a per-session basis, the maximum MDPP payment amount for achievement of all the performance goals would be approximately $18 per session.

CMS acknowledges the administrative costs that MDPP suppliers would incur to enroll in Medicare and ensure compliance with the MDPP requirements. CMS notes the total MDPP performance payment would provide some payment for the resources that would be used by MDPP suppliers to meet the administrative requirements for furnishing MDPP services.

2. Payment Considerations Related to Beneficiaries with Social Risk Factors

CMS is not proposing to risk-adjust MDPP payments for social risk factors or to adopt additional special payment policies to encourage MDPP suppliers to furnish sessions to beneficiaries with social risk factors.

b. Core Services

CMS proposes a maximum total performance payment to MDPP suppliers for furnishing core sessions of $105. These payments would be paid when beneficiaries achieve attendance performance goals, regardless of weight loss. Table 28 in the proposed rule (reproduced below) summarizes the distribution of the performance payments for the core sessions.

Table 28: Proposed Attendance-Based Performance Payments for MDPP Core Sessions

Performance Goal	Attendance-Based Performance Payment Per Beneficiary
1st core session (performance payment)	$25
4 total core sessions attended (interval performance payment)	$30
9 total core sessions attended (interval performance payment)	$50
Maximum total performance payment	**$105**

CMS proposes a performance payment of $25 for furnishing the first core session to a beneficiary. This payment would be available only once per beneficiary and would be paid whether or not the MDPP supplier qualifies for any additional performance payments for the beneficiary. CMS believes making a payment for the first core session is appropriate because the supplier would use significant resources to furnish the first session, including collecting administrative information related to the beneficiary. The first payment also provides some payment for suppliers to encourage the beneficiary's attendance at sessions following the first core session.

CMS proposes a performance payment for interval performance goals (interval performance payment) for a beneficiary's attendance at 4 total core sessions and 9 core sessions (attending 5 more sessions after the first 4 sessions) of $30 and $50, respectively. Although a MDPP supplier must offer at least 16 core sessions to a beneficiary during the initial 6 months of the core services period, CMS is not proposing any other interval payments.

CMS notes that on a per-session basis, the payments for attendance at the 4 total core sessions would be approximately $10 and for the 9 total core sessions would be approximately $4 to $10 (depending upon the number of sessions attended by the beneficiary beyond the 9 and up to the maximum of 16 core sessions that must be offered). CMS believes this payment is appropriate because it expects fewer supplier resources would be used to furnish sessions to beneficiaries with an established relationship.

c. Performance Payment for Core Maintenance Session Intervals

CMS proposes a maximum total performance payment to MDPP suppliers for MDPP core maintenance sessions of $120 for beneficiaries who achieve both the attendance and weight loss performance goals during months 7 to 12 of the core services period. The maximum total performance payment would be $20 for achieving the attendance performance goals without weight loss. Table 29 in the proposed rule (reproduced below) summarizes the distribution of the performance payments for the core sessions.

Table 29: Proposed Performance Payments for Core Maintenance Session Intervals

Performance Goal	**Performance Payment Per Beneficiary (*with* achievement or maintenance of required minimum weight loss)**	**Performance Payment Per Beneficiary (*without* achievement or maintenance of required minimum weight loss)**
3 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)	$60	$10
3 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services) period)	$60	$10
Maximum total payment (two consecutive 3-month intervals over months 7-12 of the core services period)	**$120**	**$20**

CMS proposes performance payment amounts for core maintenance sessions that value achievement of both session attendance and the required minimum weight loss, with an emphasis on achieving the weight loss performance goal. The achievement or maintenance of the required minimum weight loss would be determined based on a measurement taken in-person during any 1 session within that 3-month interval.

d. Performance Payments for Ongoing Maintenance Session Intervals

CMS proposes a maximum total performance payment to MDPP suppliers for MDPP ongoing maintenance session intervals of $400 for beneficiaries who achieve both the attendance and maintenance of the required minimum weight loss during the 24 months of the ongoing service period. The ongoing services period begins after the 12-month MDPP core services period ends.

CMS proposes that a MDPP supplier would be paid a performance payment for an ongoing maintenance session interval if a MDPP beneficiary achieves the performance goals of attending at least 3 ongoing maintenance sessions and maintains the required minimum weight loss measured in-person during a session at least once within that interval. A supplier could be paid up to 8 performance payments of $50 for each ongoing maintenance session interval. A MDPP supplier would not be paid a performance payment unless both of these performance goals are met within the 3-month interval. Table 30 in the proposed rule (reproduced below) summarizes the distribution of the performance payments for the ongoing maintenance session intervals.

Table 30: Proposed Performance Payments for Ongoing Maintenance Session Intervals

Performance Goal	**Performance Payment Per Beneficiary (*with* maintenance of the required minimum weight loss)**	**Performance Payment Per Beneficiary (*without* maintenance of the required minimum weight loss)**
3 sessions attended in 1 ongoing maintenance session interval	$50	$0
Maximum total performance payment (eight consecutive 3-month intervals over months 13-36 of the MDPP ongoing services period)	**$400**	***$0 to $350**

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 7 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

e. Weight Loss Performance Payments

CMS proposes if a beneficiary achieves the required minimum weight loss (5 percent) measured at any session attended during the core services period, a MDPP supplier would be paid the weight loss performance payment of $160. CMS proposes that if a beneficiary achieves at least a 9 percent weight loss, a supplier would be paid a performance payment of $25. Table 31 in the proposed rule (reproduced below) summarizes the proposed weight loss performance payments.

Table 31: Proposed Weight Loss Performance Payments

Performance Goal	**Performance Payment Per Beneficiary**
5 percent weight loss (required minimum weight loss)	$160
9 percent weight loss	$25
Maximum total performance payment	$185

CMS notes that the proposed performance payment of $160 for the required minimum weight loss (90 percent of the maximum total weight loss performance payment of $185) was set to be the large majority of the payment; this is based on evidence associating the required minimum weight loss with a reduction in the incidence of type 2 diabetes. CMS proposes the additional weight loss performance goal of 9 percent based on information from stakeholders that commercial payers for DPPs frequently include an incentive payment for 9 percent weight loss to try to encourage greater and/or continued weight loss and behavior change.

CMS proposes that the payment for achievement of the minimum weight loss performance goal can occur at any time during the 12 months of the MDPP core services period. The MDPP supplier may submit claims for the weight loss performance payments when the beneficiary reaches the required minimum or 9 percent weight loss. Each weight loss performance payment would be paid to only one supplier for a beneficiary. If a beneficiary achieves the 9 percent

weight loss as the first weight loss measured from baseline, the supplier could bill and be paid for both the 5 percent and the 9 percent weight loss performance payments.

f. Considerations Related to Potential Future Geographic Adjustments of MDPP Payments

CMS is not proposing geographic adjustment of performance payments for MDPP services. CMS believes the proposed performance payments include the use of supplier resources and it is unsure if there is a notable variation in the relative costs of furnishing MDPP services among geographic areas. CMS may consider proposing additional payment policies in future rulemaking.

g. Updating MDPP Payment Amounts

To account for inflation, CMS proposes to update MDPP payment amounts annually based on the CPI-U.

CMS is also proposing bridge payments – a proposed one-time payment to an MDPP supplier for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier (discussed below in section K.6.).

CMS proposes the following:

- Beginning in 2019 and each year forward, the performance payment and bridge payment amounts will be adjusted by the 12-month percent change in the CPI-I (US city average) for the period ending June 30th of the year preceding the update year.
- The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision.
- The annual MDPP services payment update will be published by a CMS transmittal.

5. Proposed Policy Changes: MDPP Supplier Billing and Payment for MDPP Services

a. Payment for MDPP Services on an Assignment-Related Basis

CMS proposes that performance payments and bridge payments to MDPP suppliers for MDPP services would be made only on an assignment-related basis. To minimize the potential administrative burden on beneficiaries, CMS also proposes that for claims for services submitted by a MDPP supplier, Medicare would deem such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDPP supplier.

b. Reporting HCPCS G-Codes on Claims for MDPP Services

CMS is proposing to establish 19 unique HCPCS G-codes for MDPP services (listed in Table 33 in the proposed rule).

TABLE 33—PROPOSED HCPCS G-CODES FOR MDPP SERVICES

Proposed HCPCS G-code for MDPP services *	Proposed payment amount	Description of MDPP service
GXXX1	$25	1st core session attended.
GXXX2	30	4 total core sessions attended.
GXXX3	50	9 total core sessions attended.
GXXX4	10	3 core maintenance sessions attended in months 7–9 (weight- loss goal not achieved or maintained).
GXXX5	10	3 core maintenance sessions attended in months 10–12 (weight loss goal not achieved or maintained).
GXXX6	60	3 core maintenance sessions attended in months 7–9 and weight loss goal achieved or maintained.
GXXX7	60	3 core maintenance sessions attended in months 10–12 and weight loss goal achieved or maintained.
GXXX8	160	5 percent weight loss from baseline achieved.
GXXX9	25	9 percent weight loss from baseline achieved.
GXX10	50	3 ongoing maintenance sessions attended in months 13–15 and weight loss goal maintained.
GXX11	50	3 ongoing maintenance sessions attended in months 16–18 and weight loss goal maintained.
GXX12	50	3 ongoing maintenance sessions attended in months 19–21 and weight loss goal maintained.
GXX13	50	3 ongoing maintenance sessions attended in months 22–24 and weight loss goal maintained.
GXX14	50	3 ongoing maintenance sessions attended in months 25–27 and weight loss goal maintained.
GXX15	50	3 ongoing maintenance sessions attended in months 28–30 and weight loss goal maintained.
GXX16	50	3 ongoing maintenance sessions attended in months 31–33 and weight loss goal maintained.
GXX17	50	3 ongoing maintenance sessions attended in months 34–36 and weight loss goal maintained.
GXX18	25	Bridge payment—first session furnished by MDPP supplier to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier.
GXX19	0	MDPP session reported as a line-item on a claim for a payable MDPP services HCPCS G-code for a session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable MDPP services HCPCS G-code.

* Illustrative HCPCS G-code numbers are placeholders to allow for comment on this proposed rule. Final HCPCS codes for MDPP services under the MDPP expanded model will be included in the CY 2018 PFS final rule.

HCPCS G-codes GXXX1 through GXXX3 and GXXX8 through GXX17 may each be paid only once in a beneficiary's lifetime. In addition, consistent with the proposed performance based payments, no more than one unit of GXXX4 through GXXX7 may each be paid in a beneficiary's lifetime. CMS is not proposing to limit the number of bridge payments, which would be reported with GXX18.

For HCPCS codes with lifetime limitations, in the circumstances where two MDPP suppliers furnished sessions during the MDPP services period and both MDPP suppliers met all the requirements for billing the same G-code, CMS would pay the first valid claim received and deny the second claim. CMS expects that circumstances where a beneficiary changes MDPP suppliers during the MDPP service period will be uncommon.

CMS plans to issue specific billing instructions to MDPP suppliers for the 16 G-codes that represent interval performance payment. CMS states that suppliers would report the applicable G-code as a line-item on the claim on the date the service was furnished where the interval attendance goal was met. On the same claim, suppliers would also report 1 line-item of GXX19 for each other session furnished by the supplier during the interval that was not previously reported on a claim but counts toward achievement of the attendance performance goal for the applicable G-code. In the proposed rules, CMS provides examples of different scenarios and the corresponding claims submission requirements.

c. Reporting the Coach NPI on Claims

In the 2017 PFS final rule, CMS established that coaches will not enroll in Medicare for the purpose of furnishing MDPP services but that coaches will be required to obtain NPIs.

CMS proposes to require MDPP suppliers to report the NPI of the coach who furnished the session as Item 24J on the line-item for each session reported on claims for performance payments for MDPP services. The coach who furnished the session would be the render provider on the CMS-1500 claim form.

d. Comparison of Supplier Requirements for Furnishing the Set of MDPP Services and Supplier Payments

Table 34 in the proposed rule (reproduced below) summarizes the requirements for coverage and payment of MDPP services.

Table 34: Set of MDPP Services and Payments

MDPP Services	MDPP Beneficiary Eligibility for Coverage	MDPP Supplier Must Offer	MDPP Supplier Payment
Core Sessions (months 1 to 6 of the MDPP services period)	An eligible beneficiary has Medicare coverage of core sessions in the first 6 months of the MDPP core services period, regardless of attendance or weight loss. NOTE: To start the MDPP services period, the beneficiary attends the first core session, which begins the beneficiary's MDPP services period timeline of a maximum of 36 months.	At least 16 core sessions, furnished no frequently than once per week, over the first 6 months of the beneficiary's MDPP services period.	• $25 performance payment for beneficiary attendance at the first core session. • $30 interval performance payment after the beneficiary has attended a total of 4 core sessions. • $50 interval performance payment after the beneficiary has attended a total of 9 core sessions. NOTE: All payments for core sessions are independent of beneficiary weight loss.
Core Maintenance Sessions (months 7 to 12)	Beneficiary has coverage of core maintenance sessions in months 7 to 12 of the MDPP service period, regardless of attendance or weight loss.	At least 1 core maintenance session per month in months 7 to 12 of the MDPP services period.	• $10 payment if a beneficiary attends 3 sessions within a 3-month core maintenance session interval but does not achieve or maintain the required minimum weight loss at least once within the 3-month core maintenance session interval; *or*

MDPP Services	MDPP Beneficiary Eligibility for Coverage	MDPP Supplier Must Offer	MDPP Supplier Payment
			• $60 payment if a beneficiary attends 3 sessions *and* achieves or maintain the required minimum weight loss at least once within the 3-month core maintenance session interval. NOTE: There are two consecutive core maintenance session intervals.
Ongoing Maintenance Sessions (months 13 to 36)	Beneficiary has coverage of ongoing maintenances sessions in the first ongoing maintenance session interval (months 13 to 15 of the MDPP service period if the beneficiary: • Attended at least 1 session during the final core maintenance session interval (months 9 to 12 of the MDPP service period) and had weight measured, and • Achieved or maintained the required minimum weight loss at least once during the final core maintenance session interval (months 10 to 12 of the MDPP services period). A beneficiary has coverage of a subsequent ongoing maintenance session interval (for up to 21 months after the end of the first ongoing maintenance session interval), if the beneficiary: • Attended at least 3 sessions and • Maintained the required minimum weight loss from baseline at least once during the previous ongoing	At least 1 ongoing maintenance session per month for up to 24 months, if the beneficiary maintains eligibility to have coverage of ongoing maintenance sessions.	• $50 payment if a beneficiary attends 3 sessions maintains the required minimum weight loss at least once within the 3-month core maintenance session interval. NOTE: There are up to eight consecutive maintenance session intervals.

MDPP Services	MDPP Beneficiary Eligibility for Coverage	MDPP Supplier Must Offer	MDPP Supplier Payment
	maintenance session interval.		

6. Proposed Policy Changes: Beneficiary Engagement Incentives

a. Definitions Specific to Beneficiary Engagement Incentives

CMS believes that allowing MDPP suppliers to furnish certain in-kind items and services to their MDPP beneficiaries may help suppliers meet the program's goal of engaging beneficiaries to make sustainable, healthy behavior changes that reduce their type 2 diabetes risk.

Furnishing beneficiary engagement incentives would be limited to the core services and ongoing services periods. CMS further specifies that a MDPP supplier may furnish engagement incentives to a MDPP beneficiary only during an "engagement incentive period". CMS defines the "engagement incentive period" as the time during which a MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom that MDPP supplier is furnishing MDPP services. An engagement incentive period would begin when a MDPP supplier furnishes any MDPP service to an MDPP beneficiary. The engagement period would end upon the earliest of the following:

- The beneficiary's MDPP services period ends for any reason,
- The MDPP supplier knows that the MDPP beneficiary will no longer be receiving MDPP services from that MDPP supplier, or
- The MDPP supplier has not had direct contact with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.
    - Direct contact may be either in person, by telephone, or via other telecommunications technology.

b. General Conditions for Beneficiary Engagement Incentives

CMS proposes additional conditions that would apply to MDPP suppliers choosing to furnish items or services as in-kind beneficiary engagement incentives during MDPP beneficiary engagement incentive periods.

- The items and services furnished must not be Medicare-covered items or services.
- The engagement incentive must be directly furnished by a MDPP supplier or by an agent under that supplier's direction and control (e.g., a MDPP lifestyle coach).
- The beneficiary engagement incentive must, within reason, be connected to or necessary for completion of the CDC-approved curriculum being delivered by the supplier to the beneficiary during the MDPP services period. Examples of appropriate incentives would include the following:
    - A gym membership that aids beneficiary participation in physical activity as recommended in the CDC-approved curriculum,

    - On-site child care while the beneficiary attends MDPP sessions, or
    - Digital scales to track and document patient weight.
- The incentive furnished must be a preventive care item or service, or one that engages the beneficiary in better health self-management while advancing progress toward achievement of one or more MDPP program clinical goals.
    - An incentive cannot be offered solely as a reward for achieving a specific outcome (e.g., weight loss, session attendance); the incentive must meet all conditions and requirements as well as support continued beneficiary progress towards one or more program goals.
- An incentive must not be tied to the receipt of items or services outside of MDPP services or to the receipt of items or services from a particular MDPP provider, supplier, or coach.
- In general, engagement incentives must not be advertised or promoted to beneficiaries. However, during an engagement incentive period, a MDPP beneficiary may be made aware of incentive items or services once the beneficiary reasonably could be expected to benefit from the incentive.
- The cost of any beneficiary engagement incentive is the sole responsibility of the MDPP supplier, and the cost of an incentive item or service must not be shifted to another federal health care program.[18]

c. Technology Furnished to a MDPP Beneficiary

CMS expresses heightened concern about misuse and abuse of beneficiary engagement incentives involving technology (e.g., a multi-function fitness tracking watch) and proposes enhanced safeguards for these items and services. In addition to meeting the previously described general conditions, CMS proposes that technology-based incentives must satisfy special stipulations as follows:

- Technology-based incentives must be the minimum needed for advancing one or more MDPP program goals.
- An item or service involving technology whose retail value exceeds $100 would remain the property of the furnishing MDPP supplier and be retrieved from the beneficiary when the engagement incentive period ends. Beneficiaries may retain less expensive items.
    - The MDPP supplier must document all retrieval attempts. Diligent, good faith retrieval attempts, even if unsuccessful, would satisfy the retrieval requirement if properly documented.
- In aggregate, technology-based incentives for any one MDPP beneficiary may not exceed a retail value of $1000 or more.
    - When a single MDPP beneficiary starts and ends multiple engagement incentive periods with the same MDPP supplier, the $1,000 limit does <u>not</u> reset at the beginning of each new incentive period.
    - When a single MDPP beneficiary switches to a new supplier, the new supplier is not obligated to identify incentives furnished previously to that beneficiary. The full $1,000 limit is reset for the new supplier, coincident with the start of the new beneficiary engagement incentive period.

[18] Federal health care program as defined at section 1128B(f) of the Act.

d. Clinical Goals of the MDPP

The overarching goal of the MDPP program is focused on preventing type 2 diabetes through sustained weight loss by Medicare beneficiaries identified to have prediabetes. Items and services furnished as beneficiary engagement incentives, therefore, should support program goals and healthy behaviors. CMS proposes the following as MDPP clinical goals suitable for advancement using beneficiary engagement incentives:

- Beneficiary attendance during the MDPP services period (i.e., core, core maintenance, ongoing maintenance sessions),
- Beneficiary weight loss,
- Long-term dietary change, and
- Beneficiary adherence to long-term health behavior changes.

CMS notes that long-term multiple free meals or meal replacement services furnished by MDPP suppliers would not be considered appropriate beneficiary engagement incentives.

e. Documentation of Beneficiary Engagement Incentives

CMS proposes specific documentation requirements to serve as program safeguards for MDPP suppliers who choose to furnish beneficiary engagement incentives.

1. Each item or service exceeding $25 in retail value must be individually documented. Beneficiary name, supplier name, item or service description, and item or service retail value must be recorded.
2. Documentation must be contemporaneous with the incentive provision and must demonstrate that the incentive was furnished to the beneficiary during the engagement incentive period. When items or services are provided for ongoing beneficiary use (including those involving technology that exceed $100 in retail value), the documentation must establish that an engagement incentive period was in progress for as long as the beneficiary possessed or had access to the item or service.
3. For items or services subject to retrieval by the MDPP supplier (technology-based, retail value over $100), all attempts by the supplier to retrieve the item or service from the beneficiary require contemporaneous documentation.
4. Documentation relating to beneficiary engagement incentives must be retained and accessible in accordance with regulations proposed at §424.205(g) (includes retention for 10 years from date of final MDPP service, or following audit, whichever is later).

f. Compliance with Fraud and Abuse Laws

CMS notes that some arrangements between MDPP suppliers and beneficiaries may implicate the CMP law or the federal anti-kickback statute.[19] Existing safe harbors and exceptions may be used in structuring compliant arrangements. The Secretary will consider whether fraud and

[19] Sections 1128(A)(a))5), (b)(1), and (b)(2) of the Act and section 1128B(b)(1) and (2) of the Act, respectively.

abuse law waivers are necessary for the MDPP expanded model. Waivers would be promulgated by OIG separately from the current proposed rule.

7. Virtual DPP and the MDPP

CMS proposes that the MDPP would not include virtual DPP services, other than a limited number of virtual make-up sessions (see discussion above section K.3). CMS refers to any modality or method of furnishing MDPP services that is not in-person as virtual DPP.

8. 2018 PFS Impact Discussion

The most widespread specialty impacts of the RVU changes are generally related to proposed 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, physical and occupational therapists, and radiation oncology, would see increases relative to other physician specialties. CMS attributes these changes to proposed increase in value for particular services, changes in how CMS allocates indirect practice expense RVUs for office-based services, and updated professional liability premium data. Other specialties, including diagnostic testing facilities, allergy/immunology, otolaryngology, oral/maxillofacial surgery, and independent laboratories, 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.

Column F of Table 40 shows the estimated 2018 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. These impacts range from an increase of 3 percent for clinical social worker, increase of 2 percent for clinical psychologist, to a decrease of 6 percent for diagnostic testing facility and a decrease of 3 percent for allergy/immunology.

TABLE 40: 2018 PFS Proposed Rule 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	$92,628	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	$245	0%	-3%	0%	-3%
ANESTHESIOLOGY	$2,009	-1%	0%	0%	0%
AUDIOLOGIST	$66	0%	0%	-1%	-1%
CARDIAC SURGERY	$311	0%	0%	-1%	-2%
CARDIOLOGY	$6,671	0%	-1%	-1%	-2%
CHIROPRACTOR	$772	0%	1%	0%	1%
CLINICAL PSYCHOLOGIST	$756	0%	2%	0%	2%
CLINICAL SOCIAL WORKER	$664	0%	3%	0%	3%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
COLON AND RECTAL SURGERY	$166	0%	0%	-1%	-1%
CRITICAL CARE	$332	0%	0%	0%	0%
DERMATOLOGY	$3,475	0%	0%	-1%	-1%
DIAGNOSTIC TESTING FACILITY	$765	0%	-6%	0%	-6%
EMERGENCY MEDICINE	$3,176	0%	0%	-1%	-1%
ENDOCRINOLOGY	$477	0%	0%	0%	0%
FAMILY PRACTICE	$6,307	0%	0%	0%	0%
GASTROENTEROLOGY	$1,792	0%	0%	-1%	-1%
GENERAL PRACTICE	$452	0%	0%	0%	0%
GENERAL SURGERY	$2,154	0%	0%	0%	-1%
GERIATRICS	$211	0%	0%	0%	1%
HAND SURGERY	$200	0%	0%	0%	1%
HEMATOLOGY/ONCOLOGY	$1,802	0%	0%	0%	0%
INDEPENDENT LABORATORY	$684	0%	-1%	0%	-2%
INFECTIOUS DISEASE	$651	0%	0%	1%	1%
INTERNAL MEDICINE	$11,022	0%	0%	0%	0%
INTERVENTIONAL PAIN MGMT	$830	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$357	0%	-1%	0%	-1%
MULTISPECIALTY CLINIC/OTHER PHYS	$139	0%	0%	0%	0%
NEPHROLOGY	$2,257	0%	0%	0%	0%
NEUROLOGY	$1,545	0%	0%	0%	0%
NEUROSURGERY	$805	0%	0%	-1%	-1%
NUCLEAR MEDICINE	$50	0%	0%	0%	0%
NURSE ANES / ANES ASST	$1,238	-1%	0%	1%	-1%
NURSE PRACTITIONER	$3,541	0%	0%	0%	0%
OBSTETRICS/GYNECOLOGY	$658	0%	0%	-1%	-1%
OPHTHALMOLOGY	$5,480	0%	0%	0%	0%
OPTOMETRY	$1,259	0%	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	$57	0%	-2%	0%	-2%
ORTHOPEDIC SURGERY	$3,784	0%	0%	0%	0%
OTHER	$28	0%	0%	0%	0%
OTOLARNGOLOGY	$1,232	0%	-1%	0%	-2%
PATHOLOGY	$1,147	0%	0%	0%	-1%
PEDIATRICS	$63	0%	0%	0%	0%
PHYSICAL MEDICINE	$1,105	0%	0%	0%	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**
PHYSICAL/OCCUPATIONAL THERAPY	$3,780	1%	1%	0%	1%
PHYSICIAN ASSISTANT	$2,232	0%	0%	0%	0%
PLASTIC SURGERY	$379	0%	0%	0%	0%
PODIATRY	$1,973	0%	1%	1%	1%
PORTABLE X-RAY SUPPLIER	$100	0%	-1%	0%	-1%
PSYCHIATRY	$1,233	0%	1%	0%	1%
PULMONARY DISEASE	$1,753	0%	0%	0%	0%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	$1,784	0%	1%	1%	1%
RADIOLOGY	$4,863	0%	-1%	0%	-1%
RHEUMATOLOGY	$553	0%	0%	0%	0%
THORACIC SURGERY	$356	0%	0%	-1%	-1%
UROLOGY	$1,772	0%	-1%	0%	-1%
VASCULAR SURGERY	$1,115	0%	-1%	0%	-2%

** 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 40:

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

7. 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.

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

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

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

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

Appendix I.

In the final rule published June 23, 2016 (81 FR 41036), CMS implemented the requirements of section 1834A of the Act, which required extensive revisions to Medicare payment, coding, and coverage for clinical diagnostic laboratory tests paid under the CLFS. Under the CLFS final rule, reporting entities are required to report to CMS certain applicable information for their component applicable laboratories. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported during a data reporting period.

CMS established the first data collection period as January 1, 2016 through June 30, 2016. The first data reporting period was January 1, 2017 through March 31, 2017. Based on industry feedback on March 30, 2017, CMS announced that it would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the CLFS and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information.

- Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity and/or any problems the reporting entity experienced with submitting applicable information to us.

- Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.

- Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.

- Did the applicable laboratory (or its reporting entity) use the sub regulatory guidance on data reporting provided on the CMS CLFS website?[20] If so, was the information presented useful?

- Was the information that the applicable laboratory required to report readily available in the applicable laboratory's record systems?

- Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?

[20] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

- If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?

- How much time (hours) was required to assemble and report applicable information to CMS?

- Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?

Appendix II.

In the 2016 PFS final rule, CMS finalized a proposal to amend the regulation text at §414.904(j) to make clear that the payment amount for a biosimilar biological product is based on the average sales price (ASP) of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code (80 FR 71096 through 71101). Beginning on January 1, 2016 products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products.

CMS is interested in assessing the effects of the Medicare payment policy on the biosimilar biological product marketplace, particularly if the policy is fostering a robust, and competitive marketplace and encouraging innovation. CMS is also interested in better understanding if and how the innate differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars. CMS requests comments on how the Medicare payment policy relates to biosimilars that are licensed for fewer than all the indications for which the reference product is licensed or situations where different biosimilars may be licensed for different subsets of indications for which the reference product is licensed.

- New or updated information of the effects of the current biosimilar payment policy that is based on experience with the US marketplace including material, such as market analyses or research articles that provide data insight into the current economics of the market. CMS notes this includes patient, plan, and manufacturer data both domestic and, where applicable, from European markets, that may provide insights for the US market.

- Data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending.

- Comments regarding other novel payment policies that would foster competition, increase access, and drive cost savings in the market. These solutions may include legislation, demonstrations, and administrative options.

CMS notes it is seeking comments for future consideration and is not making a proposal to change the existing payment policy in this proposed rule.