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Long-Awaited Stark Law Phase III Final Rule Released By CMS

On August 27, 2007, CMS released the final rule that constitutes the third phase ("Phase III") of the long, drawn out rulemaking process relating to the Federal physician self-referral prohibition (the "Stark Law"). See http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-1810-F.pdf. Phase III is scheduled for publication in the Federal Register on September 5, 2007, which would allow the rules to take effect on December 4, 2007. Although Phase III contains many technical changes and nuanced details, it also includes significant and substantive changes that will cause health care organizations, physicians, and their counsel to scramble to reevaluate and restructure longstanding relationships before the end of the year is out.

All existing hospital and physician group practice arrangements must be revisited and likely restructured before the current terms of the arrangements expire; scheduled amendments to space leases, equipment leases, and personal service arrangements must be reviewed for compliance (and likely scrapped); and group practices must reconsider and perhaps revise the manner in which they share profits with and distribute productivity bonuses to group physicians.

Phase III is a final rule wholly separate from the self-referral provisions contained in the recent, Proposed CY 2008 Medicare Physician Fee Schedule (the "Fee Schedule Rule"). See http://www.crowell.com/NewsEvents/Newsletter.aspx?id=477. In fact, certain Phase III requirements significantly differ and sometimes directly conflict with the Fee Schedule Rule, adding confusion and frustration as providers attempt to comply with a declaredly "strict liability" statute. In addition, Phase III commentary reveals that CMS may be considering yet *another* future rulemaking to address further issues raised by stakeholders.

Set forth below is a brief summary and analysis of some of Phase III's more important requirements:

Definitional Issues

CMS added, modified or commented on a handful of definitions, including, notably, "fair market value," "'incident to' services,"and "physician in the group":

- Although it noted that "reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value," CMS eliminated the "safe harbor" for fair market value methodologies established by Phase II, i.e., that compensation methodologies based on either the average hourly rates for ER physician services or the average of the 50th percentile of 4 of 6 specified salary surveys would be considered *per se* fair market value.

- CMS revised the definition of "'incident to' services" to make clear that both services and supplies (including drugs) can be considered "'incident to' services."
- CMS modified the definition of "physician in the group practice" to clarify that an independent contractor physician must furnish patient care services for the group under a contract *directly* with the group (thus preventing the inclusion of "leased" employees as "physicians in the group").

In addition, CMS indicated a willingness to revisit the definition of "entity" so that physician-owned organizations that derive a substantial portion of their revenue by furnishing items and services to organizations that, in turn, furnish DHS to Medicare enrollees (i.e. a physician-owned equipment leasing company that leases a CT scanner to a hospital) would *also* be considered "entities" for purposes of the Stark Law – even if they do not submit claims for payment to Medicare.

Group Practice

- CMS revised the regulatory text regarding permissible productivity bonuses to make clear the bonuses *can* be based directly on "incident to" services that are incidental to the physician's personally performed services, even if those "incident to" services are otherwise DHS referrals (such as physical therapy or outpatient prescription drugs).
- However, CMS retracted its Phase II preamble assertion that overall profit shares may relate directly to "incident to" services, indicating that profits must be allocated in a manner that does *not* relate directly to DHS referrals, even those billed as "incident to" services.

"Technical" Violations

- Although the Fee Schedule Rule indicated potential leniency with respect to "technical" violations, Phase III refused to expand the scope of the "temporary non-compliance" exception or establish further, analogous exceptions.
- However, CMS did establish a 6-month "holdover" allowance for personal service arrangements, similar to that which currently exists for space and office leases.

Indirect Compensation Arrangements – Physicians Will "Stand In the Shoes" of Their Group Practices

- Seeking to close what it called an "unintended loophole," CMS added a regulatory provision under which referring physicians will be treated as "standing in the shoes" of their group practices (and other physician

organizations) for purposes of applying the rules pertaining to direct and indirect compensation arrangements.
    - Whereas a DHS entity→group practice→referring physician financial relationship was previously analyzed as an indirect compensation arrangement, the "stand in the shoes" rule will require the DHS→group practice arrangement to be analyzed as a direct compensation arrangement.
    - For purposes of the new, direct compensation analysis, the arrangement must be analyzed as by and between the DHS entity and *each* of the individual physicians in the group
- The "stand in the shoes" rule affects only indirect compensation arrangements where a group practice or other physician organization is the sole intervening entity between a DHS entity and a referring physician
- Importantly, an arrangement existing as of September 5, 2007 and that previously complied with the indirect compensation arrangement exception must be revisited and restructured to comply with an applicable direct compensation arrangement exception *by the end of the arrangement's current term*. For hospitals and groups on contract terms mirroring the calendar year, full compliance must be achieved in a matter of weeks.
- CMS, in both Phase III and the Fee Schedule Rules, indicated that it is open to extending the "stand in the shoes" rule to *other* indirect compensation arrangements.

Academic Medical Centers

- CMS clarified that the *total* compensation from *each* academic medical center ("AMC") component to a faculty physician must be set in advance and not be determined in a manner that takes into account the volume or value of referrals by the referring physician within the AMC.
- In addition, when determining whether the majority of physicians on the medical staff of a hospital affiliated with an AMC consists of faculty members, the affiliated hospital must either *include* or *exclude* all individual physicians holding the same class of privileges at the hospital. For example, the hospital must either include or exclude all physicians with courtesy privileges.

In-Office Ancillary Services Exception

- In Phase III, CMS declined to make any substantive changes to the in-office ancillary services exception.
- However, CMS indicated that it is considering whether in-office pathology labs and "sophisticated imaging equipment" should continue to be subject to the exception.

- CMS revealed more detailed concerns with the in-office ancillary services exception in the Fee Schedule Rule.

Rental of Office Space and Equipment

- Although CMS made no substantive changes to these exceptions, CMS surprisingly stated that if parties to a space or equipment lease desire to change the rental rate (or methodology) during *any* term of the lease (even if during the fifth annual renewal term), the parties must terminate the lease and enter into a new arrangement, lest the change violate the "set in advance" requirement; annual renewals incorporating new rental rates (or a new methodology) would not satisfy the exception.
- Similarly, CMS stated that changes to terms material to the rental rate (e.g., amount of space rented) may *also* require termination of the lease, lest the change violate the "fair market value" or "volume or value of referrals" requirements.
- While the Fee Schedule Rule proposed to eradicate certain "per click" or "per use" space and equipment lease arrangements, in Phase III CMS declined to make any such changes.

Personal Service Arrangements

- CMS modified the personal service arrangements exception to permit a "holdover" service arrangement on terms similar to the "holdover" space and equipment leases permitted by Phase II.
- Similar to its pronouncements regarding the proper amendment or termination of space and equipment leases, CMS stated that changes to payment rates or compensation methodologies within a personal service arrangement must be effected by a termination of the agreement and the creation of a new arrangement, lest the change violate the "set in advance" requirement. However, CMS indicated that annual salary adjustments (e.g., CPI escalators) remain permissible.
- If contemplating a change to compensation rates or methodologies, keep in mind the Fee Schedule Rule wherein CMS proposed to sharply proscribe the use of percentage-based compensation.

Physician Recruitment

- CMS made several substantial changes to the physician recruitment exception:
    - Rural health clinics may now utilize the exception
    - Expansion of the definition of "geographic area served by the hospital," for both rural hospitals and non-rural hospital. This expansion, replete with detailed forays into various zip code analyses, should

allow hospitals to recruit physicians to outlying portions of the hospitals' service areas.
    - More generous income guarantees may be offered to physicians recruited to replace deceased, retiring or relocating physicians
    - Group practices may impose certain practice restrictions on recruited physicians, including:
        - Reasonable non-compete provisions, e.g., non-compete provisions compliant with State and local laws
        - Restrictions on moonlighting
        - Non-solicitation provisions (applying to both patients and employees)
        - Requiring the physician to treat Medicaid and indigent patients
        - Requiring the physician to not use confidential or proprietary information of the physician practice
        - Requiring the physician to repay losses absorbed by the practice in excess of any hospital recruitment payments
        - Requiring the physician to pay reasonable liquidated damages, should the physician leave the practice and remain in the community
    - Hospitals may "recruit" local physicians to the extent they were previously employed (for at least two years) on a full-time basis by a bureau of prisons, the DOD, the DVA, or the Indian Health Service.

- CMS also indicated its wariness of recruitment arrangements wherein a group practice assumes the obligation to repay the recruited physician's obligations.

Fair Market Value Exception

- CMS expanded the scope of the fair market value exception to include payments from a referring physician to a DHS entity.
- The application of this exception to payments *from* physicians may not be used for space leases in which the physician is a lessee; such arrangements must satisfy the exception for space leases.
- CMS specifically noted that a short-term (3-month) equipment lease (in which the DHS entity is the lessor and the referring physician is the lessee) may now be permissible if it satisfies the newly-revised, fair market value exception.

Non-Monetary Compensation Exception

- With the goal of protecting DHS entities and physicians from "disastrous and uncertain results" related to inadvertently making (or accepting) non-monetary compensation valued in excess of $329 (the current limit based on CPI increases to the original $300 limit), CMS revised this exception to allow physicians to repay certain excessive non-monetary compensation within the same calendar year or 180 days from the date the compensation was paid
    - Conflicts with solicitations for comments in the Fee Schedule Rule
- CMS asserts that once the DHS entity learns of the excess payment, "it would be prudent" for the entity to not bill and submit claims for the physician's DHS referrals until repayment is made
    - Fee Schedule Rule indicates that claims may be forever "tainted."
- In addition, DHS entities may provide one medical staff appreciation function for the entire medical staff per year.

Compliance Training

- CMS revised this exception to allow DHS entities to offer compliance training pertaining to Federal, State or local laws, even if CME credit is available for such training, as long as the compliance training is the "primary purpose" of the program.

Professional Courtesy

- CMS revised the exception to eliminate the requirement that the DHS entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation.
- CMS confirmed that he DHS entity *must* have a written policy that is approved by the entity's governing body
- CMS made clear that the exception only applies to DHS entities who are hospitals or providers with formal medical staffs, and does not apply to suppliers such as labs or DME companies.
    - For purposes of group practices who offer professional courtesy to their physicians, CMS would consider such groups to be "providers with formal medical staffs"

Retention Payments in Underserved Areas

- CMS made several modifications to the exception permitting hospitals and federally qualified health centers to make retention payments to a physician:
    - Hospital location is no longer a requirement: retention payments can be made if either the hospital is located in an HPSA, or if the physician is located in a rural area, HPSA, or "area of demonstrated need"

- Certain retention payments can be made even in the *absence* of a written recruitment offer made to the physician, but the physician must certify in writing that he or she has a bona fide opportunity for future employment that would require relocation
  - The offer no longer need be from a hospital; it can now be from a hospital, academic medical center, rural health clinic, federally qualified health center, or even a physician organization
- Retention payments can now be made on the basis of a written offer of employment (previously, they could only be made on the basis of a bona fide firm, written *recruitment* offer)
- Rural health clinics may now make retention payments

Medicaid Referrals

- Although CMS stated in the Preamble to Stark II, Phase II that it would address the applicability of the Stark self-referral prohibitions on physician referrals for Medicaid-reimbursed services in the next phase of rule-making, it did not do so in the Phase III Rule. Therefore, Medicaid referrals remain outside the scope of the Stark self-referral prohibitions.