Issue Brief

FEDERAL ISSUE BRIEF • July 10, 2015

KEY POINTS

- Proposed payment increase of 0.5 percent.
- Other discussions and proposals relating to:
  - Telehealth services
  - "Incident to" policy
  - Updates to the ambulance fee schedule
  - Physician quality reporting system
  - Medicare shared savings program
  - Value-based payment modifier

CMS Issues Proposed Changes to the MPFS and Other Part B Services for CY 2016

The Centers for Medicare and Medicaid Services has issued a proposed rule regarding revisions to payment policies and payment rates under the Medicare Physician Fee Schedule for calendar year 2016. A copy of the document is available on the *Federal Register* website at: https://www.federalregister.gov/articles/2015/07/15/2015-16875/medicare-programs-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

The rule is scheduled for publication on July 15. A 60-day comment period ending Sept. 8 is provided.

The PFS Addenda along with other supporting documents and tables are available CMS' website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSCMS-1612-P_13_Federal-Regulation-Notices.html. Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS *Federal Register* and other related documents. For the CY 2016 PFS proposed rule, refer to item CMS-1631-P.

The proposal's table of contents offers a concise list of items discussed in the document.

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COMMENT

As always the MPFS rule is a long, complex and detailed document. This version is 815 pages. Again, there is much material on the continued emphasis and data requirements for quality reporting. And, again there is much history being repeated in numerous sections. To reduce the size of this analysis many of the rule's tables and their pages are referenced rather than extracted.

RECENT LEGISLATIVE ITEMS

The following legislative changes weigh on numerous items being proposed.

Section 220(d) of the Protecting Access to Medicare Act of 2014, enacted on April 1, 2014, added a new subparagraph (O) to section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. The PAMA originally applied the target to CYs 2017 through 2020 and set the target amount to 0.5 percent of the estimated amount of expenditures under the PFS for each of those four years.

Section 202 of the Achieving a Better Life Experience Act of 2014, enacted Dec. 19, 2014 accelerated the application of the target to specify that targets would apply for CYs 2016, 2017, and 2018 and set a 1.0 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018.

The Medicare Access and CHIP Reauthorization Act of 2015 enacted on April 16, 2015 makes several changes to the statute, including but not limited to:

(1) Repealing the sustainable growth rate update methodology for physicians' services.

(2) Revising the PFS update for 2015 and subsequent years.

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(3) Establishing a Merit-based Incentive Payment System under which eligible professionals (initially including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) receive annual payment increases or decreases based on their performance in a prior period.

CONVERSION FACTOR

The conversion factor details are located in the rule's regulatory impact analysis. CMS estimates the CY 2016 PFS conversion factor to be $36.1096, which reflects a budget neutrality adjustment of 0.9999 and a 0.5 percent update factor specified under MACRA. The current CY 2015 CF is $35.9335.

CMS estimates the CY 2016 anesthesia conversion factor to be $22.6296, which reflects the 0.9999 budget neutrality adjustment, a 0.99602 anesthesia fee schedule practice expense and malpractice adjustment, and the 0.5 percent update specified under the MACRA.

I. Provisions of the Proposed Rule for PFS

A. **Determination of Practice Expense Relative Value Units**

Practice expense is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses. CMS is proposing a number of adjustments as follows:

- Incorporating available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014.
- In cases where the American Medical Association/Specialty Society Relative (Value) Update Committee (RUC)-recommended times differed from existing standards, CMS has refined the time for those tasks to align with the values as reflected in the rule's Table 6 (refer page 48).
- Proposing adjustments for CPT codes 22510 (percutaneous vertebroplasty (bone biopsy included when performed and 22511 (percutaneous vertebroplasty (bone biopsy included when performed.

The PE RVUs are displayed in Addendum B on CMS' website.

B. Determination of Malpractice Relative Value Units

For CY 2016, CMS is proposing to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services, and to adjust MP RVUs for risk. For CY 2016, CMS is proposing to modify the specialty mix assignment methodology to use an average of the three most recent years of available data instead of a single year of data, as is current policy.

For CY 2016, in order to appropriately update the MP resource costs for anesthesia, CMS is proposing to make adjustments to the anesthesia conversion factor to reflect the updated premium information collected for the five-year review.

The CY 2016 PFS proposed MP RVUs, as displayed in Addendum B reflect MP RVUs calculated following CMS' established methodology, with the inclusion of proposals and refinements.

C. Potentially Misvalued Services Under the Physician Fee Schedule

Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services.

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CMS is proposing 118 codes listed in the rule's Table 8 (refer page 75) as potentially misvalued codes, identified using the high expenditure screen under the statutory category, "codes that account for the majority of spending under the PFS."

If the net reductions in misvalued codes in 2016 are not equal to or greater than 1.0 percent of the estimated expenditures under the fee schedule, a reduction equal to the percentage difference between 1.0 percent and the estimated net reduction in expenditures resulting from misvalued code reductions must be made to all PFS services.

CMS is proposing a methodology for the implementation of this provision, which includes how net reductions in misvalued codes would be calculated. Based on that methodology, CMS has identified changes that achieve 0.25 percent in net reductions. However, CMS could make further misvalued code changes in the final rule to move closer to the statutory goal of 1.0 percent based on public comment and new recommendations.

Section 523 of the MACRA addresses payment for global surgical packages. Section 523(a) adds a new paragraph at section 1848(c)(8) of the Act. Section 1848(c)(8)(A)(i) of the Act prohibits the Secretary from implementing the policy established in the CY 2015 PFS final rule that would have transitioned all 10-day and 90-day global surgery packages to 0-day global periods.

D. Refinement Panel

Beginning in CY 2016, CMS is proposing to permanently eliminate the refinement panel that was established in 1993, and instead publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. For example, CMS will publish the proposed rates for all CY 2016 interim final codes in the CY 2017 PFS proposed rule.

E. Improving Payment Accuracy for Primary Care and Care Management Services

Because CY 2015 is the first year for which CMS is making separate payment for CCM services, CMS is seeking information regarding the circumstances under which this service is furnished. This information includes the clinical status of the beneficiaries receiving the service and the resources involved in furnishing the service, such as the number of documented non-face-to-face minutes furnished by clinical staff in the months the code is reported.

F. Target for Relative Value Adjustments for Misvalued Services

To implement the PFS expenditure reduction target provisions under section 1848(c)(2)(O) of the Act, CMS notes that it must identify a subset of the adjustments in RVUs for a year to reflect an estimated "net reduction" in expenditures.

CMS says it believes that the best approach is to define the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values.

CMS is proposing to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.

The list of codes with proposed changes for CY 2016 included under this proposed definition of "adjustments to RVUs for misvalued codes" is available

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on the CMS website under downloads for the CY 2016 PFS proposed rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.

CMS is proposing to net the increases and decreases in values for services, including those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes.

CMS is proposing to use the approach of comparing the total RVUs (by volume) for the relevant set of codes in the current year to the update year, and divide that result by the total RVUs (by volume) for the current year.

CMS did not incorporate the impact of the target into the calculation of the proposed PFS payment rates.

G. Phase-in of Significant RVU Reductions

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, also specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. Although section 220(e) of the PAMA required the phase-in to begin for 2017, section 202 of the ABLE Act amended section 1848(c)(7) of the Act to require that the phase-in begin for CY 2016.

CMS is proposing to apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and to exclude codes that describe different services in the current and update year.

CMS is proposing to reduce a service by the maximum allowed amount (that is, 19 percent) in the first year, and then phase in the remainder of the reduction in the second year. Under this approach, the code that is reduced by 19 percent in a year and the code that would otherwise have been reduced by 20 percent would both be reduced by 19 percent in the first year, and the latter code would see an additional 1 percent reduction in the second year of the phase-in.

CMS is proposing to estimate whether a particular code meets the 20 percent threshold for change in total RVUs by taking into account the total RVUs that apply to a particular setting or to a particular component.

The list of codes subject to the phase-in, and the RVUs that result from this proposed methodology, is available on the CMS website under downloads for the CY 2016 PFS proposed rule at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.

H. Changes for Computed Tomography under the Protecting Access to Medicare Act of 2014 (CY 2016 only)

Section 218(a) of PAMA is entitled "Quality Incentives To Promote Patient Safety and Public Health in Computed Tomography Diagnostic Imaging." It amends the statute by reducing payment for the technical component (and the TC of the global fee) of the PFS service and the hospital outpatient prospective payment system (OPPS) payment (5 percent in 2016 and 15 percent in 2017 and subsequent years) for computed tomography services identified by CPT codes 70450-70498, 71250-71275, 72125-72133,

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72191-72194, 73200-73206, 73700-73706, 74150-74178, 74261-74263, and 75571-75574 furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management."

To implement this provision, CMS will create modifier "CT" (Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association XR-29-2013 standard). Beginning in 2016, claims for CT scans described by above-listed CPT codes (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scans must include modifier "CT" and that modifier will result in the applicable payment reduction for the service.

I. Valuation of Specific Codes

CMS notes that establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS.

For CY 2016, CMS is proposing new values in the proposed rule for the codes for which it received complete RUC recommendations by Feb. 10, 2015. For recommendations regarding any new or revised codes received after the Feb. 10, 2015, deadline, including updated recommendations for codes included in this proposed rule, CMS will establish interim final values in the final rule with comment period, consistent with previous practice.

Tables 9 and 10 detail the invoices received for new and existing items in the direct PE database. (refer pages 128-130)

The rule's Table 11 contains a list of proposed work RVUs for all codes with RUC recommendations received by February 10, 2015. (refer pages 131-139)

Table 12 identifies CY 2016 Proposed Codes with Direct PE Input Recommendations Accepted Without Refinement. (refer pages 139-140)

The rule's Table 13 details CMS' refinements of the RUC's direct PE recommendations at the code-specific level. (refer pages 141-221)

Table 14 contains a crosswalk for establishing CY 2016 new, revised, and potentially misvalued codes malpractice RVUs (refer pages 222-224)

Table 15 lists the CY 2016 HCPCS codes and their respective source codes used to set the proposed CY 2016 MP RVUs. (refer pages 227-229)

Based on information provided with the Relative Value Update Committee recommendations for the increased use of equipment, CMS is proposing to change the utilization rate assumption used to determine the per minute cost of the capital equipment by assuming that the equipment is generally used for 35 hours per week (a 70 percent utilization rate) instead of 25 hours per week (a 50 percent utilization rate). CMS is proposing to implement this change over two years.

COMMENT

This is a long and detailed section – some 162 pages – containing changes to specific codes. In addition to the many tables listed above, the material also addresses Lower GI Endoscopy Services, Radiation Treatment and Related Image Guidance Services, Advance Care Planning Services, and Proposed Valuation of Other Codes for CY 2016.

J. Medicare Telehealth Services

CMS proposes to add the following

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services to the telehealth list on a category 1 basis for CY 2016:

- CPT code 99356 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service); and 99357 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service).
- CPT codes 90963 (end-stage renal disease) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (end-stage renal disease) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (end-stage renal disease related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (end stage renal disease) related services for home dialysis per full month, for patients 20 years of age and older).

K. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

CMS is proposing to amend §410.26(b)(5) to state that the physician or other practitioner who bills for incident to services must also be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services. Also, to further clarify the meaning of the proposed amendment to this regulation, CMS is proposing to remove the last sentence from §410.26(b)(5) specifying that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

L. Portable X-ray: Billing of the Transportation Fee

Portable X-ray suppliers receive a transportation fee for transporting portable X-ray equipment to the location where portable X-rays are taken.

CMS is proposing to revise the Medicare Claims Processing Manual (Pub. 100-4, Chapter 13, Section 90.3) to remove the word "Medicare" before "patient" in section 90.3. CMS is also proposing to clarify that this sub-regulatory guidance means that, when more than one patient is X-rayed at the same location, the single transportation payment under the PFS is to be prorated among all patients (Medicare Parts A and B, and non-Medicare) receiving portable X-ray services during that trip, regardless of their insurance status.

II. Other Provisions of the Proposed Regulations

A. Proposed Provisions associated with the Ambulance Fee Schedule

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met.

CMS is continuing to apply a 22.6 percent rural bonus to ground ambulance

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services with dates of service before Jan. 1, 2018, where transportation originates in a qualified rural area.

CMS is proposing to continue implementation of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13-01 for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes.

CMS is proposing to revise §410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished, and the current Medicare requirements under §410.41(b).

B. Chronic Care Management Services for Rural Health Clinics and Federally Qualified Health Centers

CMS proposes to provide an additional payment for the costs of CCM services that are not already captured in the RHC all-inclusive rate or the FQHC PPS payment, beginning on Jan. 1, 2016. Services that are currently being furnished and paid under the RHC AIR or FQHC PPS payment methodology will not be affected by the ability of the RHC or FQHC to receive payment for additional services that are not included in the RHC AIR or FQHC PPS.

The requirements for RHCs and FQHCs to receive payment for CCM services are consistent with those finalized in the CY 2015 PFS final rule for practitioners billing under the PFS and are summarized in the rule's Table 17. (refer page 332)

C. Healthcare Common Procedure Coding System Coding for Rural Health Clinics

CMS proposes that all RHCs must report all services furnished during an encounter using standardized coding systems, such as level I and level II of the HCPCS, for dates of service on or after Jan. 1, 2016.

D. Payment to Grandfathered Tribal FQHCs That Were Provider-Based Clinics On Or Before April 7, 2000

CMS is proposing that IHS and tribal facilities and organizations that met the conditions of section 413.65(m) on or before April 7, 2000, and have a change in their status on or after April 7, 2000, from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital such that the organization no longer meets the CoPs, may seek to become certified as grandfathered tribal FQHCs.

E. Part B Drugs

The FDA approved the first biosimilar product under the new biosimilar approval pathway required by the Affordable Care Act on March 6, 2015. CMS is proposing to update the regulations to clarify that the payment amount for a billing code that describes a biosimilar biological drug product is based on the average sales price of all biosimilar biological products that reference a common biological product's license application.

F. Productivity Adjustment for the Ambulance, Clinical Laboratory, and DMEPOS Fee Schedules

Beginning with CY 2016, for the AFS, CLFS and DMEPOS fee schedule, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs.

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A complete description of the MFP projection methodology is available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.

G. 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 for advanced diagnostic imaging services.

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after Jan. 1, 2017 (section 1834(q)(5)).

CMS is proposing to provide definitions for areas of the statute that require clarification. For example, a definition is required for "provider-led entity" in order to identify which organizations are eligible to develop or endorse appropriate use criteria. In addition, CMS proposes to establish a process by which the agency will identify clinical areas of priority, specify appropriate use criteria, and lay out a timeline to accomplish these goals. CMS is proposing that provider-led entities must apply to CMS to become qualified.

This proposed AUC program only applies in applicable settings. An applicable setting would include a physician's office, a hospital outpatient department (including an emergency department) and an ambulatory surgical center. The inpatient hospital setting, for example, is not an applicable setting.

H. Physician Compare Website

The rule's Table 18 provides a summary of previously finalized policies for public reporting data on Physician Compare. (refer page 379)

In addition to continuing existing policies, such as making all individual and group-level PQRS measures available for public reporting, CMS also proposes several new policies:

- To include an indicator on profile pages for individual eligible professionals who satisfactorily report the new PQRS Cardiovascular Prevention measures group in support of Million Hearts and group practices and individual EPs who receive an upward adjustment for the Value Modifier;
- To make individual-level QCDR measures available for public reporting, and, new to 2016, to publicly report group-level QCDR measures;
- To publicly report an item (or measure)-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology.
- To include in the downloadable database the Value Modifier tiers for cost and quality, noting if the group practice or EP is high, low, or neutral on cost and quality; a notation of the payment adjustment received based on the cost and quality tiers; and an indication if the individual EP or group practice was eligible to but did not report quality measures to CMS; and

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- To publicly report in the downloadable database utilization data for individual EPs.

Consistent with existing policies, all data must meet the minimum sample size of 20 patients and prove to be statistically valid and reliable. For individual and group-level measures, CMS will publicly report all measures submitted, reviewed, and deemed valid and reliable in the Physician Compare downloadable file. However, not all measures will be included on the Physician Compare profile pages.

CMS proposes to publicly report an item (or measure)-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology, which is annually based on the PQRS performance rates most recently available. A benchmark would allow consumers to more easily evaluate the published information by providing a point of comparison between groups and between individuals. On Physician Compare, the benchmark would be displayed as a five star rating.

The rule's Table 19 summarizes the Physician Compare measure and participation data proposals being discussed.

Data Collection Year*	Publication Year*	Data Type	Reporting Mechanism	Proposed Quality Measures and Data for Public Reporting
2016	2017	PQRS, PQRS GPRO, EHR, and Million Hearts	Web Interface, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS, participants in the EHR Incentive Program, and EPs who satisfactorily report the Cardiovascular Prevention measures group proposed under PQRS in support of Million Hearts.
2016	2018	PQRS, PQRS GPRO	Web Interface, EHR, Registry, Claims	Include an indicator for individual EPs and group practices who receive an upward adjustment for the VM.
2016	2017	PQRS GPRO	Web Interface, EHR, Registry	All PQRS GPRO measures reported via the Web Interface, EHR, and registry that are available for public reporting for group practices of two or more EPs. Publicly report an item-level benchmark, as appropriate.
2016	2017	ACO	Web Interface, Survey Vendor Claims	All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs.
2016	2017	CAHPS for PQRS	CMS-Specified Certified CAHPS Vendor	All CAHPS for PQRS measures for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2016	2017	PQRS	Registry, EHR, or Claims	All PQRS measures for individual EPs collected through a registry, EHR, or claims. Publicly report an item-level benchmark, as appropriate.
2016	2017	QCDR data	QCDR	All individual EP and group practice QCDR measures.

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Data Collection Year*	Publication Year*	Data Type	Reporting Mechanism	Proposed Quality Measures and Data for Public Reporting
2016	2017	Utilization data	Claims	Utilization data for individual EPs in the downloadable database.
2016	2017	PQRS, PQRS GPRO	Web Interface, EHR, Registry, Claims	The following data for group practices and individual EPs in the downloadable database: The VM quality tiers for cost and quality, noting if the group practice or EP is high, low, or neutral on cost and quality per the VM. A notation of the payment adjustment received based on the cost and quality tiers. An indication if the individual EP or group practice was eligible to but did not report quality measures to CMS.

** Note that these data are proposed to be reported annually. The table only provides the first year in which these proposals would begin on an annual basis, and such dates also serve to illustrate the data collection year in relation to the publication year. Therefore, after 2016, 2017 data would be publicly reported in 2018, 2018 data would be publicly reported in 2019, etc.*

I. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

This section contains the proposed requirements for the Physician Quality Reporting System.

Please note that section 101(b)(2)(A) of MACRA amends section 1848(a)(8)(A) by striking "2015 or any subsequent year" and inserting "each of 2015 through 2018." This amendment authorizes the end of the PQRS in 2018 and beginning of a new program, which may incorporate aspects of the PQRS, the Merit-based Incentive Payment System (MIPS).

The proposed requirements primarily focus on proposals related to the 2018 PQRS payment adjustment, which will be based on an EP's or a group practice's reporting of quality measures data during the 12-month calendar year reporting period occurring in 2016 (that is, Jan. 1 through Dec. 31, 2016).

If the EP does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

The proposals for this year reflect CMS' intent to continue to implement the PQRS by proposing requirements for the 2018 PQRS payment adjustment consistent with the requirements for the 2017 PQRS payment adjustment. CMS proposes to establish the same criteria for satisfactory reporting and, in lieu of satisfactory reporting, satisfactory participation in a qualified clinical data registry, that was established for the 2017 PQRS payment adjustment, which is generally to require the reporting of nine measures covering three National Quality Strategy domains.

continued

The rule's Tables 20 and 21 reflect CMS' proposed criteria for satisfactory reporting — or, in lieu of satisfactory reporting, satisfactory participation in a QCDR — for the 2018 PQRS payment adjustment:

Table 20: Summary of Proposed Requirements for the 2018 PQRS Payment Adjustment: Individual Reporting Criteria for the Satisfactory Reporting of Quality Measures Data via Claims, Qualified Registry, and EHRS and Satisfactory Participation Criterion in QCDRS

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting/Satisfactory Participation Criteria
12-month (Jan. 1–Dec. 31, 2016)	Individual Measures	Claims	Report at least nine measures, covering at least three of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least one Medicare patient in a face-to-face encounter, the EP will report on at least one measure contained in the PQRS crosscutting measure set. If less than nine measures apply to the EP, the EP would report on each measure that is applicable), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.
12-month (Jan. 1–Dec. 31, 2016)	Individual Measures	Qualified Registry	Report at least nine measures, covering at least three of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least one Medicare patient in a face-to-face encounter, the EP will report on at least one measure contained in the PQRS crosscutting measure set. If less than nine measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.
12-month (Jan. 1–Dec. 31, 2016)	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product	Report nine measures covering at least three of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least nine measures covering at least domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least one measure for which there is Medicare patient data.
12-month (Jan. 1–Dec. 31, 2016)	Measures Groups	Qualified Registry	Report at least one measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a zero percent performance rate will not be counted.
12-month (Jan. 1–Dec. 31, 2016)	Individual PQRS measures and/or non- PQRS measures reportable via a QCDR	Qualified Clinical Data Registry (QCDR)	Report at least nine measures available for reporting under a QCDR covering at least three of the NQS domains, AND report each measure for at least 50 percent of the EP's patients. Of these measures, the EP would report on at least two outcome measures, OR, if two outcomes measures are not available, report on at least 1 outcome measures and at least one of the following types of measures – resource use, patient experience of care, efficiency/appropriate use, or patient safety.

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

Reporting Period	Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
12-month (Jan. 1–Dec. 31, 2016)	25+ Eps (if CAHPS for PQRS does not apply)	Individual GPRO Measures in the GPRO Web Interface	GPRO Web Interface	Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least one measure for which there is Medicare patient data.
12-month (Jan. 1–Dec. 31, 2016)	25+ EPs (if CAHPS for PQRS applies)	Individual GPRO Measures in the GPRO Web Interface + CAHPS for PQRS	GPRO Web Interface + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS- certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least one measure for which there is Medicare patient data. Please note that, if the CAHPS for PQRS survey is applicable to a group practice who reports quality measures via the GPRO web interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the GPRO web interface measures.

continued

TABLE 21: Summary of Proposed Requirements for the 2018 PQRS Payment Adjustment: Group Practice Reporting Criteria for Satisfactory Reporting of Quality Measures Data via the GPRO				
Reporting Period	**Group Practice Size**	**Measure Type**	**Reporting Mechanism**	**Satisfactory Reporting Criteria**
12-month (Jan. 1–Dec. 31, 2016)	2+ EPs	Individual Measures	Qualified Registry	Report at least nine measures, covering at least three of the NQS domains. Of these measures, if a group practice sees at least one Medicare patient in a face-to-face encounter, the group practice would report on at least one measure in the PQRS crosscutting measure set. If less than nine measures covering at least three NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.
12-month (Jan. 1–Dec. 31, 2016)	2+ EPs that elect CAHPS for PQRS	Individual Measures + CAHPS for PQRS	Qualified Registry + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS- certified survey vendor, and report at least six additional measures, outside of the CAHPS for PQRS survey, covering at least two of the NQS domains using the qualified registry. If less than six measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any EP in the group practice sees at least one Medicare patient in a face-to-face encounter, the group practice must report on at least one measure in the PQRS cross-cutting measure set.
12-month (Jan. 1–Dec. 31, 2016)	2+ EPs	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product	Report nine measures covering at least three domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least nine measures covering at least three domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least one measure for which there is Medicare patient data.

continued

TABLE 21: Summary of Proposed Requirements for the 2018 PQRS Payment Adjustment: Group Practice Reporting Criteria for Satisfactory Reporting of Quality Measures Data via the GPRO				
Reporting Period	**Group Practice Size**	**Measure Type**	**Reporting Mechanism**	**Satisfactory Reporting Criteria**
12-month (Jan. 1–Dec. 31, 2016)	2+ EPs that elect CAHPS for PQRS	Individual Measures + CAHPS for PQRS	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS- certified survey vendor, and report at least six additional measures, outside of CAHPS for PQRS, covering at least two of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is Medicare patient data. Of the additional six measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least one measure for which there is Medicare patient data.
12-month (Jan. 1–Dec. 31, 2016)	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR	Qualified Clinical Data Registry (QCDR)	Report at least nine measures available for reporting under a QCDR covering at least three of the NQS domains, AND report each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least two outcome measures, OR, if two outcomes measures are not available, report on at least one outcome measures and at least one of the following types of measures — resource use, patient experience of care, efficiency/appropriate use, or patient safety.

In Tables 22 through 30, CMS proposes changes to the PQRS measures set. The current PQRS measures list is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/PQRS_2015_Measure-List_111014.zip.

Table 22: Proposed Individual Quality Cross-Cutting Measures for the PQRS to be Available for Satisfactory Reporting via Claims, Registry, and EHR beginning in 2016 — refer page 441.

Table 23: New Individual Quality Measures and those Included in Measures Groups for the PQRS to be Available for Satisfactory Reporting Beginning in 2016 — refer page 443.

Table 24: Proposed NQS Domain Changes for Individual Quality Measures and those Included in Measures Groups for the PQRS beginning in 2016 — refer page 474.

Table 25: Measures Proposed for Removal from the Existing PQRS Measure Set Beginning in 2016 — refer page 475.

Table 26: Existing Individual Quality Measures and those Included in Measures Groups for the PQRS for Which Measure Reporting Updates will be Effective beginning in 2016 — refer page 482.

CMS proposes to add 3 new measures groups as shown in Tables 27, 28 and 29 that will be available for reporting in the PQRS beginning in 2016.

Table 27: Cardiovascular Prevention Measures Group for 2016 and Beyond (Millions Hearts) — refer page 490.

Table 28: Diabetic Retinopathy Measures Group for 2016 and Beyond — refer page 491.

Table 29: Multiple Chronic Conditions Measures Group for 2016 and Beyond — refer 491.

CMS proposes to amend the following previously finalized measures groups for reporting in the PQRS beginning in 2016. Please note that, in these tables, CMS provides the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these proposed measures groups that are proposed to be added, as indicated in Table 23, do not have a PQRS number. Therefore, in lieu of a PQRS number, an "NA" is indicated.

Table 29A: Coronary Artery Bypass Graft Measures Group for 2016 and Beyond.

Table 29B: Dementia Measures Group for 2016 and Beyond.

Table 29C: Diabetes Measures Group for 2016 and Beyond.

Table 29D: Preventive Care Measures Group for 2016 and Beyond.

Table 29E: Rheumatoid Arthritis Measures Group for 2016 And Beyond.

CMS is proposing to adopt STAT-1 (Statin) in Table 30 for reporting via the GPRO web interface beginning in 2016: *The Merit-based Incentive Payment System* Section 1848(q) of the Act, added by section 101(c) of the MACRA, requires creation of the MIPS, applicable beginning with payments for items and services furnished on or after January 1, 2019, under which the Secretary shall: (1) develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards for a performance period for a year; (2) using the methodology, provide for a composite performance score for each eligible professional for each performance period; and (3) use the composite performance score of the MIPS eligible professional for a performance period for a year to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the professional for the year.

J. Electronic Clinical Quality Measures and Certification Criteria; and Electronic Health Record Incentive Program-Comprehensive Primary Care Initiative and Medicare Meaningful Use Aligned Reporting

CMS proposes to retain the group reporting option for CPC practice sites as finalized in the CY 2015 PFS final rule, but for CY 2016, to require CPC practice sites to submit at least nine CPC CQMs that cover three domains.

CMS is proposing that for CY 2016, EPs who are part of CPC practice site and are in their first year of demonstrating meaningful use may also use this CPC

continued

group reporting option to report their CQMs electronically instead of reporting CQMs by attestation through the EHR Incentive Program's Registration and Attestation System.

K. Potential Expansion of the Comprehensive Primary Care Initiative

The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. It is being conducted under the authority of section 1115A of the Act (added by section 3021 of the Affordable Care Act). There are approximately 480 participating practices spread across the regions, and 38 participating payers.

CMS is soliciting input from the public for any potential expansion of the CPC initiative

L. Medicare Shared Savings Program

CMS is proposing to add one new measure to the Preventive Health domain, which would increase the current total number of measures from 33 to 34 measures — Statin Therapy for the Prevention and Treatment of Cardiovascular Disease. Data collection for the new measure would occur through the CMS web interface.

Table 31 lists the Shared Savings Program quality measure set, including the one measure being proposed, that would be used to assess ACO quality starting in 2016.

Measures for Use in Establishing Quality Performance Standards that ACOS Must Meet for Shared Savings								
Domain	ACO Measure #	Measure Title	New Measure PY 1	NQF #/Measure Steward PY 2 PY 3	Method of Data Submission	Pay for Performance Phase-in R -Reporting P-Performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF #0005, AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Doctors Communicate		NQF #0005 AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Doctor		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 Making		NQF #N/A CMS/AHRQ	Survey	R	P	P

continued

Measures for Use in Establishing Quality Performance Standards that ACOS Must Meet for Shared Savings								
Domain	ACO Measure #	Measure Title	New Measure PY 1	NQF #/Measure Steward PY 2 PY 3	Method of Data Submission	Pay for Performance Phase-in R -Reporting P-Performance		
						PY1	PY2	PY3
	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 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)		NQF #TBD 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	P
	ACO -38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions		NQF#TBD CMS	Claims	R	R	P
	ACO - 9	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease or Asthma in Older Adults (AHRQ Prevention Quality Indicator (PQI) #5)		Adapted NQF #0275 AHRQ	Claims	R	P	P
	ACO - 10	Ambulatory Sensitive Conditions Admissions: Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)		Adapted NQF #0277 AHRQ	Claims	R	P	P
	ACO - 11	Percent of PCPs who Successfully Meet Meaningful Use Requirements		NQF #N/A CMS	EHR Incentive Program Reporting	R	P	P
	ACO -39	Documentation of Current Medications in the Medical Record		NQF #0419 CMS	CMS Web Interface	R	P	P

continued

Measures for Use in Establishing Quality Performance Standards that ACOS Must Meet for Shared Savings								
Domain	ACO Measure #	Measure Title	New Measure PY 1	NQF #/Measure Steward PY 2 PY 3	Method of Data Submission	Pay for Performance Phase-in R -Reporting P-Performance		
						PY1	PY2	PY3
	ACO - 13	Falls: Screening for Future Fall Risk		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI		R	P	P
	ACO – 15	Pneumonia Vaccination Status for Older Adults		NQF #0043 NCQA	CMS Web Interface	R	P	P
	ACO – 16	Preventive Care and Screening: Body Mass Index Screening and Follow Up		NQF #0421 CMS	CMS Web Interface	R	P	P
	ACO – 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO – 18	Preventive Care and Screening: Screening for 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	P
	ACO – 20	Breast Cancer Screening		NQF #NA NCQA	CMS Web Interface	R	R	P
	ACO - 21	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented		CMS	CMS Web Interface	R	R	P
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	X	NQF #TBD MUC ID: X3729 CMS	CMS Web Interface	R	R	P
Clinical Care for At Risk Population - 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: Hemoglobin A1c Poor Control		NQF #0059 NCQA (individual component)	CMS Web Interface	R	P	P

continued

Measures for Use in Establishing Quality Performance Standards that ACOS Must Meet for Shared Savings								
Domain	ACO Measure #	Measure Title	New Measure PY 1	NQF #/Measure Steward PY 2 PY 3	Method of Data Submission	Pay for Performance Phase-in R -Reporting P-Performance		
						PY1	PY2	PY3
	ACO - 41	ACO - 41: Diabetes: Eye Exam		NQF #0055 NCQA (individual component)	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension: Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Ischemic Vascular Disease	ACO - 30	Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic		NQF #0068 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Heart Failure	ACO - 31	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction		NQF #0083 AMA-PCPI	CMS Web Interface	R	R	P

Table 32 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes with the proposed additional measure in the At-Risk Population domain. The total possible points for the Preventive Health domain would increase from 16 points to 18 points. Otherwise, the current methodology for calculating an ACO's overall quality performance score would continue to apply. CMS is also seeking comment on whether the proposed Statin Therapy measure, with multiple denominators, should be scored at more than two points if commenters believe this measure should be treated as multiple measures within the Preventive Health domain instead of a single measure. For instance, the measure could be scored as three points, one point for each of the three denominators, due to the clinical importance of prevention and treatment of cardiovascular disease and the complexity of the measure. The EHR measure is currently the only measure scored more than two points in the current measure set, but given the multiple denominators that exist within the Statin Therapy measure, it could be scored greater than two points as well. (refer page 531)

CMS is also proposing to:

- Preserving flexibility to maintain or revert measures to pay for reporting if a measure owner determines the measure no longer aligns with updated clinical practice or causes patient harm;

continued

- Clarifying how PQRS-eligible professionals participating within an ACO meet their PQRS reporting requirements when their ACO satisfactorily reports quality measures; and
- Amending the definition of primary care services to include claims submitted by Electing Teaching Amendment hospitals and exclude claims submitted by Skilled Nursing Facilities.

M. Value-Based Payment Modifier and Physician Feedback Program

Section 1848(p) of the Act requires that CMS establish a value-based payment modifier and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting Jan. 1, 2015, and to all physicians and groups of physicians by Jan. 1, 2017.

Under the Value Modifier Program, performance on quality and cost measures can translate into payment incentives for EPs who provide high quality, efficient care, while EPs who underperform may be subject to a downward adjustment. This program is set to expire in CY 2018, as a new comprehensive program, required by MACRA, -- the Merit-Based Incentive Program begins in CY 2019.

This year, CMS proposes the following key provisions:

- To use CY 2016 as the performance period for the CY 2018 Value Modifier;
- To apply the Value Modifier to nonphysician EP-only groups -- e.g., Physician Assistants, Nurse Practitioners, Clinical Nurse Specialists, Certified Registered Nurse Anesthetists and nonphysician EP solo practitioners, beginning with the CY 2018 payment adjustment period;
- To continue to apply the CY 2018 Value Modifier based on participation in the PQRS by groups and solo practitioners;
- To apply the quality-tiering methodology to all groups and solo practitioners that satisfactorily report PQRS and are determined to be in Category 1 for the CY 2018 payment adjustment period. Groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception finalized in the CY 2015 PFS final rule with comment period - that groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018;
- To waive application of the Value Modifier for groups and solo practitioners, as identified by Tax Identification Number, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the Value Modifier participated in the Pioneer ACO Model, CPCI, or other similar Innovation Center model during the performance period, beginning with the CY 2017 payment adjustment period;
- To continue to set the maximum upward adjustment under the CY 2018 Value Modifier at: +4.0 times an adjustment factor (to be determined after the conclusion of the performance period), for groups with ten or more EPs; +2.0 times an adjustment factor, for groups with between two to nine EPs and physician solo practitioners; and +2.0 times an adjustment factor for groups and solo practitioners that consist only of nonphysician EPs; and

continued

- To set the amount of payment at risk under the CY 2018 VM to -4.0 percent for groups with ten or more EPs, -2.0 percent for groups with between two to nine EPs and physician solo practitioners, and -2.0 percent for groups and solo practitioners that consist only of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

In the CY 2014 PFS final rule CMS finalized inclusion of the Medicare Sending Per Beneficiary measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. CMS finalized a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a TIN's cost composite.

CMS proposes to increase the episode minimum to 100 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period. Although this reduces the number of groups and solo practitioners for whom CMS would be able to include an MSPB calculation in the cost composite (from 29,190 to 8,543 based on 2013 data), CMS says it does not believe it should use the measure in calculating the cost composite if it is not reliable at the 20 episode minimum.

COMMENT

This section is quite detailed. Failure to comply could result in reduced payments.

N. Physician Self-Referral Updates

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services.

This rule would update the physician self-referral regulations to accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance.

Recruitment and Retention

CMS is proposing a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the employment of a nonphysician practitioner. The proposed exception would apply only where the nonphysician practitioner is a bona fide employee of the physician receiving the remuneration from the hospital (or of the physician's practice) and the purpose of the employment is to provide primary care services to patients of the physician practice.

CMS is proposing two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the nonphysician practitioner: (1) at least 90 percent of the patient care services furnished by the nonphysician practitioner must be primary care services; or (2) substantially all of the patient care services furnished by the nonphysician practitioner must be primary care services. CMS would define "substantially all" patient care services consistent with regulations; that is, at least 75 percent of the nonphysician practitioner's services to patients of the physician's practice must be primary care services.

CMS is proposing that records of the actual amount of remuneration provided to the physician (and to the nonphysician practitioner) be maintained for a period of at least six years and be made available to the Secretary upon request.

continued

Geographic Area Served by Federally Qualified Health Centers and Rural Health Clinics

CMS is proposing to revise §411.357(e)(6) to add a new definition of the geographic area served by a FQHC or RHC. The purpose of this revision is to ensure that the definition of the geographic area served by FQHCs and RHCs appropriately captures the areas where their patients actually reside and to provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception at §411.357(e).

Conforming Terminology: "Takes into Account"

CMS proposes to modify §411.357(e)(1)(iii) to conform to the exact language in section 1877(e)(5)(B) of the Act. Specifically, CMS proposes to amend §411.357(e) to require that the compensation provided to a recruited physician may not take into account (directly or indirectly) the volume or value of the recruited physician's referrals to the hospital, FQHC, or RHC providing the recruitment remuneration.

Retention Payments in Underserved Areas

CMS proposes to modify its regulations at §411.357(t)(2)(iv)(A) to reflect the regulatory intent which state that such retention payments may not exceed the lower of: (1) an amount equal to 25 percent of the physician's current income (measured over no more than a 24-month period), using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician.

Reducing Burden and Improving Clarity Regarding the Writing, Term, and Holdover Provisions in Certain Exceptions and other Regulations

CMS proposes the following changes:

- To clarify that the writing required in the exceptions can be a collection of documents and make the terminology that describes the types of arrangements consistent throughout the regulations;
- To clarify that the term of a lease or personal services arrangement need not be in writing if the arrangement lasts at least one year and is otherwise compliant.
- To allow expired leasing and personal services arrangements to continue on the same terms if otherwise compliant;
- To allow a 90-day grace period to obtain missing signatures without regard to whether the failure to obtain the signature was inadvertent;
- To clarify that DHS entities can give items used solely for certain purposes to physicians;
- To clarify that a financial relationship does not necessarily exist when a physician provides services to patients in the hospital if both the hospital and the physician bill independently for their services;
- To update obsolete language in the exception for ownership in publicly traded entities to allow over-the-counter transactions and delete certain unnecessary language;
- To establish a new exception to permit timeshare arrangements for the use of office space, equipment, personnel, supplies and other services that will benefit rural or underserved areas;
- To clarify that compensation paid to a physician organization cannot take into account the referrals of any physician in the physician organization, not just a physician who stands in the shoes of the physician organization; and

continued

- To seek comments on physician self-referral changes and guidance needed to advance alternative payment models and value-based purchasing.

COMMENT

The subject of physician referrals has always been viewed with extreme complexities. While CMS claims it is reducing burdens, the changes being proposed have many facets that need careful review. This subject is not simple.

O. Private Contracting/Opt-out

Section 106(a) of MACRA amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every two years. Therefore, physicians and practitioners that file opt-out affidavits on or after June 16, 2015 will no longer be required to file renewal affidavits in order to continue their opt-out status.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting