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### CHANGES TO STARK LAW, NEW ADVANCE CARE PAYMENTS INCLUDED IN 2016 PHYSICIAN FEE SCHEDULE

The Centers for Medicare & Medicaid Services (CMS) recently published a final rule (Final Rule) regarding physician payment policies and rates in the Medicare Physician Fee Schedule. Included among the finalized policies were a number of notable revisions and additions to the physician self-referral law (Stark Law). Also included were modifications to “incident to” billing rules, the creation of separate payments to physicians for advance care planning, and modifications to the Medicare Shared Savings Program (MSSP). The Final Rule took effect January 1, 2016 (with one exception noted below). Highlights of the Final Rule are described below.

#### **Stark Law**

The Stark Law prohibits a physician from making referrals for designated health services (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship unless the relationship satisfies an exception to the general prohibition. The Final Rule creates new Stark Law exceptions and makes several regulatory updates and clarifications to existing exceptions.

#### ***Newly Created Exceptions***

- **Recruitment of Nonphysician Practitioners.** The Final Rule creates a Stark Law exception allowing hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs) to pay physicians to help them employ certain nonphysician practitioners. Nonphysician practitioners include only physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical social workers, and clinical psychologists. To qualify for the exception, the arrangement must meet the following criteria: (1) it must be in writing and signed by the nonphysician practitioner, the physician, and the hospital; (2) it must not be conditioned on referrals by the physician or nonphysician practitioner to the hospital; (3) financial assistance must be limited to 50 percent of the actual compensation (including benefits and signing bonus) paid to the nonphysician practitioner during a period not to exceed the first two consecutive years of the arrangement and must not be based on the volume or value of referrals by the physician, by any physician in his or her practice, or by the

nonphysician practitioner or any other business between the parties; (4) the compensation must not exceed the fair market value of the patient care services provided by the nonphysician practitioner to the practice; (5) during the one-year period prior to the arrangement, the nonphysician practitioner must not have practiced within the geographic area served by the hospital or provided services to a physician or practice with an office in the hospital's geographic service area; (6) the nonphysician practitioner must have a compensation arrangement (for example, employment arrangement) with the physician or the physician's practice, and substantially all of the services provided must be primary care or mental health services; (7) the physician must not restrict the nonphysician practitioner from providing patient care in the hospital's geographic area; and (8) the arrangement must not violate other federal or state billing or claims submission laws, including the Anti-Kickback Statute. In addition, eligible practitioners are subject to geographic and temporal restrictions to prevent the "cycling" of practitioners through multiple practices in the area. In general, hospitals, FQHCs, and RHCs may only provide recruiting assistance to the same physician once every three years.

- **Timeshare Arrangements.** CMS created a new Stark Law exception allowing timeshare arrangements for the use of office space, equipment, personnel, supplies, and other services that meet the following criteria: (1) the arrangement must be set out in writing, signed by the parties, and specify the premises, items, and services covered by the arrangement; (2) must be between a physician or the physician's organization and either a hospital or a physician organization of which the physician is not an owner, employee, or contractor; (3) the items and services must be used predominantly for evaluation and management (E/M) services and used on the same schedule; (4) equipment (a) must be located in the building where the E/M services are provided, (b) must not be used to furnish DHS except DHS that are incidental to the E/M services at the time of the patient's visit, and (c) cannot be advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than certain exempt laboratory equipment); (5) the arrangement must not be conditioned on patient referrals; (6) compensation (a) must be set in advance, at fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business between the parties and (b) must not be determined using a formula based on percentage of revenue or based on a per unit of service other than a time-based unit, to the extent that the unit-based fee reflects services provided to patients referred by the party authorizing the timeshare; (7) the arrangement must be commercially reasonable even if no referrals take place; (8) it cannot violate the federal Anti-Kickback Statute or other federal or state billing or claims submission laws; and (9) it must not convey a leasehold interest in the office space.

While rental fee formulas under the timeshare arrangements exception may be time based or based on a flat fee, CMS emphasized that rental fees may not be based on a percentage of revenue earned or otherwise attributable to the party's use of the timeshare, or on a per unit of service basis, where the revenue or service calculation is based on services provided to patients referred by the licensor. In its Final Rule commentary, CMS explained that fee formulas based on revenue or service units present a risk of overutilization and patient steering because the licensor receives a payment each time the physician uses the premises, items, or services that are the subject of the timeshare arrangement. CMS also clarified in commentary that the timeshare arrangement exception will not protect potentially abusive practices, such as a licensor giving preferred time slots to a physician based on referrals to the licensor or short-term timeshare arrangements that are frequently modified to account for referrals to the licensor.

#### ***Additional Clarifications and Revisions***

- For Stark exceptions that require arrangements to be set out in writing or in a written agreement or lease agreement (such as the rental of office space exception), the Final Rule clarifies that there is no requirement for a particular kind of writing or even a singular document, such as a formal contract; rather, depending on the facts, a collection of

documents, including contemporaneous documents proving the course of conduct between the parties, may suffice. As a result of this clarification, the Final Rule revises certain Stark compensation exceptions that previously required a contract or agreement in writing between the parties to instead require that the arrangement be in writing. CMS, however, is retaining the written agreement requirement in the electronic prescribing items and electronic health records exceptions to keep those exceptions aligned with their corresponding safe harbors under the Anti-Kickback Statute.

- Stark Law exceptions for the rental of office space, rental of equipment, and personal services arrangements require that the arrangement have a term of at least one year. The Final Rule revises these exceptions to replace the word “term” with “duration” to clarify that the written agreement does not need to include a provision setting forth the length of the arrangement. This modification reflects current CMS policy that an arrangement will satisfy the one-year term requirement of the applicable Stark Law exception if the arrangement actually lasts for at least one year or is terminated within the first year and a new arrangement for the same space equipment or services is not entered into within the first year.
- The Final Rule amends the holdover provisions in the office space rental, equipment rental, and personal services exceptions to allow arrangements that have expired to continue indefinitely if certain safeguards are met. To continue to satisfy the applicable exception, the holdover must (1) have satisfied the exception when the arrangement expired, (2) continue on the same terms and conditions as the original arrangement, and (3) continue to satisfy all requirements of the applicable exception throughout its duration. Importantly, the fair market value requirement must be met throughout the term of the holdover.
- The Final Rule also provides that arrangements satisfying the fair market value compensation exception to the Stark Law may be renewed any number of times as long as the terms of the arrangement and compensation do not change. Previously, only arrangements of less than one year could be renewed any number of times.
- The previous Stark Law definition of remuneration stated that remuneration did not include devices, supplies, or items “used solely” to collect, process, store, or transport specimens for the entity providing such devices, supplies, or items or to order or communicate the results of tests or procedures for such entity. The Final Rule clarifies that a device item or supply can be used for any one or more of such purposes and does not have to be limited to one such purpose (such as transporting specimens).
- Prior to the Final Rule, parties to an arrangement could remedy their failure to comply with an exception’s signature requirement by obtaining the signature within 90 days for an inadvertent failure or 30 days for any other failure. The Final Rule gives parties 90 days to remedy this temporary noncompliance regardless of whether the missing signature is inadvertent.
- The Patient Protection and Affordable Care Act (PPACA) imposes additional restrictions on hospitals seeking to maintain physician ownership under the rural provider and whole hospital ownership exceptions. For a physician-owned hospital to qualify for these exceptions, it must, among other things, disclose on public websites and advertisements that physicians fully or partially own or hold investments in the hospital. The Final Rule clarifies the information that must be disclosed and provides guidance on the type of websites that may be used for disclosure. Under the Final Rule, social media websites and electronic patient payment portals are not considered public websites for purposes of the disclosure requirement. PPACA also requires physician-owned hospitals to maintain the percentage of the total value of physician ownership or investment in the hospital (the bona fide investment level). The Final Rule revises the method for determining the bona fide investment level by requiring that the hospital account for ownership or investment interests of both referring and nonreferring physician owners. The above-described changes to the definition of “ownership or investment interest” for purposes of the physician-owned hospital provisions of the Stark Law will not take effect

until January 1, 2017.

#### **“Incident to” Billing Rule**

Physicians and other practitioners may bill Medicare for “incident to” services provided by auxiliary personnel supervised by a physician (or other practitioner) as long as certain criteria are satisfied. Prior to the Final Rule, regulations specified that the physician (or other practitioner) supervising the auxiliary personnel did not need to be the same individual upon whose service the incident to service was based and who was billing for the incident to services. The Final Rule now requires that the supervising physician (or other practitioner) be the same physician upon whose service the incident to service is based. The Final Rule also specifies that only the supervising physician (or other practitioner) may bill Medicare for the incident to services provided by auxiliary personnel.

#### **Advance Care Planning Payments**

Medicare currently reimburses physicians and qualified nonphysician practitioners a single bundled payment for the “Welcome to Medicare” visit, available to Medicare beneficiaries when they first enroll. Certain end-of-life planning discussions are included as part of this visit. The Final Rule activates two separate payment codes for advance care planning (ACP) that physicians or qualified nonphysician practitioners provide to Medicare beneficiaries. For purposes of the codes, ACP includes end-of-life planning such as the discussion and/or completion of advance directives. The first code is used for the initial 30 minutes of an ACP discussion, and the second code is used for each additional 30 minutes of discussion. CMS has stated that there will be relative value units for each code; however, the Final Rule notes that CMS has not made a national coverage determination regarding these codes, meaning that local coverage decisions will govern their usage. Advance care planning will also be included as an optional and separately payable element of a beneficiary’s annual wellness visit.

#### **Medicare Shared Savings Program**

Under the MSSP, CMS assigns beneficiaries to an accountable care organization (ACO) based on their historical use of primary care services furnished by primary care physicians. ACO participants who submit claims for primary care services used by CMS to make a beneficiary assignment may only participate in a single ACO. Therefore, the definition of primary care services can dictate whether an ACO participant is able to participate in multiple ACOs. The Final Rule revises the primary care services definition to exclude certain services provided in a skilled nursing facility (SNF). This change is applicable beginning in the 2017 MSSP performance year.

Additionally, the Final Rule creates a new quality performance measure and a policy to address out-of-date quality measures. The new quality measure will report the percentage of certain beneficiaries who are prescribed or taking statin for the treatment or prevention of cardiovascular disease. This measure will be pay for reporting as opposed to pay for performance. Under the Final Rule, quality measures that do not align with clinical guidelines or that could result in patient harm will either be maintained as pay-for-reporting measures or, in the case of pay-for-performance measures, revert to pay-for-reporting measures.

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#### **CONGRESS LIMITS PROVIDER-BASED PAYMENTS BEGINNING IN 2017**

As part of its Bipartisan Budget Act of 2015, Congress eliminated provider-based status for new off-campus outpatient departments of a provider. The Centers for Medicare & Medicaid’s (CMS) provider-based rules currently allow a hospital or health system to treat certain off-campus facilities as part of the hospital or health system for purposes of reimbursement. In general, CMS reimburses provider-based facilities at a higher rate than freestanding facilities. Under the Bipartisan Budget Act of 2015, provider-based status will no longer be available for items and services provided in an off-campus outpatient department of a hospital on or after January 1, 2017; however, off-campus outpatient departments that were billing as provider based prior to November 2, 2015, as well as services

provided in a dedicated emergency department, are excluded from this new limitation.

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## U.S. DISTRICT COURT UPHOLDS MEDICARE “NARRATIVE REQUIREMENT” REGULATION

Recently, in *National Association for Home Care & Hospice, Inc. v. Burwell*, the U.S. District Court for the District of Columbia upheld the Department of Health and Human Services’ (HHS) “face-to-face narrative requirement” regulation that requires physicians to submit a detailed explanation of the medical necessity of home health services provided to Medicare beneficiaries. The regulation was issued pursuant to an Affordable Care Act (ACA) provision that conditions Medicare beneficiary eligibility for home health benefits on physician documentation of a “face-to-face encounter” with the beneficiary. The National Association for Home Care & Hospice, Inc. (NAHCH) challenged the narrative requirement regulation on the grounds that HHS exceeded its authority by requiring physicians to adhere to a more burdensome requirement than that set forth in the ACA. The court, however, upheld the narrative requirement, holding that, while HHS’s interpretation of the authorizing statute is “not the most natural one,” such interpretation is reasonable in light of the statute’s purpose and the substantial deference owed to governmental agencies in drafting regulations. As a result of the court’s decision, Medicare claims submitted prior to January 1, 2015, must include an explanation of why the findings of the face-to-face encounter necessitate home health services for the Medicare beneficiary.

Although HHS eliminated the narrative requirement, effective January 1, 2015, HHS still applies the requirement for claims submitted prior to this date. Consequently, the DC Circuit’s ruling is unwelcome news for those home health agencies appealing Medicare claim denials related to the narrative requirement.

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