

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Stark Phase III Regulations First of Two-Part Series: “What Meets the Eye”

September 14, 2007

On August 27, 2007, CMS posted to its website the long-awaited “Phase III” regulations that further implement the federal physician self-referral statute known as the “Stark Law.” The Phase III regulations appear in their official form in the Federal Register dated September 5, 2007,¹ and are effective on December 4, 2007. While the Phase III provisions contain fewer changes to the actual text of the Stark Law regulations than many observers expected, the commentary to the Phase III provisions includes a significant number of “clarifying” statements and other statements by CMS that may have a significant impact on the way that enforcement authorities interpret existing provisions.

In order to aid our clients and friends in understanding both the official changes to the regulatory text implemented by Phase III as well as the significant “clarifying” statements, we are issuing a two-part series of Health Law Updates on Phase III. This first part of the series addresses the actual changes to the regulatory text, or “what meets the eye;” and the second part will address the significant “clarifying” and other interpretive statements, or the portion of Phase III that is “more than meets the eye.”

Group Practice Changes

A favorable group practice determination is critical for pertinent arrangements to comply with several of the Stark Law exceptions. In the Phase III commentary, CMS reiterates that physicians in a group practice must have a strong and meaningful nexus to the group practice. CMS has incorporated this interpretation into the Phase III final rule by modifying the definition of “physician in the group practice” to make clear that an independent contractor must have a contractual arrangement *directly*

¹ See 72 Fed. Reg. 51012 *et seq.* (September 5, 2007).

with the group practice. The arrangement cannot be between the group practice and an intermediary entity, such as a staffing agency or, presumably, another group practice.²

Additionally, CMS provides regulatory text refinement to the special rule for productivity bonuses and profit shares within group practices. Generally, for purposes of the group practice definition, members of a group practice cannot be compensated in any way that directly or indirectly relates to the volume or value of their referrals for designated health services (DHS). Despite this general prohibition, groups may pay productivity bonuses and overall profit shares that indirectly relate to DHS referrals in the manner provided in the regulations. Moreover, CMS has clarified in Phase III that productivity bonuses may *directly* reflect services furnished “incident to” a physician’s personally performed services, even if the “incident to” services are not personally performed by the physician and are otherwise DHS. CMS also modifies the definition of “incident to” services to clarify that the term includes services *and* supplies (such as drugs). Note, however, that services or supplies covered by separate Medicare benefit categories, such as diagnostic tests, may not be included in these “incident to” bonuses (unless the diagnostic test is personally performed by the physician).

Compensation

- *Fair Market Value* - Previously, under the definition of “fair market value,” the Stark Law allowed health care providers to rely upon various physician compensation surveys to establish that the compensation paid to the physician was fair market value. Several factors made this safe harbor impractical, such as the unavailability of some of the surveys identified in the former Stark Law regulations. In addition, it proved to be infeasible to obtain information regarding hourly rates for emergency room physicians at competitor hospitals. Noting these aforementioned factors in its commentary, CMS has eliminated this safe harbor for payments to physicians in Phase III.
- *“Stand in the Shoes” Provision – Converts Many Indirect Compensation Arrangements to Direct Compensation Arrangements* - The Phase III regulations significantly broaden the definition of direct compensation arrangements by indicating that a direct compensation arrangement now exists between a physician and an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her “physician organization.” A “physician organization” means the physician himself or herself (including a professional corporation of which he or she is the sole owner), a physician practice, or a group practice that meets the Stark definition of “group practice.”³

² This change to the definition of “physician in the group” could have an important effect on existing arrangements. For example, a typical existing arrangement might be for a physician group to contract with a radiology practice to obtain radiology reads performed by a one of the practice’s radiologists on the premises of the physician group. A literal reading of the new rule might require the physician group practice to execute individual contracts with each radiologist in the radiology practice, or, at the very least, might require the joining of all individual radiologists to the contract between the physician group and the radiology practice, even if the individual radiologists have otherwise filed 855-R Forms in favor of the physician group.

³ The Stark definition of “group practice” appears at 42 C.F.R. § 411.352.

In such situations, CMS has deemed that the physician “stands in the shoes” of the physician organization.⁴ This “stand in the shoes” provision now imputes to the physician the same compensation arrangements (with the same parties and on the same terms) as the physician organization has with DHS providers.⁵ As a result, many arrangements that could formerly be sheltered under the Stark exception for indirect compensation arrangements now will have to meet a direct compensation exception.

Fortunately, CMS does not require the unwinding of any current indirect compensation arrangements that were entered into prior to the publication date of the final rule, i.e., prior to September 5, 2007. Those entities and physicians who find themselves in this position are not required to revise the terms of their agreements immediately. Rather, the agreements may remain in effect during the original term or the current renewal term of the agreement (that is, the renewal term that is in effect on the publication date of the final rule), provided that the agreement satisfied the indirect compensation exception on the publication date of the final rule. The agreement will need to be revised at the end of the original term or the current renewal term.⁶

- *New Flexibility Regarding Non-Monetary Compensation* - From the perspective of many providers, some of the welcome changes in the Phase III final rule are the revisions to the non-monetary compensation exception. This exception permits an entity to provide to a physician non-cash items and services up to a stated limit (currently \$329 per physician, adjusted annually for inflation). In the Phase III final rule, CMS has given entities and physicians increased flexibility in complying with this exception by providing a mechanism by which a physician can repay certain excess payments and by permitting an entity to hold a medical staff “appreciation party” without risk of exceeding the limits.

Inadvertent Excess Payments. CMS has recognized that entities may inadvertently provide compensation under this exception in excess of the stated limits. The Phase III final rule permits continued compliance notwithstanding the excess payments if such excess payments were made inadvertently, do not exceed the applicable limit by more than 50%, and are repaid by the physician. The physician must repay the excess payments by either the end of the calendar year in which it was received, or 180 days from the date of the excess payment, whichever is sooner. The ability to rectify excess payments is not unlimited, however. Entities are not permitted to use the repayment mechanism more than once every three years with respect to the same physician.

⁴ 42 C.F.R. § 411.354(c)(1)(ii).

⁵ 42 C.F.R. § 411.354(c)(3)(i). The Phase III final rule states that the “parties” to an arrangement for this purpose are the DHS entity and the physician organization (including all members, employees, or independent contractor physicians). Some commentators have suggested that this requirement means that the referring physician is deemed to stand in the shoes not only of the financial relationships that his or her physician organization *entity* has with DHS providers but also of the financial relationships that any other member, employee or independent contractor of the physician organization has with DHS providers. Given the complexities that could result from such an analysis, a hopefully more plausible interpretation is simply that CMS will consider all members, employees, and independent contractors of the physician organization to be additional parties to each agreement that the physician organization *entity* has with a DHS provider, so that the compensation under that particular agreement cannot take into account the volume or value of referrals of either the referring physician who is standing in the shoes of the physician organization or any other member, employee, or independent contractor of the physician organization.

⁶ 42 C.F.R. § 411.354(c)(3)(ii).

Medical Staff Party. Additionally, the Phase III final rule permits hospitals and other entities with formal medical staffs to provide one medical staff appreciation party per year without such event counting toward the applicable non-monetary compensation limit (although any gifts, including door prizes, given to attendees would count toward the stated dollar amount limit in the exception). The party must be local and open generally to all medical staff, including physicians and other medical practitioners who order hospital services for patients.

While these changes to the non-monetary compensation exception will make it easier for entities and physicians to comply, the exception still poses challenges. For example, CMS has commented that the amount attributable to each item or service provided pursuant to this exception is equal to its fair market value to the physician, rather than the cost to the entity. In many cases, this value may be difficult to ascertain, and the entity must have in place valuation mechanisms to determine such fair market value (i.e., the amount the physician would have paid for the item or service if he or she purchased it in a fair market value transaction).

- *Payments By a Physician – Now Subject to Stricter Requirements* - The Phase III final rule alters the language of the fair market value exception so that this exception now applies not only to the provision of items or services *by* a physician or immediate family member to an entity but also to the provision of items or services by an entity *to* a physician or immediate family member. Formerly, physicians paying an entity for items or services provided by the entity to the physician relied on the exception for “payments by a physician,” appearing at 42 C.F.R. § 411.357(i), which does not contain as many requirements as the fair market value exception. The “payments by a physician” exception states that it may not be utilized if the parties’ arrangement is specifically addressed by another Stark exception, including the fair market value exception. Since CMS has now expanded the fair market value exception to include payments by a physician for items or services, the parties to most such arrangements now must comply with the requirements of the fair market value exception rather than the somewhat less stringent requirements of the “payments by a physician” exception.
- *Security Interest Held By a Physician in Equipment Sold to a Hospital* - CMS has also revised the characterization of certain financial relationships that are based on a physician’s security interest in a piece of equipment sold by the physician to a hospital. Previously, CMS considered this type of relationship to constitute an ownership interest in a part of a hospital that would not qualify for an ownership exception; however, the Phase III final rule clarifies that this type of relationship will now be considered a compensation relationship, for which more exceptions are available. 42 C.F.R. § 411.354(b)(3)(v). The Phase III final rule does not include any other types of security interests in this rather narrow carve-out and CMS has specifically declined to expand the exception to protect the referrals of physicians who, by virtue of a security interest in a hospital (which might itself be protected by the “whole hospital” exception), have an indirect ownership interest in DHS entities owned by the hospital.
- *“Hold-Over” Provision Now Available for Personal Services Contracts as Well as Leases* - The exception for personal service arrangements⁷ was expanded to resemble more closely the lease exceptions contained in the same section. Therefore, personal services arrangements that are held over for up to six months following the expiration of the arrangement are not prohibited, if

⁷ See 42 C.F.R. § 411.357(d).

the arrangement was for at least one year and meets the conditions otherwise required by this section (such as having a written agreement, etc.).

Recruitment

CMS has reorganized the physician recruitment exception in the Phase III final rule and made the exception more flexible to address the concerns of providers about the difficulty encountered in meeting this exception.

CMS redefines the meaning of the “geographic area served by the hospital.” The definition in the Phase III final rule now allows greater flexibility in determining what geographic area is served by the hospital. This revision increases the location to which a doctor could establish, or join an existing, practice. With respect to hospitals that draw fewer than 75% of their inpatients from contiguous zip codes, the geographic area is now comprised of all contiguous zip codes from which the hospital draws its inpatients. In addition, CMS has created a special option for rural hospitals, whereby rural hospitals may look to the contiguous counties from which they draw 90% of their inpatients. The area also may include noncontiguous zip codes in decreasing order by percentage of inpatients drawn from each zip code area.

The final rule continues to require that physicians relocate their medical practice to the geographic area served by the hospital. Unlike the Phase II regulations, certain physicians are not subject to the relocation requirements (previously residents and physicians in practice for a year were deemed to have met these requirements). This category of physicians now includes not only residents or physicians in practice for less than one year, but also certain physicians who were employed by any of the following: federal or state prisons; the U.S. Department of Defense or the U.S. Department of Veteran Affairs; a facility of the Indian Health Service; and those determined at the Secretary’s discretion in an advisory opinion.

CMS has also expanded the determination of the permitted amount of an income guarantee in circumstances where a hospital provides an income guarantee to a physician joining an existing practice group in a rural area or a HPSA. If the recruited physician is replacing a physician who, in the previous 12-month period, retired, relocated outside of the geographic area served by the hospital or died, the income guarantee may include either the actual incremental costs of the recruited physician or the lesser of a per capita allocation of the practice’s entire overhead, or 20% of the practice’s aggregate costs.

In perhaps the most significant adjustment to the physician recruitment section, CMS now explicitly permits an employer group practice to apply practice restrictions that do not “unreasonably” restrict a physician’s ability to practice medicine in the geographic area served by the hospital upon termination of the physician support arrangement. CMS has revised the relevant provision to state: “The physician practice may not impose on the recruited physician[,] practice restrictions that unreasonably restrict the recruited physician’s ability to practice medicine in the geographic area served by the hospital.” This change should give some comfort to a practice that it will be able to protect the goodwill associated with the practice if the physician leaves and sets up his own practice or joins another one.

Retention Payments In Underserved Areas Exception

CMS has also expanded the applicability of the retention payments exception not only to bona fide written recruitment offers, but also to both bona fide written offers of employment and certain unwritten employment offers.

The final rule does not significantly change the requirements related to bona fide written recruitment offers aside from now including bona fide written employment offers. Where a physician receives a bona fide offer of employment, CMS requires that the retained physician certify to the hospital in writing certain information sufficient for the hospital to verify the physician's employment opportunity. Information to be certified includes, but is not limited to, the following: (i) that he has received a bona fide recruitment or employment offer; (ii) the details regarding how the physician obtained the employment opportunity; and (iii) the date on which the physician anticipates relocating his medical practice outside of the geographic area served by the hospital. Further, the hospital must take reasonable steps to verify that the physician does have a bona fide employment opportunity to relocate outside of the geographic area served by the hospital.

In addition to the current requirement, the retention payment exception now adds greater flexibility by making physicians eligible for retention payments if at least 75% of such physician's patients reside in a medically underserved area or are members of a medically underserved population.

Under the final rules the amount of the retention payment remains the same – the payment cannot exceed the lower of the following amounts: the difference between the physician's current income and what he would receive for comparable services in the written recruitment or employment offer, and the reasonable costs that the hospital would incur to recruit a replacement physician to the geographic area served by the hospital.

Other Changes

- *Additional Definitions* – In Phase III, CMS adds a definition for “downstream contractor”⁸ and moves the definition of “rural area” from 42 C.F.R. § 411.356 to the definitions section at 42 C.F.R. § 411.351.⁹
- *Leases of Space Do Not Qualify for Fair Market Value Exception* – The Phase III regulations specifically exclude the rental of office space from fair market value exception appearing at Section 411.357(l). This change is consistent with prior assertions by CMS that a lease of office space is not an “item or service” for purposes of this exception. By specifically excluding leases for office space, CMS has ensured that such leases must comply with more restrictive conditions contained in the exception for rental of office space set forth in Section 411.357(a).

⁸ A “downstream contractor” means a “first tier contractor” as defined at 42 C.F.R. § 1001.952(t)(2)(iii) or a “downstream contractor” as defined at 42 C.F.R. § 1001.952(t)(2)(i). This definition is relevant largely to the physician incentive plan exception at 42 C.F.R. § 411.357(d)(2).

⁹ “Rural area” means an area that is not an urban area as defined at 42 C.F.R. § 412.62(f)(1)(ii). 72 Fed. Reg. 51080, 51084 (September 5, 2007).

- *Academic Medical Center Exception* – The Phase III regulations clarify that the compensation from each academic medical center component need not separately satisfy a fair market value test but rather that the only relevant fair market value standard is that the compensation paid by all academic medical center components, considered in the aggregate, must not exceed fair market value for the services provided. The compensation paid by each academic medical center component must still, however, not be determined in a manner that reflects the value or volume of referrals. 42 C.F.R. § 355(e)(1)(ii). CMS has also clarified that for the purpose of determining whether the majority of physicians on the medical staff consist of faculty members (and therefore whether the facility constitutes an “academic medical center”), an affiliated hospital may exclude courtesy staff. However, all physicians holding the same class of privileges (for example, courtesy staff) must be either included or excluded when making this calculation. 42 C.F.R. § 355(e)(2)(iii).
- *Intra-Family Referrals* - CMS has provided an alternative test for calculating when the availability of practitioners in a rural area is sufficiently limited that an intra-family referral otherwise meeting the requirements of this section is permitted. In rural areas, a referral of a patient to a physician’s family member is permitted so long as no other provider is available to furnish the services in a timely manner within 25 miles or, once Phase III takes effect, within 45 minutes transportation from the patient’s residence. Either test may be utilized to determine whether a referral to a physician’s family member may be made. 42 C.F.R. § 355 (j)(1)(ii). Note that, for services furnished to patients where they reside (for example, home health services or DME), the test remains the same, i.e., that no other person or entity is available to furnish the services in a timely manner in light of the patient’s condition.
- *Compliance Training* - Previously, an entity could provide compliance training to a physician in reliance on this exception only if the training did not include continuing medical education (“CME”). In response to comments that this requirement unnecessarily prevented entities from providing useful compliance training to physicians if even a small element of the training included CME, CMS modified the exception to allow for otherwise permissible compliance training programs that offer CME credit, so long as the primary purpose of the program is compliance training. In addition, although CMS declined to modify this exception’s requirements that the training be held in the local community or service area, it did provide commentary approving the use of internet or distance training if the physician is in the local area when accessing the online training program.
- *Charitable Donations by a Physician* - Previously, this exception was unavailable for charitable donations that were either “solicited” or “made” in any manner taking into account the volume or value of referrals. In the Phase III final rule, the word “made” is replaced with “offered.” CMS made this one-word change in response to concerns that a charitable donation is outside the protection of the statute if the physician intends that the donation is in exchange for future or past referrals, even if the entity has no knowledge of the improper purpose. However, merely changing the word “made” to “offered” leaves open the question of to the extent to which an entity must look into the intent of an offer prior to accepting a donation.
- *Professional Courtesy* - CMS clarifies that this exception, which permits an entity to provide professional services to members of its medical staff in certain circumstances, applies only to hospitals and other providers with formal medical staffs and only if those entities have a written

professional courtesy policy approved by the governing body. In response to comments that certain aspects of the exception were unnecessarily restrictive, CMS deletes the requirement that an entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation.

Conclusion

Our next Health Law Update will focus on the more subtle aspects of the Phase III regulations – those that are “more than meets the eye.” Please contact one of our attorneys in the Healthcare Practice Area listed below if you have any questions or would like additional information.

Bass, Berry & Sims Healthcare Attorneys

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

Starr Brown
(615) 742-6530
sbrown@bassberry.com

Valere B. Fulwider
(615) 742-7742
vfulwider@bassberry.com

Elisa E. Harris
(615) 742-6553
eharris@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Leslie Maclellan
(615) 742-7818
lmaclellan@bassberry.com

Brenda N. Phillips
(615) 742-6237
bnphillips@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Krista L. Thornton
(615) 742-7734
kthornton@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Leigh Walton, Chair
(615) 742-6201
lwalton@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Renard François
(615) 742-7792
rfrancois@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Clevonne M. Jacobs
(615) 742-7769
vjacobs@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

The materials contained herein have been abridged from the statutory sources and should not be construed or relied upon for legal advice. Readers are urged to consult legal counsel concerning particular situations and specific legal questions.

To ensure compliance with requirements imposed by the IRS, we inform you that this message is not intended to be used, and cannot be used, by the addressee or any other person for the purpose of avoiding penalties that may be imposed under the Internal Revenue Code.

NASHVILLE Downtown
315 Deaderick St. · Ste. 2700
Nashville, TN 37238-3001
(615) 742-6200

KNOXVILLE
1700 Riverview Tower
900 S. Gay St.
Knoxville, TN 37902
(865) 521-6200

MEMPHIS
The Tower at Peabody Place
100 Peabody Place · Ste. 900
Memphis, TN 38103-3672
(901) 543-5900

NASHVILLE Music Row
29 Music Square East
Nashville, TN 37203-4322
(615) 255-6161