In the proposed Medicare Physician Fee schedule (PFS) update for 2016, CMS announces a number of new policies, making changes to several of the quality reporting initiatives that are associated with PFS payment, and begins implementation of the new payment system for physicians and other practitioners (the Merit-Based Incentive Payment System (MIPS)) required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), all as highlighted below.

**Physician Quality Reporting Modifications**
CMS tracks the quality of care provided to Medicare beneficiaries through the Physician Quality Reporting System (PQRS). CMS proposes to establish the same criteria for satisfactory reporting in 2018 as it established for 2017. The agency proposes to make changes to the PQRS measure set to add measures where gaps exist, as well as to eliminate measures that are topped out, duplicative, or being replaced. If all measure proposals are finalized, there will be 300 measures in the PQRS measure set for 2016.

If an individual practitioner or group practice does not satisfactorily report or satisfactorily participate while submitting data on PQRS quality measures, a 2 percent negative payment adjustment would apply in 2018. The adjustment (98 percent of the fee schedule amount that would otherwise apply to such services) would apply to covered professional services furnished by an individual practitioner or group practice during 2018. The 2018 PQRS payment adjustment is the last adjustment that will be issued under the PQRS. Following the 2018 PQRS payment adjustment, adjustments to payment for quality reporting and other factors will be made under MIPS, as required by MACRA. Physician Compare and Benchmark

As part of the 2016 PFS proposed rule, CMS will continue its phased approach to public reporting on Physician Compare. Consistent with existing policies, all data must meet the minimum sample size of 20 patients and 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.

CMS proposes to publicly report an item- (or measure)-level benchmark derived using the Achievable Benchmark of Care methodology, which is based on the PQRS performance rates most recently available. On Physician Compare, the benchmark would be displayed as a five-star rating.

**The Medicare EHR Incentive Program**
CMS proposes to revise the definition of *certified EHR technology* to require certification of EHR technology in accordance with criteria proposed by the Office of the National Coordinator for Health Information Technology.
The Medicare Shared Savings Program  
The proposed rule includes proposals specific to certain sections of the Shared Savings Program regulations and solicits feedback on the following:

- Adding a measure of Statin Therapy for the Prevention and Treatment of Cardiovascular Disease in the Preventive Health domain of the Shared Savings Program quality measure set to align with PQRS;
- 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;
- 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.

Advanced Care Planning
CMS proposes to establish separate payment and payment rates for two advance care planning services provided to Medicare beneficiaries by physicians and other practitioners. The statute currently provides coverage for advance care planning under the “Welcome to Medicare” visit available to all Medicare beneficiaries, but beneficiaries may not need these services when they first enroll. By establishing separate payment for advance care planning codes, CMS hopes to provide beneficiaries and practitioners greater opportunity to utilize these planning sessions at the most appropriate time for patients and their families.

Advance care planning is a service that includes early conversations between patients and their practitioners, both before an illness progresses and during the course of treatment, to decide on the type of care that is right for the patient.

Part B Drugs/Payment for Biosimilar Biological Products
In 2010, CMS issued regulations regarding payment for biosimilar biological products using a payment approach specified by the Affordable Care Act. CMS now proposes 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.

Misvalued Code Changes for Radiation Therapy
CMS has identified the codes for radiation therapy as potentially misvalued. Based on information provided with the Relative Value Update Committee (RUC) recommendations for the increased use of equipment, CMS proposes 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 proposes to implement this change over two years. CMS is seeking comment on additional sources of data regarding how often the machines are in use.

Misvalued Code Changes for Lower GI Endoscopy Services
CMS proposes to implement the revised set of codes and revised values for lower gastrointestinal endoscopies. In the 2015 PFS proposed rule, CMS noted that the practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. Due to changes in practice patterns, CMS considered establishing a uniform approach to valuation for all services that currently include moderate sedation in that rule.

CMS is seeking recommendations from the RUC and other interested parties regarding the valuation of the work associated with moderate sedation alone before proposing an approach that allows Medicare to make payments based on the resource costs associated with the moderate sedation or anesthesia services.
Additionally, CMS is proposing to identify anesthesia procedure codes 00740 and 00810 as potentially misvalued.

"Incident to" Policy
CMS is proposing that the billing physician or practitioner for “incident to” services must also be the supervising physician or practitioner. Additionally, CMS is proposing to require that auxiliary personnel providing “incident to” services and supplies cannot have been excluded from Medicare, Medicaid, or other federal health care programs by the Office of Inspector General, or have had their enrollment revoked for any reason at the time that they provide such services or supplies.

Potential Expansion of Comprehensive Primary Care Initiative (CPCI)
Through the CPCI, CMS is testing the impact of collaborating with 38 other payers – both private and public – to coordinate care for Medicare beneficiaries by providing population-based care management fees and shared savings opportunities for approximately 480 primary care practice sites in seven markets. CMS is soliciting comments on issues related to the potential expansion of CPCI, although the agency is not proposing an added expansion at this time.

Physician Value-Based Payment Modifier
The Value-Based Payment Modifier (Value Modifier or VM) provides for differential payments under the PFS to physicians, groups of physicians, and other eligible professionals (EPs) based on the quality and cost of care they furnish to beneficiaries enrolled in the traditional Medicare Fee-for-Service (FFS) program. The VM approach is set to expire in CY 2018, and MIPS will begin in CY 2019. In light of this, CMS is proposing certain steps to provide a smooth transition from the VM approach to MIPS.

CMS proposes the following key provisions:

- Use CY 2016 as the performance period for the CY 2018 Value Modifier.
- Apply the Value Modifier to nonphysician EP-only groups – e.g., Physician Assistants (PAs), Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs) and nonphysician EP solo practitioners, beginning with the CY 2018 payment adjustment period.
- Continue to apply the CY 2018 Value Modifier based on participation in the PQRS by groups and solo practitioners;
- 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 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.
- Waive application of the Value Modifier for groups and solo practitioners, as identified by Tax Identification Number (TIN), 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.
- 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.
- 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 with one to nine EPs.
percent for groups and solo practitioners that consist only of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

**Changes to Medicare Physician and Practitioner Opt-out**

Prior to MACRA, the statute provided that the longest period for which a Medicare opt-out affidavit from a physician or practitioner could be effective was two years. Section 106(a) of MACRA provides that opt-out affidavits filed on or after 60 days following the date of enactment automatically renew every two years. Physicians and practitioners are able to rescind their opt-out status if they notify CMS at least 30 days prior to the start of the next two-year period. CMS proposes conforming existing regulations to the MACRA requirement.

**Request for Comments on the MACRA**

In addition to repealing the Sustainable Growth Rate formula, MACRA established MIPS and encouraged participation in alternative payment models.

To help with implementation, CMS is requesting comments on a number of pieces of MACRA, including the selection of low-volume threshold, the definition of clinical practice improvement activities, and how to define a physician-focused payment model, as discussed in section 101(e) of MACRA.