

Analysis of Key Provisions Contained in the 2016 Medicare Physician Fee Schedule Proposed Rule

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Introduction

On July 8, 2015, the Centers for Medicare & Medicaid Services (CMS) released the 2016 Medicare Physician Fee Schedule (PFS) Proposed Rule (Proposed Rule). The Proposed Rule was published in the *Federal Register* on July 15, 2015.¹ As in prior years, CMS took the opportunity to issue updates and proposals to account for changes associated with health care reform, such as advancements in patient care and payment methodologies. The Proposed Rule also introduces changes brought about by the Medicare Access and CHIP Reauthorization Act (MACRA).² Other important topics included in the Proposed Rule are changes to and clarification of various requirements relating to the Physician Self-Referral Law (Stark Law), changes in rules concerning “incident to” services, expanded coverage for telehealth services, physician payment for advance care planning (ACP), and changes to the Physician Quality Reporting System (PQRS). This Member Briefing highlights the most important provisions contained in the Proposed Rule and explains their impact on health care providers and their counsel. The deadline for submitting comments on the Proposed Rule is September 8, 2015.

MACRA Implementation

MACRA was signed into law on April 16, 2015 with the primary purpose of repealing Medicare’s sustainable growth rate formula for determining physician compensation and stabilizing physician payment rates. With the goal of additional improvements to physician payment methodologies, MACRA also established the Merit-Based Incentive Payment System (MIPS) and authorized additional alternative physician payment models. Current incentive-based payment/penalty programs, i.e., the PQRS, the Electronic Health Record (EHR) Meaningful Use (MU) Program, and the Value-Based Payment Modifier Program, will end at the close of 2018. Beginning in 2019, all incentive-based physician payment programs will be based on performance metrics to be developed under the MIPS. MACRA begins to implement the goals set forth in the

¹ 80 Fed. Reg. 41686-41966 (July 15, 2015).

² Pub. L. No. 114-10, 129 Stat. 87 (2015).

Affordable Care Act of shifting from fee-based reimbursement to reimbursement based on quality and value.

CMS seeks input on these specific MACRA provisions:

- (1) Section 101(b): Consolidation of existing incentive payment programs with the new MIPS;
- (2) Section 101(c): The MIPS itself; and
- (3) Section 101(e): Promoting Alternative Payment Models (APMs).

The MIPS³

MACRA directs the U.S. Department of Health and Human Services (HHS) Secretary to create the MIPS by January 1, 2019. The Secretary must:

- (1) Develop a methodology for assessing the total performance of each MIPS eligible professional (EP) according to performance standards for a performance period for a year;
- (2) Using the methodology, provide for a composite performance score for each EP for each performance period; and
- (3) Use the composite performance score of the MIPS EP for a performance period for a year to determine and apply an MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the EP for the year.

To accomplish these goals, CMS seeks comment on the low-volume provider threshold it should use to determine which EPs⁴ will be permitted to participate in the MIPS.⁵

The low-volume threshold may include one or more, or a combination, of the following:

³ Section 1848(q) of the Social Security Act (Act), added by Section 101(c) of the MACRA.

⁴ Eligible professional (EP) is defined in Section 1848(k)(3)(B) of the Act.

⁵ See Section 1848(q)(1)(c)(iv) of the Act.

- (1) The minimum number of Medicare Part B enrollees treated by the EP for the performance period involved;
- (2) The minimum number of items and services furnished to Medicare Part B enrollees by the EP during the performance period; and
- (3) The minimum amount of allowed charges billed by the EP under Medicare Part B for the performance period.

CMS specifically asks:

- (1) What would be an appropriate low-volume threshold for purposes of excluding EPs from the definition of an MIPS EP;
- (2) Should CMS consider establishing a low-volume threshold using more than one or a combination of factors listed above or, alternatively, should CMS focus on establishing a low-volume threshold based on one factor; and
- (3) Which factors should CMS include, individually or in combination, in determining a low-volume threshold?

CMS indicates it is considering thresholds similar to those in use for the Medicaid EHR Incentive Program,⁶ such as to exclude EPs that do not have at least 10% of their patient volume derived from Medicare Part B encounters from participating in the MIPS. CMS asks whether this is an appropriate low-volume threshold for the MIPS. In addition, CMS invites comments on the applicability of existing low-volume thresholds used in other CMS reporting programs toward the MIPS.

⁶ For example, as required by Section 1903(t)(2) of the Act, EPs and acute care hospitals must meet certain Medicaid patient volume thresholds (in general, 30% for EPs and 10% for acute care hospitals) to be eligible for the Medicaid EHR Incentive Program.

Clinical Practice Improvement Activities

Clinical practice improvement activities are one of the performance categories used in determining the composite performance scores under the MIPS.⁷ Clinical practice improvement activities are defined as activities that relevant EP organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that CMS determines are likely to result in improved outcomes.⁸

Clinical practice improvement activities must include at least the following subcategories:

- (1) Expanded practice access, such as same-day appointments for urgent needs and after-hours access to clinician advice;
- (2) Population management, such as monitoring of individuals' health conditions to provide timely health care interventions or participation in a qualified clinical data registry;
- (3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth;
- (4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms;
- (5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification; and
- (6) Participation in an APM (as defined in Section 1833(z)(3)(C) of the Social Security Act (Act)).⁹

⁷ Section 1848(q)(2)(A)(iii) of the Act.

⁸ Section 1848(q)(2)(C)(III) of the Act.

⁹ Section 1848(q)(2)(B)(iii) of the Act.

CMS seeks comment on what activities could be classified as clinical practice improvement activities according to this definition.

APMs

Section 101(e) of the MACRA, Promoting Alternative Payment Models, introduces a framework for promoting and developing APMs and providing incentive payments for EPs who participate in APMs. Payment implications for EPs under this section begin in 2019. At this point, CMS is “broadly seeking public comment on the topics in this section.” In the Proposed Rule, CMS states it will issue a Request for Information (RFI) with specific questions related to specific APM provisions, including the following:

- (1) The criteria for assessing physician-focused payment models;
- (2) The criteria and process for the submission of physician-focused payment models eligible APMs, qualifying APM participants;
- (3) The Medicare payment threshold option and the combination all-payer and Medicare payment threshold option for qualifying and partial-qualifying APM participants, eligible APM entities, quality measures, and EHR-use requirements; and
- (4) The definition of nominal financial risk for eligible APM entities.

In anticipation of the future RFI, CMS seeks input on approaches to implementing APMs in advance of notice-and-comment rulemaking.

“Incident to” Rules

In the Proposed Rule, CMS indicates its intent to modify the current incident to rules for physician reimbursement under the Medicare program to:

- (1) Require that the physician or other practitioner who bills for the incident to services *a/so* be the physician or other practitioner who supervises the auxiliary personnel who provide the incident to services;¹⁰ and
- (2) Explicitly prohibit the provision of incident to services by auxiliary personnel who have:
 - Been excluded from Medicare, Medicaid, or other federal health care programs; or
 - Had their enrollment revoked for any reason.¹¹

Under the Medicare program, incident to services are defined, in part, as professional services or supplies furnished as an integral, although incidental, part of a physician's or other practitioner's personal professional services in the course of diagnoses or treatment of an injury or illness.¹² Incident to services generally require "direct supervision" (which, in the office setting, requires that the physician be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure)¹³ by the physician or other practitioner of the auxiliary personnel providing the services.¹⁴ When submitting claims to the Medicare program, physicians and other practitioners attest to either performing the service or directly supervising the auxiliary personnel who performed the service.¹⁵ However, the current regulations provide 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.¹⁶ CMS believes the current regulation is inconsistent with the attestation and requirements imposed for Medicare billing purposes. CMS is proposing to modify the incident to regulations to:

¹⁰ See 80 Fed. Reg. 41686, 41785 (July 15, 2015).

¹¹ *Id.*

¹² See 80 Fed. Reg. at 41785.

¹³ See 45 C.F.R. § 410.26(b)(ii).

¹⁴ See 45 C.F.R. § 410.26(b)(5).

¹⁵ See 80 Fed. Reg. at 41785.

¹⁶ See 45 C.F.R. § 410.26(b)(5)

(1) Require That the Billing Physician Be the Supervising Physician. The Proposed Rule would modify the regulations such that, consistent with Medicare billing rules, the physician or other practitioner who bills for the incident to services also *must* be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services.¹⁷ To avoid confusion, CMS also proposes to delete the last sentence contained in 42 C.F.R. § 410.26(b)(5), which states 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 services are based.¹⁸ Under the Proposed Rule, a physician or other practitioner who orders the service, but also does not directly supervise the auxiliary personnel providing the service, cannot bill for the incident to services.¹⁹

(2) Explicitly Prohibit Auxiliary Personnel Whose Rights to Participate in Medicare Have Been Revoked or Who Have Been Excluded from Providing Incident to Services. CMS proposes to amend the regulations to include an additional safeguard such that auxiliary personnel who have been excluded or revoked from participating in Medicare, Medicaid, or other federal health care programs are prohibited from providing incident to services.²⁰ Regulations already prohibit excluded or revoked individuals from providing services to Medicare beneficiaries, so this proposed revision would implement an additional safeguard to ensure that excluded individuals, or individuals whose ability to participate in Medicare, Medicaid, or other federal health care programs has been revoked, do not provide incident to services, like all other services.

CMS also requests comments on how best to ensure that qualified individuals provide incident to services to beneficiaries in a manner consistent with the Medicare statute and regulations, including the following options:

- Creating new categories of enrollment;

¹⁷ See 80 Fed. Reg. at 41785

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

- Implementing a mechanism for registration short of full enrollment;
- Requiring the use of claim elements, such as modifiers, to identify the types of individuals providing services; or
- Relying on post-payment audits, investigations, and recoupments by CMS contractors.²¹

CMS believes that the proposed revisions to the incident to rules would provide the agency with additional avenues to deny or recover Part B payments for incident to services or supplies that are rendered in violation of applicable regulations and program requirements.²² If the Rule, as proposed, is finalized, physician groups may need to restructure current arrangements under which one physician orders and bills incident to services and another supervises them because the physician (e.g., another physician member of the practice) would no longer be able to bill the Medicare program for incident to services unless the physician (or other practitioner) who initiated the encounter with the beneficiary also serves as the supervising physician. From a practical standpoint, the implementation of the proposed changes to the incident to rules could result in a decrease in reimbursement (e.g., services previously billed as incident to services and reimbursed at 100% of the fee schedule amount now may have to be billed as services provided by, for example, a Physician Assistant (PA), which is reimbursed at 85% of the fee schedule amount); inability to use cost-effective methods to provide incident to services (e.g., other physicians/practitioners could not be separately utilized to supervise incident to services); and imposition of added administrative burdens on physicians and practices (e.g., scheduling and billing issues).

CCM and TCM

The Proposed Rule would expand Chronic Care Management (CCM) reimbursement to Federally Qualified Health Center (FQHC) and Rural Health Clinic (RHC) settings for

²¹ *Id.* at 41786.

²² *Id.*

CCM services that are not already included in payments to FQHCs and RHCs and set forth payment conditions consistent with those for physicians and other practitioners.²³

In its commentary, CMS acknowledged that CCM and Transitional Care Management (TCM) service elements and billing requirements are “relatively extensive” and have been criticized as burdensome, and that excessive requirements possibly could undermine the policy goals for CCM and TCM.²⁴ CMS is requesting input on how to balance beneficiary access to CCM and TCM services with administrative burdens so that beneficiaries can obtain the full benefit of CCM and TCM services.

In addition, CMS requested information regarding the circumstances under which CCM is furnished, so that the agency can consider possible changes in CCM payment and coding, including the possibility of establishing separate payment amounts, such as payment for complex care coordination codes.²⁵

Payment for ACP

Previous attempts to address ACP were criticized as “death panels” and withdrawn. CMS proposes to establish separate payment codes for physicians conducting ACP sessions with patients. These sessions, which ideally occur before the advancement of a serious illness, are designed to assist the patient in determining the type of treatment that best meets the patient’s needs. There are no restrictions on the type of treatment that the patient can request or receive (subject to Medicare coverage requirements), and the physician does not dictate care contrary to the patient’s wishes.

²³ *Id.* at 41793-8.

²⁴ *Id.* at 41711.

²⁵ *Id.*

Medicare Telehealth Services

Billing and Payment for Telehealth Services

To qualify for Medicare reimbursement, telehealth services must be:

- On the list of Medicare telehealth services;
- Furnished via an interactive telecommunications system;
- Furnished by a physician or an authorized practitioner; and
- Furnished to an eligible telehealth individual located in a telehealth originating site.

Medicare telehealth services include the following, when furnished via an interactive telecommunications system:

- Consultations;
- Office visits;
- Office psychiatry services; and
- Any additional services specified by the HHS Secretary.

The list of currently covered telehealth services is available at www.cms.gov/telehealth/.

Generally, telehealth services must be provided through an “interactive telecommunications system,” defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant-site physician or practitioner. An exception is provided for asynchronous “store-and-forward” technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii.

Practitioners furnishing the telehealth services are not required to be at the same location as the beneficiary. An eligible telehealth individual means the individual: (1) is enrolled under Part B; and (2) receives a telehealth service at an originating site.

The “originating site” is the location of the eligible telehealth individual when the service is being furnished via a telecommunications system. The originating site must be either: (1) located in a health professional shortage area; or (2) in a county that is not included in a metropolitan statistical area. An exception is provided for entities participating in federal telemedicine demonstration projects approved or funded by the HHS Secretary as of December 31, 2000. An originating site’s geographic status is established and reviewed on an annual basis.

If all conditions are met, Medicare will pay a facility fee to the originating site and a separate payment to the distant-site practitioner. Claims for telehealth services should be submitted to the Medicare Administrative Contractor (MAC) that processes claims for the service area covering the distant site. Practitioners must be paid an amount equal to the amount the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

HHS provides a process for the public to submit requests for additions to Medicare’s accepted list of telehealth services. Under this process, requests fall under two categories:

- Category 1: Services similar to professional consultations, office visits, and office psychiatry services that currently are on the list of telehealth services.

When reviewing requests under Category 1, HHS considers: (1) similarities between the requested and existing telehealth services; (2) the roles of, and interactions among, the beneficiary, the distant-site practitioner, and, if applicable, the telepresenter; and (3) similarities in the telecommunications system used to deliver the proposed service.

- Category 2: Services dissimilar to the current list of health services.

When reviewing requests under Category 2, HHS considers: (1) whether the corresponding code accurately describes the service when furnished via telehealth; and (2) whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. Submitted evidence of “clinical benefit” to the patient should include a description of relevant clinical studies demonstrating the service improves the diagnosis or treatment, including dates, findings, and a list and copies of published peer-reviewed articles relevant to the service. Examples of clinical benefit are:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate, in-person diagnostic services;
- Treatment options for a patient population without access to clinically appropriate, in-person treatment options;
- Reduced rate of complications;
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process);
- Decreased number of future hospitalizations or physician visits;
- More-rapid beneficial resolution of the disease process treatment;
- Decreased pain, bleeding, or other quantifiable symptom; and
- Reduced recovery time.

Requests must be submitted and received no later than December 31 of each Calendar Year (CY) to be considered for the next rulemaking cycle, and must include any supporting documentation the requester wishes HHS to consider.

Services to Be Added to the Telehealth List for CY 2016

Prolonged Service Codes

- Current Procedural Terminology (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 (E/M) service); and
- CPT Code 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).

ESRD Codes

- CPT Code 90963 (End-Stage Renal Disease- (ESRD-)) related services for home dialysis per full month, for patients younger than two years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents);
- CPT Code 90964 (ESRD-related services for home dialysis per full month, for patients two to 11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents);
- CPT Code 90965 (ESRD-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
- CPT Code 90966 (ESRD-related services for home dialysis per full month, for patients 20 years of age and older).

For CPT Codes 90963, 90964, 90965, and 90966, a patient's home is not an authorized originating site. Clinical examination of the catheter access site must be furnished face-to-face "hands on" (without the use of an interactive telecommunications system) by a

physician, certified nurse specialist, Nurse Practitioner (NP), or PA. A distant-site provider may use an interactive telecommunications system for additional visits required under the two-to-three visit Monthly Capitation Payment (MCP) code and the four-or-more visit MCP code.

Rejected CPT Codes

- All E/M Services;
- All telerehabilitation services; and
- All palliative care, pain management, and patient navigation services for cancer patients.

These services were rejected for failure to identify the specific codes requested, or failure to include evidence of clinical benefit when the services are furnished via telehealth.

- CPT Code 99291 (critical care, E/M of the critically ill or critically injured patient; first 30-74 minutes); and
- CPT Code 99292 (critical care, E/M of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service)).

Because of the acuity of critically ill patients, CMS does not consider critical care services similar to any services on the current list of Medicare telehealth services, and these services previously have been rejected on a Category 1 basis. CMS similarly rejects the American Telemedicine Association's submission of these codes on a Category 2 basis, finding no evidence that the implementation of ICU telemedicine significantly reduced mortality rates or hospital lengths of stay, and the evidence failed to demonstrate a clinical benefit to patients.

- CPT Code 99358 (prolonged E/M service before and/or after direct patient care; first hour); and
- CPT Code 99359 (prolonged E/M service before and/or after direct patient care; each additional 30 minutes (list separately in addition to code for prolonged service)).

CMS rejects these services because they are not separately payable by Medicare.

- CPT Code 99444 (online E/M service provided by a physician or other qualified health care professional who may report an E/M service provided to an established patient or guardian, not originating from a related E/M service provided within the previous seven days, using the internet or similar electronic communications network).

CMS rejects this service because: (1) this service is not face to face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Providers of telehealth services are reimbursed only the amount that would have been paid if the service was furnished without the use of a telecommunications system, and because CPT Code 99444 currently is non-covered, there would be no Medicare reimbursement for the code.

- CPT Code 99490 (CCM services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored).

CMS rejects this service because it can be furnished without the beneficiary's face-to-face presence, and adding the service to the telehealth list is unnecessary.

- CPT Code 99605 (medication therapy management service(s) provided by a pharmacist, individual, face to face with patient, with assessment and intervention if provided; initial 15 minutes, new patient);
- CPT Code 99606 (medication therapy management service(s) provided by a pharmacist, individual, face to face with patient, with assessment and intervention if provided; initial 15 minutes, established patient); and
- CPT Code 99607 (medication therapy management service(s) provided by a pharmacist, individual, face to face with patient, with assessment and intervention if provided; each additional 15 minutes (list separately in addition to code for primary service)).

CMS rejects these services because they are non-covered services for which no payment may be made under the PFS.

CRNAs Are to Be Added as Practitioners for Telehealth Services

Because Certified Registered Nurse Anesthetists (CRNAs) may be licensed in some states to furnish certain services on the telehealth list without physician supervision, CMS proposes to revise Section 410.78(b)(2) to include a CRNA, as described under Section 410.69, to the list of distant-site practitioners who can furnish telehealth services.

New Quality Measures for the MSSP

The Proposed Rule would modify the current Medicare Shared Savings Program (MSSP) regulations related to quality measures, health information technology incentives, and assignment of beneficiaries to Accountable Care Organizations (ACOs). To be eligible for any shared savings under the MSSP, a participating ACO must achieve a certain level of performance on specified quality measures. For 2016, CMS proposes to add another quality measure, station therapy for the prevention and

treatment of cardiovascular disease, to the list of quality measures. CMS requests comment on the proper manner to implement this new measure.

The Proposed Rule also would amend the definition of “primary care services” to include claims submitted by “Electing Teaching Amendment Hospitals” and exclude claims submitted by skilled nursing facilities. In addition, the Proposed Rule preserves flexibility to maintain or revert to pay for reporting if a measure owner determines that the measure does not align with clinical practice or causes harm.

Treatment of Technical Stark Violations

The Proposed Rule includes several proposed changes to the regulations under the Stark Law²⁶ with respect to “technical violations.” The Stark Law is a strict liability statute such that if a financial arrangement does not fall precisely within an exception, the statute is violated. In the past, many prosecutors dismissed the notion of a technical violation. However, since the establishment of the Self-Referral Disclosure Protocol, CMS has received numerous disclosures of actual or potential “technical” violations of the Stark Law that involve virtually no financial risk to the Medicare program. These technical violations often include such things as unsigned or expired agreements or arrangements documented through a series of “writings.”

In an effort to reduce the burden of and facilitate future regulatory compliance, the Proposed Rule includes proposals that would:

(a) Clarify the Writing Requirement. CMS clarifies that a single “formal” written contract (i.e., single document that includes all material aspects of the arrangement) is *not* required to satisfy the writing requirement contained in several compensation exceptions,²⁷ including, for example, the personal services exception and the space rental and equipment rental exceptions.²⁸

²⁶ See 42 U.S.C. § 1395 nn.

²⁷ Specifically, CMS cites to the following exceptions that contain writing requirements: (1) office space rental at 45 C.F.R. § 411.357(a); (2) equipment rental at 45 C.F.R. § 411.357(b); (3) personal services at § 411.357(d); (4) physician recruitment at 45 C.F.R. § 411.357(e); (5) group practice arrangement at 45 C.F.R. § 411.357(h); (6) fair market value compensation at 45 C.F.R. § 411.357(l); (7) indirect

- (1) CMS clarified that while different terminology is used in the statutory and regulatory exceptions with respect to the writing requirement (e.g., the personal service agreement exception requires that the “arrangement be set out in writing” whereas the office space exception requires that an “agreement” be set out in writing), the writing requirements are the same in the exceptions. CMS proposes to revise the language used in the various exceptions to reflect the identical writing requirement in the exceptions and make clear that a particular kind of writing, such as a formal contract (e.g., replace terms such as “contract” and “agreement” with “arrangement”), is not required to satisfy the requirement.²⁹
- (2) CMS notes that, in most circumstances, a single written document containing the key terms in an arrangement is the surest and most straightforward way to establish compliance with the writing requirement.³⁰ However, depending on the facts and circumstances of the situation, a collection of documents, including contemporaneous documents to show the course of conduct between the parties, could satisfy the writing requirement.³¹

(b) Clarify the Documentation Requirement Related to the One-Year Term

Requirement. Consistent with CMS’ guidance provided in the 1998 proposed rule, the Proposed Rule would provide clarification that a formal contract with an explicit “term” (i.e., length of the arrangement) is not required to meet the one-year term requirement in the office space lease, equipment lease, and personal service arrangement exceptions.³² As with the writing requirement, CMS stated that a collection of documents, including contemporaneous documents showing the course of conduct between the parties that establish that the arrangement, in fact, lasted for

compensation arrangements at 45 C.F.R. § 411.357(p); (8) obstetrical malpractice insurance subsidies at 45 C.F.R § 411.357(r); (9) retention payments at 45 C.F.R. § 411.357(t); (10) electronic prescribing at 45 C.F.R § 411.357(v); (11) electronic health records at 45 C.F.R § 411.357(w).

²⁸ See 80 Fed. Reg. at 41915.

²⁹ *Id.* at 41916.

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

the required one-year period, could be used to show that the one-year requirement has been satisfied.³³

(c) Amend the Holdover Provision to Permit Indefinite Holdover Periods. If certain safeguards are met, CMS proposes to: (1) extend the holdover period indefinitely; or (2) extend the holdover period for a period greater than six months (e.g., one year, two years, or three years).³⁴ CMS seeks comments on whether any additional safeguards are needed to ensure that holdover arrangements lasting longer than six months do not pose risks for program or patient abuse.³⁵

CMS proposes to revise the holdover provisions at 45 C.F.R. § 411.357(a)(7) (rental of office space), Section 411.357(b)(6) (rental of equipment), and Section 411.357(d)(1) (personal service arrangement) to permit indefinite holdovers if the following requirements are met: (1) the arrangement must comply with the applicable exception when it expires by its own terms; (2) the holdover must be on the same terms and conditions as the immediately preceding arrangement; and (3) the holdover must continue to satisfy the requirements of the applicable exception (which must be established by documentary evidence maintained by the parties).³⁶

CMS believes that if the foregoing safeguards are satisfied, concerns related to program or patient abuse, such as frequent renegotiations of short-term arrangements based on a physician's referral, will be avoided.

(d) Amends the FMV Exception to Permit Renewal of Arrangements of Any Length. The Proposed Rule would revise the Fair Market Value (FMV) exception, which currently allows arrangements for less than one year to be renewed, to permit renewals of arrangements of any length of time, including arrangements that are one

³³ *Id.*

³⁴ *Id.* at 41917.

³⁵ *Id.* at 41918.

³⁶ *Id.*

year or longer.³⁷ CMS seeks comments as to whether this amendment is needed if indefinite holdovers are permitted.

(e) Amends the Temporary Non-Compliance with Signature Requirement. CMS proposes to amend the current regulation to allow parties 90 days to obtain required signatures regardless of whether the non-compliance was inadvertent. Currently, the regulations have two separate timeframes—30 days to obtain signatures if the failure to obtain signatures is not inadvertent and 90 days to obtain signatures if the failure is inadvertent³⁸—to come into compliance where required signatures are missing.

(1) The regulation also would be revised to include reference to the new regulatory exceptions proposed for payments to physicians to employ non-physician practitioners and timeshare arrangements.³⁹

(2) CMS does not believe the proposed revision would pose a risk of program or patient abuse because the proposed regulation is narrowly tailored to apply only to the signature requirement; requires that the arrangement satisfy all other requirements of the applicable exception; and an entity may use the exception only once every three years with respect to the same referring physician.⁴⁰

If adopted, the proposed changes would not only reduce administrative regulatory compliance burdens imposed on physicians and other health care entities, but also would prevent the unintended consequence of imposing sanctions for technical violations of the Stark Law for arrangements that otherwise are in compliance with applicable requirements and have minimal risk of program or patient abuse. However, providers should continue to be extremely diligent in managing contracts with referral sources, such as ensuring that longer-term relationships remain consistent with FMV.

³⁷ *Id.*

³⁸ See 45 C.F.R. § 411.353(g).

³⁹ See 80 Fed. Reg. at 41923.

⁴⁰ *Id.*

Proposed Regulatory Changes Related to Stark

CMS also proposes the following substantive changes to regulations under the Stark Law, in addition to making technical corrections, that are intended to accommodate reform, reduce regulatory burden, and clarify and facilitate compliance.

Regulatory Changes Related to Recruitment and Retention

(a) New Stark Exception for Assistance to Employ a Non-Physician Practitioner

CMS proposes a new exception for financial assistance to employ a non-physician to address concerns regarding the primary care workforce shortage as well as changes in the health care delivery and payment systems that have resulted in an increased role for non-physician practitioners, who have helped to improve patient outcomes while reducing costs. Notably, the exception would apply only to hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the physician's employment of a non-physician practitioner in the geographic area served by the hospital, FQHC, or RHC. Also, the exception would protect a direct compensation arrangement between one of these entities and a physician as well as a "deemed" direct compensation arrangement between one of these entities and the physicians standing in the shoes of the physician organization (including a group practice or any other type of physician practice) to which the entity provided the remuneration; however, the exception is not structured to directly apply to remuneration from one of these entities to a physician organization.

In addition, the proposed exception would apply only if the non-physician practitioner is a bona fide employee of the physician who receives the remuneration; however, CMS solicits comments as to whether the exception should be extended to non-physician practitioners who are independent contractors of the physicians who receive the remuneration. Further, because CMS' goal in proposing the exception is to promote the

expansion of primary care services, the exception would be available only for non-physician practitioners who furnish primary care services—which CMS considers to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services—to patients of the physician’s practice. Thus, the exception would not be available to arrangements in which the non-physician practitioner provides specialty care services (such as cardiology or surgical services) to the physician practice’s patients. That said, CMS is soliciting comments regarding whether more or fewer types of services should be considered “primary care services” for purposes of complying with the exception: (1) at least 90% of the patient care services furnished by the non-physician practitioner must be primary care service; or (2) substantially all (at least 75%) of the patient care services furnished by the non-physician practitioner must be primary care services.

In addition, CMS proposes to limit the definition of “non-physician practitioner” to PAs, NPs, clinical nurse specialists, and certified nurse-midwives; however, CMS solicits comments as to whether the definition should be expanded to include CRNAs or additional types of non-physician practitioners. The exception would not be available if the non-physician practitioner: (1) has practiced in the geographic area serviced by the hospital, FQHC, or RHC within the two years prior to becoming employed by the physician; or (2) was employed or engaged by a physician with a medical office in the geographic area served by the hospital, FQHC, or RHC within the two years prior to becoming employed by the physician.

The proposed exception is intended to limit the subsidies provided to physicians to those necessary to expand access; accordingly, CMS proposes a cap on the duration of the assistance of the first two consecutive years of employment and the amount of remuneration from the hospital, FQHC, or RHC to the lower of: (1) 50% of the actual salary, signing bonus, and benefits paid by the physician to the non-physician practitioner; or (2) an amount calculated by subtracting the receipts attributable to the services furnished by the non-physician practitioner from the actual salary, signing bonus, and benefits paid by the physician to the non-physician practitioner. The exception contains a definition of “referral” that applies to non-physician practitioners

similar to that applicable to physicians in 42 C.F.R. § 411.351. Additional requirements found in most of the other exceptions set forth in 42 C.F.R. § 411.357 are proposed by CMS for purposes of this exception to safeguard against abuse.

(b) Clarification to the Physician Recruitment Exception to Stark

As it pertains to the physician recruitment exception to Stark, CMS proposes to revise the exception to add a new definition of the geographic area served by an FQHC or a RHC to ensure that such definition appropriately captures the areas where their patients actually reside and provide certainty to those entities that their physician recruitment arrangements meet the exception. CMS offers two alternative approaches for this revision. The first approach would closely mirror CMS' current definition of a rural hospital's geographic service area in recognition that FQHCs and RHCs also often serve patients dispersed in wide geographic areas. The second approach would define the geographic area served by an FQHC or RHC as the area comprised of the lowest number of contiguous or noncontiguous zip codes from which the entity draws at least 90% of its patients, as determined on an encounter basis.

(c) Retention Payments in Underserved Areas

CMS proposes that the Stark exception for retention payments in underserved areas, set forth at 42 C.F.R. § 411.357(t), be revised to reflect the regulatory intent that CMS articulated in the preamble language of Phase III. To avoid confusion as to whether entities are permitted to consider only part of the prior 24-month period instead of the entire period in determining the retention payments, as CMS intended, the proposed regulatory language pertaining to the physician's current annual income would be changed to state that the income would be "averaged over the previous 24 months."

Definitions

CMS proposes the revisions described below to certain Stark definitions in an effort to provide clarity and guidance.

(a) Remuneration

CMS proposes to revise the definition of “remuneration” to make clear that the provision of items, devices, or supplies does not constitute remuneration if they are used solely for one or more of the following six purposes: to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or if they are used to order or communicate the results of tests or procedures for such entity. In addition, CMS addressed a recent Third Circuit decision (in *United States ex rel. Kosenske v. Carlisle HMA*) regarding whether a hospital confers remuneration to a physician in a “split-bill” arrangement when both the facility and professional services are provided to patients in a hospital-based department. CMS stated that such an arrangement does not involve remuneration between the parties because the benefits are not provided to one another; however, if either party were to bill a non-Medicare payer (commercial payer or self-pay patient) globally for the facility and professional services, a benefit would be conferred on the party receiving payment, and the arrangement would involve a remuneration that implicates Stark.

(b) Stand in the Shoes

CMS proposes revising the “stand-in-the-shoes” rules to clarify that, for all purposes of applicable Stark exceptions other than the signature requirements, all physicians in a physician organization (including, without limitation, owners, investors, employees, and contractors) are considered parties to the compensation arrangement between the physician organization and the designated health services (DHS) entity.

(c) Locum Tenens Physician

CMS proposes to remove the phrase “stand in the shoes” from Stark’s definition of a “*locum tenens* physician,” to avoid confusion with the stand-in-the-shoes rules related to whether an arrangement involves a direct or an indirect compensation arrangement. CMS confirms that it likens a *locum tenens* physician to a physician who substitutes in exigent circumstances for another physician.

(d) Exception for Ownership of Publicly Traded Securities

The Stark exception for publicly traded securities references securities traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD); however, NASD no longer exists, and it is no longer possible to purchase publicly traded securities under the automated interdealer quotation system formerly operated by NASD. In an effort to update the regulation, CMS proposes to revise the Stark exception to include securities listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(e) New Exception for Timeshare Arrangements

CMS describes timeshare arrangements as those between a licensor and licensee that do not transfer dominion or control over, and instead confer a privilege (license) to use, the premises, equipment, personnel, items, supplies, and services of the licensor. Under current Stark regulations, there is no exception for timeshare arrangements, although such arrangements could fit into other exceptions, such as equipment leases or personal services agreements. In recognition of the fact that a timeshare arrangement differs from a lease, which transfers complete dominion and control of the property from a lessor to a lessee, CMS proposes a new Stark exception to protect legitimate timeshare arrangements that meet specific criteria. Notably, the exception only would protect arrangements in which a hospital or physician organization is the licensor and a physician is the licensee. It would not protect arrangements where the

licensor is another type of DHS entity, such as a clinical laboratory. Further, the exception would not protect arrangements where the licensed premises, equipment, personnel, items, supplies, and services are used predominantly to furnish E/M services to the patients of the licensee. Accordingly, the equipment used must: (1) be located in the office suite where the physician performs E/M services; (2) be used only to furnish DHS that are incidental to such services and furnished at the time of such services; and (3) not be advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform Clinical Laboratory Improvement Amendments-waived tests). Further, CMS proposes to prohibit certain per unit-of-service and percentage compensation methodologies while permitting time-based compensation methodologies. Among prohibited compensation methodologies are those that take into account (directly or indirectly) the volume or value of referrals or other business generated between the parties and those that are based on the percentage of revenue raised, earned, billed, collected, or otherwise attributable to the services provided by the physician while using the licensor's premises, equipment, personnel, items, supplies, or services. Notably, the Stark exception for rental of office space would continue to be available for traditional lease arrangements where dominion and control of the premises are transferred to the lessee for a specified period of time for the lessee's exclusive use. Hospitals and physician organizations should examine current timeshare arrangements and modify them as necessary to fit within the new exception.

(f) Temporary Non-Compliance with Signature Requirements

CMS proposes to modify the regulation's provision regarding temporary non-compliance with signature requirements to: (1) allow parties 90 days to obtain the required signatures, regardless of whether the failure to obtain the signatures was inadvertent; and (2) revise the provision to include reference to the two new proposed regulatory Stark exceptions.

(g) Physician-Owned Hospitals

CMS proposes to revise the public website and public advertising disclosure requirements pertaining to physician-owned hospitals. For purposes of public website disclosure requirements, CMS proposes to revise the regulation to enumerate a nonexclusive list of types of websites that do not constitute a “public website for the hospital,” such as social media websites, electronic patient payment portals, electronic patient care portals, and electronic health information exchanges. As it pertains to the public advertising disclosure, CMS proposes to define “public advertising for the hospital” as “any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital,” which would not include communications for recruiting hospital staff, public service announcements, or community outreach, among other types of communications depending on the specific facts and circumstances. Further, CMS proposes to clarify that language that would put a reasonable person on notice that the hospital may be physician-owned is sufficient to meet the advertising disclosure requirements.

With regard to the percentage of ownership or investment interests held by physicians (or “bona fide investment level” as referred to by CMS) in physician-owned hospitals, CMS proposes to revise the regulations to make them consistent with the statutory definition of “physician owner or investor” by specifying that the ownership or investment interests held by both referring and non-referring physicians are included, and by defining ownership or investment interests as direct or indirect ownership or investment interests in a hospital with accompanying regulatory language similar to that set forth in 42 C.F.R § 411.354. Given the reliance of physician-owned hospitals on CMS’ previous interpretation of these requirements, CMS proposes to delay the effective date of these revised regulations to afford such hospitals sufficient time to comply with the changes.

The Stark Law as a Barrier to Health Care Reform

Under MACRA, the HHS Secretary is required to study and report to Congress on the vulnerability of APMs to fraud and to examine the implications of waivers of fraud

prevention laws to support the development of APMs. In addition, MACRA requires that the HHS Secretary submit a report to Congress with options for amending current fraud and abuse laws and regulations through exceptions, safe harbors, or other narrow provisions tailored to permit gainsharing arrangements that otherwise would be illegal, and similar arrangements between hospitals and physicians that improve care, reduce waste, and increase efficiency.

In the Proposed Rule, CMS specifically seeks comments regarding “perceived barriers to achieving clinical and financial integration posed by the Stark Law”, and, in particular, the “volume and value” and “other business generated standards.”⁴¹

In addition, CMS expresses interest in learning whether the industry sees “a need for guidance on the application of our regulations as they relate to physician compensation that is unrelated to participation in alternative payment models.”⁴² While it specifically refers to the “volume or value” or “other business generated” standards, CMS indicates that it welcomes comments regarding any of its rules for determining physician compensation. Providers should take this opportunity to submit comments to demonstrate how the Stark Law impedes clinical integration and other legitimate arrangements designed to, for example, improve quality and lower costs.

The PQRS

CMS tracks the quality of care provided to Medicare beneficiaries through the PQRS. CMS proposes to retain the same criteria for satisfactory reporting in 2018 as it established for 2017. CMS announced its intent to add measures where gaps exist and to eliminate measures that are topped out or are duplicative of other measures. When finalized, the number of measures for 2016 will be 300.

If a practitioner or group practice does not satisfactorily report or satisfactorily participate while submitting data on PQRS measures, a negative payment adjustment of

⁴¹ 80 Fed. Reg. at 41929.

⁴² *Id.*

2% will be applied to 2018 services. After 2018, adjustments to payment for quality reporting and other factors will be made under the MIPS as established by MACRA.

Changes to Physician Compare Website

CMS will continue its phased approach to public reporting on the Physician Compare website. CMS requests comments on whether to make “Open Payments data,” required by the Physician Payments Sunshine Act, available on the individual Physician Compare website, in addition to the current posting on www.cms.gov/openpayments. Physicians should be made aware of this proposal so that comments can be made. In light of the multitude of problems associated with the Open Payments data, the inclusion of this information on the Physician Compare website could be problematic.

EHR Incentive Program

Background

The Health Information Technology for Economic and Clinical Health Act authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of Certified EHR Technology (CEHRT). Reporting under the EHR Incentive Program may not be duplicative of reporting requirements under other programs. Under the EHR Incentive Program, EPs must report certain “clinical quality measures” (CQMs) selected by CMS using CEHRT as part of being a “meaningful EHR user,” in the form and manner specified by CMS.

Certification Requirements for Reporting eCQMs

- CY 2014 PFS Final Rule: HHS finalized rules requiring EPs who seek to electronically report CQMs to use the most recent version of the electronic specifications for the CQMs and corresponding CEHRT.

- CY 2015 PFS Final Rule: HHS finalized rules stating that, beginning in CY 2015, EPs are not required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Note that EPs still must report the most recent version of the electronic specifications for the CQMs if they choose to report CQMs electronically.
- The 2016 Inpatient Prospective Payment Proposed Rule: The Office of the National Coordinator for Health Information Technology (ONC) proposed a certification criterion that would require health information technology to allow users to electronically create a data file for transmission of CQM data in accordance with the Quality Reporting Document Architecture (QRDA) Category I (individual patient-level report) and Category III (aggregate report) standards, at a minimum. ONC also proposed to offer optional certification for EHRs according to the “form and manner” that CMS requires for electronic submission to participate in the EHR Incentive Programs and the PQRS. The latest set of QRDA requirements combines the requirements for EPs, eligible hospitals, and Critical Access Hospitals (CAHs).

Proposal to Change the Definition of CEHRT

- For 2015-2017: HHS proposes to revise the CEHRT definition for 2015 through 2017 to require EHR technology to be certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept (CMS’ “form-and-manner” requirements) if certifying to the 2015 Edition “CQMs–report” certification criterion at § 170.315(c)(3). To clarify, this would require technology to be certified to the QRDA Category I and III standards and the optional CMS form-and-manner requirements. Note that this CEHRT definition change would not affect the change made in May’s Stage 3 rule allowing providers to use 2014 Edition or 2015 Edition CEHRT.
- For 2018 and beyond: HHS proposes to revise the CEHRT definition for 2018 and subsequent years to require EHR technology to be certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically

accept. To clarify, this would require technology to be certified to the QRDA Category I and III standards and the optional CMS form-and-manner requirements. These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

CPCI-Aligned Reporting—Group Reporting Option

The Comprehensive Primary Care Initiative (CPCI) is a multi-payer initiative aimed at fostering collaboration between public and private health care payers to increase the quality of primary care. Under the CPCI, CPC practice sites report to CMS a subset of the CQMs in exchange for a “care management fee” from CMS.

In the CY 2015 PFS final rule, HHS finalized a group reporting option for CQMs that allowed EPs who are part of a CPC practice site that successfully reports at least nine electronically specified CQMs across two domains for the relevant reporting period to satisfy the CQM reporting requirement using CEHRT. This option is available only to those EPs who already have demonstrated meaningful use for the first year, and the CQM data must be submitted in the form and manner required by the CPCI.

Proposed Changes to CPCI Group Reporting Option

HHS proposes to:

- Keep the group reporting option, but to require CPC practice sites to submit at least nine CPC CQMs that cover three domains for CY 2016; and
- Allow EPs who are part of the CPC practice site and are in their first year of demonstrating meaningful use to use the CPC group reporting option to report their CQMs electronically instead of reporting CQMs by attestation through the EHR Incentive Program’s Registration and Attestation System for CY 2016.

Note that EPs who choose this CPC group reporting option must use a reporting period for CQMs of one full year as opposed to 90 days, and the data must be submitted

during the submission period, from January 1, 2017 through February 28, 2017. This means that EPs who electronically report through the CPC practice site will miss the October 1, 2016 deadline, and therefore, will receive reduced payments under the PFS in CY 2017, unless they have been approved for a significant hardship exception.

Expansion of the CPCI

The Center for Medicare & Medicaid Innovation launched the CPCI in seven regions in 2012. Participating practices receive a monthly care management fee for each attributed patient to fund a “whole-practice care delivery transformation strategy” and to receive shared savings payments. CMS now is considering expanding the CPCI to additional regions or nationwide. To accomplish that objective, CMS is soliciting comments on various considerations, including practice readiness, practice standards and reporting, practice groupings, interplay with state initiatives, and the provision of data feedback to practices.

Proposed Regulatory Changes to Private Contracting/Medicare Opt-Out

Section 1802(b) of the Act provides a mechanism for certain physicians and practitioners to opt out of Medicare and provide services to patients that otherwise Medicare would cover. Through private contracts, physicians and practitioners that opt out of Medicare may charge Medicare beneficiaries directly for services rendered. In the private contract, a Medicare beneficiary agrees to pay the physician or practitioner for services rendered, without regard to any limits that otherwise would have applied if the physician or practitioner had submitted a claim to Medicare for the services.

In addition to entering into private contract, a physician or practitioner must file an affidavit with all MACs to which the physician/practitioner submits claims. The physician or practitioner must submit the affidavit within ten days of entering into the first private contract. The affidavit must include a number of required elements, including, but not limited to:

- (1) State that, other than emergency or urgent care services, the physician/practitioner will provide services only to Medicare beneficiaries through private contracts;
- (2) State that, during the opt-out period, the physician/practitioner will not submit claims to Medicare for services rendered to a Medicare beneficiary; and
- (3) State the physician's/practitioner's understanding that during the opt-out period, the physician/practitioner will not accept Medicare reimbursement, either directly or indirectly, for services provided to Medicare beneficiaries with whom the physician/practitioner has entered into a private contract.

In April 2015, MACRA amended Section 1802(b) of the Act. Before the amendments, physicians and practitioners were permitted to opt out of Medicare for two-year periods. If physicians or practitioners wished to continue their opt-out period longer than two years, they were required to file new affidavits with their MAC. Pursuant to MACRA, however, affidavits filed by physicians and practitioners on or after June 16, 2015, automatically will renew every two years. Due to the amendments in MACRA, physicians and practitioners that do not wish their Medicare opt-out status to automatically renew must affirmatively cancel the automatic renewal at least 30 days before their opt-out is renewed.

In the Proposed Rule, CMS announced that it proposes to revise the Medicare opt-out regulations to coincide with the statutory changes enacted through MACRA, which includes revising the definition of "Opt-Out Period" at 42 C.F.R. 405.400 to allow opt-out affidavits to automatically renew unless the physician or practitioner cancels the opt-out as provided above. In addition, 42 C.F.R. 405.445(a) would provide more information regarding proper cancellation of Medicare opt-out, including the requirement that the physician or practitioner submit written notice no later than 30 days before the end of the current two year opt-out period. The changes in the Proposed Rule would ensure consistency between the statutory and regulatory language.

Conclusion

As has become customary for CMS, the Proposed Rule contains a number of regulatory proposals in addition to the payment provisions. Some of the more important provisions have been summarized, such as the MACRA implementation provisions and the changes to regulations under the Stark Law. Physicians, physician organizations, and their counsel are advised to review the proposed changes and submit comments to CMS regarding any concerns or suggestions for change. Comments are due to CMS no later than 5:00 pm on September 8, 2015.

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