McDermott Will & Emery

CMS Proposes Stark Law Amendments, Requests Comments on Whether Stark Law Is Barrier to Health Care Reform

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SPECIAL REPORT

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On July 8, 2015, the Centers for Medicare & Medicaid Services (CMS) published a notice of proposed rulemaking to amend its regulations implementing and interpreting the Stark Law (the Proposed Rule). 80 Fed. Reg. 41,686, 41,909–30 (July 15, 2015), amending 42 C.F.R. § 411.351 *et seq.* CMS also used this Proposed Rule to state its positions on certain questions of Stark Law interpretation and application, and to solicit comments from the industry on whether the Stark Law is a barrier to health care delivery and payment innovation, and whether the industry needs more guidance on how the Stark Law applies to physician compensation.

Notably, the Proposed Rule adds two new Stark Law exceptions—one for financial assistance to practices to recruit primary care non-physician practitioners and one for "time-share" arrangements. In addition, CMS proposes the following amendments:

- Expanding the 30-day grace period for the signature requirement of various Stark Law exceptions to a 90-day grace period (consolidating the distinct 30-day and 90-day grace periods into a single 90-day grace period)
- Extending the six-month holdover provision of various Stark Law exceptions, provided the terms of the arrangement do not change
- Making textual changes to clarify that signed writings need not be formal agreements or contracts for the purpose of various Stark Law exceptions
- Clarifying how the signed writing and volume/value standards apply when direct compensation arrangements arise from the "stand in the shoes" rule

Other important provisions of the Proposed Rule include the following:

- CMS's clarification that the one-year term requirement of certain compensation exceptions is satisfied when an arrangement, in fact, lasts for at least one year
- CMS's detailed requests for comments on a range of topics and questions relating to physician compensation, including a request for comments on the sufficiency of CMS's guidance on the Stark Law's "volume and value" and "other business generated" standards

CMS makes numerous requests for comments on its proposals. Comments are due **September 8, 2015.**

A full discussion of the Proposed Rule follows, starting with a review of the basic terms of the Stark Law for readers new to the subject.

The Stark Law – Basic Terms

Unless an exception applies, the Stark Law prohibits a physician from making a referral to an entity for the furnishing of designated health services (DHS)[1] that would otherwise be covered by Medicare if the physician (or an immediate family member) has a financial relationship with the entity (DHS Entity). 42 U.S.C. § 1395nn(a)(1)(A). Further, a DHS Entity may not submit a claim or bill any payor for DHS furnished pursuant to a prohibited referral unless an exception applies. *Id.* § 1395nn(a)(1)(B). Financial relationships can arise from ownership/investment interests and compensation arrangements, and compensation arrangements can arise from any "remuneration," subject to certain exceptions. Financial relationships can be direct or indirect. *Id.* § 1395nn(a)(2); 42 C.F.R. § 411.354.

The Stark Law has many exceptions, including 24 compensation exceptions. 42 C.F.R. § 411.357. For purposes of this article, note that there are compensation exceptions for space leases, equipment leases, employment compensation, personal services arrangements, physician recruitment incentives and physician retention incentives. Generally, the compensation exceptions require that the compensation to the physician be set in advance, be fair market value and not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the DHS Entity.

[1] The "designated health services" or "DHS" are:

1. Clinical laboratory services
2. Physical and occupational therapy services
3. Radiology and other imaging services
4. Radiation therapy services and supplies
5. Durable medical equipment and supplies
6. Parenteral and enteral nutrients, equipment and supplies
7. Prosthetics, orthotics, and prosthetic devices and supplies
8. Home health services
9. Outpatient prescription drugs
10. Inpatient and outpatient hospital services

42 C.F.R. § 411.351.

The New Non-Physician Practitioner Recruitment Assistance Exception

Citing to "[s]ignificant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections," 80 Fed. Reg. at 41,910, CMS proposes an exception to permit hospitals, federally qualified health centers (FQHCs) and rural health clinics (RHCs) to contribute to the costs incurred by a physician or group to employ a non-physician practitioner to provide primary care services. The proposal mirrors many of the requirements in the physician recruitment exception, 42 C.F.R. § 411.357(e), but contains some potentially significant limitations and numerous specific requests for comments.

The proposed exception, which would be found at *id.* § 411.357(x), would only apply to (1) a "*bona fide*" employee of the physician or group (2) who is a "non-physician practitioner" that (3) provides "only primary care services" to the physician's or group's patients. "Non-physician practitioner" is defined exclusively as a physician assistant, nurse practitioner, clinical nurse specialist or certified nurse-midwife, as defined by Medicare law.

The term "primary care services" is not defined in the proposed regulatory text. In the preamble to the Proposed Rule, however, CMS lists general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services as primary care specialties. CMS proposes that at least 90 percent or 75 percent of the services furnished by the non-physician practitioner constitute primary care services to qualify for the exception. The proposed regulatory text, however, requires that the non-physician practitioner furnish "*only* primary care services."

To qualify for the recruitment assistance, the physician must hire a non-physician practitioner that has not, within the past three years, practiced in the geographic area served by the hospital or been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the non-physician practitioner furnished services at the medical practice site located in the geographic area served by the hospital. Once hired, the physician or group cannot impose practice restrictions on the non-physician practitioner that unreasonably restrict the non-physician practitioner's ability to provide patient care services in the geographic area served by the hospital.

The remuneration to the physician or group may only be provided during the first two consecutive years of employment. CMS proposes to cap the remuneration amount to not exceed the *lower* of either 1) 50 percent of the actual salary, signing bonus and benefits paid by the physician to the non-physician practitioner, or 2) an amount calculated by subtracting all receipts attributable to services furnished by the non-physician practitioner from the actual salary, signing bonus and benefits paid to the non-physician practitioner by the physician. CMS does not specify whether receipts from the non-physician practitioner's "incident to" services billed under a supervising physician's name and number would count towards the cap. "Benefits" are defined in the preamble as "only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees." 80 Fed. Reg. at 41,911. This "benefits" definition is not in the regulatory text, possibly leaving unanswered questions about how to comply, especially for smaller practices that do not have a history of employing non-physician practitioners and thus may not have "similarly situated employees" to use as a comparison.

The agreement must be in writing and signed by the physician, hospital and non-physician practitioner, and cannot be conditioned on the physician's or non-physician practitioner's referrals to the hospital. The proposed exception contains the familiar prohibition on the remuneration taking into account the "volume or value" of any actual or anticipated referrals or other business generated by the physician or any physician in the physician's practice. CMS adds to this prohibition any remuneration taking into account the volume or value of referrals or other business generated by a non-physician practitioner in the physician's practice, including a specific definition of "referral" to capture non-physician practitioner referrals.

In addition, the exception states that the salary, signing bonus and benefits paid to the non-physician practitioner cannot

exceed fair market value *for the patient care services furnished* by the non-physician practitioner to patients of the physician's practice. This fair market value element, not found in the physician recruitment exception, will unfortunately introduce an element of uncertainty for the donor DHS Entity, fair market value being so easily a subject of dispute. The proposal does not, however, contain a "set in advance" requirement, which will give the physician-employers the flexibility to adjust compensation.

CMS solicits comments on specific aspects of the proposed exception, including the following:

- Permitting independent contractor relationships, and if permitted, what additional requirements to include, such as a minimum term of one year
- Adding other types of non-physician practitioners
- Considering other, more or fewer types of services to be primary care services
- Expanding the exception to non-physician practitioners who do not provide primary care services, and if expanded, what additional safeguards to include
- Using 90 percent or 75 percent for the minimum amount of primary care services furnished by the non-physician practitioner, and what type of documentation is necessary to measure compliance with this requirement
- Whether the proposed remuneration cap is appropriate, including whether to have additional or different safeguards or to include all receipts for all services furnished by the practitioner regardless of payor and regardless of whether the services were for primary care
- Addressing the potential tax implications for the physician or group in receiving the remuneration
- Using the two-year and three-year time limitations discussed above
- Creating any additional safeguards

The New Time-Share License Exception

CMS proposes a new exception at 42 C.F.R. § 411.357(y) for timeshare arrangements, which are described as arrangements where a physician obtains the right to use a licensor's premises, equipment, personnel, items, supplies or services on a limited or as-needed basis. CMS distinguishes timeshare arrangements from lease arrangements by noting that in a lease arrangement, dominion and control of the property is transferred from the lessor to the lessee, whereas in a timeshare arrangement, ownership and control remains with the licensor, and the licensee obtains only the "privilege to act on another's property." 80 Fed. Reg. at 41,921. CMS explains that it has become aware of the utility of time-share arrangements, particularly in rural and underserved areas, through the Self-Referral Disclosure Protocol and stakeholder inquiries.

The new exception differs from the space and equipment lease exceptions in that it does not require a minimum one-year term or exclusive use and control requirements. The exception is limited to licenses of property and services by a hospital or physician organization to a physician, and the property and services must be used predominantly for evaluation and management (E&M) services. In addition, the exception would exclude licensing of advanced imaging, radiation therapy, pathology or clinical laboratory equipment, except laboratory equipment used for specified simple testing.

The new exception would protect timeshare arrangements that meet the following specific criteria:

- The arrangement is set out in writing; signed by the parties; and specifies the premises, equipment, personnel, items, supplies and services covered by the arrangement.
- The arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor's premises, equipment, personnel, items, supplies or services.
- The licensed premises, equipment, personnel, items, supplies and services are used predominantly to furnish E&M services to patients of the licensee.

- The equipment covered by the arrangement, if any, (1) is located in the office suite where the physician performs the E&M services; (2) is used only to furnish DHS that is incidental to the physician's E&M services; and (3) is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform Clinical Laboratory Improvement Amendments-waived laboratory tests).
- The arrangement is not conditioned on the licensee's referral of patients to the licensor.
- The compensation over the term of the arrangement is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties.
- The arrangement would be commercially reasonable even if no referrals were made between the parties.
- The arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

CMS clarifies that license fees could be determined on an hourly, daily or other time-based basis. Compensation methodologies based on number of patients seen or the amount of revenue raised, earned, billed, collected or otherwise attributable to the services provided by the licensee while using the licensor's property and services would be prohibited.

The absence of an exclusive use and control requirement will provide the industry with much-needed flexibility to structure time-share arrangements. Time-share arrangements currently rely on the space lease and fair market value or personal services exceptions, and managing the space lease's exclusive use requirement is challenging. Although there is still a "set in advance" standard, the flexibility to enter into arrangements for less than one year will afford greater flexibility to adapt pricing to changed circumstances, such as demand for the facility and the costs of improvements.

Although the exception does not mandate that the license involve premises, equipment, personnel, items, supplies *and* services, it does not accommodate equipment-only licenses; the licensed equipment must be located in the same space where the licensee provides E&M services and must be used to provide DHS that is incidental to the physician's E&M services. Combined with the fact that the equipment cannot be for advanced imaging, radiation therapy, pathology or complex laboratory testing, it is unlikely that any licensor or licensee would want the license fee to be in whole or in part on an equipment per-service or "per-click" fee basis. Accordingly, the exception's prohibition on per-unit-of-service license fees is unlikely to interfere with the parties' business objectives, and the recent decision in *Council for Urological Interests*, striking down CMS's prohibition on per-unit-of-service or "per-click" equipment *leases*, is unlikely, as a practical matter, to have significant implications for the proposed time-share exception. (For more on *Council for Urological Interests*, click here.) The fact that the exception permits per-hour rates gives licensors the flexibility to tie fees to the physicians' actual use of the facility.

CMS solicits comments on a number of specific questions regarding the proposed timeshare exception:

- Whether the scope of the exception is sufficiently broad to improve beneficiary access to care (especially in rural or underserved areas)
- Whether there is a compelling need to allow DHS entities other than hospitals and physician organizations to enter into timeshare arrangements with referring physicians
- Whether the exception should apply if the licensor is a physician who is a source of DHS referrals to the licensee
- Whether the exception should be limited to arrangements in rural and underserved areas
- Whether "predominant use" is an appropriate measure of the use of the licensed premises and, if it is, how that standard should be defined (for example, whether "predominant" should mean "substantially all")
- Whether the equipment location requirement should be expanded to include equipment located in the same building as the licensed office suite or an off-site location

- Whether the license of equipment in the absence of a corresponding license of office space should be prohibited
- Whether the limitations on the compensation methodologies are necessary and whether a timeshare arrangement for use of a licensor's property or services would pose a risk of program or patient abuse in the absence of a prohibition on per-click and percentage compensation methodologies

Amendments and Clarifications Regarding the Signed Writing,One-Year Term and Holdover Provisions

CMS proposes regulatory revisions to (1) clarify that signed writings need not be formal agreements for the purpose of various Stark Law compensation exceptions; (2) clarify that the one-year term requirement of certain compensation exceptions is satisfied when an arrangement, in fact, lasts for at least one year; (3) extend the six-month holdover provision of various exceptions; and (4) expand the 30-day grace period for the signature requirement of various exceptions to a 90-day grace period. These proposals, if implemented, would be a welcome aid to the industry in seeking to comply with the technical requirements of these exceptions.

SIGNED WRITING REQUIREMENT

Many of the compensation exceptions require that the lease or other arrangement be set out in writing. CMS learned that there is uncertainty in the industry regarding whether an arrangement must be a single, formal written agreement to satisfy this requirement, particularly due to the fact that some exceptions use the term "agreement" (in the rental of office space and rental of equipment exceptions, 42 C.F.R. §§ 411.357(a)(1) and (b)(1)), and others use the term "arrangement" (in the personal service arrangements exception, *id.* § 411.357(d)(1)(i)) in relation to the writing requirement. CMS clarifies that *the writing requirement is the same* for these exceptions, despite the different terminology. CMS further clarifies:

> In most instances, a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception. However, *there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract*. Depending on the facts and circumstances of the arrangement and the available documentation, *a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing*.

80 Fed. Reg. at 41,915 (emphasis added). Consistent with this stated position, CMS proposes to change "agreement" to "lease arrangement" in the space and equipment lease exceptions, and to change "agreement" and "contract" to "arrangement" where it appears in the exceptions and special rules on compensation, in order to clarify that a formal contract is not required (although there may be a writing requirement).

CMS does not, however, propose to revise the term "written agreement" in the "certain group practice arrangements with a hospital" exception (42 C.F.R. § 411.357(h)), because this exception is rarely used. Further, CMS does not propose to revise this term in the e-prescribing and electronic health records donation exceptions (*id.* §§ 411.357(v) and (w)), to avoid creating inconsistencies between these exceptions and the parallel federal anti-kickback statute safe harbors related to providing these items and services (even though CMS believes the principles it sets forth regarding the writing requirements of the other compensation exceptions also apply to these exceptions).

TERM REQUIREMENT

The space rental, equipment rental and personal service arrangements exceptions require a compensation arrangement with a term of at least one year. Some in the industry interpreted the term "agreement" in the one-year term provisions of the space and equipment rental exceptions to mean that a formal written contract, with an explicit provision identifying the arrangement's term, was necessary to satisfy this one-year term requirement. CMS clarifies that the arrangement must in fact last for at least one year; a formal contract with an explicit term provision is generally not necessary. Rather, "a collection of documents, including

contemporaneous documents evidencing the course of conduct between the parties, can establish that the arrangement in fact lasted for the required period of time." 80 Fed. Reg. at 41,917. CMS proposes to remove the term "agreement" in the one-year term provisions of the space and equipment rental exceptions to make it evident that a written agreement with a formal term provision is not necessary.

Notably, these statements do more than simply permit a DHS Entity to establish that an arrangement had a term of at least one year by referencing multiple documents; they indicate that a term of at least one year can be established simply by documentary evidence of a course of conduct *lasting* a year. Even if the parties had no particular understanding between them regarding the duration of the arrangement into which they entered, they can satisfy the one-year term requirement if they happen to perform the arrangement for at least one year. This liberalization of the one-year term requirement does not, however, appear to help parties relying on the fair market value exception to protect an arrangement with a term of *less* than one year. The fair market value exception still requires that the "writing specif[y] the timeframe for the arrangement, which can be for any period of time . . . ." 42 C.F.R. § 411.357(*l*)(2).

HOLDOVER ARRANGEMENTS

The space rental, equipment rental and personal service arrangements exceptions allow a "holdover" arrangement for up to six months following the expiration of an arrangement that lasted at least one year, as long as the arrangement satisfied the requirements of the exception when it expired and continues on the same terms and conditions during the holdover period. CMS proposes to amend the holdover provisions of these three exceptions to permit holdovers indefinitely, but requests comments on whether it should instead specify a length of time greater than six months, such as two years. Like the current holdover provisions, the holdover arrangement must be on the same terms and conditions as the original arrangement. To address its concern, however, that extending the holdover term indefinitely would protect arrangements that over time fall out of fair market value, CMS proposes a new requirement: the arrangement must not only satisfy the elements of the exception at the time the arrangement expires, it must *continue* to satisfy all of the elements of the exception throughout the holdover period. CMS requests comments on what, if any, additional safeguards are needed to ensure that holdovers longer than six months do not pose a risk of program or patient abuse.

Additionally, CMS proposes to revise the fair market value compensation exception, which currently allows for arrangements of less than one year to be renewed any number of times as long as the terms and compensation do not change, to allow unlimited renewals of arrangements of *any* length of time, as long as the terms and compensation do not change. CMS specifically seeks comments on whether this revision is necessary if the personal service arrangements exception is revised to permit indefinite holdovers. There is no apparent benefit to this proposed change, because while the fair market value exception expressly allows for multiple renewals of arrangements of less than one year as long as the terms and compensation do not change, it has never *prohibited* multiple renewals of arrangements of one or more years, be they on the same or different terms. In other words, the exception's requirements that the writing specify the timeframe for the arrangement, which can be any period of time, and that the compensation be set in advance, have always accommodated multiple renewals of arrangements with a term of one year or more. The special restriction on changing the terms of renewed arrangements having a term of less than one year appears intended to prevent renegotiation of the compensation more frequently than once a year.

TEMPORARY NONCOMPLIANCE WITH THE SIGNATURE REQUIREMENT

Current regulations at *id.* § 411.353(g) allow temporary noncompliance with the signature requirement of various compensation exceptions for 90 days if the failure to comply with the signature requirement is inadvertent, and for 30 days if the failure to comply is not inadvertent, as long as the arrangement otherwise satisfies all other requirements of the applicable exception and is only used once every three years with respect to the same referring physicians. CMS proposes to consolidate the distinct 30-day and 90-day grace periods into a single 90-day grace period, regardless of whether or not

the failure to comply with the signature requirement was inadvertent.

In proposing this change, CMS recognizes that it often takes up to 90 days to obtain required signatures and, as long as the arrangement otherwise complies with the Stark Law, allowing this 90-day grace period does not pose a risk of program or patient abuse. If this proposal is finalized, the additional time allowed to obtain necessary signatures would be a helpful change for the industry and would remove the challenge of determining what is and is not an "inadvertent" failure to comply with the signature requirement. CMS emphasizes, however, that this provision is limited to the *signature* requirement, not the writing requirement. This is unfortunate because the greatest challenge to documenting a personal services arrangement that arises unexpectedly, such as a back-up emergency room call arrangement, is completing the writing before the services are provided. Arguably, a grace period for having a *writing* would be of greater benefit to the industry, and, as long as the set in advance, fair market value and volume/value standards are met from the first day of the arrangement, there is no apparent increased risk to the program. Nevertheless, the proposal permitting contemporaneous documentation rather than a single, written agreement, combined with the relaxation of the signature timing, should provide significant relief to the industry.

Solicitation of Comments on Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

Both Congress and CMS are hearing concerns from the health care industry that the Stark Law and certain other fraud, abuse and waste prevention laws are an impediment to health care delivery and payment reform. Congress acknowledged the validity of the industry's concerns when, as part of the Affordable Care Act, it authorized CMS to create waivers from the Stark Law and certain other laws for the Medicare Shared Savings Program and certain care delivery and payment models sponsored by the Centers for Medicare & Medicaid Innovation. These waivers do not, however, extend to commercial payor-sponsored innovations that potentially implicate the Stark Law, or to the all-payor pay-for-performance and gainsharing arrangements that many hospitals are pursing, or desire to pursue, with doctors. CMS acknowledges that it has received many inquiries regarding "performance-based or incentive compensation" and that it has "not issued any formal guidance to date, either through a binding advisory opinion or rulemaking." 80 Fed. Reg. at 41,929.

In addition, CMS, in consultation with the Office of Inspector General, must deliver two reports to Congress within the next two years regarding the relationship between the fraud prevention laws and alternative care delivery and payment models. First, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), enacted April 16, 2015, requires the Secretary of the Department of Health and Human Services to study and report to Congress on the vulnerability of alternative payment models to fraud, and to examine the implications of waivers to the fraud prevention laws to support alternative payment models (the APM Report). Second, MACRA requires the Secretary to submit to Congress a report with options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors or other narrowly tailored provisions to permit gainsharing arrangements that would otherwise be illegal and similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency (the Gainsharing Report).

To inform the APM Report and Gainsharing Report, and to aid CMS in determining whether additional rulemaking or guidance is desirable or necessary, CMS solicits comments in the Proposed Rule regarding the effect of the Stark Law on health care delivery and payment reform, including application of the Stark Law to performance-based and incentive compensation models. CMS makes two broad requests for comments, and sets out 10 specific topics or questions to "encourage robust commentary" from the industry.

BROAD REQUESTS FOR COMMENTS

- First, CMS requests comments "regarding perceived barriers to achieving clinical and financial integration posed by the physician self-referral law generally and, in particular, the 'volume or value' and 'other business

generated' standards set out in our regulations." 80 Fed. Reg. at 41,929.

- Second, CMS indicates that it is interested 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." On this subject, CMS specifically solicits comments regarding the "volume or value" and "other business generated" standards, but welcomes comments regarding any of its rules for determining physician compensation. *Id.*

10 SPECIFIC TOPICS OR QUESTIONS

The major themes of CMS's 10 detailed topics and questions are the two broad topics set forth above. While a discussion of these 10 specific requests for comments is beyond the scope of this article, hospitals and health systems will certainly want to take advantage of this opportunity to press CMS to address the uncertainty and ambiguity that plagues application of the Stark Law to the array of financial arrangements they wish to have with physicians to achieve gains in quality and cost-effectiveness. Further, the U.S. Court of Appeals for the Fourth Circuit's handling of the volume/value standard in *Tuomey*, and the U.S. District Court for the Middle District of Florida's handling of the volume/value standard in *Halifax*, highlight the need for CMS to provide better guidance to both the industry and the courts on the volume/value standard generally, and the employment exception's productivity bonus exception specifically. Because the Stark Law is a Medicare payment rule and strict-liability statute, and plaintiffs' counsel in False Claims Act cases will assert the most literal and restrictive interpretation of the law, CMS owes it to the industry to establish "bright-line" guidance on application of the Stark Law's volume/value standard, risk-sharing exception and other relevant provisions to physician compensation, both in traditional and innovative delivery and payment settings.

CMS asks for comments on the following 10 specific topics and questions (80 Fed. Reg. at 41,929–30):

- Does the physician self-referral law generally and, in particular, the "volume or value" and "other business generated" standards set out in our regulations, pose barriers to or limitations on achieving clinical and financial integration? If so, are the barriers or limitations more pronounced for hospitals than for other providers or suppliers because all Medicare revenue is from DHS (and, thus, any compensation might be considered to take into account the volume or value of referrals or other business generated by the physician to whom it is paid)?
- Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?
- Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to protect against program or patient abuse? Should a new exception be structured to protect services, rather than a specific type of financial relationship, when established conditions are met (similar to the in-office ancillary services exception at § 411.355(b), which protects referrals for certain services performed by physician practices that meet the requirements of § 411.352)? Would legislative action be necessary to establish exceptions to support alternative payment models?
- Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?
- Is there need for new exceptions to the physician self-referral law to support shared savings or "gainsharing" arrangements? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to address accountability, transparency and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care? Would legislative action be necessary to establish exceptions to support shared savings or "gainsharing" arrangements?
- Should certain entities, such as those considered to provide high-value care to our beneficiaries, be permitted

to compensate physicians in ways that other entities may not? For example, should we permit hospitals that meet established quality and value metrics under the Hospital VBP to pay bonus compensation from DHS revenues to physicians who help the hospital meet those metrics? If so, what conditions should we impose to protect against program and patient abuse? How should we define "high-value care" or "high-value entity"? Are there standards other than the value of the care provided to patients that would be appropriate as threshold standards for permitting a hospital or other entity furnishing DHS to compensate physicians in ways that other entities may not?

- Could existing exceptions, such as the exception at § 411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and payment model sponsored by a non-federal payor? If so, what conditions should we impose to protect against program and patient abuse from the compensation arrangements resulting from participation in such models?
- Have litigation and judicial rulings on issues such as compensation methodologies, fair market value or commercial reasonableness generated a need for additional guidance from CMS on the interpretation of the physician self-referral law or the application of its exceptions? We are particularly interested in the need for guidance in the context of delivery system reform.
- Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at § 411.357(p) for indirect compensation arrangements?
- Given the changing incentives for health care providers under delivery system reform, should we deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should we impose for this deemed status to ensure that compensation paid to a physician is sufficiently attenuated from the volume or value of his [or her] referrals to or other business generated for the entity paying the compensation? Should we apply such a deeming provision only to certain types of entities furnishing DHS, such as hospitals that provide high-value care to our beneficiaries?

Amendments to Certain Definitions

CMS proposes to amend the regulatory definitions of "remuneration" and "*locum tenens* physician," and to clarify what the "stand in the shoes" rule means for the application of Stark Law exceptions to arrangements between DHS Entities and physician organizations. Finally, CMS proposes an amendment to the "geographic area" definition for FQHCs and RHCs.

REMUNERATION

The Stark statute defines a "compensation arrangement" as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C)." 42 U.S.C. § 1395nn(h)(1)(A). Subparagraph (C), in pertinent part, excludes from "remuneration" the "provision of items, devices, or supplies that are *used solely to*—(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the results of tests or procedures for such entity." *Id.* § 1395nn(h)(1)(C). CMS regulations track this definitional language at 42 C.F.R. § 411.351. Read literally, this text does not permit the item, device or supply to perform more than one of the specified functions of collecting, transporting, processing or storing specimens, or ordering or communicating results. CMS regulations track this text, but CMS indicates that it has not interpreted "used solely" literally. Concerned that this language "may misleadingly suggest" that an item, device or supply used for more than one of the six listed purposes would constitute "remuneration" creating a compensation arrangement (unless a compensation exception applied), CMS proposes to change "used solely" to "used solely for one or more of the following [six] purposes: . . . ." 80 Fed. Reg. at 41,918, 41,954.

Although not proposing any regulatory revisions at this time, CMS uses the occasion of this rulemaking to address the

issue of whether a physician's professional service in a hospital setting constitutes "remuneration" to the physician because of the physician's use of the hospital's resources, such as its examination rooms, nursing personnel and supplies. The U.S. Court of Appeals for the Third Circuit in *United States ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009), had taken the position that such use by the physician constituted remuneration to the physician, apparently not appreciating the fact that the hospital would separately bill charges for the facility component of the physician's professional services. Such "split-billing" is routine in the hospital context. CMS clarifies that when a DHS entity provides its resources to a patient and bills the payor for the resources, and the physician separately bills the payor for his or her services, there is no remuneration between the parties for purposes of the Stark Law. Only when the physician or the DHS entity submits a "global bill" for both the professional and facility components of the service, CMS states, will one of the two have provided "remuneration" to the other implicating the Stark Law. 80 Fed. Reg. at 41,918.

LOCUM TENENS *PHYSICIAN*

CMS regulations define a "*locum tenens* physician" because the regulatory definition of a "member of the group or member of a group practice" includes a *locum tenens* physician. The definition of a *locum tenens* physician, in pertinent part, is "a physician who substitutes (that is, 'stands in the shoes') in exigent circumstances for a physician, in accordance with applicable reassignment rules and regulations, . . ." 42 C.F.R. § 411.351. Concerned that use of the phrase "stands in the shoes" potentially created an ambiguity because of the "stand in the shoes" rule within the Stark regulations, CMS proposes removing "stands in the shoes" from the definition of a *locum tenens* physician.

STAND IN THE SHOES

A physician who holds more than a titular ownership or investment interest in a physician organization (PO) is deemed to stand in the shoes of the PO for purposes of determining whether the physician has a direct or indirect compensation arrangement with a DHS Entity. A PO's employed or contracted physicians who are not deemed to stand in the shoes of the organization can elect to be treated as standing in the shoes of the organization. *Id.* § 411.354(c)(2)(iv). When a physician stands in the shoes of a PO, the physician is deemed to have compensation arrangements with the same parties and on the same terms as the PO. *Id.* § 411.354(c)(3).

The "stand in the shoes" concept required that CMS explain how the Stark exceptions work when multiple physicians are deemed to have the same compensation arrangement with a DHS Entity based on a compensation arrangement between the PO and the DHS Entity; the exceptions were made under the assumption that there would only be one physician involved. For example, if the exception requires a writing signed by the parties, and there are multiple physicians standing in the shoes of a PO that has a personal services arrangement with a DHS Entity, must all of the physicians sign the writing between the PO and the DHS Entity because they are all considered to have a compensation arrangement with the DHS Entity? And when an exception prohibits compensation that takes into account the volume or value of referrals or other business generated by the physician for the DHS Entity, does this mean that the compensation cannot take into account the volume or value of the referrals of the physicians standing in the shoes of the PO, or are the referrals of the PO's affiliated physicians *not* standing in the shoes of the PO also implicated?

A CMS FAQ: provided guidance that a signature by an authorized signatory for the PO would be imputed to the physicians standing in the shoes of the PO for purposes of the exceptions requiring a signed writing. And regulations provide that "[w]hen applying the exceptions . . . to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated 'between the parties' are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians)." 42 C.F.R. § 411.354(c)(3)(i). This regulatory text makes it clear that, when an exception prohibits compensation that takes into account the volume or value of referrals or other business generated by the physician, the relevant referrals and business generation are the referrals and business generation of *all* members, employees and independent contractors of the PO,

not just the physicians standing in the shoes of the PO. This text, however, was issued as part of the Stark II, Phase III rulemaking, at which time *all* of a PO's physicians, owners and non-owners, were deemed to stand in the shoes of the PO. Now that only physician-owners are deemed to stand in the shoes of POs, CMS was asked to clarify whether its intention was still for *all* of the PO's physicians to be considered "parties" to the arrangement for purposes of applying the exceptions.

To incorporate the guidance provided in the above-cited FAQ, and to confirm its intention that all of the terms of the exceptions except the signature requirement are to apply to *all* of a PO's physicians, not just the physicians standing in the shoes of the PO, CMS proposes to amend the regulations at *id.* § 411.354(c)(3)(i) as follows:

> When applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the "parties to the arrangements" are considered to be—
>
> (A) With respect to a signature requirement, the physician organization and any physician who "stands in the shoes" of the physician organization . . . ; and
>
> (B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

80 Fed. Reg. at 41,954.

"GEOGRAPHIC AREA" DEFINITION FOR FQHCS AND RHCS

In this Proposed Rule, CMS acknowledges that the current regulatory definition of "geographic area" is contingent on *inpatient* volume, and as a result, it "provides no guidance as to the geographic area into which [FQHCs and RHCs] may recruit a physician" since these entities only treat patients as outpatients or ambulatory patients. *Id.* at 41,913. Thus, although CMS intended to make the physician recruitment exception available to FQHCs and RHCs in its Stark II, Phase III rulemaking, "a concept critical for compliance with the exception's requirements" was not addressed. *Id.*

CMS proposes two alternative approaches for defining "geographic area." The first proposed approach, which is included in the proposed regulatory text, closely mirrors the current definition of a rural hospital's geographic service area. The geographic area would be the area composed of the lowest number of contiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. If the FQHC or RHC draws fewer than 90 percent of its patients from all of the contiguous zip codes from which it draws patients, the geographic area served by the FQHC or RHC may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of its patients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of patients. The geographic area served by the FQHC or RHC may include one or more zip codes from which it draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which it draws at least 90 percent of its patients.

As an alternative, CMS proposes a seemingly more straightforward method to define the geographic area as the area composed of the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. This would be determined by beginning with the zip code in which the highest percentage of the FQHC's or RHC's patients reside, and continuing to add zip codes in decreasing order of percentage of patients. Although CMS acknowledges that this approach would potentially result in larger geographic service areas than in the first approach, CMS states that it sees no potential for program or patient abuse in selecting noncontiguous zip codes to identify 90 percent of the patient base as long as there are patients in those areas.

CMS seeks comments on each alternative, including whether patient encounters is the appropriate measure. CMS also solicits comments specifically from FQHCs and RHCs regarding whether the exception at 42 C.F.R. § 411.357(e) for physician recruitment is useful to such entities, and on any perceived barriers to its use.

Discrete Textual Changes Clarifying CMS Intent[2]

CMS proposes discrete textual changes regarding the phrase "takes into account" and to the text of the retention payments exception to clarify its intent and avoid confusion.

TAKES INTO ACCOUNT

CMS proposes to revise various exceptions to conform the language used to describe the volume/value standard. CMS notes that certain exceptions use phrasing such as "based on the volume or value of referrals," or "without regard to the volume or value of referrals." CMS is concerned that this language may be misunderstood to reflect a different rule than the more common phrasing, "takes into account the volume or value of referrals." CMS clarifies that it views these alternative phrasings as having the same meaning as the "takes into account" language, and that it has a single, unitary understanding of the volume/value standard. To avoid confusion, CMS proposes revisions to conform the language across all exceptions.

RETENTION PAYMENTS EXCEPTION

Currently, 42 C.F.R. § 411.357(t) permits certain retention payments made to a physician with a practice located in an underserved area. This exception was first established in Stark II, Phase II and covered only retention payments made to a physician who had a *bona fide* firm, written recruitment offer. The exception was later modified in Phase III to permit a hospital, RHC or FQHC to retain a physician who does not have a *bona fide* written offer of recruitment or employment if the physician certifies in writing that he or she has a *bona fide* opportunity for future employment that meets the requirements at 42 C.F.R. § 411.357(t)(2). In Phase III, CMS explained that a retention payment based on a physician certification may "not exceed the lower of the following: (1) an amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital in order to join the medical staff of the hospital to replace the retained physician." 72 Fed. Reg. 51,012, 51,066 (Sept. 5, 2007). CMS clarifies that it intended the regulations to mirror the preamble language precisely, but the regulations at 42 C.F.R. § 411.357(t)(2)(iv) currently state that the "retention payment [may] not exceed the lower of—(A) An amount equal to 25 percent of the physician's current income (*measured over no more than a 24-month period*), using a reasonable and consistent methodology that is calculated uniformly; or (B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician." (Emphasis added.)

CMS recognizes that as written, the current regulation text appears to permit entities to make retention payments that consider only part of the prior 24-month period instead of the entire period as was intended. Furthermore, CMS affirms its position that the policy stated in the Phase III preamble is correct and remains its policy. As such, in order to avoid confusion due to potentially conflicting regulatory text, CMS proposes modifying the regulations at 42 C.F.R. § 411.357(t)(2)(iv)(A) to read: "[a]n amount equal to 25 percent of the physician's current annual income (*averaged over the previous 24 months*), using a reasonable and consistent methodology that is calculated uniformly." 80 Fed. Reg. at 41,957 (emphasis added).

Physician-Owned Hospitals

PUBLIC WEBSITE AND PUBLIC ADVERTISING DISCLOSURE REQUIREMENT

CMS proposes to clarify the terms "public website for the hospital" and "public advertising for the hospital" at 42 C.F.R. § 411.362(b)(3)(ii)(C) for purposes of the requirements established in Section 6001(a)(3) of the Affordable Care Act that a physician-owned hospital must disclose the fact that the hospital is owned or invested in by physicians on any public website for the hospital and in any public advertising for the hospital.

[2] In addition to the discrete textual changes described in this section, CMS proposes to change the term "Web site" to "website" throughout the regulations, proposes to revise manual citations listed in the regulations that are no longer correct and proposes to make certain typographical corrections.

Public website disclosure requirement. CMS proposes to amend 42 C.F.R. § 411.362(b)(3)(ii)(C) to list examples of the types of websites that do not constitute a "public website for the hospital," namely (1) social media websites, and (2) electronic payment portals, electronic patient care portals or electronic health information exchanges. CMS acknowledges that the foregoing is a non-exhaustive list and solicits public comments on whether the proposed examples are appropriate given the statutory language; whether it should include different or additional examples of websites in the list; and whether it should, in the alternative, provide an inclusive definition of what would be considered a "public website for the hospital." CMS also notes that even if a website does not constitute a "public website for the hospital" under the proposal, the online content may, depending on the facts and circumstances, constitute public advertising for the hospital that would require a disclosure statement.

Public advertising disclosure requirement. CMS proposes to amend *id.* § 411.362(b)(3)(ii)(C) to refer to "public advertising *for the hospital*" (adding the term "for the hospital" to the existing regulatory text in order to synchronize the language with the statute), and to define the term as "any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital." 80 Fed. Reg. at 41,924, 41,958. CMS also proposes to specify the types of communications that would be excluded from the definition. CMS does not enumerate specific exclusions in the proposed revision to the regulation, but rather states in commentary that "[w]e are proposing that the definition of 'public advertising for the hospital' does not include, by way of example, communication made for the primary purpose of recruiting hospital staff (or other similar human resources activities), public service announcements issued by the hospital, and community outreach issued by the hospital." *Id.* at 41,924. CMS iterates that the facts and circumstances of the communication, rather than the medium by which the message is communicated, determine whether a communication constitutes "public advertising for the hospital." CMS solicits public comments on the proposed definition of "public advertising for the hospital," as well as the proposed list of examples that do not constitute "public advertising for the hospital."

Types of statements that constitute a sufficient statement of physician ownership or investment. CMS proposes to further amend 42 C.F.R. § 411.362(b)(3)(ii)(C) to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment. CMS provides examples of statements that would meet the standard, such as "this hospital is partially owned or invested in by physicians," or a statement that the hospital is founded, managed or operated by physicians or is part of a health network that includes physician-owned hospitals. 80 Fed. Reg. at 41,924. CMS comments that a hospital's name, by itself, such as "Doctors Hospital at Main Street, USA," would also put a reasonable person on notice that the hospital may be physician-owned. CMS solicits public comments on the proposed examples of language that would satisfy the standard and suggestions regarding alternative standards for deeming language sufficient for the disclosure requirements.

Location and legibility of disclosure statements. CMS reiterates its statement from the calendar year 2011 Outpatient Prospective System/Ambulatory Surgical Center (OPPS/ASC) final rule, 75 Fed. Reg. 71,800, 72,248 (Nov. 24, 2010), that the disclosure should be located in a conspicuous place on the website and on a page that is commonly visited by current or potential patients, such as the home page or "about us" section. CMS further provides that the disclosure should be displayed in a clear and readable manner and in a size that is generally consistent with other text on the website. CMS declines to propose to prescribe a specific location or font size for disclosure statements on either a public website or public advertising, stating that "physician-owned hospitals have flexibility in determining exactly where and how to include the disclosure statements, provided that the disclosure would put a reasonable person on notice that the hospital may be physician-owned." 80 Fed. Reg. at 41,925.

Duration of period of noncompliance. CMS notes that September 23, 2011, is the date by which a physician-owned hospital had to be in compliance with the public website and advertising disclosure requirements, and therefore would be the earliest possible beginning date for noncompliance. CMS clarifies that the period of noncompliance is the "duration of the applicable advertisement's predetermined initial

circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date." *Id.* (For example, if a hospital pays for an advertisement to be included in one issue of a monthly magazine and fails to include the disclosure in such advertisement, the period of noncompliance likely would be the applicable month of circulation, even if the magazine continued to be available in the publisher's archives, waiting rooms of physician offices or other public places.) CMS solicits public comments on additional guidance that may be necessary regarding the periods of noncompliance for both disclosure requirements.

DETERMINING *BONA FIDE* INVESTMENT LEVEL

CMS proposes revisions to the calculation of the *bona fide* ownership or investment level of physicians in a hospital to include non-referring physicians. Section 6001(a)(3) of the Affordable Care Act established a requirement that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors, in the aggregate, cannot exceed the percentage of such interests as of March 23, 2010. In the calendar year 2011 OPPS/ASC final rule, CMS established that this "baseline *bona fide* investment level" would be calculated without regard to ownership or investment interests held by physicians who do not make any referrals to the hospital, including physicians who are no longer practicing medicine. CMS describes two objections to this position: (1) the statutory definition of "physician owner or investor" is broad, and if Congress had intended to limit the definition to only "referring physicians," it would have included such qualifying language; and (2) including only "referring physicians" in the definition of "physician owner or investor" for purposes of establishing the baseline *bona fide* investment level frustrates the purpose of an explicit deadline set forth in the statute. (That is, in the Affordable Care Act, Congress required physician-owned hospitals seeking to rely on the rural provider or hospital ownership exceptions to have had physician ownership or investment as of March 23, 2010, but allowed them until December 31, 2010, to obtain a provider agreement. Stakeholders asserted that the position makes the March 23, 2010, deadline meaningless because a pre-operational physician-owned hospital that did not have a provider agreement until December 31, 2010, likely would not have had physician owners or investors referring to the hospital as of the March 23 date. The stakeholders stated that CMS's position precluded pre-operational hospitals from satisfying the requirement for physician ownership as of March 23, 2010, thus preventing the hospitals from availing themselves of the hospital ownership or rural provider exceptions.)

CMS proposes to revise the previous policy to require that the baseline *bona fide* investment level and subsequent measurement of the *bona fide* investment level include direct and indirect ownership and investment interests held by a "physician," as defined in section 1861(r) of the Social Security Act and in 42 C.F.R. § 411.351, *regardless* of whether the physician refers patients to the hospital. This would include a retired physician who still holds his or her license to practice medicine. CMS solicits public comments regarding this policy revision.

Proposed definition of ownership or investment interest. CMS proposes to establish a definition of ownership or investment interest at *id.* § 411.362 solely for purposes of the section that would apply to all types of owners or investors, regardless of their status as referring or non-referring physicians. Under the proposed definition, a *direct* ownership or investment interest in a hospital would exist "if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an *indirect* ownership or investment interest in a hospital exists if: (1) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital," even if "the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the *precise composition* of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain." 80 Fed. Reg. at 41,926, 41,958 (emphasis added). (CMS does not clarify whether an ownership or investment interest comprising a link in the chain can run any direction, or

whether the interest must run *towards* the hospital. Presumably, CMS intended for the definition to track the Stark definition of an indirect ownership or investment interest for other Stark purposes, in which case, the ownership or investment interests must all run *towards* the hospital. For example, a physician's investment in an entity in which the hospital is also an investor would not make the physician an owner or investor in the hospital (see 42 C.F.R. § 411.354(b)(5)(iii)-(iv))). CMS also solicits public comments on an alternative proposal under which it "would revise [the] regulations in an even more comprehensive manner and remove the references to a 'referring physician' throughout existing § 411.354" (which defines various financial relationships for purposes of the Stark Law). 80 Fed. Reg. at 41,926.

Delay in enforcement. CMS acknowledges that some physician-owned hospitals may have relied on CMS's previous policy to calculate *bona fide* investment levels that would now exceed the baseline *bona fide* investment levels calculated under CMS's proposed revisions. CMS therefore proposes a delay in the effective date of the proposed revisions "until such time as physician-owned hospitals would have sufficient time to come into compliance with the new policy." *Id.* CMS solicits public comments on how long it should delay the effective date and the impact of the proposed regulatory revisions on physician-owned hospitals and on the measures or actions such hospitals would need to undertake to come into compliance with the proposed revision.

Publicly Traded Securities[3]

Acknowledging that certain elements of the existing exception for publicly traded securities, 42 C.F.R. § 411.356(a), are antiquated (specifically, the National Association of Securities Dealers (NASD) no longer exists, and it is no longer possible to purchase a publicly traded security traded under the automated interdealer quotation system it formerly operated), CMS undertook an investigation to determine whether the exception for ownership of publicly traded securities could be modernized by including currently existing systems that are the equivalent to the NASD's now-obsolete automated interdealer quotation system. Ultimately, CMS concluded that electronic stock markets such as National Association of Securities Dealers Automated Quotation Systems (NASDAQ) and the Financial Industry Regulatory Authority's over-the-counter (OTC) market are "outgrowths and modern day equivalents to an automated interdealer quotation system." 80 Fed. Reg. at 41,920. CMS thus proposes to revise the existing regulations "to include securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent." *Id.* In order to maintain standardization and transparency, CMS clarifies that it is "not proposing to include any electronic stock markets or OTC quotation systems that trade unlisted stock or that involve decentralized dealer networks." *Id.* CMS is specifically soliciting comments "regarding whether fewer, different, or additional restrictions on electronic stock markets or OTC quotation systems are necessary to effectuate the Congress' intent and to protect against patient or program abuse." *Id.*

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[3] CMS is removing the hyphen from the phrase "publicly-traded" in the regulations. 80 Fed. Reg. at 41,930.

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