

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P]

Summary of Proposed Rule

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I. Introduction and Background

On July 7, 2016, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2017¹ and other revisions to Medicare Part B policies. The proposed rule is slated for publication in the July 15, 2016 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2017. **The 60-day comment period ends at close of business on September 6, 2016.**

The proposed rule would update the PFS payment policies that apply to services furnished by physicians and other practitioners in all sites of services. In the proposed rule includes new payment policies for services provided to patients with multiple chromic conditions, mental and behavioral health issues, cognitive impairment, and mobility-related disabilities. The proposed rule also includes proposals related to the Medicare Shared Savings Program and release of pricing data submitted to CMS by Medicare Advantage (MA) organization and medical loss ratio (MLR) reports submitted by MA plans and Part D plans.

The **CF for 2017 is \$35.7751.** Tables 41 from the proposed rule, is reproduced below showing the calculation of the updated conversion factor.

TABLE 41: Calculation of the Proposed 2017 PFS Conversion Factor

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Conversion Factor in effect in 2016		\$35.8043			
Update Factor	0.50 percent (1.0050)				
2017 RVU Budget Neutrality Adjustment	-0.51 percent (0.9949)				
2017 Target Recapture Amount	0 percent (1.0000)				
2017 Imaging MPPR Adjustment	-0.07 percent (0.9993)				
2017 Conversion Factor		\$35.7751			

Specialty specific impacts are shown in the table in Appendix I.

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

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

II. Provisions of the Proposed Rule for PFS

A. Medicare Telehealth Services

CMS proposes to add the following CPT and HCPCS codes in CY 2017 because they believe these services are sufficiently similar to services currently on the telehealth services list (this is known as qualifying on a category 1 basis):

- ESRD-related services (CPT codes 90967-90970). These four codes describe ESRD-related services for dialysis for less than a full month of service, per day, broken down into four age groups: < 2 years, 2-11 years, 12-19 years and ≥ 20 years.
 - o The required clinical examination of the catheter access site must be furnished face-to-face "hands on"
- Advanced care planning services (CPT codes 99497-99498). These two codes describe the first 30 minutes and each additional 30 minutes, respectively, during which a qualified health care professional explains and discusses advance directives with the patient, family member(s), or surrogate; advance directive form completion time is included if performed during the encounter.
- Critical care (CPT codes 99291 and 99292). CMS proposes to add to the telehealth list for 2017 two new codes for initial and subsequent critical care consultations furnished via telehealth. CMS proposes that these services be limited to once per day per patient and that they be valued by comparisons to other E/M services. Additional information about these new codes (GTTT1 and GTTT2) can be found later in the section of this summary addressing specific new code valuation proposals for 2017.

CMS is not proposing to add the following services:

- Observation care (CPT codes 99217-20; 99224-26; 99234-36).
- Emergency Department (ED) Visits (CPT codes 99281-99285).
- Psychological Testing (CPT codes 96101-2, 96118-9).
- Physical and Occupational Therapy and Speech-Language Pathology Services (CPT codes 95207-08; 92521-24; 92526; 92610; 97001-04; 97110, 97112, 97116; 97532, 97533, 97535, 97537; 97542; 97550; 97555; 97660-02).

B. Potentially Misvalued Services Under the Physician Fee Schedule

- 2. CY 2017 Identification and Review of Potentially Misvalued Services
- a. 0-day Global Services that are Typically Billed with an Evaluation and Management (E/M) Service with Modifier 25

Routine E/M services are included in the valuation of codes with global periods. Medicare only makes a separate payment for E/M services that are provided in excess of services included in the global period. Modifier 25 allows physicians to be paid for E/M services that would otherwise be denied as a bundled service.

A review of Medicare claims data for 2015 showed that 19 percent of the codes that describe 0-day global services were billed over 50 percent of the time with an E/M service with Modifier 25. Since a routine E/M service is included in the RVU valuation of 0-day global services, CMS believes this billing pattern may indicate a possible problem with the valuation of the 0-day global services, which includes all the routine care associated with the service.

To develop a proposed list of potentially misvalued services that are 0-day global codes, CMS identified 0-day global codes billed with an E/M service 50 percent of the time or more, on the same day of the service, with the same physician and the same beneficiary. CMS reviewed this list and identified 83 codes that have not been reviewed in the last 5 years and have greater than 200,000 services. For 2017, CMS proposes these 83 codes as potentially misvalued (see Table 7 from the proposed rule included in Appendix II).

b. End-Stage Renal Disease (ESRD) Home Dialysis Services (CPT codes 90963-90970)

A 2015 GAO report² examined utilization of home dialysis and concluded that based on information from experts and stakeholders a realistic target for home dialysis would be 25 percent of dialysis patients. The report noted that as of March 2015, approximately 10 percent of adult Medicare dialysis patients used home dialysis. The GAO recommended that CMS examine Medicare policies for monthly payments to physicians managing the care of home dialysis patients and revise them if necessary to ensure the policies are consistent with encouraging appropriate use of home dialysis.

CMS agrees with the GAO recommendation and is proposing to identify CPT codes 90963 through 90970 as potentially misvalued codes based on the volume of claims submitted for these services as compared to those submitted for facility based ESRD services.

c. Direct PE Input Discrepancies

1. Appropriate Direct PE Inputs Involved in Procedures Involving Endoscopes
In response to stakeholders concerns about potential inconsistencies with the inputs and the prices related to endoscopic procedures in the direct PE database, CMS reviewed this issue and identified 45 different pieces of endoscopic related-equipment and 25 different pieces of endoscopic related-supplies associated with endoscopies. As compared to other kinds of equipment items in the direct PE input, CMS states this unusual degree of variation is likely to result in code misevaluation.

² End-Stage Renal Disease Medicare: Payment Refinements Could Promote Increased Use of Home Dialysis. (GAO-16-125). Washington DC: US Government Accountability Office, 2015. http://www.gao.gov/products/GAO-16-125.

2. <u>Appropriate Direct PE Inputs in the Facility Post-Service Period When Post-Operative Visits are Excluded</u>

CMS identified a potential inconsistency for 13 codes that have direct PE inputs included in the facility post service period even though the post-operative visit are not included in the service (see Table 8 in Appendix III). CMS notes that it does not know if this discrepancy is caused by inaccurate direct PE inputs or inaccurate post-operative data in the work time file.

d. Insertion and Removal of Drug Delivery Implants (CPT codes 11981 and 11983)

In response to stakeholders request for CMS to create new codes for the insertion and removal of drug delivery implants for buprenorphine hydrochloride, CMS identified existing drug delivery implant CPT codes 11981and 11982 as potentially misvalued

3. <u>Valuing Services that Include Moderate Sedation as an Inherent Part of Furnishing the Procedure</u>

The CPT manual identifies more than 400 diagnostic and therapeutic procedures (listed in Appendix G) that have moderate sedation as an inherent part of providing the procedure. CMS has raised concerns that for many endoscopic procedures, anesthesia was increasing being separately reported and that the resources associated with sedation were no longer an inherent part of the procedure. For the 2017 CPT Manual, the CPT Editorial panel created CPT codes for separately reporting moderate sedation services in association with the elimination of Appendix G codes. The RUC also provided a recommended methodology to remove work RVUs for moderate sedation from the Appendix G codes and also recommended values for separately provided moderate sedation (not provided by the physician providing the procedure).

CMS is concerned that based on the RUC recommendations, the overall resource costs for the procedure with sedation are higher when moderate sedation is not included in the payment for the procedure. CMS states that the overall resource costs of these services should be the same as the current resource assumptions for these procedures when the same provider or a different provider furnishes moderate sedation and that the current resources should be redistributed instead of increased

4. Collecting Data on Resources Used in Furnishing Global Services

b. Data Collection Required to Accurately Value Global Packages

CMS discusses the need to have objective data on all of the resources used to furnish the services that are included in the global surgical packages. Although CMS believes that most of the services furnished in the global period are visits for follow-up care, it lacks accurate information available on the number and level of visits typically furnished because providers billing for global services are not required to submit claims for post-operative visits. CMS also states there isn't any information that supports the assumption that the resources, including work, used in providing pre- and post-operative visits are similar to those used in providing E/M visits. Another concern that CMS raises about the follow-up visits included in the global period is the difference in the indirect PE inputs; calculating payments for follow-up visits within the global

are based on the specialty mix of the physicians furnishing the global service and not the specialty mix of the physicians furnishing E/M services which result in a different valuation for the E/M services included in global packages than for separately billable E/M services.

As discussed below, CMS proposes a three-pronged approach to collect timely, accurate and comprehensive data on the frequency of, and the inputs involved in furnishing global services including the procedure and the pre-operative visits, the post-operative visits, and other services for which payment is included in the global surgical payment. The approach would include:

- Comprehensive claims-based reporting about the number and level of pre-and post-operative visits furnished for 10- and 90-day global services.
- A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time.
- A more in-depth study, including direct observation of the pre-and post-operative care delivered in a small number of sites, including some ACOs.

2. Claims-based Data Collection

As discussed below, CMS proposes a claims-based data collection for all 10-and 90-day global services furnished on or after January 1, 2017.

a. Information to be Reported. CMS discusses the various recommendations it received for the collection of information. The most frequent recommended approach was for practitioners to report the CPT code 99024 for follow-up visits included in the surgical package (Postoperative follow-up visit, normally included in the surgical package) coupled with modifiers to provide both the number of and level of visits.

CMS modified the RAND contract to include the development of G-codes that could be used to collect data about follow-up visits. They recommended a set of time-based (per10 minutes), post-operative visit codes that are distinguished by the setting of care and whether they are furnished by a physician/NPP or clinical staff.

CMS proposes the codes listed in Table 9 (copied below) for reporting on claims the services actually furnished. No separate payment would be made for these codes.

Table 9: Proposed Global Service Codes

		<u> </u>
	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package
Inpatient	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package
	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical
		package
	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included
Office or		in surgical package
Other	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in
Outpatient		surgical package
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in
		surgical package
	GXXX7	Patient interactions via electronic means by physician/NPP, per 10
		minutes, included in the surgical package

Via Phone or	GXXX8	Patient interactions via electronic means by physician/NPP, per 10
Internet		minutes, included in the surgical package

(i) Coding for Inpatient Global Service Visits

CMS proposes three codes for reporting inpatient pre- and post-operative visits that distinguish the intensity involved in furnishing the services, referred to as typical, complex, and critical illness. The activities listed in Table 10 (copied below) are the activities that RAND recommended to be reported as involved in a typical visit. A typical visit could involve any combination or number of these services.

Table 10: Activities Included in Typical Visit (GXXX1 & GXXX5)

Review vital, laboratory or pathology results, imaging, progress notes
Take interim patient history and evaluate post-operative progress
Assess bowel function
Conduct patient exam with a specific focus on incisions and wounds, post-surgical pain,
complications, fluid and diet intake
Manage medications (for example, wean pain medications)
Remove stitches, sutures, and staples
Change dressings
Counsel patient and family in person or via phone
Write progress notes, post-operative orders, prescriptions, and discharge summary
Contact/coordinate care with referring physician or other clinical staff
Complete forms or other paperwork

CMS discusses the use of GXXX2 to report inpatient pre- and post-operative visits that are more complex than the typical visit and the need to have documentation that indicates what services were provided that exceeded those included in a typical visit. Examples of when this code might be used include primary management of a complex patient with numerous comorbidities or a high likelihood of or death.

CMS states that GXXX3 would be reported when the physician is providing primary management of the patient at a level of care that would be reported using critical care codes if the service occurred outside the global period.

(ii) Coding for Office and Other Outpatient Global Services Visits

CMS proposes three codes for reporting post-operative visits in the office or other outpatient settings. CMS also proposes that the time for these codes would be defined as the face-to-face time with the patient, the same rules for time-based outpatient codes. CMS notes that even though the codes for both inpatient and outpatient settings use the same time increment, the services differ by setting, which is consistent with the existing E/M codes.

CMS proposes that GXXX5 would be used for visits involving any combination of activities listed in Table 10. RAND reports that the vast majority of office or other outpatient visits would be expected to be reported using GXXX5. Consistent with the inpatient codes, CMS notes that they expect GXXX6, the complex visit code, to be used infrequently and documentation indicating the services provided beyond the typical activities would be necessary. CMS provides

examples of when this code might be used including management or discussion of a complex diagnosis such as a new cancer diagnosis.

(iii) Coding for Services Furnished via Electronic Means

CMS proposes that GXXX7 and GXXX8 would be used to report non-face-to-face services that are provided outside the context of a face-to-face visit. CMS also proposes that practitioner would not report these services if they are furnished the day before, the day of, or the day after a visit because these would be included in the pre-and post-service activities in the typical visit. CMS notes that these requirements to report on clinical labor time are consistent with the need to report clinical labor time associated with chronic care management service.

For services that meet the requirements of a Medicare telehealth service visit, CMS proposes the appropriate global service G-code would be reported with the GT modifier indicating the service was furnished "via interactive audio and video telecommunications systems."

(v) Alternative Approach to Coding

CMS again acknowledges that many stakeholders expressed strong support for the use of CPT code 99024, including the option of using the code with modifiers to indicate the level of the visit. CMS seeks comments about the following issues related to using CPT code 99024:

- How the code could be used to capture the statutorily required data on the number and level of visits and the data that would be needed to value global services in the future?
- Why practitioners would find it easier to report CPT code 99024 with modifiers corresponding to the proposed G-code levels rather than reporting the new proposed Gcodes?
- Would practitioners find it difficult to use the proposed G-codes for pre-operative visits?
- Can the time of a visit be a proxy for the level of the visit? CMS seeks comments on the whether the reporting of CPT code 99024 in 10-minute increments could be used to collect claims based data on the number and level of visits.

b. Reporting of Claims. CMS proposes that the proposed G-codes would be reported for all services related to and within the 10- and 90-day global periods for procedures furnished on or after January 1, 2017. CMS does not propose any special reporting requirements; the codes could be reported on a rolling basis as they are furnished or they could be reported on one claim after all the services have been furnished, as long as they requirements for filing claims are met. CMS expects documentation in the patient's medical record to include a visit occurred and sufficient information to determine that the appropriate G-code was reported.

d. Who Reports. CMS proposes that <u>any practitioner</u> who furnishes a procedure that is a 10- or 90-day global report the pre- and post-operative services furnished on a claim using the proposed G-codes. CMS notes that the proposed reporting would require submission of additional claims but it believes that the benefits of accurate data for valuation of global services merit the imposition of this requirement.

3. Survey of Participants

In addition to the claims-based reporting, CMS proposes to survey a large, representative sample of practitioners and their clinical staff to obtain information about approximately 20 discrete pre-

operative and post-operative visits and other global services such as care coordination and patient training.

CMS proposes to develop a sampling approach that would be a random sample of providers who billed Medicare for more than a minimum threshold of surgical procedures (e.g. 200 procedures) in the most recent available prior year of claims data.

4. Required Participation in Data Collection

CMS proposes to require all practitioners who furnish a 10- or 90-day global service to submit claims information on all services furnished within the relevant global service period, beginning with surgical or procedural services furnished on or after January 1, 2017. CMS is also proposing to require participation by practitioners selected for the proposed broad-based survey.

Section 1848(a)(9) of the Act authorizes the Secretary to withhold payment of up to 5 percent of the payment for services on which the practitioner is required to report until the practitioner has completed the required reporting. CMS is not proposing to implement this option but if compliance with required claims-based reporting is not acceptable, CMS states it would consider in future rulemaking imposing up to a 5 percent payment withhold.

C. Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

1. Non-Face-to-Face Prolonged E/M Services (CPT codes 99358 and 99359)

CMS proposes to recognize the two CPT codes for non-face-to-face prolonged E/M services (CPT codes 99358, first hour and 99359, each additional 30 minutes) for separate payment under the PFS. CMS notes that these codes are broadly described but only include time spent personally by the physician or other billing practitioner and have a relatively high time threshold since the time counted must be beyond the usual service time for the companion E/M code that is also billed.

CMS also proposes to require the services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. CMS notes that the CPT guidance for codes 99358 and 99359 indicates that these codes should not be reported during the same period as complex CCM services (CPT codes 99487 and 99488) or transitional care management (TCM) services (CPT codes 99495 and 99496) and acknowledges this might be due to overlap of the substantial non-face-to-face work provided in these code sets.

2. Establishing Separate Payment for Behavioral Health Integration (BHI)

As discussed below, CMS is proposing four G-codes for care management for Medicare beneficiaries with behavioral health conditions, a practice known as behavioral health integration (BHI). CMS notes that the time spent by the treating physician or other qualified health care professional on activities for services reported separately may not be included in the services reported for the proposed G-codes. Similarly, time spent by the behavioral health care manager on activities reported separately may not be included in these proposed services. The services

provided by the psychiatric consultant may be reported separately but this time cannot be included in the proposed codes.

a. General Behavioral Health Integration (BHI) (GPPPX)

CMS proposes to make payment for care management for beneficiaries diagnosed with behavioral health conditions for the broadly defined application of integration in the primary care setting. The proposed code is:

• GPPPX: Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month.

b. Psychiatric Collaborative Care Management (GPPP1, GPPP2, and GPPP3)

CMS proposes to require an initiating visit for psychiatric collaborative care management, GPP1, (both for the psychiatric CoCM model and other BHI models of care). The proposed initiating and subsequent codes are summarized below.

- GPP1: Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health professional with described required elements.
- GPP2: Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health professional with described required elements.
- GPP3: Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health professional (List separately in addition to code for primary procedure) (Use GPPP3 in conjunction with GPPP1 and GPPP2).

The proposed rule lists the required services provided in each proposed G-code.

CMS states the initiating visit would establish the beneficiary's relationship with the billing practitioner, ensures the billing treating physician or other qualified health care professional assesses the patient prior to initiating other care management processes, and provides an opportunity to obtain beneficiary consent (discussed below).

c. Beneficiary Consent

CMS proposes a *general beneficiary consent* to consult with relevant specialists prior to initiating these services, recognizing that applicable rules regarding privacy continue to apply. The general consent would encompass conferring with a psychiatric consultant. Similar to the proposed beneficiary consent process for CCM services (discussed below), CMS proposes that the billing practitioner must document in the medial record that the beneficiary's consent was obtained to consult with a relevant specialist, including a psychiatric consultant, and that the beneficiary is informed that there is beneficiary cost-sharing, including potential deductible and

coinsurance, for both in-person and non-face-to-face services that are provided. CMS says it lacks statutory authority to waive the coinsurance for these services.

CMS does not believe it would be reasonable for multiple providers to be reporting these codes for the same beneficiary during the same month but it is not proposing a formal limit on these codes.

3. Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services

CMS is proposing to recognize and reimburse for additional CPT codes for complex CCM:

- CPT code 99487: Complex care management services, with described required elements, including 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month and
- CPT code 99489: Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

Consistent with the complete definitions of these codes, less than 60 minutes of clinical staff time could not be reported with CPT code 99487 and similarly, less than 30 minutes in addition to the first 60 minutes of complex CCM in a service period could not be reported.

CMS proposes that CPT codes 99487, 99489, and 99490 may only be reported once per service period (calendar month). A beneficiary can receive either a complex or non-complex CCM service during a given calendar month and only one practitioner can be reimbursed for CCM services for a given calendar month. CMS also proposes to require the same CCM service elements for all CCM codes. *Table 11 in the proposed rule* (see Appendix IV) *summarizes the service elements and payment rules for CCM, including the current requirements and the proposed revisions (discussed below).*

a. Initial Visit

CMS requires that CCM must be initiated by the billing practitioner during a "comprehensive" E/M visit, annual wellness visit (AWV) or initial physical exam (IPPE). Level 2 through 5 E/M visits (CPT codes 99212 through 99215) and the face-to-face visit included in TCM services (CPT codes 99495 and 99496) qualify as the "comprehensive" visits for CCM initiation.

CMS continues to believe that an initiating face-to-face visit is appropriate before initiating CCM, but is proposing to require the initiating visit only for new patients or patients not seen within one year instead of requiring the initiating visit for all beneficiaries receiving CCM services.

CMS is also proposing to create a new add-on G code that would be billable for beneficiaries who require extensive face-to-face assessment for care planning by the billing practitioner (as opposed to the clinical staff):

• GPPP7: Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring CCM services (billed separately

from monthly management services) (Add-on code, list separately in addition to primary service).

CMS proposes that when the billing practitioner initiating CCM *personally* performs extensive assessment and care planning outside of the usual effort described by the billed E/M code (or AWV or IPPE), the practitioner could bill GPPP7.

b. 24/7 Access to Care and Continuity of Care

CMS proposes several revisions to both the 24/7 Access to Care and the Continuity of Care service elements to both accommodate a range of potential care models and to reduce the administrative complexity of the current payment rules.

CMS proposes to adopt the CPT language to describe the service elements for 24/7 Access to Care and Continuity of Care. For 24/7 Access to Care, the scope of the service would be to provide 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 the week. CMS notes that the CPT language more accurately reflects the potential role of clinical staff or call-sharing in addressing after-hour care. CMS also proposes to remove the requirement that the individuals providing CCM after hours must have access to the electronic health plan.

For Continuity of Care, the CPT language references successive routine appointments "with a designated member of the care team" and does not make specific reference to requiring the appointment with the billing practitioner. As the billing practitioner is a member of the CCM care team, CMS proposes to adopt the CPT language.

c. Electronic Care Plan

CMS proposes to change the CCM service element to require timely electronic sharing of care plan information within and outside the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.

d. Clinical Summaries

The CCM scope of service element, Management of Care Transitions, requires the creation and electronic transmission and exchange of continuity of care documents referred to as "clinical summaries." As a condition of payment for CCM services, CMS requires standardized content for clinical summaries. The rule proposes to require the billing practitioner to create and exchange/transmit continuity of care document(s) timely with other practitioners.

e. Beneficiary Receipt of Care Plan

CMS proposes to simplify the requirement to provide the beneficiary with a written or electronic care plan and proposes adopting the CPT language which requires that a copy of the care plan must be given to the patient or the caregiver. CMS does not believe it is necessary to specify the

format of the care plan and recognizes that there may be times that sharing the care plan with a caregiver may be appropriate.

f. Beneficiary Consent

CMS proposes to continue to require billing practitioners to inform the beneficiary of the currently required information. However, instead of requiring a written agreement, CMS proposes that the practitioner be allowed to document in the medical record that the information was explained and note whether the beneficiary accepted or declined CCM services.

CMS also proposes to remove the language requiring beneficiary authorization for the electronic communication of their medical information as a condition of payment for CCM services.

g. Documentation

CMS proposes to no longer require the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits. CMS would continue to require documentation in the medical record that the communication occurred.

4. CCM Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

CMS is proposing revisions for CCM services furnished by RHCs and FQHCs similar to the proposals discussed above. Specifically, CMS proposes to:

- Require that CCM be initiated during an AWV, IPPE, or comprehensive E/M visit only for new patients or patients not seen within one year.
- Require 24/7 access to a RHC or GQHC practitioner or auxiliary staff with a means to
 make contact with a RHC or FQHC practitioner to address urgent health needs regardless
 of the time of day or day of week. This proposal would no longer require the health care
 practitioners in the RHC or FQHC to have 24/7 access to the patient's electronic care
 plan.
- Require timely electronic sharing of care plan information within and outside the RHC or FQHC, but not necessarily on a 24/7 basis and allow transmission of the care plan by fax.
- Require that in managing care transmissions, the RHC or FQHC transmit continuity of care documents in a timely manner with other providers. This proposal would no longer require a standard format for the documentation and transmission of the information.
- Require that a copy of the care plan be given to the patient or caregiver.
- Require that the RHC or FQHC practitioner document in the medical record that all elements of beneficiary consistent were provided, and whether the beneficiary accepted or declined CCM services.
- Require that communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits be documented in the medical record.

CMS notes it is not proposing an additional payment adjustment for patients who require extensive assessment and care planning as part of the initiating visit, because payments for RHC and FQHC services are not adjusted for length or complexity of the visit.

5. Assessment and Care Planning for Patients with Cognitive Impairment

CMS proposes a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment:

• GPPP6: Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home.

CMS proposes the following as required service elements of GPPP6:

- Cognition-focused evaluation including a pertinent history and examination.
- Medical decision making of moderate or high complexity (defined by the E/M guidelines).
- Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity.
- Use of standardized instruments to stage dementia.
- Medication reconciliation and review for high-risk medications, if applicable.
- Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized instrument(s).
- Evaluation of safety (for example, home), including motor vehicle operation, if applicable.
- Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks.
- Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference.
- Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed; care plan shared with the patient and/or caregiver with initial education and support.

CMS discusses that the proposed valuation of GPPP6 (discussed in section II.L in this summary) assumes that this code would include services that are personally performed by the physician (or other appropriate billing practitioner) and would significantly overlap with services described by certain E/M visit codes, advance care planning services, and certain psychological or psychiatric service codes that are currently separately payable under the PFS. CMS proposes that GPPP6 could not be billed on the same date of service as the following CPT codes: 90785, 90791, 90792, 96103, 96120, 96127, 99201- 99215, 99324-99337, 99431-99350, 99366-99368, 99497, and 99498. CMS states these codes all reflect face-to-face services provided by the physician or other billing practitioners for related services that are separately payable. In addition, CMS proposes to prohibit billing of GPPP6 with other care planning services.

6. Improving Payment Accuracy for Care of People with Disabilities

CMS proposes a new add-on G-code to describe the additional services furnished in conjunction with E/M services to beneficiaries with disabilities that impair their mobility:

• GDDD1: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient E/M service visit (Add-on code, list separately in addition to primary procedure).

CMS proposes this add-on code could be billed with new and established patient office/outpatient E/M codes and TCM codes when the additional resources described by the codes are medically necessary and used in the provision of care.

7. Supervision for Requirements for Non-face-to-face Care Management Services

CMS notes that many of the codes it is proposing are similar to CCM services in that a critical element of the service is non-face-to-face care management/care coordination services provided by clinical staff when the billing practitioner may not be physically present. Thus, CMS is proposing to amend §410.26(a)(3) and §410.26(b) to better define general supervision and to allow general supervision not only for CCM services and the non-face-to-face portion of TCM services, but also for proposed codes GPPP1, GPPP2, GPPP3, GPPPX, CPT code 99487 and CPT code 99489. Instead of adding each code on an individual basis, CMS proposes to revise the regulation under paragraph §410.26(b)(1) to allow general supervision of the non-face-to-face portion of designated care management services, and it would designate the applicable services through notice and comment.

D. Improving Payment Accuracy for Services: Diabetes Self-Management Training (DSMT)

CMS is concerned about the low utilization of DSMT services and the potential barriers to DSMT access. CMS plans to clarify and provide additional guidance in Chapter 15 of the Medicare Benefit Policy Manual. CMS states that the manual update will clarify where DSMT services can be provided and will include:

- DSMT services furnished by an entity that submits professional claims to the A/B Medicare Administrative Contractor (MAC), such as a physician's office, may also furnish DSMT services at alternate locations used by the entity as a practice location; and
- DSMT services furnished by an entity that is a hospital outpatient department, must furnish these services in the hospital (including a provider-based department) and cannot be furnished at alternate non-hospital locations.

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

Effective for services furnished beginning January 1, 2017, PFS for the technical component (TC) (including the TC of a global service) of imaging services that are X-rays taken using *film* is reduced by 20 percent. The reduction is made prior to any other adjustment under this section.

CMS proposes to establish a new modifier (modifier "XX") to be used on claims. Beginning January 1, 2017, this modifier would be required on claims for X-rays that are taken using film; the modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally.

There is also a 7 percent reduction in payments 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 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 states it will address implementation of this section in future rulemaking.

F. Procedures Subject to the Multiple Procedure Payment Reduction and the OPPS Cap

As way of background, in 2012 CMS implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. The reduction applies when multiple imaging procedures are furnished by the same physician (or physician in the same group practice) to the same patient, in the same session, on the same day. Full payment is made for the PC of the highest priced procedure and payment for the PC of subsequent services is reduced by 25 percent.

The Consolidated Appropriations Act of 2016 revises the payment reduction from 25 percent to 5 percent, effective January 1, 2017 (added to section 1848(b)(10) of the Act). In addition, the statute exempts the reduced expenditures attributable to the revised 5 percent MMPR on the PC of imaging from the PFS budget neutrality provision (added to section 1848(c)(2)(B)(v)(XI) of the Act). CMS proposes to implement these provisions for services furnished on or after January 1, 2017 (section IV of this summary discusses the adjustment necessary to the proposed PFS conversion factor).

The list of imaging services in 2017 that are subject to the MPPR and subject to the OPPS cap (under section 5102(b) of the DRA), are available on the CMS website. See http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.

G. Valuation of Specific Codes

2. Rationales for Specific Code Valuations

CMS provides specific comments about codes for which its work RVU or direct PE inputs vary from RUC recommendations, and for codes for which there are no RUC recommendations (e.g., new G-codes). For 2017, these codes are subdivided into two groups: one with codes having 2016 interim final values plus 2017 proposed values and another with codes having only 2017 proposed values.

a. Codes having 2016 Interim Final Values and 2017 Proposed Values

The affected codes are shown in the table below; the Code Topic numbers correspond to the numbers in the proposed rule. The evolution of the work RVUs and direct PE inputs are somewhat more complicated for these codes because they were first valued with interim final values during 2016, and then valued again for 2017; the table notes help describe their evolution. Readers with a particular interest in any of these codes should review the relevant portion of the proposed rule for code-specific details, which are beyond the scope of this summary. The table below shows for each code topic whether the codes have been identified as potentially misvalued, number of codes impacted by topic, and whether there was a work or direct PE change.

Code(s) Topic (CPT codes)	Potentially Misvalued ?	Number of Codes	RVU Work Change	Direct PE Change?
1. Soft Tissue Localization (10035, 10036)		2		X
2. Repair Flexor Tendon (26356, 26357,26358)		3	X	
3. Transoral Esophagogastric Fundoplasty (43210)		1	X^1	X
4. Percutaneous Biliary Procedure Bundling ² (47531-47544)		14		X
5. Percutaneous Image Guided Sclerotherapy (49185)		1	X^1	X
6. Genitourinary Procedures (50606, 50705, 50706)		3		X
7. Laparoscopic Radical Prostatectomy (55866)		1	X^1	
8. Intracranial Endovascular Interventions (61645,61650,61651)		3	X ¹	X
9. Paravertebral Block Injection (64461-64463)		3	X	
10. Implantation Neuroelectrodes (64553-64555)	X	2		
11. Ocular Reconstruction Transplant (65780)	X	1	X	
12. Laser Trabeculoplasty (65855)	X	1	X^4	
13. Glaucoma Surgery (66170, 66172)	X	2	X^4	

Potentially	Number	RVU	Direct
Misvalued			PE
?	Codes	Change	Change?
		?	
X	4	X^4	
	2	X^4	
	2	X	
	3	X	
	7		X^6
	4	X	
	6	X	
	1		X^7
	Misvalued ? X	Misvalued ? of Codes X 4 2 2 3 7 4 6	Misvalued ? of Codes Change ? Work Change ? X 4 X ⁴ 2 X ⁴ 2 2 X 3 X 7 4 X 6 X 1 1

¹Work RVU is changed from original RUC work RVU, no change from interim final work RVU.

b. Codes having only 2017 Proposed Values

There are 45 code categories discussed in this section. Readers with a particular interest in any of these codes should review the relevant portion of the proposed rule for code-specific details. This summary provides highlights about changes within selected code categories affecting large code subsets, high volume codes, or codes for which CMS discusses potential beneficiary access concerns.

²CMS considered in single combined review.

³CMS deferred changes in work RVU and direct PE input while CPT referral pending.

⁴Work RVU is changed from interim final work RVU, no change from original RUC work RVU.

⁵These are actually gastric emptying studies, see code long descriptors for details.

⁶Direct PE refinements from original, interim final values retained.

⁷Corrected error in CMS Work Time file.

1. <u>Anesthesia Services Furnished in Conjunction with Lower Gastrointestinal (GI)</u> Procedures

Over 50 percent of several colonoscopy codes are reported with separate anesthesia services (00740 and 00810). The RUC recommended maintaining the base unit of 5 RVUs as an interim base value for both codes and expressed significant concern about the specialty society surveys (i.e., survey vignettes did not reflect current typical patients). **CMS agreed with the RUC recommendation but continues to regard these services as potentially misvalued and seeks additional input**.

2. Mammography – Computer-Aided Detection (CAD) Bundling

To comply with statutory requirements, CMS created G-codes and higher payments for digital mammography versus film mammography in 2002. Film mammography and CAD, however, have been reported with CPT codes. The CPT Editorial Panel deleted five mammography codes and created three new codes describing mammography bundled with CAD.

The RUC recommended work RVUs and direct PE inputs for the new codes. CMS believes that the new RUC values are closer to the real resource-based costs of modern mammography. However, CMS also believes that if it were to adopt the RUC recommended work RVUs and direct PE inputs, overall Medicare payment for mammography services would be drastically reduced compared to the mandated G-code payments; the technical component alone could decline by almost 50%. For 2017, CMS proposes only to adopt the RUC recommended work values for these new codes without incorporating the RUC direct PE inputs. Therefore, for 2017, the technical component PE RVUs will be crosswalked to the existing corresponding G-codes. CMS also plans to seek further equipment pricing information to add to the RUC's PE inputs before proposing new PE RVU values at some future date. (Table 17 in the proposed rule lists the recommended equipment items for mammography services.)

3. Evaluative Procedures for Physical Therapy (PT) and Occupational Therapy (OT) For 2017, the CPT Editorial Panel deleted four and created eight codes for PT and OT evaluative services. In response to CMS' nomination of therapy codes as potentially misvalued, a CPT workgroup was formed in 2012 to develop new codes. As a result, there are three new codes, stratified by complexity, to replace a single PT evaluation (CPT code 97001); three new codes, also stratified by complexity, to replace a single OT evaluation (CPT code 97003); and one new code each to replace the reevaulation codes for PT and OT (CPT codes 97002 and 97004. Table 19 in the proposed rule lists the eight new CPT codes for PT and OT services, including the required components of each code.

The HCPAC recommended work RVUs for the six new PT and OT evaluation codes. CMS states that these recommendations are intended to be work neutral relative to the valuation for the previous single evaluation code for PT and OT, respectively. Work neutrality is intended to reflect that despite changes in coding, the overall amount of work RVUs for a set of services is held constant from one year to the next. Work neutrality can only be assessed with an understanding of the relative frequency of how often the particular codes will be reported.

CMS is proposing to adopt the new CPT code series for Medicare in 2017. However, CMS will price each series as a group rather than individually, using authority granted in the Protecting Access to Medicare Act (PAMA). CMS is proposing a work RVU of 1.2 for both the PT and the OT evaluation groups of services.

4. <u>Proposed Valuation of Services Where Moderate Sedation is an Inherent Part of the Procedure and Proposed Valuation of Moderate Sedation Services</u>

For 2017, CMS proposes to accept the RUC work RVUs for the new codes with one exception (991X4), to which it applies an incremental valuation approach. CMS also proposes to adopt the direct PE inputs developed by the RUC for all six new codes. To reflect the distinct service work pattern of GI specialists, CMS proposes a G-code (GMMM1) to report moderate sedation during GI endoscopy when sedation is delivered by the endoscopist, with a work RVU of 0.10. Moderate sedation as described by 991X2 when delivered during services other than GI endoscopy, will be valued at 0.25 RVU. Table 22 in the proposed rule indicates whether GMMM1 should be used in lieu of a CPT moderate sedation code (991XX series) for each combination of moderate sedation with codes that were formerly in Appendix G where moderate sedation was inherent in the service.

The RUC also provided CMS with work RVU recommendations for Appendix G codes from which moderate sedation has been removed, but CMS believes that insufficient work RVUs were removed. CMS instead substitutes work RVUs for the Appendix G codes created by removing 0.25 for non-GI-endoscopy codes and 0.10 for GI endoscopy codes. The CMS proposed work RVUs for Appendix G codes are also shown in Table 22.³ The information in this table will be maintained going forward on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1654-P.html (Moderate Sedation Work Values Table file).

III. Other Provisions of the Proposed Rule

A. FQHC-Specific Market Basket

Proposed 2017 FQHC Market Basket Update Compared to the MEI Update for 2017 Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, the projected proposed FQHC market basket increase factor for 2017 is 1.7 percent. This is based on a 2.1 percent increase of FQHC input prices and a 0.4 percent productivity adjustment. For comparison, the 2006-based MEI is projected to be 1.3 percent in 2017. Table 33 compares the proposed 2013-based FQHC market basket updates and the 2006-based MEI market basket updates for 2017. The 0.4 percentage point difference is mostly from the inclusion of pharmaceuticals in the proposed FQHC market basket; this cost category is not included in the MEI.

CMS estimates that the cost of switching from a MEI-adjusted based payment to a FQHC PPS market basket-adjusted based payment rate would be approximately \$170 million over 10 years

³ Although Table 22 is titled "Proposed Valuations for Endoscopy Services Minus Moderate Sedation", the table actually contains all of the former Appendix G codes, many of which are not GI endoscopy codes.

from 2017-2026. CMS estimates that \$35 million would be paid through beneficiary premiums and the remaining \$135 million would be paid through Part B (Table 44).

B. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

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. The 2016 PFS final rule addressed the first component of the AUC program – specifying applicable AUC.

This rule proposes the requirements and process for specifications of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of clinical priority areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. CMS proposes to announce the first list of qualified CDSMs no later than June 30, 2017 and anticipates that furnishing providers could begin reporting AUC information starting January 1, 2018.

1. Background

Section 1834(q)(4)(B) of the Act requires that information be reported on the claim form indicating whether the imaging service would or would not adhere to the specified AUC consulted through a CDSM, or whether the AUC was not applicable to the service. CMS notes that it does not believe there is one correct approach to communicating this information and acknowledges that some CDSMs provide a scale with numeric ratings, some output a red, yellow or green light, and others provide a dichotomous yes or no.

2. Statutory Authority and Requirements

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 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 <u>first major component</u> – the process for establishment of AUC, along with relevant aspects of the definitions. CMS finalized that an "applicable imaging service" is defined to include 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 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.⁴

The <u>second major component</u> of the AUC program is the identification of qualified CDSMs that could be used by ordering professionals for consultation with applicable AUC. CMS envisions a CDSM for consultation with AUC as an interactive tool that communicates AUC information to the user and that is ideally integrated directly into, or be seamlessly interoperable with, existing health information technology (IT) systems.

The third major component of the AUC program is Consultation with Applicable Appropriate Use Criteria. This 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. 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 <u>fourth component</u> of the AUC program is Identification of Outlier Ordering Professionals. This facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020. CMS does not include proposals to implement these sections in this proposed rule, but does propose a list of priority clinical areas, which may serve as part of the basis for identifying outlier ordering professionals.

3. Proposals for Implementation

CMS proposes to amend its regulations to add a new §414.94, "Appropriate Use Criteria for Certain Imaging Services."

a. Definitions

CMS proposes to define <u>CDSM</u> as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. A CDSM would incorporate specified applicable AUC sets from which an ordering professional could select. A CDSM may be a module within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology. If within or available through certified EHR technology, a qualified CDSM would incorporate patient-specific information into the assessment of the appropriateness of an applicable imaging service.

⁴ 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.

b. Priority Clinical Areas

CMS proposes the top eight clinical groupings, by volume of procedures, as the initial list of priority clinical areas. CMS states that the eight clinical areas account for approximately 40 percent of Part B advanced diagnostic imaging services paid for by Medicare in 2014.

Table 34: Proposed Priority Clinical Areas with Corresponding Claims Data

Table 34. Troposcu Triority Chinesi Areas with Corresponding Chains Data					
Proposed Priority Clinical Area	Total	% Total	Total	% Total	
	Services	Services ¹	Payments	Payments ¹	
Chest Pain (includes angina,	4,435,240	12%	\$470, 395, 545	14%	
suspected myocardial infarction,					
and suspected pulmonary					
embolism)					
Abdominal Pain (any locations and	2,973,331	8%	\$235,424,592	7%	
flank pain)					
Headache, traumatic and non-	2,107,868	6%	\$89,382,087	3%	
traumatic					
Low back pain	1,883,617	5%	\$180,063,352	5%	
Suspected stroke	1,810,514	5%	\$119,574,141	4%	
Altered mental status	1,782,794	5%	\$83,296,007	3%	
Cancer of the lung (primary or	1,114,303	3%	\$154,872,814	5%	
metastatic, suspected or					
diagnostic)					
Cervical or neck pain	1,045,381	3%	\$83,899,299	3%	

Percentage of 2014 Part B non-institutional claim line file for advanced imaging services from Medicare claims for beneficiaries who are enrolled in the FFS program (source: CMS Chronic Conditions Data Warehouse).

Although CMS is proposing priority clinical areas based on an analysis of claims data alone, CMS notes it may consider factors other than volume when proposing priority clinical areas including incidence and prevalence of disease and the variability of the use of a particular imaging service.

c. CDSM Qualifications and Requirements

Section 1834(q)(3)(A)(iii) of the Act provides relative flexibility for qualified CDSMs, and states that they may include mechanisms that are within certified EHR technology, private sector mechanisms that are independent from certified EHR technology or mechanisms that are established by the Secretary. CMS states its belief that, at least initially, it is best to establish CDSM requirements that are not prescriptive about specific IT standards and proposes an approach that focuses on the functionality and capabilities of qualified CDSMs. In the future, CMS may consider pointing to developed standards as a requirement for qualified CMSMs.

CMS' proposals for CDSM qualifications and requirements are listed below.

- 1. CMS proposes that qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority areas.
- 2. CMS proposes that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE.
- 3. CMS proposes that specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM.
- 4. CMS proposes that the qualified CDSM must clearly identify the appropriate use criterion if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.
- 5. CMS proposed that the qualified CDSM must provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of "not applicable" when the mechanism does not contain a criterion that would apply to the consultation.
- 6. CMS proposes that the qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and PI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, and whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered. CMS also proposes to require that this certification or documentation must be issued each time an ordering professional consults the qualified CDSM
- 7. CMS proposes that the documentation or certification by the qualified CDSM must include a unique consultation identifier.
- 8. CMS proposes that the specified applicable AUC content within qualified CDSMs be updated at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion. CMS also proposes that qualified CDSMs have a protocol in place to more expeditiously remove AUC that are determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.
- 9. CMS proposes that qualified CDSMs must make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS.
- 10. CMS proposes that the qualified mechanism must meet privacy and security standards under applicable provisions of law.
- 11. CMS proposes that qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding

their consultations with specified applicable AUC. CMS also proposes that a qualified CDSM must maintain electronic storage of clinical, administrative and demographic information of each unique consult for a minimum of 6 years.

- 12. CMS proposes that in the event requirements are modified through rulemaking during the course of a qualified CDSM's 5-year approval cycle, CMS proposes that the CDSM would be required to comply with the modification(s) within 12 months of the effective date of the modification.
- d. Process for CDSMs to Become Qualified and Determination of Non-Adherence

CMS proposes that CDSMs must apply to CMS to be specified as a qualified CDSM. CDSMs must submit an application to CMS for review that documents adherence to each of the requirements to be a qualified CDSM. Application must be submitted by January 1 of a year in order to be reviewed within that year's review cycle. CMS states that the first applications would be accepted from the date of publication of the 2017 PFS final rule until January 1, 2017 and a determination on whether the applicants are qualified would be made by June 30, 2017.

CMS proposes that all qualified CDSMs must reapply every 5 years and their applications must be received by January 1 during the 5th year that they are qualified CDSMs. Thus, a CDSM that is specified as qualified for the first 5-year cycle beginning on July 1, 2017 would be required to submit an application for requalification by January 1, 2022 and a determination would be made by June 30, 2022. If the application was approved, the second 5-year cycle would begin on July 1, 2022.

CMS proposes that, at any time, it may remove from the list of qualified CDSMs a CDSM that fails to meet the criteria to be a qualified CDSM or consider this information during the requalification process.

e. Consultation by Ordering Professional and Reporting by Furnishing Professional

CMS states that at the earliest, the first qualified CDSM(s) will be specified on June 30, 2017 and it anticipates that furnishing professionals may begin reporting as early as January 1, 2018. CMS expects physicians and other stakeholders/regulated parties to begin preparing to report on January 1, 2018. CMS will adopt procedures for capturing this information on claims forms and the timing of the reporting requirements through 2018 PFS rulemaking.

CMS notes 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. In the situation that an AUC may not be available in a particular qualified CDSM, the furnishing professional can meet the requirement to report information on the ordering professional's AUC consultation by indicating that AUC is not applicable to the service ordered.

f. Exceptions to Consulting and Reporting Requirements

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

The first exception is when an applicable imaging service is ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. CMS proposes to provide for an exception to the AUC consultation and reporting requirements for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. CMS intends to propose more details about this exception in the 2018 proposed rule.

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. CMS proposes 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.

C. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

1. Background

CMS proposes to release to the public MA bid pricing data (but not Part D pricing data) and Parts C and D MLR data on a specific schedule, subject to specified exclusions. These data releases would be reflected in newly added contract terms. CMS explains its rationale for making these data available to the research community, beneficiaries, and the public more generally. In addition to CMS' interest in promoting accountability in the MA and Part D programs by making these data available, the proposed data disclosures would respond to past and future requests under the Freedom of Information Act (FOIA) for these data.

3. Proposed Regulatory Changes for Release of MA Bid Pricing Data

CMS proposes to add a new §422.272 to subpart F of Part 422 relating to MA to provide for the annual release to the public (after the first Monday in October) of pricing data that CMS accepted or approved for a contract year at least five years prior to the upcoming calendar year (with exclusions, see proposed §422.272(c)). Under the proposed rule, CMS would release MA bid pricing data for MA plan bids accepted or approved by CMS for a contract year. The annual public release would contain MA bid pricing data from the final list of MA plan bids accepted or approved by CMS for a contract year that is at least 5 years prior to the upcoming year. Given that bid submissions may go through some changes before they are finalized CMS proposes that

the MA bid pricing data to be released would only be the data found in the final list of accepted bids.

Regarding the "5 year" proposed policy, CMS posits this as an appropriate length of time for the pricing data to no longer be competitively sensitive. Since the bid data will be released annually, the public will be able to trend bid cost projections across years, to compare actual costs from the MA BPT with projections from prior years, and to observe bidding behavior over longer periods of time.

The rule proposes CMS release MA bid pricing data on an annual basis after the first Monday in October. CMS explains that the annual bidding cycle has come to a close at this point and it has completed the approval of MA plan bids for the upcoming year. CMS intends that the first time it implements a public release of MA bid submission data, it may release data for multiple contract years that meet the criterion of at least 5 years prior to the upcoming calendar year.

6. Background on Part C and Part D Medical Loss Ratio (MLR) Data

MAOs and Part D plan sponsors are required by statute to report MLR data to CMS. In general, the MLR for each MA and Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. The percentage of revenue that is used for other items such as administration, marketing and profit is excluded from the numerator of the MLR. More specifically, for each contract year, each MAO and Part D sponsor is required to submit a report to CMS the data needed to calculate and verify the MLR and remittance amount, if any, for each contract. The reported information includes incurred claims for medical services and prescription drug costs; expenditures on activities that improve health care quality; taxes, licensing and regulatory fees; non-claims costs; and revenue.

7. Proposed Regulatory Changes for Release of MLR Data

a. Overview and Terminology

CMS proposes to add new contract requirements that would authorize release to the public by CMS of certain MLR data submitted by MAOs and Part D sponsors. For example, these data would include for MAOs the average per member per month CMS payment for A/B benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

CMS proposes to release to the public the MLR data for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

D. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

CMS reminds all Medicare providers (including providers of services defined in section 1861 of the Act and physicians) that federal law prohibits them from collecting Medicare Part A and Medicare Part B deductibles, coinsurance or copayments, from beneficiaries enrolled in the Qualified Medicare (QMB) program.

E. Recoupment of Offset of Payments to Providers Sharing the Same Taxpayer Identification Number (TIN)

Medicare payments to providers and suppliers may be offset or recouped, in whole or in part, by a Medicare contractor if the contractor or CMS has determined that a provider or supplier has been overpaid. CMS notes it has historically used the Medicare provider billing number or National Provider Identifier (NPI) to recoup overpayments until these debts were paid in full or eligible for referral to the Department of Treasury (Treasury) for further collection action. Treasury uses various tools to collect the debt, including federal payments against entities that share the same TIN.

Section 1866(j)(6) of the Act, established by Section 6401(a)(6) of the ACA, allows the Secretary to make any necessary adjustments to the payments of an applicable provider of services or supplier to satisfy any amount due from an obligated provider of services or supplies. The statute defines an applicable provider of services or supplier (*applicable provider*) as a provider of services or supplier. The statue defines the obligated provider of services or supplier (*obligated provider*) as a provider of services or supplier that owes a past-due overpayment to the Medicare program. CMS states that for purposes of this provision, the applicable and obligated providers must share a TIN, but may possess a different billing or NPI than one another.

CMS provides the following example: A health care system may own a number of hospital providers and these providers may share the same TIN but have different NPI numbers. If one of the hospitals in the system receives a demand letter for a Medicare overpayment, then the hospital (Hospital A) will be considered the obligated provider while the other hospitals in the same TIN (Hospital B and C) will be considered the applicable providers. CMS states this authority allows it to recoup the obligated provider Hospital A, against any or all of the applicable providers, Hospital B and C, with which it shares a TIN.

CMS discusses how with the passage of section 1866(j)(6) of the Act, the requirements in §405.373(a) could be interpreted to require the Medicare contractor to provide notification to both the obligated provider and the applicable provider of its intention to recoup or offset payment. CMS states it does not believe notification to both the obligated and the applicable provider is necessary, and it proposes to amend the notice requirement to state that §405.373(a) does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount from an obligated provider of services or supplier when applicable and obligated provider of services or supplier share the same TIN.

CMS discusses its plans to notice all potentially affected Medicare providers of the implementation of section 1866(j)(6) before the effective date of this rule. CMS states its notification plans would provide adequate notice to providers and suppliers sharing a TIN, if they choose, the opportunity to implement a tracking system of Medicare overpayments on the corporate level for the affected providers.

F. Accountable Care Organizations (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

CMS is proposing to amend the regulation at §425.504 to permit EPs that bill under the TIN of an ACO participant to report separately for purposes of the 2017 and 2018 payment adjustment when the ACO fails to report on behalf of the EPs who bill under the TIN of an ACO participant.

CMS proposes that for the purpose of the reporting period for the 2018 PQRS payment adjustment (January 1, 2016 through December 31, 2016), EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs of group practices. If the ACO fails to satisfactorily report, CMS is proposing to consider this separately reported data for purposes of determining whether the EPs or group practices are subject to the 2018 PQRS payment adjustment. Since affected EPs are not able to register for the PQRS GPRO by the applicable deadline for the PQRS GPRO (June 30 was the registration deadline), CMS proposes to eliminate the registration process for groups submitting data using third party entities. CMS states that it is able to obtain group information from the third party entity and determine whether the data submitted represents a group or individual submission. CMS proposes that an affected EP may report either as an individual EP or as a group practice. CMS notes that individual EPs would not be able to use the claims reporting option and group practices would not be able to use the Web Interface and certified survey vendor options.

CMS acknowledges that certain EPs have a similar situation with the 2017 PQRS payment adjustment, which will be applied beginning on January 1, 2017. Consistent with the proposal for the 2018 PQRS payment adjustment, CMS is proposing to permit EPs that bill through the TIN of an ACO participant to report separately for purposes of the 2017 PQRS payment adjustment if the ACO failed to report on behalf of the EPs who bill under the TIN of an ACO participant. The established reporting period for the 2017 PQRS payment adjustment was January 1, 2015 through December 31, 2015. CMS is proposing to establish a secondary PQRS reporting period for the 2017 PQRS payment adjustment for individual EPs or group practices who bill under the TIN of an ACO participant if the ACO failed to report during the previously established reporting period for the 2017 PQRS payment adjustment. This option would not be available to EPs that failed to report for purposes of PQRS outside the Shared Savings Program.

CMS proposes that the secondary reporting period for the 2017 PQRS payment adjustment would coincide with the reporting period for the 2018 PQRS payment adjustment (January 1, 2016 through December 31, 2016. CMS also proposes to assess the individual EP or group practice's 2016 data using the applicable satisfactory requirement for the 2018 PQRS payment adjustment (including, but not limited to, the applicable PQRS measure set).

Based on the above proposals, CMS notes that individual EP or group practice data could be used for the secondary reporting period for the 2017 payment adjustment or for the 2018 payment adjustment or for both payment adjustments if the ACO in which the affected EPs participate failed to report for purposes of the applicable payment adjustment. CMS stresses that if an affected individual EP or group decide to use the secondary reporting period for the 2017 payment adjustment, the affected EP or group practice should expect to receive a PQRS payment adjustment for services furnished in 2017 until CMS is able to determine that the EP or group

practice satisfactorily reported PQRS for the purposes of the 2017 PQRS payment adjustment. CMS proposes the informal review submission period for this secondary reporting period for the 2017 payment adjustment would occur during the 60 days following the release of the PQRS feedback reports for the 2018 PQRS payment adjustment. CMS notes as discussed in section III.L, the EP or group practice would also avoid the automatic downward VM adjustment, but would not qualify for an upward adjustment. (See discussion section III.L. of this summary).

G. Medicare Advantage Provider Enrollment

1. Background

a. General Overview

This proposed rule would require MAO providers and suppliers to be enrolled in Medicare in an approved status. CMS refers to an "approved status" as a status whereby a provider or supplier is enrolled in, and is not revoked from, the Medicare program. A provider or supplier that has submitted an application, but has not completed the enrollment process with their respective MAC is not enrolled in an approved status. The submission of an enrollment application does not deem a provider or supplier enrolled in an approved status. A provider or supplier that is currently revoked from Medicare is not in an approved status. Out-of-network or non-contract providers and suppliers are <u>not</u> required to enroll in Medicare to meet the requirements of this proposed rule.

MAOs are required to conduct screening of their providers but CMS does <u>not</u> have direct oversight over all providers and suppliers in MAOs. CMS does not currently require, for example, that MAOs review a provider or supplier's final adverse action history (as defined in §424.502), nor verify a provider or supplier's practice location, ownership, or general identifying information. CMS believes that, through its own enrollment processes, it can further ensure that only qualified providers and suppliers treat Medicare beneficiaries. Under the provisions of this proposed rule, if a provider or supplier fails to meet its requirements or violates federal rules and regulations, CMS could revoke their enrollment, thereby removing them from consideration as an MAO provider or supplier.

3. Major Provisions

CMS proposes to add new §422.222, "Enrollment of MAO network providers and suppliers; first-tier, downstream, and related entities (FDRs); and providers and suppliers in PACE, cost HMO or Competitive Medical Plan (CMP) and demonstration and pilot programs." Providers or suppliers (in accordance with section 1861 of the Act) would have to be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MAO. MAOs that fail to ensure compliance on the part of their providers and suppliers would be subject to sanctions under §422.750 and termination under §422.510.

Under proposed new §423.224(a), an MAO would be prohibited from paying, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services

as defined in §422.2) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program. An exception would be provided under paragraph (b) that if an MAO received a request for payment by, or on behalf of, an individual or entity excluded by the OIG or revoked in the Medicare program, the MAO would have to notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that future payments not be made. Payment would not be made to, or on behalf of, an individual or entity after the first payment was made or was permitted in writing by CMS.

Under proposed §422.501(c), as a condition of contracting with CMS, an MAO would have to agree to provide documentation that all providers and suppliers in the MA or MA-PD plan who could enroll in Medicare, were enrolled in an approved status. The authorized individual would have to thoroughly describe how the entity and MA plan met, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in §422.222 are enrolled in Medicare in an approved status.

CMS would revise existing §422.504(a)(6) to add "supplier" to the conditions of contracting so that the revised text would say that the organization must comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and Medicare provider and supplier enrollment requirements.

In §§422.504(i)(2)(v), 417.484, and 460.70, CMS would add provisions that require MAOs, Cost plans, and PACE organizations to require all first-tier, down-stream and related entities and contracted entities to agree to comply with the provider and supplier enrollment provision. In §§422.510(a)(4)(xiii) and 460.50, CMS proposes provisions that would give it authority to terminate a contract if an MAO or PACE organization failed to meet provider and supplier enrollment requirements in accordance with §422.222 and payment prohibitions in §422.224. Provisions would be added to §§422.752(a) and 460.40 that would give CMS the authority to impose sanctions in the case of an MAO or PACE organization that failed to meet the provider and supplier enrollment requirements.

These provisions would be effective the first day of the next plan year that begins 2 years from the date of publication of the CY 2017 PFS final rule with comment period.

H. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

1. Background

In 2012, CMMI awarded a Health Care Innovation Award (HCIA) to The Young Men's Christian Association (YMCA) of the USA (Y-USA) to test whether DPP services could be successfully furnished by non-physician, community-based organization to Medicare beneficiaries diagnosed with prediabetes and at high risk for development of Type 2 diabetes. The HCIA model is conducted under the authority of section 1115A of the Act. According to the

second year independent evaluation report of the Y-USA DPP model, beneficiaries who attended at least one core session lost an average of 7.6 pounds and beneficiaries who attended at least four core sessions lost an average of 9 pounds.⁵

Based on the evidence form the evaluation of the Y-USA DPP and other DPPs in the CDC Diabetes Prevention Recognition Program, in March 2016, CMS' Office of the Actuary determined that DPP is likely to reduce Medicare expenditures if made available to eligible Medicare beneficiaries. This finding allows for the expansion of the model under Section 1115A(c)

3. Proposed Expansion of Medicare Diabetes Prevention Program (MDDP)

CMS proposes to expand the duration and scope of the DPP model as the Medicare Diabetes Prevention Program with an effective date beginning January 1, 2018.

MDPP Benefit Description

CMS proposes MDPP to be a 12-month program using the CDC-approved DPP curriculum, which consists of 16 core sessions over 16-26 weeks and an option for monthly core maintenance sessions over the subsequent 6 months if the beneficiary achieves and maintains a minimum weight loss in accordance with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures. The CDC-approved DPP session curriculum requirements are discussed in the proposed rule.

CMS also proposes:

- Beneficiaries who meet the coverage criteria (discussed below) would be able to enroll in the MDPP only once.
- Beneficiaries who complete the 12-month program and achieve and maintain a required minimum weight loss would be eligible for additional monthly maintenance sessions as long as the weight loss is maintained.
- Ongoing maintenance sessions adhere to the same curriculum requirements as the core.
- Require that each MDPP session be at least an hour induration.

CMS notes its will continue to test and evaluate the nationwide MDPP.

Enrollment of New Medicare Suppliers

As of 2015, more than 800 organizations have preliminary or full recognition from the CDC Diabetes Prevention Recognition Program (DPRP) to provide DPP services.

CMS proposes that any organization recognized by the CDC to provide DPP services (preliminary or full recognition) would be eligible to apply for enrollment in Medicare as a supplier beginning on or after January 1, 2017. In addition, CMS proposes:

• If an organization loses its CDC recognition status, or withdraws from the CDC recognition program, or fails to move from preliminary to full recognition within 36

⁵ The first and second independent evaluation reports are available at https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/.

- months of applying for CDC recognition, the organization would be subject to revocation of its Medicare billing privileges for MDPP services.
- If an organization loses its CDC recognition status and reapplies and obtains recognition, the organization would be eligible to re-enroll in Medicare as an MDPP supplier.
- Existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform CMS that they satisfy all other requirements and would *not need* to enroll a second time. CMS considered requiring existing Medicare providers and suppliers to submit a separate enrollment application for MDPP services and seeks comments on this alternative.

CMS proposes that MDPP suppliers would be subject to enrollment regulation set forth in 42 CFR part 424, subpart P. In addition, CMS proposes that potential MDPP suppliers would be screened according to the high categorical risk category defined in §424.518(c). As suppliers, enrolled MDPP organizations would be obligated to comply with all statutes and regulations that establish applicable requirements for Medicare suppliers.

CMS proposes to require personnel who would deliver MDPP services (referred to as "coaches") obtain a National Provider Identifier (NPI) to help ensure coaches meet CMS program integrity standards. CMS is also considering requiring coaches to enroll in the Medicare program in addition to obtaining an NPO. In addition, CMS proposes:

- To require MDPP suppliers to submit the active and valid NPIs of all coaches who would furnish MDPP services on behalf of the MDPP supplier as an employee or contractor.
- If the MDPP suppliers fail to provide active and valid NPIs of their coaches, the MDPP supplier may be subject to compliance action or revocation of MDPP supplier status.

CMS proposes that if a MDPP supplier has its Medicare enrollment revoked or deactivated for reasons independent of DPRP recognition, that supplier would lose its ability to bill Medicare for MDPP services. CMS proposes that MDPP Suppliers may appeal these decisions in accordance with the current procedures specified for Medicare suppliers.

Expected MDPP Reimbursement

CMS proposes payment for MDPP services tied to the number of services attended and the achievement of a minimum weight loss of 5 percent of baseline weight. For example, payment per beneficiary for 1 core session would be \$25, payment for 4 sessions attended would be \$50 and payment for a beneficiary with a weight loss of 5% from baseline would be \$160. Table 35 lists the proposed reimbursement for MDPP.

MDPP supplies would be required to attest to beneficiary session attendance and weight loss at the time claims are submitted. MDPP suppliers would be required to securely maintain beneficiary attendance records and measured weights and make them available for audit.

CMS proposes that claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance session attendance, and maintenance of minimum weight loss. For example, MDPP suppliers would not be able to submit another claim after session one until the beneficiary has completed four sessions, and maintenance sessions

would not qualify for payment unless a minimum weight loss is achieved and maintained. CMS notes this is similar to payments offered by commercial insurers.

IT Infrastructure and Capabilities

CMS proposes that MDPP suppliers would be required to submit claims to Medicare using standard claims forms and procedures. CMS would provide technical assistance to MDPP suppliers to comply with Medicare claims submission standards.

MDPP Eligible Beneficiaries

CMS proposes that MDPP services would be available for beneficiaries who meet 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;
- (3) Have within the 12 months prior to attending the first Core session a hemoglobin A1c 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).

CMS proposes to permit beneficiaries who meet the above proposed criteria to obtain MDPP by self-referral, community-referral, or health care practitioner-referral.

Site of Service

CMS proposes to allow MDPP suppliers to provide MDPP services via remote technologies. CMS states that as part of the evaluation of the MDPP expansion, it will evaluate the effectiveness of MDPP services provided virtually as compared to in-person services and may modify or terminate this component of the expansion as appropriate. CMS plans to monitor administrative claims for virtual services to identify any unusual and/or adverse utilization of the MDPP benefit.

CMS notes that MDPP services provided via a telecommunications system or other remote technology will not be part of the current Medicare telehealth benefits and will not have any impact on how telehealth services are defined by Medicare.

I. Medicare Shared Savings Program

CMS proposes numerous changes related to quality reporting and assessment which include:

- 1. Changes to quality measures
 - Quality validation audits
- 2. Issues related to aligning MSSP policies with policies proposed in the new Quality Payment Program (QPP) with respect to Merit-based Incentive Payment Systems (MIPS) and Alternative Payment Models (APMs)
- 3. Beneficiary attestation
- 4. Beneficiary protections related to the SNF 3-day waiver
- 5. Technical changes

- Merged and acquired TINs
- o Financial reconciliation issues for ACOs that fall below 5,000 assigned beneficiaries

1. ACO Quality Reporting

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

CMS proposes modifications to the quality measure set that an ACO is required to report in order to better align the MSSP quality measure set with the measures recommended by the Core Quality Measure Collaborative and proposed for reporting through the QPP proposed rule. Overall, CMS proposes to add three measures and retire or replace six measures. The total number of measures would decrease from 34 to 31 measures. Table 36 from the proposed rule (also included in the Appendix V) lists the quality measure set. 6

The three ACO measures CMS proposes to add to the care coordination/patient safety domain are listed below. Each of these measures would be designated as pay for reporting in 2017 and 2018 and then phase into pay for performance starting with PY2 of an ACO's first agreement period.

- ACO-12 Medication Reconciliation Post-Discharge (NQF #0097). This measure is intended to address adverse drug events (ADEs) through medication reconciliation, as a means to improve care coordination.
- ACO-44 Use of Imaging Studies for Low Back Pain (NQF #0052). This measure was added
 to address a gap in measures related to resource utilization and align with the ACO measures
 recommended by the Core Quality Measures Collaborative core measure set.
- ACO-43 Ambulatory Sensitive Condition Acute Composite (AHRQ PQI #91). This is an AHRQ composite measure, currently used in the Physician VBP modifier, which includes reporting on admissions related to dehydration, bacterial pneumonia, and urinary tract infections. These admissions may occur as a result of inadequate access to ambulatory care or poorly coordinated ambulatory care. CMS notes that this measure will be risk-adjusted for demographic variables and comorbidities.

CMS proposes to retire or replace six measures. CMS states that these measures do not align with the core measure set recommendations from the Core Quality Measures Collaborative and the measures proposed for reporting through the CMS web interface in the QPP proposed rule:

- ACO-39 Documentation of Current Medications in the Medical Record.
- ACO-21 Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented.

⁶ CMS also lists ACO-11 Use of Certified EHR Technology as a new measure. CMS is proposing substantial revisions to this existing measure, and, as such, CMS proposes considering it as a newly introduced measure.

- ACO-31 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- ACO-33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).
- ACO-9 Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease or Asthma in Older Adults (AHRQ Prevention Quality Indicator (PQI) #5)
- ACO-10 Ambulatory Sensitive Conditions Admissions: Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)

Table 37 (also included in Appendix VI) provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes. b. Improving the Process Used to Validate ACO Quality Data Reporting

CMS proposes four improvements to address certain issues of its current approach: (1) changes to address the number of records to be reviewed per measure, (2) the number of audit phases, (3) the calculation of an audit match rate, and (4) the consequences if the audit match rate falls below 90 percent. CMS proposes to:

- Increase the number of records audited per measure (more than the current 30) to achieve a high level of confidence that the true audit match rate is within 5 percentage points of the calculated result. CMS is not proposing a specific number of records, but does not anticipate more than 50 records will be required per audit.
- Modify its regulations in order to conduct the quality validation audit in a single step rather than the current multi-phased process described at §425.500(e)(2). CMS would review all submitted medical records and calculate the match rate. CMS states the education it provides to ACOs and the opportunity for ACOs to explain the mismatches would occur at the conclusion of the audit. CMS notes that there *would not* be an opportunity for ACOs to correct and resubmit data for any measure with a >10 percent mismatch. Instead, CMS proposes to make adjustments to an ACO's quality score (as described below) without requiring re-opening of the CMS Web Interface, which CMS states is not operationally feasible.
- Revise §425.500(e)(3) to provide for an assessment of the ACO's overall audit match rate across all measures, instead of assessing the ACO's audit mismatch rate at the measure level. CMS would calculate an overall audit match rate which would be derived by dividing the total number of audited records that match the information reported in the Web Interface by the total number of records audited. CMS states that this change is necessary to minimize the number of records that must be audited to achieve the desired level of statistical certainty. Otherwise, CMS states it would need to request a much larger number of measures (approximately 200 per measure based on CMS' estimates) to achieve a 90 percent confidence interval for each measure.
- Adjust the quality score proportionally for an ACO that fails an audit. If an ACO fails the audit (audit match rate of less than 90 percent), the ACO's overall quality score would

be adjusted proportional to its audit performance. For example, if an ACO's quality score is 75 percent and the ACO's audit match rate is 80 percent, the ACO's audit-adjusted quality score is 60 percent. This score would be used to determine the percentage of any earned savings that the ACO may share or the percentage of any losses for which the ACO is accountable.

2. Alignment with the Quality Payment Program

In its review of the MSSP rules, CMS identified several modifications to program rules to better support and align CMS' efforts related to the QPP. These modification include sunsetting MSSP alignment with PQRS and EHR Incentive Program,

a. Proposals Related to Sunsetting PQRS and EHR Incentive Program Alignment and Alignment with APM Reporting Requirements under the Quality Payment Program

CMS notes that the VM, PQRS and the EHR incentive programs are sunsetting and the last quality reporting period under these programs is proposed to be 2016, which would impact payments in 2018. Quality reporting under the QPP, as proposed, would begin in 2017 for payment year 2019. As a result, CMS proposes several changes to align with the policies proposed in the QPP proposed rule:

- Proposes to amend §§425.504 and 425.506 to indicate that these reporting requirements apply to ACOs and their EPs through the 2016 performance year.
- CMS proposes to require that ACOs, on behalf of ECs who bill under the TIN of an ACO participant, must submit all the ACO CMS web interface measures required by the Shared Savings Program using a CMS web interface, to meet reporting requirements for the quality performance category under MIPS. This would parallel the current requirement at \$425.504 for reporting on behalf of EPs who bill under the TIN of an ACO participant for purposes of PQRS
- Proposes to maintain flexibility for EPs to report quality performance category data separately from the ACO, and therefore, does not propose to include a provision that would restrict an EP from reporting outside the ACO. CMS notes no quality data reported apart from the ACO will be considered for purposes of assessing the quality performance of the ACO.
- b. Proposals related to alignment with the Quality Payment Program

For purposes of meeting the CEHRT requirement, CMS proposed in the QPP proposal that an Advanced APM must require at least 50 percent of ECs who are enrolled in Medicare (or each hospital if hospitals are the APM participants) to use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals. However, CMS proposed an alternative criterion available only to the MSSP, which would allow the EHR criterion to be satisfied if the APM Entities were held accountable for their ECs' use of CEHRT by applying a financial penalty or reward based on the

degree of CEHRT use. CMS notes that the current EHR quality measure at ACO #11 satisfies this requirement.

In order to align its MSSP policies with the QPP proposal, CMS proposes to modify the title and specifications of the EHR quality measures (ACO #11). CMS proposes to change the specifications of the EHR measure to assess the ACO on the degree of CEHRT use by all providers and suppliers designated as ECs under the QPP proposed rule that are participating in the ACO rather than narrowly focusing on the degree of use of CEHRT of only the primary care physicians participating in the ACO. CMS believes this modification would better align with the QPP proposals and ensure a subset of ACOs in the MSSP could qualify to be Advanced APM entities. CMS also would modify the title of the measure to remove the reference to PCPs. Given that the specifications will be extensive, CMS proposes that this be considered a newly introduced measure and be considered pay for reporting for the 2017 and 2018 performance years.

During the years in which this measure if designated as pay for reporting, CMS proposes to include the requirement that at least one EC participating in the ACO must meet the reporting requirements under the Advancing Clinical Information category under the QPP. CMS states that this would ensure that Tracks 2 and 3 meet the letter and spirit of the statutory criteria for designation as an Advanced APM. Further, CMS proposes that during pay for performance years, assessment of EHR adoption is measured based on a sliding scale. CMS notes that the measure will remain double weighted. CMS proposes to retain the existing EHR measure requirements at §425.506(a)-(c) and to modify §425.506(d) to sunset the current EHR reporting requirement as noted in the prior section.

3. Incorporating Beneficiary Preference into ACO Assignment

Beneficiaries are required to be assigned to an ACO participating in the MSSP based on the beneficiary's utilization of primary care services rendered by physicians participating in the ACO. Under the current approach, beneficiaries are preliminary assigned to an ACO at the beginning of the year, but final beneficiary assignment is determined at the end of the performance year based on whether the beneficiary received the plurality of their primary care services.

Stakeholders have expressed interest in giving beneficiaries the opportunity to voluntarily "align" with the ACO in which their primary care provider participates, referred to as beneficiary attestation. This could potentially reduce year-to-year churn in beneficiary assignment lists and increase beneficiary engagement to the ACO in which their primary care provider participates. CMS had tested an approach in Pioneer ACO model. CMS states the process developed thus far appears to be resource intensive for ACOs and may not significantly impact assignment.

To address the resource intensive aspects, CMS proposes to implement an automated approach under which it could determine which healthcare provider a FFS beneficiary believes is responsible for coordinating their overall care (their "main doctor") using information that is collected in an automated and standardized way directly from beneficiaries, rather than requiring individual ACOs, to directly obtain this information from beneficiaries annually and then

communicate it to CMS. This beneficiary attestation approach would be available for ACOs participating in Track 1, 2 or 3 unless such an automated system is not available by spring of 2017. In this case, the voluntary alignment process will be limited to ACOs participating in Track 3 until an automated system is available. These changes would be effective for assignment for the 2018 performance year.

4. SNF 3-Day Rule Waiver Beneficiary Protections

In the June 2015 MSSP final rule, CMS provided ACOs participating in Track 3 with additional flexibility to attempt to increase quality and decrease costs by allowing these ACOs to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries when they are admitted to certain "SNF affiliates. Since publication of the June 2015 final rules, CMS has become concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day rule waiver under the Shared Savings Program.

CMS proposes to modify the waiver to include a 90-day grace period to allow sufficient time for CMS to notify the ACO of any beneficiary exclusions, and for the ACO then to inform its SNF affiliates, ACO participants, and ACO providers/suppliers of those exclusions. For example, CMS states concern that there could be limited situations when a beneficiary's Part B coverage terminates during a quarter when the beneficiary is also receiving SNF services. In this situation there could be a communication lag that could cause the SNF affiliate to unknowingly admit a beneficiary who no longer qualifies for the waiver and the beneficiary could be financially liable for such services.

CMS also proposes that it would make no payment to the SNF, and the SNF may not charge the beneficiary for the non-covered SNF services, in the event that a SNF that is a SNF affiliate of a Track 3 ACO that has been approved for the SNF 3-day rule waiver admits a FFS beneficiary who was never prospectively assigned to the waiver-approved ACO (or was assigned but later excluded and the 90 day grace period has lapsed), and the claim is rejected only for lack of a qualifying inpatient hospital stay.

In this situation, CMS proposes that it would apply the following rules:

- CMS would make no payment to the SNF affiliate for such services.
- The SNF affiliate must not charge the beneficiary for the expenses incurred for such services; and the SNF affiliate must return to the beneficiary any monies collected for such services.
- The ACO may be required to submit a corrective action plan to CMS for approval as specified at §425.216(b) addressing what actions the ACO will take to ensure that the SNF 3-day rule waiver is not misused in the future. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance, approval to use the waiver will be terminated in accordance with §425.612(d).

5. <u>Technical Changes</u>

a. Financial reconciliation for ACOs that fall below 5,000 Assigned Beneficiaries

Specifically, CMS proposes to update the regulations at §425.110(b)(1) to indicate that in the event an ACO falls below 5,000 assigned beneficiaries at the time of financial reconciliation, the ACO participating under a two-sided risk track will be eligible to share in savings (or losses) and the MSR/MLR will be set at a level consistent with the choice of MSR/MLR that the ACO made at the start of the agreement period. For example, if at the beginning of the agreement period the ACO chose a 1.0 percent MSR/MLR and the ACO's assigned population falls below 5,000, the MSR/MLR will remain 1.0 percent for purposes of financial reconciliation.

b. Requirement for Merged of Acquired TINs

CMS proposes a technical change to §425.204(g) to clarify that the merged/acquired TIN is not required to remain Medicare enrolled after it has been merged or acquired and no longer used to bill Medicare. CMS states that it was not its intent to establish such a requirement and believes there would be no program purpose to require the TIN of a merged or acquired entity to maintain Medicare enrollment if it is no longer used to bill Medicare.

J. Value-Based Payment Modifier (VM)

1. Expansion of the Informal Inquiry Process to Allow Corrections for the VM

CMS proposes to update the VM informal review policies and establish how the quality and cost composites would be affected for the 2017 and 2018 payment adjustment periods when an unanticipated program issue arises. CMS states that re-running QRURs and recalculating the quality composite is not always practical or even possible. CMS notes that the intent of these proposals is not to provide relief for EPs and groups who fail to report under PQRS, but rather to provide a mechanism for addressing unexpected issues.

CMS following highlights some of the issues raised during the VM informal review process:

- EHR and QCDR Issue. CMS was unable to determine the accuracy of PQRS data submitted via EHR and QCDR for the 2014 performance period due to data integrity issues.
- Incomplete Claims Identification Issue. After the release of the 2014 Annual QRURs in September 2015, CMS discovered a defect in the program used to identify the claims for 2014, which is the performance period for the VM 2016 payment adjustment period. Claims from January 1 through January 11, 2014 were incorrectly omitted from 2016 VM calculations. CMS discusses the steps it took to correct this issue, including notifying the TINs that were affected by this issue.
- Specialty Adjustment Issue. CMS discovered a defect in the program used to specialtyadjust the cost measures for the 2015 Mid-Year QRURs and determined that the 2016 VM for a small number of TINs were incorrectly calculated. CMS discusses the steps it took to correct this issue.

Table 38, copied below, summarizes CMS' proposals. CMS proposes to apply these policies for the 2017 and 2018 VM.

Table 38: Proposed Quality and Cost Composite Status for TINs Due to Informal Review Decisions and Widespread Quality and Cost Date Issues

	Scenario 1		Scenario 2		Scenario 3		Scenario 4		
	TINS Mo	oving	Non-GPRO		Category 1 TINs		Category 1 TINs		
	from Category 2		Category 1 TINs		with Wid	with Widespread		with Widespread	
	to Catego	ory 1	with Add	itional	Quality I	D ata	Claims D	ata	
			EPs Avoiding		Issues		Issues		
			PQRS Payment						
			Adjustment						
Composite	Initial	Revised	Initial	Revised	Initial	Revised	Initial	Revised	
Score									
	N/A	Average	Low	Average	N/A	Average	Low	Average	
Quality	N/A	Average	Average	Average	N/A	Average	Average	Average	
	N/A	Average	High	High	N/A	Average	High	High	
	Low	Low	Low	Low	Low	Low	Low	Low	
Cost	Average	Average	Average	Average	Average	Average	Average	Average	
	High	Average	High	High	High	Average	High	Average	

<u>Scenario 1</u>: TINs Moving from Category 1 to Category 2 as a Result of PQRS or VM Informal Review Process

If a TIN is initially classified as Category 2, and subsequently through the PQRS or VM informal review process, the TIN is classified as Category 1, CMS proposes to classify the TINs quality composite as "average quality" instead of recalculating the quality composite. If the TIN is classified as "average cost" or "low cost", CMS proposes that the TIN would retain the calculated cost designation. CMS notes that its proposal to revise a cost composite initially classified as "high cost" to "average cost" would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment as a result of being classified as average quality and high costs.

<u>Scenario 2</u>: Non-GPRO Category 1 TINs with Additional EPs Avoiding PQRS Payment Adjustment as a Result of PQRS Informal Review Process

For the 2017 and 2018 VM, Category 1 will include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the 2017 PQRS payment adjustment as individuals. If a TIN is classified as Category 1 for the 2017 VM by having at least 50 percent of the group's EPs meet the criteria to avoid the 2017 payment adjustment as individuals, and subsequently, through the PQRS informal review process, it is determined that additional EPs that are in the TIN also meet the criteria to avoid the 2017 and 2018 PQRS payment adjustment as individuals, then CMS proposes the following policies to determine the TIN's quality and cost composites:

• If the TIN's quality composite is initially classified as "low quality", CMS proposes to reclassify the TIN's quality as "average quality." If the TIN's quality composite is

initially classified as "average" or "high" quality then CMS proposes that the TIN would retain the quality designation.

• CMS would maintain the initial cost composite.

Scenario 3: Category 1 TINs with Widespread Quality Data Issues

When there is a systematic issue with any of a Category 1 TIN's quality data that renders it unusable for calculating a TIN's quality composite, CMS proposes to classify the TIN's quality composite as "average quality". CMS notes it considers widespread quality data issues, as issues that impact multiple TINs and it is unable to determine the accuracy of the data submitted. For the cost composite, CMS proposes to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN is classified as "high cost", CMS proposes to reclassify the TIN's cost composite as "average cost". If the TIN is classified as "average' or "low" cost, CMS proposes that the TIN would retain the cost calculation. CMS notes that it would continue to show and designate these groups as high costs in their annual QRURs so they have the opportunity to understand and improve their performance.

Scenario 4: Category 1 TINs with Widespread Claims Data Issues

If CMS determines after the release of QRURs that there is a widespread claims data that impacts the calculation of the quality and/or cost composite for Category 1 TINs, CMS proposes to recalculate the quality and cost composite for affected TINs. CMS states it considers widespread claims data issues as issues that impact multiple TINs and require the recalculation of the quality and/or cost composites.

After recalculating the composites, if the TIN's cost composite is classified as either "low" or "high", then CMS proposes to reclassify the quality composite as "average quality". If the TIN is classified as "average quality", "high quality", "average cost" or "low cost", then CMS proposes that the TIN would retain the calculated quality or cost tier designation. CMS is proposing to assign "average quality" if the quality composite is classified as "low quality" and assign "average cost" if the cost composite is classified as high after recalculating the quality and cost composites.

K. Physician Self-referral Updates

- 1. Unit-based Compensation in Arrangements for the Rental of Office Space or Equipment
- a. The Physician Self-referral Statute and Regulations

Section 1877(e)(1)(A)(iv) and (b)(iv) of the Act provide that, for an arrangement for the rental of office space or equipment to satisfy the relevant exceptions to the physician self-referral law, the rental charges over the term of the lease must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into the account the volume or value of any referrals or other business generated between the parties.

In the 2008 PFS proposed rule, CMS stated that arrangements between a physician lessor and an entity lessee under which the physician receives unit-of-service payments are inherently

susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. CMS proposed that space and equipment leases may not include per-click payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity (72 FR 38183).

In the FY 2009 IPPS final rule CMS finalized regulations prohibiting certain per-unit of service compensation formulas for determining office space and equipment rental (73FR 48434). Specifically CMS revised §411.357(a)(4) and (b)(4) to prohibit rental charges for the rental of office space or equipment that are determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. CMS stated it determined it was necessary to limit the type of per-click compensation formulas available for arrangements for the rental of office space and equipment because it believed that the lessor had an incentive to profit from referring a higher volume of patients to the lessee and from referring patients to the lessee that might otherwise go elsewhere.

b. Development of this Rulemaking

On June 12, 2015, the D.C. Circuit (the Court) issued an opinion in <u>Council for Urological Interests v. Burwell</u> addressing the prohibition on per-click rental charges for the lease of equipment. The Court agreed with CMS that section 1877(e)(1)(B)(vi) of the Act provides the Secretary the authority to prohibit per-click leasing arrangements.

The Court also concluded, however, that CMS' discussion of the House Conference Report in the FY 2009 IPPS rule contained an unreasonable interpretation of the conferees' statements concerning 1877(e)(l)(A)(iv) and (B)(iv) of the Act, and it remanded the case to the agency to permit a fuller consideration of the legislative history.

c. Re-proposal of Limitation on the Types of Per-unit of Service Compensation Formulas for Determining Office Space and Equipment Rental Charges

CMS re-proposes certain requirements for arrangements involving the rental of office space or equipment. CMS is proposing a requirement that rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients by the lessor to the lessee.

CMS emphasizes that it is not proposing an absolute prohibition on rental charges based on units of services furnished; in general, per-unit of service rental charges for the rental of office space or equipment are permissible. CMS states it is proposing to limit the general rule by prohibiting per-unit of service rental charges where the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rental office space or using the rented equipment. Per-unit of service rental charges for the rental of office space or equipment would be permissible, but only in those instances, where the referral for the service to be provided in the rental office or using the rented equipment did not come from the lessor.

Appendix I.

TABLE 43: 2017 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty

		(C)	(D)	(E)	
		Impact of			
(A) Specialty	(B) Allowed	Work	PE RVU	MP RVU	Combined
	Charges (mil)	RVU	Changes	Changes	Impact**
		Changes			
TOTAL	\$89,467	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	\$230	0%	1%	0%	2%
ANESTHESIOLOGY	\$1,977	0%	-1%	0%	0%
AUDIOLOGIST	\$61	0%	0%	0%	1%
CARDIAC SURGERY	\$322	0%	0%	0%	0%
CARDIOLOGY	\$6,461	0%	0%	0%	1%
CHIROPRACTOR	\$779	0%	0%	0%	0%
CLINICAL PSYCHOLOGIST	\$727	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	\$601	0%	0%	0%	0%
COLON AND RECTAL	\$160	0%	0%	0%	0%
CRITICAL CARE	\$308	0%	0%	0%	0%
DERMATOLOGY	\$3,305	0%	0%	0%	1%
DIAGNOSTIC TESTING	\$750	0%	-2%	0%	-2%
EMERGENCY MEDICINE	\$3,133	0%	0%	0%	0%
ENDOCRINOLOGY	\$458	1%	1%	0%	2%
FAMILY PRACTICE	\$6,087	1%	1%	0%	3%
GASTROENTEROLOGY	\$1,744	0%	0%	0%	-1%
GENERAL PRACTICE	\$451	1%	1%	0%	2%
GENERAL SURGERY	\$2,157	0%	0%	0%	0%
GERIATRICS	\$211	1%	1%	0%	2%
HAND SURGERY	\$182	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	\$1,746	1%	1%	0%	2%
INDEPENDENT LABORATORY	\$701	0%	-5%	0%	-5%
INFECTIOUS DISEASE	\$652	0%	0%	0%	1%
INTERNAL MEDICINE	\$10,849	1%	1%	0%	2%
INTERVENTIONAL PAIN	\$767	1%	0%	0%	0%
INTERVENTIONAL	\$315	-1%	-5%	0%	-7%
MULTISPECIALTY					
** Column E may not aqual the sum	\$128	1%	1%	0%	1%

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

The following is an explanation of the information for Table 43:

- Column A (Specialty): Identifies the specialty for which data is shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2015 utilization and 2016 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated 2017 impact on total allowed charges of the proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- <u>Column D (Impact of PE RVU Changes):</u> This column shows the estimated 2017 impact on total allowed charges of the proposed changes in the PE RVUs.
- <u>Column E (Impact of MP RVU Changes):</u> This column shows the estimated 2017 impact on total allowed charges of the proposed changes in the MP RVUs.
- <u>Column F (Combined Impact)</u>: This column shows the estimated 2017 combined impact on total allowed charges of all the changes in the previous columns

Appendix II.

TABLE 7—0-DAY GLOBAL SERVICES THAT ARE TYPICALLY BILLED WITH AN EVALUATION AND MANAGEMENT (E/M) SERVICE WITH MODIFIER 25

	SERVICE WITH MODIFIER 25
HCPCS	Long descriptor
11100	Removal of inflamed or infected skin, up to 10% of body surface.
11100	Biopsy of single growth of skin or tissue. Shaving of 0.5 centimeters or less skin growth of the trunk, arms, or legs.
11301	
11302	
11305	Shaving of 0.5 centimeters or less skin growth of scalp, neck, hands, feet, or genitals.
11306	
11307	
11311	
11312	Shaving of 1.1 to 2.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11740	
11755	Biopsy of finger or toe nail. Injection of up to 7 skin growths.
11900	
12001	Repair of wound (2.5 centimeters or less) of the scalp, neck, underarms, trunk, arms or legs.
12002	Repair of wound (2.6 to 7.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms or legs.
12004	
12011	Repair of wound (2.5 centimeters or less) of the face, ears, eyelids, nose, lips, or mucous membranes. Repair of wound (2.6 to 5.0 centimeters) of the face, ears, eyelids, nose, lips, or mucous membranes.
17250	Application of chemical agent to excessive wound tissue.
20526	Injection of carpal tunnel.
20550	Injections of tendon sheath, ligament, or muscle membrane.
20551	Injections of tendon attachment to bone.
20552	Injections of trigger points in 1 or 2 muscles. Injections of trigger points in 3 or more muscles.
20600	
20604	Arthrocentesis, aspiration or injection, small joint or bursa (e.g., fingers, toes); with ultrasound guidance, with permanent re-
	cording and reporting.
20605	Aspiration or injection of medium joint or joint capsule.
20606	Arthrocentesis, aspiration or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.
20610	Aspiration or injection of large joint or joint capsule.
20611	Arthrocentesis, aspiration or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound
	guidance, with permanent recording and reporting.
20612	
29105 29125	Application of long arm splint (shoulder to hand). Application of non-moveable, short arm splint (forearm to hand).
29515	
29540	
29550	
30901	
31231	
31238	
31500	Emergent insertion of breathing tube into windpipe cartilage using an endoscope.
31575	Diagnostic examination of voice box using flexible endoscope.
31579	Examination to assess movement of vocal cord flaps using an endoscope. Assiration of lung secretions from lung singuity using an endoscope.
	Aspiration of lung secretions from lung airways using an endoscope. Removal of fluid from between lung and chest cavity, open procedure.
	Removal of fluid from chest cavity.
40490	Biopsy of lip.
43760	Change of stomach feeding, accessed through the skin.
45300 46600	Diagnostic examination of rectum and large bowel using an endoscope. Diagnostic examination of the anus using an endoscope.
51701	Insertion of temporary bladder catheter.
51702	Insertion of indwelling bladder catheter.
51703	Insertion of indwelling bladder catheter.
56605	Biopsy of external female genitals.
57150 57160	Irrigation of vagina or application of drug to treat infection. Fitting and insertion of vaginal support device.
58100	Biopsy of uterine lining.
64405	Injection of anesthetic agent, greater occipital nerve.
64418	Injection of anesthetic agent, collar bone nerve.
64455 65205	Injections of anesthetic or steroid drug into nerve of foot. Removal of foreign body in external eye, conjunctiva.
65210	Removal of foreign body in external eye, conjunctiva. Removal of foreign body in external eye, conjunctiva or sclera.
65222	Removal of foreign body, external eye, comea with slit lamp examination.
67515	Injection of medication or substance into membrane covering eyeball.
67810	Biopsy of eyelid.
6/820	Removal of eyelashes by forceps.

68200	Injection into conjunctiva.
69100	Biopsy of ear.
69200	Removal of foreign body from ear canal.
69210	Removal of impact ear wax, one ear.
69220	Removal of skin debris and drainage of mastoid cavity.
92511	Examination of the nose and throat using an endoscope.
92941	Insertion of stent, removal of plaque or balloon dilation of coronary vessel during heart attack, accessed through the skin.
92950	Attempt to restart heart and lungs.
98925	Osteopathic manipulative treatment to 1–2 body regions.
98926	Osteopathic manipulative treatment to 3–4 body regions.
98927	Osteopathic manipulative treatment to 5–6 body regions.
98928	Osteopathic manipulative treatment to 7–8 body regions.
98929	Osteopathic manipulative treatment to 9–10 body regions.
G0168	Wound closure utilizing tissue adhesive(s) only.
G0268	Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing.

Appendix III.

TABLE 8—CODES THAT HAVE DIRECT PE INPUTS IN THE FACILITY POSTSERVICE PERIOD WHEN POST-OPERATIVE VISITS ARE EXCLUDED

CPT Code	Long descriptor
21077	Impression and preparation of eye socket prosthesis. Impression and custom preparation of temporary oral prosthesis. Impression and custom preparation of permanent oral prosthesis. Impression and custom preparation of lower jaw bone prosthesis. Impression and custom preparation of prosthesis for roof of mouth enlargement. Impression and custom preparation of roof of mouth prosthesis. Impression and custom preparation of speech aid prosthesis. Insertion of hardware to foot bone dislocation with manipulation, accessed through the skin. Insertion of hardware to toe joint dislocation with manipulation, accessed through the skin. Incision of vagus nerves of stomach using an endoscope. Chemical destruction of anal growths.
47570 66986	Connection of gall bladder to bowel using an endoscope. Exchange of lens prosthesis.

Appendix IV.

TABLE 11-CHRONIC CARE MANAGEMENT (CCM) SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS

CCM Scope of service element/billing requirement	Propose to retain	Propose to remove	Proposed revision
Initiating Visit—Initiation during an AWV, IPPE, or face-to-face E/M visit for all patients (Level 4 or 5 visit not required).			Initiation during an AWV, IPPE, or face-to-face E/M visit (Level 4 or 5 visit not required) for new patients or patients not seen within 1 year.
Structured Recording of Patient Information Using Certified EHR Technology—Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record, using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.			Structured Recording of Patient Information Using Certified EHR Technology—Structured recording of demographics, problems, medications and medication allergies using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
24/7 Access to Care—Access to care management services 24/7 (providing the beneficiary with a means to make timely contact with health care practitioners in the practice who have access to the patient's electronic care plan to address his or her urgent chronic care needs regardless of the time of day or day of the week).			Provide 24/7 access to physicians or other qualified health 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.
Continuity of Care—Continuity of care with a designated practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.			Continuity of care with a designated member of the care team with whom the beneficiary is able to schedule successive routine appointments.
Comprehensive Care Management—Care management for chronic conditions including systematic assessment of the beneficiary'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 beneficiary self-management of medications.	x		
Electronic Comprehensive Care Plan—Creation of an electronic patient-centered 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.	x		
Electronic Sharing of Care Plan—Must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within the practice whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (by fax in extenuating circumstance) as appropriate with other practitioners and providers.			Must at least electronically capture care plan informa- tion, and make this information available timely within and outside the billing practice as appro- priate. Share care plan information electronically (can include fax) and timely within and outside the billing practice to individuals involved in the bene- ficiary's care.

Beneficiary Receipt of Care Plan—Provide the bene- ficiary with a written or electronic copy of the care			A copy of the plan of care must be given to the pa- tient or caregiver.
plan. Documentation of care plan provision to beneficiary— Document provision of the care plan as required to the beneficiary using certified EHR technology.		х	
Management of Care Transitions 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. Format clinical summaries according to certified EHR technology (content standard). Not required to use a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (by fax in extenuating circumstance).			Management of Care Transitions 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. Create and exchange/transmit continuity of care document(s) timely with other practitioners and providers.
Home- and Community-Based Care Coordination— Coordination with home and community based clinical service providers. Documentation of Home- and Community-Based Care Coordination—Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record using certified EHR technology.	X		Communication to and from home- and community- based providers regarding the patient's psycho- social needs and functional deficits must be docu- mented in the patient's medical record.
Enhanced Communication Opportunities—Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary'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.	x		
Beneficiary Consent— Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month) and the effect of a revocation of the agreement on CCM services. Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month. Document the beneficiary's written consent and authorization using certified EHR technology.			Inform the beneficiary of the availability of CCM services. Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month. Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month). Document in the beneficiary's medical record that the required information was explained and whether the beneficiary accepted or declined the services.

Appendix V.

TABLE 36—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS

Domain	ACO measure #	Measure title	New NQF #/measure steward		Method of data submission	Pay for performance phase in R—reporting P—performance		ince in rting nance	_
		AIM: Better Care fo	- Individuals			PY1	PY2	PYS	_
		AIM: Better Care to	or Individuals						_
Patient/Caregiver Experience	ACO-1	CAHPS: Getting Timely Care, Appointments, and Informa- tion.		N#0005 AHRQ	Survey	R	P	P	
	ACO-2	CAHPS: How Well Your Pro- viders Communicate. 13		NQF #0005 AHRQ.	Survey	R	P	P	
	ACO-3	CAHPS: Patients' Rating of Provider. 2		NQF #0005 AHRQ.	Survey	R	P	P	
	ACO-4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ.	Survey	R	P	P	
	ACO-5	CAHPS: Health Promotion and Education.		NQF #N/A CMS/AHRQ.	Survey	R	P	P	
	ACO-6	CAHPS: Shared Decision Mak- ing.		NQF #N/A CMS/AHRQ.	Survey	R	P	P	
	ACO-7	CAHPS: Health Status/Functional Status.		NQF #N/A CMS/AHRQ.	Survey	R	R	R	
	ACO-34	CAHPS: Stewardship of Patient Resources.		NQF #N/A CMS/AHRQ.	Survey	R	P	P	
Care Coordination/Patient Safety.	ACO-8	Risk-Standardized, All Condition Readmission.		Adapted NQF #1789 CMS.	Claims	R	R	P	
	ACO-35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).	Adapted NQF #2510 CMS.		Claims	R	R	P	
	ACO-36	All-Cause Unplanned Admissions for Patients with Diabetes.		NQF #TBD CMS.	Claims	R	R	P	
	ACO-37	All-Cause Unplanned Admissions for Patients with Heart Failure.		NQF #TBD CMS.	Claims	R	R	Р	
	ACO-38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.		NQF #TBD CMS.	Claims	R	R	P	
	T		T					Pay for	
Domain	Domain ACO Measure title		New measure	NQF Method #/measure data steward submiss		of pe		performance phase in R—reporting —performance	
							PY1	PY2	PY
	ACO-43	Ambulatory Sensitive Condition Acute Composite (AHRC Prevention Quality Indicator (PQI) #91).	2	AHRQ	Claims		R	Р	P
	ACO-11		- x	NQF #N/A CMS.	As propose the QPP propose rule.		R	Р	Р
	ACO-12	Medication Reconciliation Post- Discharge.	- x	NQF #0097 CMS.			R	Р	Р
	ACO-13		·	NOT TOTAL			R	Р	Р
	ACO-44		/ X	NQF #0052 NCQA.			R	Р	P

Appendix V. - Continued

AIM: Better Health for Populations

Preventive Health	ACO-14	Preventive Care and Screen- ing: Influenza Immunization.	 NQF #0041 AMA-PCPL	CMS Web	R	Р	Р
	ACO-15	Pneumonia Vaccination Status for Older Adults.	 NQF #0043 NCQA	CMS Web	R	Р	Р
	ACO-16	Preventive Care and Screen- ing: Body Mass Index (BMI) Screening and Follow Up.	 NQF #0421 CMS.	CMS Web Interface.	R	Р	Р
	ACO-17	Preventive Care and Screen- ing: Tobacco Use: Screening and Cessation Intervention.	 NQF #0028 AMA-PCPI.	CMS Web Interface.	R	Р	Р
	ACO-18	Preventive Care and Screen- ing: Screening for Clinical Depression and Follow-up Plan.	 NQF #0418 CMS.	CMS Web Interface.	R	P	P
	ACO-19	Colorectal Cancer Screening	 NQF #0034 NCQA.	CMS Web Interface.	R	R	Р
	ACO-20	Breast Cancer Screening	 NQF #2372 NCQA.	CMS Web Interface.	R	R	Р
	ACO-42	Statin Therapy for the Preven- tion and Treatment of Car- diovascular Disease.	 NQF #N/A CMS.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Popu- lation—Depression.	ACO-40	Depression Remission at Twelve Months.	 NQF #0710 MNCM.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Diabetes.	ACO-27	Diabetes Composite (All or Nothing Scoring): ACO-27: Diabetes Mellitus: Hemo- globin A1c Poor Control.	 NQF #0059 NCQA (indi- vidual com- ponent).	CMS Web Interface.	R	P	P
	ACO-41	ACO-41: Diabetes: Eye Exam	 NQF #0055 NCQA (indi- vidual com- ponent).	CMS Web Interface.	R	P	Р
Clinical Care for At Risk Population—Hypertension.	ACO-28	Hypertension (HTN): Control- ling High Blood Pressure.	 NQF #0018 NCQA.	CMS Web Interface.	R	Р	Р
Clinical Care for At Risk Popu- lation—Ischemic Vascular Disease.	ACO-30	Ischemic Vascular Disease (IVD): Use of Aspirin or An- other Antithrombotic.	 NQF #0068 NCQA.	CMS Web Interface.	R	P	P

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	8	C management of the state of th	16	25
Care Coordination/Patient Safety	10	10 measures, including double-scored EHR measure.	22	25
Preventive Health	8	8 measures	16	25

¹³The quality measure title has been updated to "Providers" and is not only referencing "Doctors."

Table VI.

TABLE 37—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience Care Coordination/Patient Safety		8 individual survey module measures	16 22	25 25
Preventive Health	8	measure. 8 measures	16	25

¹³ The quality measure title has been updated to "Providers" and is not only referencing "Doctors."