PAAC meeting
11-10-15

NAME	
Ellaine Buenteng	R.N. Harbor Orthotics
Jim Connaughton	Bay Street Orthopaedics
Vickie Shepherd	Peabody Child Health
Laura Hughey	" "
Jen Powers	Bayside Family : Sports Med
Karen Williams	FMNM
Cindy Bedulu	FMNM
Pam Stoner	Digestive Health
Sandra Vanderwagen	ID & Nephrology
Robert Farrell	Innovis
Marty Zuke Whitcomb	Bayside
Hannah Howard	Digestive Health
Rosemary Fielding	IMNM
Hope Afferding	IMNM
Teresa Migda	IMNM
JANET BANGO	PSPC

Laura Simon - Healthcare Law Update

HEALTH CARE LAW UPDATE

NPO PAAC Petoskey

November 10, 2015

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I. Proposed policy, payment, and quality provisions changes to the Medicare Physician Fee Schedule for Calendar Year 2016 (October 30, 2015)

A. Final rule issued October 30, 2015 updating payment policies, payment rates, and quality revisions for services furnished under the Medicare Physician Fee Schedule on or after January 1, 2016.

B. Quality Provisions

1. Modifications to the Physician Quality Reporting System

2. Physician Compare

3. Physician Compare Benchmark

4. The Medicare EHR Incentive Program

5. Physician Value-Based Payment Modifier

6. Medicare Shared Savings Program

C. Advance Care Planning

D. Payment Provisions

1. Part B Drugs/Payment for Biosimilar Biological Products

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4. Implementation of the Statutory Phase-In of Significant RVU Reductions

5. Misvalued Code Changes for Lower GI Endoscopy Services

6. "Incident to" Policy for Calendar Year 2016

7. Physician Self-Referral Updates

8. MACRA Changes to Medicare Physician and Practitioner Opt Out

9. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

II. CMS and OIG Final ACO Waiver Rules (October 29, 2015)

A. Preamble states "We are waiving application of these fraud and abuse laws to ACO's formed in connection with the Medicare Shared Savings Program so that the laws do not unduly impede the development and operation of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal Health Care Programs."

The Final Rule adopted the following five waivers:

1. a "pre-participation" waiver of the Stark Law and the AKS for ACO start-up arrangements;

2. a "participation" waiver of the Stark Law and AKS that broadly applies to ACO-related arrangements during the term of the ACO's participation in the MSSP;

3. a "shared savings distribution" waiver of the Stark Law and AKS that applies to distributions and uses of shared savings generated by the ACO through the MSSP;

4. a "compliance with the physician self-referral law" waiver of the AKS for arrangements that implicate the Stark Law and satisfy an existing Stark Law exception; and

5. a patient incentive waiver of the Beneficiary Inducements CMP and the AKS for medically-related incentives offered by ACO's, ACO participants and ACO provider/suppliers to Medicare beneficiaries to encourage preventative care and compliance with treatment regimens.

B. Parties considering this option should undertake careful prior legal analysis to ensure that any actions will explicitly comply with the terms of the applicable waivers.

C. CMS and OIG will continue to monitor ACPs and the MSSP for fraud and abuse, including but not limited to:

- Billing for medically unnecessary or upcoded services;
- Stinting on medically necessary services
- Submitting false or fraudulent data; or
- Providing worthless or substandard care.

III. Affordable Care Act

A. 60 Day Rule for Identifying Overpayments

1. Health care providers that receive an overpayment from Medicare or Medicaid are required to report and return the overpayment to the government within 60 days after the date on which the overpayment was identified.

2. Overpayments retained after 60 days constitutes an "obligation" for purposes of potential False Claims Act. Obligations that are knowingly concealed, or knowingly and improperly avoided or decreased, which often provide the legal basis for liability under the FCA.

3. Difficulty lies in determining when an overpayment has been actually identified.

4. In *Kane ex.rel. United States v Healthfirst, Inc.* (S.D.N.Y. 2015), the Court held that for purposes of FCA liability, notice of potential overpayment is sufficient to start the 60 day clock ticking, rejecting defendant's argument that the 60 days start running when the overpayments have been calculated and properly quantified. The totality of the circumstances are important. In this case, an employee audited and charted a million dollars of suspected overpayments due to a billing system computer glitch. He was fired 4 days later and filed the FCA lawsuit. Addtionally, the claims weren't addressed for two years. The Court stated, that normally an obligation will not ripen into FCA liability without a finding of knowing concealment or knowing and improper avoidance or decrease of the obligation.

IV. FALSE CLAIMS ACT

A. Since January 2009 the Justice Department has recovered a total of more than $25.3 **billion** through False Claims Act cases, with more than $16.1 billion of that amount recovered in cases involving fraud against federal health care programs.

1. Columbus Regional Health Care System and Dr. Pippas agreed to pay $25 million to resolve allegations they violated the False Claims Act by submitting claims in violation of Stark, misrepresenting the level of services

they provided, with an additional contingent payment of $10 million, plus $425,000 from the doctor. (Settled September 4, 2015)

2. North Broward Hospital District agreed to pay the US $69.5 million to settle allegations that it violated the False Claims Act by engaging in improper financial relationships with referring Physicians. Allegations were that the hospital district provided compensation to nine employed physicians that exceeded the fair market value of their services. A whistleblower Physician filed a qui tam lawsuit and will receive $12,045,655.51 from the recovery. (Settled September 15, 2015).

3. Adventist Health System agreed to pay $115 million to settle allegations that it violated the False Claims Act by maintaining improper compensation arrangements with referring physicians and by miscoding claims. Allegedly it paid doctors bonuses based on the number of test and procedures they ordered. In addition, allegations that Adventist submitted bills to Medicare for its employed physicians professional services containing certain improper coding modifiers and thereby obtained greater reimbursement for these services than entitled, were settled. Whistleblowing employees in two separate cases will receive an as yet undetermined amount of settlement. (Settled September 21, 2015)

4. Tuomey Healthcare System resolved a $237 million judgment arising out of violations of the Stark Act, whereby it entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey and in exchange they were paid compensation that far exceeded fair market value and included part of the money Tuomey received from Medicare for the referred services. A physician who refused to sign such a contract, filed a False Claims Act lawsuit and will receive $18.1 million under the settlement. The Health system agreed to pay $72.4 million and to be sold to another health system. (Settled October 16, 2015)

V. OFFICE OF INSPECTOR GENERAL

A. COMPLIANCE GUIDANCE: Risks of Emerging Trends in the Healthcare Industry

1. New Types of Reimbursement such as value-based purchasing, service bundles and global payments for maintaining and promoting the health of individual patients or general populations have resulted in health care providers consolidating their services and significantly increased the use of contractual arrangements between providers.

a. Caution: Healthcare boards need to heighten their vigilance regarding relationships between the physicians they employ and

other healthcare entities. Must be alert to potential violations of federal anti-kickback statute and the False Claims Act (FCA) due to improper referral relationships/arrangements and billing issues that could lead to organizations to submit claims for services not rendered and/or medically unnecessary services.

2. Recent efforts to increase transparency in the healthcare industry have increased the amount of information available to the public. Organizations should use this information to measure their data against others in the industry and incorporate national benchmarks when assessing organizational risk and compliance.

3. Healthcare organizations should have completely independent compliance officers.

B. **2016 Work Plan** (November 3, 2015)

1. Increased scrutiny of protections of electronic protected health information with respect to networked medical devices.

- Dialysis machines
- Radiology systems
- Medication dispensing machines

that are integrated with EMRs and the large health network.

2. Plans to determine the extent to which hospitals comply with contingency planning requirements of HIPAA regarding their use of electronic health records.

a. Document the ways you have considered the disclosure statements for networked medical devices as part of HIPAA security risk assessments and overall HIPAA compliance plans.

b. Also be aware of the HIPAA risks when disposing of such devices. (erase hard drives)

3. Plans to step up audits in 2016, both onsite visits and remote desk reviews.

VI. MISCELLANEOUS

A. HHS Proposed Anti-Discrimination Regulations

1. Attempt to flush out the ACA's mandate prohibiting discrimination on the basis of race, color, national origin, sex, age or disability in the provision of services with respect to any health program or activity that receives federal financial assistance.

2. Apply to all health care providers (including providers who do not accept Medicare or Medicaid)

3. Sanctions available for violations include possible exclusion from Medicare.

4. The regulations change the ability fo providers to decline or terminate patients.

5. They require providers to incur additional expenses for items that many small providers have not previously been required to possess.

6. All health care providers will be required to provide a "qualified interpreter" in a timely manner to any person with limited English speaking ability whom they serve (patients) or encounter (anyone else) in administering services. Interpreters are required when oral communication is a reasonable step to provide meaningful access to the healthcare system.

7. Also protected:

- Gender Identity
- Sex Stereotyping
- Association Discrimination

8. Adopt grievance procedures

B. Proposed Changes to Medicare Reimbursement for Clinical Diagnostic Laboratory Tests.

1. Proposed rule published October 1, 2015, comment period closes November 24, 2015.

2. Requires applicable laboratories to collect and report private payor payment information from July 1, 2015 to December 31, 2015 and report the info to CMS by March 31, 2016. Then CMS will publish new payment rates effective January 1, 2017.

Because of the generality of this information, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations. It is presented strictly for informational purposes.

CMS.gov
Centers for Medicare & Medicaid Services

Proposed policy, payment, and quality provisions changes to the Medicare Physician Fee Schedule for Calendar Year 2016

Date	2015-10-30
Title	Proposed policy, payment, and quality provisions changes to the Medicare Physician Fee Schedule for Calendar Year 2016
Contact	go.cms.gov/media

Proposed policy, payment, and quality provisions changes to the Medicare Physician Fee Schedule for Calendar Year 2016

On October 30, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a final rule updating payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2016. CMS finalized a number of new policies, including several that are a result of recently enacted legislation. The rule also finalizes changes to several of the quality reporting initiatives that are associated with PFS payments, including the Physician Quality Reporting System (PQRS), the Physician Value-Based Payment Modifier (Value Modifier), and the Medicare Electronic Health Record (EHR) Incentive Program, as well as changes to the Physician Compare website on Medicare.gov.

This is the first PFS final rule since the repeal of the Sustainable Growth Rate (SGR) formula by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

The calendar year 2016 PFS final rule is one of several final rules reflecting a broader Administration-wide strategy to create a health care system that results in better care, smarter spending, and healthier people.

Background on the Physician Fee Schedule

The PFS pays for services furnished by physicians and other practitioners in all sites of service. These services include but are not limited to office visits, surgical procedures, diagnostic tests, therapy services, and certain preventive services.

In addition to physicians, the physician fee schedule pays a variety of practitioners and entities, including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities.

Payments are based on the relative resources typically used to furnish the service. Relative value units (RVUs) are applied to each service for physician work, practice expense (PE), and malpractice (MP). These RVUs become payment rates through the application of a conversion factor, which is calculated using the formula set forth in statute.

QUALITY PROVISIONS

Modifications to the Physician Quality Reporting System

The Physician Quality Reporting System (PQRS) encourages individual eligible professionals (EPs) and group practices to report information on the quality of care to Medicare.

The requirements we are finalizing reflect CMS' intent to continue implementing the PQRS by finalizing requirements for the 2018 PQRS payment adjustment consistent with the requirements for the 2017 PQRS payment adjustment. CMS establishes the same criteria for satisfactory reporting 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. If an individual EP or group practice does not satisfactorily report or satisfactorily participate in PQRS for 2016, a 2 percent negative payment adjustment will apply to covered professional services furnished by that individual EP or group practice during 2018.

CMS makes changes to the PQRS measure set to add measures where gaps exist, as well as to eliminate measures that are topped out, duplicative, or are being replaced with a more robust measure. There will be 281 measures in the PQRS measure set and 18 measures in the GPRO Web Interface for 2016. Also, as recently authorized under MACRA, CMS is adding a reporting option that will allow group practices to report quality measure data using a Qualified Clinical Data Registry (QCDR).

Please note that the 2018 PQRS payment adjustment is the last adjustment that will be issued under the PQRS. Starting in 2019, adjustments to payment for quality reporting and other factors will be made under the Merit-Based

Incentive Payment System (MIPS), as required by MACRA. CMS sought comment related to other MACRA provisions in the CY 2016 PFS proposed rule and in a previously published Request for Information.

Physician Compare

The 2016 PFS final rule continues the phased approach to public reporting on Physician Compare. CMS will continue to make all 2016 individual EP and group practice PQRS measures available for public reporting. All CAHPS for PQRS measures for groups of two or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified Consumer Assessment of Healthcare Providers and Systems (CAHPS) vendor are available for public reporting. In addition, all Accountable Care Organization (ACO) measures, including CAHPS for ACOs, are available for public reporting. CMS is also finalizing the following proposals:

- To include Certifying Board, and specifically add American Board of Optometry (ABO) Board Certification and American Osteopathic Association (AOA) Board Certification.
- To include an indicator on profile pages for individual eligible professionals (EPs) who satisfactorily report the new PQRS Cardiovascular Prevention measures group in support of the Million Hearts initiative;
- To continue making 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. More on this item below;
- 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
- To publicly report in the downloadable database utilization data for individual EPs.

CMS is not finalizing the proposal to include a visual indicator on profile pages for group practices and individual EPs who receive an upward adjustment for the Value Modifier.

Consistent with existing policies, all data must meet the public reporting standards – measures must be statistically accurate, valid, reliable, and comparable and must resonate with consumers. 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.

Physician Compare Benchmark

CMS is finalizing our proposal to publicly report an item-level benchmark for group practice and individual EP PQRS measures using the ABC methodology. The benchmark will be stratified by reporting mechanism to ensure comparability and reduce the interpretation burden for consumers.

Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark allows consumers to more easily evaluate the published information by providing a point of comparison between groups and between individuals. On Physician Compare, the benchmark will be displayed as a five-star rating. CMS will conduct analysis and stakeholder outreach around the star attribution methodology prior to public reporting in 2017.

The Medicare EHR Incentive Program

CMS is revising the definition of certified EHR technology in accordance with criterion finalized by the Office of the National Coordinator for Health Information Technology and CMS' form and manner requirements for electronic submission of CQMs.

Physician Value-Based Payment Modifier

The Value-Based Payment Modifier (Value Modifier) 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.

Under the Value Modifier, performance on quality and cost measures can translate into increased payment for physicians and other EPs who provide high quality, efficient care and decreased payment for low-performing physicians and other EPs who underperform. The Value Modifier is set to expire at the end of CY 2018, as a new comprehensive program, required by MACRA, called the MIPS begins in CY 2019. The final policies established in this rule are intended to help provide a smooth transition from the Value Modifier to MIPS. For more information on the Value Modifier, visit here.

This year, CMS is finalizing the following key provisions:

- To apply the Value Modifier to nonphysician EPs who are Physician Assistants (PAs), Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), and Certified Registered Nurse Anesthetists (CRNAs) (and not to other nonphysician EP types) in groups and to PAs, NPs, CNSs, and CRNAs who are solo practitioners, in the CY 2018 payment adjustment period;
- To apply the quality-tiering methodology to all groups and solo practitioners that meet the criteria to avoid the downward adjustment under the PQRS. Groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception that PAs, NPs, CNSs, and CRNAs in groups consisting of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo

practitioners will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018;

- To continue to set the maximum upward adjustment under the quality-tiering methodology for the CY 2018 Value Modifier at: +4.0 times an adjustment factor (to be determined after the conclusion of the performance period), for groups of physicians with ten or more EPs; +2.0 times an adjustment factor, for groups of physicians with between two to nine EPs and physician solo practitioners; and +2.0 times an adjustment factor for groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs; and
- To set the amount of payment at risk under the CY 2018 Value Modifier to -4.0 percent for groups of physicians with ten or more EPs, -2.0 percent for groups of physicians with between two to nine EPs and physician solo practitioners, and -2.0 percent for groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs.
- To waive application of the Value Modifier for groups and solo practitioners, as identified by their Taxpayer 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, Comprehensive Primary Care Initiative (CPCI), or other similar Innovation Center model (such as Comprehensive ESRD Care Initiative, Oncology Care Model (OCM), and the Next Generation ACO Model) during the performance period, beginning with the CY 2017 payment adjustment period;
- To use CY 2016 as the performance period for the CY 2018 Value Modifier and continue to apply the CY 2018 Value Modifier based on participation in the PQRS by groups and solo practitioners;
- Beginning with the CY 2017 payment adjustment period, we are increasing the minimum episode size for the Medicare Spending per Beneficiary measure to be included in the Value Modifier to 125 episodes for all groups and solo practitioners. Also, beginning with the CY 2017 payment adjustment period, for solo practitioners and groups with two to nine EPs, we are finalizing that the All-Cause Hospital Readmissions measure will not be used in the quality composite calculation for the Value Modifier. These changes are being made to be consistent with our policy to only use measures that have moderate to high reliability.
- To not apply the automatic downward adjustment applicable to TINs that do not meet the criteria to avoid the downward adjustment under PQRS, when PQRS determines on informal review that at least 50 percent of the TIN's EPs meet the criteria to avoid the downward PQRS payment adjustment. Also, we note that if the group was initially determined to have not met the criteria to avoid the PQRS downward payment adjustments and consequently was initially subject to the automatic downward adjustment under the Value Modifier, then we do not expect to have data for calculating their quality composite, in which case they would be classified as "average quality."

Medicare Shared Savings Program

The Medicare Shared Savings Program (Shared Savings Program) was established to promote accountability for a patient population, coordinate items and services under parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery through provider and supplier participation in an ACO. The CY 2016 PFS final rule with comment period finalizes policies specific to certain sections of the Shared Savings Program regulations including:

- 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 updated clinical guidelines and PQRS reporting;
- 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 to exclude certain claims for services furnished in Skilled Nursing Facilities.

ADVANCE CARE PLANNING

The rule also finalizes a proposal that will better enable seniors and other Medicare beneficiaries to make important decisions that give them control over the type of care they receive and when they receive it.

Consistent with recommendations from the American Medical Association (AMA) and a wide array of stakeholders, CMS is establishing separate payment and a payment rate for two advance care planning services provided to Medicare beneficiaries by physicians and other practitioners. The Medicare statute currently provides coverage for advance care planning under the "Welcome to Medicare" visit available to all Medicare beneficiaries, but they may not need these services when they first enroll. Establishing separate payment for advance care planning codes to recognize additional practitioner time to conduct these conversations provides beneficiaries and practitioners greater opportunity and flexibility to utilize these planning sessions at the most appropriate time for patients and their families. CMS is also finalizing payment for advance care planning when it is included as an optional element of the "Annual Wellness Visit."

The AMA Current Procedural Terminology (CPT) Editorial Panel and the AMA Relative Value Update Committee (RUC) recommended new CPT codes and associated payment amounts for calendar year 2015. CMS did not make the new codes payable for 2015 in order to allow the public full opportunity to comment.

For Medicare beneficiaries who choose to pursue it, 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 them.

PAYMENT PROVISIONS

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 (ACA). CMS has finalized its proposal to update the regulations to clarify that the payment amount
for a biosimilar biological product is based on the ASP of all biosimilar biological products included within the same billing and payment code.

Misvalued Code Target

The ACA instructed CMS to identify "misvalued codes" in the Physician Fee Schedule, which CMS does through the annual rulemaking process.

In the Protecting Access to Medicare Act of 2014 (PAMA), Congress set a target for adjustments to misvalued codes in the fee schedule for calendar years 2017 through 2020, with a target amount of 0.5 percent of the estimated expenditures under the PFS for each of those four years. Subsequently, the Achieving a Better Life Experience Act of 2014 (ABLE) accelerated the application of the target by specifying it would apply for calendar years 2016 through 2018, and increasing the target to 1.0 percent for 2016. If the estimated net reductions in PFS expenditures resulting from changes in values for misvalued codes in 2016 are not equal to or greater than the target, a reduction equal to the percentage difference between target and the estimated net reduction in expenditures resulting from misvalued code reductions must be made to all PFS services.

In this rule, CMS is adopting a methodology to implement this provision, including how net reductions in misvalued codes would be calculated. Based on that methodology, CMS has identified changes that achieve 0.23 percent in net reductions. This will require a 0.77 percent reduction to all PFS services, as required by the statute.

Misvalued Code Changes for Radiation Therapy

In 2012, CMS identified the codes for radiation therapy as potentially misvalued. Through the Relative Value Update Committee (RUC), the AMA provided recommended values for the new codes issued in 2015, including changes to the assumed number of services that are furnished with the capital equipment.

Based on a review of public comments, CMS is not finalizing the proposal to implement the new code set for payment of radiation therapy treatment under the PFS and will continue work to address the radiation therapy codes and pricing in future years. However, CMS is finalizing the proposed change in the utilization rate assumption used to determine the per minute cost of the capital equipment used for radiation therapy. Final assumptions adopted in this final rule are 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 will implement this change over two years. CMS is also seeking comment on additional sources of accurate data regarding the price of the linear accelerators used in radiation therapy and how often the machines are in use.

Implementation of the Statutory Phase-In of Significant RVU Reductions

The PAMA specified that if the total RVUs for a service would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total RVUs for the previous year, the adjustments must be phased-in over a two-year period. This requirement applies only to services described by existing codes, and not to services described by new or revised codes.

CMS is finalizing the proposal to phase in these reductions by reducing the value for a service by the maximum allowed amount (19 percent) in the first year, and to phase in of the percent remainder of the reduction in the second year. CMS believes that this approach avoids differential treatment among related codes that would occur due to the 20 percent phase-in cutoff.

Misvalued Code Changes for Lower GI Endoscopy Services

The AMA Current Procedural Terminology (CPT) Editorial Panel revised the lower gastrointestinal endoscopy code set for CY 2015 following identification of some of the codes as potentially misvalued. The RUC subsequently provided recommendations to CMS for valuing these services. For 2016, CMS is finalizing implementation of the revised set of codes, including the revised values. After considering public comments received on the proposed values, CMS is finalizing payment rates more closely tied to the RUC recommended values.

"Incident to" Policy for Calendar Year 2016

In the calendar year 2014 PFS final rule, CMS required that, as a condition for Medicare Part B payment, all "incident to" services and supplies must be furnished in accordance with applicable state law. The definition of auxiliary personnel was also clarified to require that the individual furnishing "incident to" services must meet any applicable requirements to provide such services, including licensure, imposed by the state in which the services are furnished.

In some cases, the physician or practitioner supervising the service is not the same individual treating the patient more broadly. For 2016, CMS is finalizing a proposal to specify that, in those cases, only the supervising physician or practitioner may bill Medicare for "incident to" services. Additionally, CMS is finalizing a proposal 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.

Physician Self-Referral Updates

The physician self-referral law prohibits: (1) a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

This rule updates the physician self-referral regulations to accommodate health care delivery and payment systems reform, to reduce burden, and to facilitate compliance. We have learned from stakeholder inquiries, review of the relevant literature, and self-disclosures submitted to the Self-Referral Disclosure Protocol (SRDP) that additional clarification of certain provisions of the physician self-referral law would be helpful. In addition to clarifying the regulations, we are also interested in expanding access to needed health care services. In keeping with these goals, this rule expands the regulations to establish two new exceptions and clarifies certain regulatory terminology and requirements.

New Exceptions:

The rule establishes a new exception to permit payment by hospitals, Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs) to physicians for the purpose of compensating nonphysician practitioners under certain conditions. It also establishes a new exception to permit timeshare arrangements for the use of office space, equipment, personnel, items, supplies, and other services. CMS believes these new exceptions will enhance access to care across all areas and will be particularly helpful in rural and underserved areas.

Updating Physician-Owned Hospital Requirements:

The ACA established new restrictions on physician-owned hospitals, including setting a baseline physician ownership percentage that they cannot exceed and requiring them to state on their websites and in their advertising that they are owned by physicians.

CMS updated the regulations to clarify that a broad range of actions comply with the website and advertising requirements. CMS also finalized conforming changes that better align the regulations to the statute so that the baseline and future calculations of a hospital's physician ownership percentage includes all physicians rather than only those physicians who refer to the hospital. The physician ownership calculation change takes effect on January 1, 2017.

Reducing Burden Through Clarifying Terminology and Providing Policy Guidance:

The SRDP allows CMS to settle overpayments resulting from physician self-referral law violations. Review of self-disclosures indicates that clarifying terminology and providing policy guidance could reduce perceived or actual noncompliance without risk of abuse. CMS is making the following updates:

- Clarifying 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 that employees and independent contractors need not sign arrangements between the physician organization and a DHS entity;
- Clarifying that the writing required in many of the exceptions to the physician self-referral law's referral and billing prohibitions can be a collection of documents (as opposed to a single formal contract) and making the terminology that describes types of arrangements consistent throughout the regulations;
- Clarifying that the term of a lease or personal service arrangement need not be in writing if the arrangement lasts at least 1 year and is otherwise compliant;
- Allowing expired leasing and personal services arrangements to continue indefinitely on the same terms if otherwise compliant;
- Allowing a 90-day grace period to obtain missing signatures without regard to whether the failure to obtain the signature was inadvertent;
- Clarifying that DHS entities can give to physicians items used solely for one or more of the purposes identified in the statute;
- Clarifying that a financial relationship does not exist when a physician provides services to hospital patients in the hospital if both the hospital and the physician bill independently for their services;
- Updating obsolete language in the exception for ownership in publicly traded entities to allow over-the-counter transactions and removing unnecessary language from the definition of a locum tenens physician;
- Clarifying the geographic service area for the FQHCs and RHCs using the physician recruitment exception; and
- Correcting a drafting error so that the retention exception indicates that retention payments based on physician certification may be no more than 25 percent of the physician's current annual salary averaged over 24 months (as opposed to no more than 24 months).

MACRA Changes to Medicare Physician and Practitioner Opt-Out

Prior to MACRA, physicians and practitioners that wished to renew their opt-out were required to file new valid affidavits with their Medicare Administrative Contractors (MACs) every 2 years.

Section 106(a) of MACRA indicates that valid opt-out affidavits filed on or after June 16, 2015 automatically renew every 2 years. Therefore, physicians and practitioners that filed valid opt-out affidavits on or after June, 16, 2015 are not

required to file renewal affidavits. If physicians and practitioners that filed affidavits effective on or after June 16, 2015 do not want their opt-out to automatically renew at the end of a two-year opt-out period, they may cancel the renewal by notifying all MACs with which they filed an affidavit in writing at least 30 days prior to the start of the new two-year opt-out period.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

In the Protecting Access to Medicare Act (PAMA), Congress required that providers that order advanced diagnostic imaging services consult with appropriate use criteria via a clinical decision support mechanism. To implement the first component of this section of the PAMA, CMS is required to specify appropriate use criteria from among those developed or endorsed by national medical professional specialty societies and other provider-led entities. Additional components also required by the PAMA include CMS approval of clinical decision support mechanisms, collection of additional information on the Medicare claim form, and the development of a prior authorization program based upon the claims information.

CMS is implementing the first component of this program in this PFS final rule with Comment Period by establishing which organizations are eligible to develop or endorse appropriate use criteria, the evidence-based requirements for AUC development and the process CMS will follow for qualifying provider-led entities.

For a press release on the final rule, visit, http://cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-10-30.html

For more information, visit, https://www.federalregister.gov/public-inspection

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