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Healthcare and White Collar Defense – Regulatory Update

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STARK REGULATIONS – PHASE III
NEW REGULATIONS GO INTO EFFECT DECEMBER 4, 2007

On September 5, 2007, the Centers for Medicare and Medicaid Services (CMS) published Phase III of the Stark regulations. These regulations went into effect on December 4, 2007. Phase III responds to many of the criticisms of Phase II. There are several clarifications, amendments, and additions of which you should be aware. This primer provides an overview of the most significant changes that may impact your medical practice or hospital.

I. PHYSICIANS NOW STAND IN THE SHOES OF THEIR GROUP PRACTICES

In Phase II, CMS solicited comments as to whether it should permit physicians to stand in the shoes of their group practices when determining whether they have a direct or an indirect compensation arrangement with a designated health-service entity. In Phase III, CMS decided to adopt a stand-in-the-shoes provision. As a result, physicians are now treated the same as their group practice or their physician organization (as newly defined) when determining the type of compensation arrangement. As a practical matter, a physician will have a direct-compensation arrangement with a designated health-service entity if the only intervening entity between the physician and the entity is the physician's group practice.

For example, if a designated health-services entity leases office space to a group practice, then each physician within the group practice will be treated as though she made the lease directly with the entity. Consequently, each group physician would have a direct-compensation arrangement through the lease. Therefore, the lease would need to be drafted to fit within the office-rental exception if the entity wants to submit claims for designated health-service referrals from any of the group physicians.

CMS recognized that many existing indirect-compensation arrangements would become direct compensation arrangements. It decided to ease the medical community's administrative burden by exempting all existing, proper indirect-compensation arrangements that were created before September 5, 2007. These exempted arrangements may continue to use the indirect-compensation exception during the original or current renewal term of the agreement. After that time, the arrangements must satisfy a direct compensation exception. In addition, any indirect-

compensation arrangements created on or after September 5, 2007 will need to satisfy a direct-compensation exception on December 4, 2007.

CMS has not made any substantive changes to the indirect-compensation exception. Therefore, if the compensation arrangement is still an indirect one after applying the new, stands-in-the-shoes provision, then the normal, indirect-compensation rules still apply.

II. THE PHYSICIAN-RECRUITMENT EXCEPTION IS NOW MORE FLEXIBLE

CMS made significant changes to the physician-recruitment exception. The exception is designed to protect the payments that hospitals make to physicians to encourage them to relocate their medical practices into the hospital's geographic service area. There are four major modifications to this rule:

A. Reasonable Practice Restrictions are Permitted

Group practices may now impose practice restrictions upon the recruited physician as long as those restrictions do not unreasonably restrict the physician's ability to practice within the hospital's geographic service area. Reasonable restrictions include:

(1) Restrictions on moonlighting;
(2) Prohibitions on soliciting the group's patients and/or employees;
(3) Requiring the physician to treat Medicaid and indigent patients;
(4) Prohibiting the physician from using confidential or proprietary group-practice information;
(5) Requiring the physician to repay the losses of the practice that are absorbed by the group in excess of any hospital-recruitment payments; and
(6) Requiring the physician to pay a predetermined amount of reasonable damages if the physician leaves the group but remains in the community.

B. New Rule Adopted to Determine a Rural Hospital's Geographic Service Area

Under Phase II, the geographic area served by a rural hospital was determined in the same manner as all other hospitals. In response to concerns raised by several commenters, CMS revised the rule to include a special provision for rural hospitals. There are now three ways that a rural hospital can determine its geographic service area:

(1) It may include the lowest number of contiguous zip codes from which the hospital draws at least 90% of its inpatients;

(2) If the hospital draws fewer than 90% of its patients from all of the contiguous zip codes, then the geographic area served by the hospital

may include non-contiguous zip copes, beginning with the non-contiguous zip code in which the highest percentage of the hospital's in-patients reside, and continuing to add non-contiguous zip codes in decreasing order of in-patient percentage; and

(3) It may use the same methodologies applicable to all other hospitals.

C. Recruitment Rules for Rural Areas and for Health Professional Shortage Areas are Relaxed

Practice groups in rural areas and in health professional shortage areas that recruit a physician to replace a retired, deceased, or relocated physician may allocate the costs attributed to the recruited physician using either of the following two methods:

(1) The actual additional incremental costs; or

(2) The lower of a per-capita allocation or 20% of the group's aggregate costs.

Also, rural hospitals may now recruit physicians into an area outside of their geographic service area if the Secretary of Health and Human Services issues an advisory opinion that the area has a demonstrated need for the physician. In addition, the recruitment exception now applies to all rural health clinics in the same way that it applies to hospitals and federally-qualified health centers.

D. Some Physicians are Exempt from the Relocation Requirement

Recruited physicians are exempt from the relocation requirement if they were employed full-time for at least the last two years by a federal or state prison system, the Department of Defense, the Department of Veterans Affairs, or an Indian health-service facility <u>and</u> they did not maintain a separate private practice during that time. Also, the Secretary of Health and Human Services may grant a physician an individual exemption in an advisory opinion if the physician has not established a medical practice.

III. EXCEPTION FOR RETENTION PAYMENTS IN UNDERSERVED AREAS SUBSTANTIALLY AMENDED

CMS clarified that retention payments can take into account experience, training, and a physician's length of service. Both the direct and indirect costs of replacement can be included, provided that they are actual costs. In addition, CMS received multiple comments requesting an expansion of the exception for retention payments in underserved areas. It adopted the following changes to the exception:

A. Retention Payments are now Permitted in the Absence of a *Bona Fide*, Written Recruitment Offer

If a physician does not have a *bona fide*, written recruitment offer, a hospital, a rural health clinic, or a federally-qualified health center may now offer assistance to the physician if the physician certifies in writing that the physician has a *bona fide* opportunity for future employment that would require the physician to relocate at least 25 miles outside of the entity's geographic service area. But an entity can only use this exception for a physician once every five years.

In these types of certification situations, the retention payment cannot exceed the lower of:

(a) An amount equal to 25% of the physician's annual income; or

(b) The reasonable costs the entity would otherwise spend to recruit a new physician.

B. The Designated Health-Service Entity no Longer Needs to be in a Health Professional Shortage Area

A designated health-service entity no longer needs to be in a health professional shortage area to qualify for the retention-payments exception. CMS now permits retention payments that otherwise satisfy the exception to be made in two additional circumstances. First, the payments can be made when the physician's current medical practice is located in a rural area, a health professional shortage area, or an area that has a demonstrated need as determined by the Secretary of Health and Human Services in an advisory opinion. Second, the payments can be made when at least 75% of the physician's patients reside either in a medically-underserved area or are members of a medically-underserved population.

IV. FAIR MARKET VALUE SAFE-HARBOR PROVISION ELIMINATED

In Phase II, CMS created a fair market value safe-harbor provision consisting of two methods for calculating hourly rates that would be deemed fair market value for the purposes of the physician self-referral statute. Several commenters criticized these methodologies and asked for more flexible ways to determine fair market value. Rather than amend the safe-harbor provision, CMS decided to eliminate it altogether. Nonetheless, fair market value remains relevant to many regulatory exceptions, and CMS will therefore continue to scrutinize financial arrangements for it.

Any commercially-reasonable method may be used to determine fair market value that is appropriate to the type of transaction at hand, provided that it otherwise satisfies the definitions of fair market value in the statute and in the regulations. Physicians should nonetheless continue to reference multiple objective, independently-published salary surveys. CMS will determine whether an arrangement is for fair market value based upon the totality of the circumstances. And even though a good-

faith reliance on an independent valuation does not automatically establish the accuracy of the determination of the fair market value of the arrangement, CMS does consider it relevant on the question of intent. In addition, CMS will look at the nature of the transaction, the location where it took place, and other information indicative of fair market value.

V. FAIR-MARKET-VALUE EXCEPTION EXPANDED

This final rulemaking amends the fair-market-value exception. Arrangements involving fair-market-value compensation from a designated health-service entity to a physician or from a physician to an entity now fall within the exception. But now that these arrangements fall within the exception, parties to these arrangements cannot use the payments-by-a-physician exception when physicians make payments to a hospital for equipment leases of less than one year. In addition, the fair-market-value exception does not apply to rental agreements for office space. Such arrangements must be structured to satisfy the office-space rental exception.

VI. OWNERSHIP INTERESTS

A. Security Interests in Equipment Sold to a Hospital are not Ownership Interests

Previously, a physician who retained a security interest in equipment sold to a hospital would have created an impermissible financial relationship with the hospital. Under Phase III, security interests are permitted. CMS now treats them as compensation arrangements between the hospital and the physician. They are no longer considered ownership interests in the hospital. But CMS continues to treat loans or bonds secured by, or otherwise linked to, the revenue of a department or of another discrete hospital operation as ownership interests in hospitals.

B. Purchasing an Ownership Interest in a Hospital with Retirement Funds is an Ownership Interest

Some physicians purchase an ownership interest in designated health-service entities through their retirement funds. In this final rulemaking, CMS explained that these interests are inconsistent with congressional intent. Nonetheless, such arrangements may be part of an indirect-compensation agreement between a referring physician-owner and a designated health-service entity, as long as they fall within an exception for indirect-compensation arrangements. CMS also noted that these arrangements should be carefully reviewed because they could constitute violations of the anti-kickback statute.

VII. INSTALLMENT PAYMENTS FOR ISOLATED TRANSACTIONS ARE PERMITTED

Under Phase III, installment payments for isolated transactions are now permitted, but there must be a mechanism in place to ensure payment. The new regulations provide several options to fulfill this requirement. First, a third party can guarantee payments or the payments can be immediately negotiable. Second, the payments can be secured by a negotiable promissory note. Finally, payments can be secured by any method similar to the first two that ensures payment in the event of default.

Take note, however, that there is a six-month, post-closing window during which the parties can make adjustments to the transaction and have the adjustment treated as part of the original transaction. After that window expires, any adjustments will be treated as a separate, additional transaction that would need to satisfy another exception. And, importantly, the same parties cannot take shelter under the isolated-transactions exception if they engage in another transaction within one year of the original transaction.

VIII. EXCESS NON-MONETARY COMPENSATION CAN BE RETURNED

Under Phase I, CMS exempted non-monetary compensation given to physicians if the value given was $300 or less (adjusted for inflation). Phase III makes two changes to this exception. First, if a designated health-service entity accidentally pays excess non-monetary compensation to a physician, they can now remain in compliance with the exception if the physician repays the excess amount within the same calendar year (or within 180 days, whichever is earlier). But this new rule does not apply if the excess value surpasses 50% of the annual limit (i.e., $450, adjusted for inflation). In addition, the entity cannot use this rule for the same physician more than once every three years. Second, designated health-services entities are now permitted to provide one medical staff-appreciation function (e.g., a holiday party), and the cost of this event does not count toward the $300 cap.

IX. PRODUCTIVITY BONUSES PERMITTED

Several commenters expressed confusion over CMS's group-practice definition and whether it precluded productivity bonuses. CMS changed the definition to clarify that physicians can be paid productivity bonuses based upon services they have personally performed and upon "incident to" services (even if those services are otherwise designated health-service referrals); however, their overall profit shares can no longer directly relate to "incident to" services. For example, a physician can be paid a productivity bonus based directly upon physical-therapy services provided incident to the physician's services. But the physician cannot be paid a productivity bonus for any other designated health-service referrals, such as referrals for diagnostic tests.

X. SHARED-SERVICES ARRANGEMENTS MUST BE CAREFULLY STRUCTURED AND OPERATED TO QUALIFY FOR THE IN-OFFICE ANCILLARY-SERVICES EXCEPTION

CMS received comments seeking guidance on whether physicians who provide designated health services to their patients in a shared space could qualify for the in-office ancillary-services exception. It stated that physicians who share a designated health-service facility must control the facility and the staffing at the time the designated health service is provided to the patient. To satisfy the exception, an arrangement must meet all of the requirements of the rule in practice, not just on paper. As a practical matter, this requires a block-lease arrangement for the space and equipment used to provide the service. In addition, CMS noted that common, per-use fee arrangements are unlikely to satisfy the supervision requirement of the in-office ancillary-services exception. They may also implicate the anti-kickback provision.

XI. PERSONAL-SERVICE ARRANGEMENTS CAN NOW BE HELD OVER FOR SIX MONTHS

CMS modified the personal-services arrangements exception to permit services to continue beyond the term of the contract for up to six months, if the arrangements otherwise meet the other requirements for the exception. It noted that this holdover provision is similar to one CMS created for office space and equipment leases in its previous rulemaking.

XII. ACADEMIC MEDICAL CENTERS EXCEPTION CLARIFIED

CMS revised the exception for academic medical centers to clarify that the total compensation to a faculty physician from each component of the academic medical center must be set in advance. As always, the compensation cannot take into account the volume or value of the physician's referrals or of any other business generated by the physician within the academic medical center.

In addition, CMS clarified that the Stark regulations do not preclude academic medical centers from compensating faculty members for providing indigents with medical care or for providing community service. There are, however, limitations on how the compensation may be structured. The funds cannot come from research money, the total amount of compensation must be fair market value, and the physician must also perform the requisite clinical teaching or academic services required by the regulations.

CMS also clarified confusion among commenters who were unclear how academic medical centers should determine whether a majority of the physicians on the medical staff of a hospital affiliated with an academic medical center consists of faculty members. It explained that the affiliated hospital must include or exclude everyone who holds the same class of privileges at the affiliated hospital. For example, an affiliated hospital may exclude courtesy staff when making the calculation, but it must then exclude all other staff members who hold the same class of privileges as the courtesy staff.

XIII. "PHYSICIAN IN THE GROUP PRACTICE" & INDEPENDENT CONTRACTORS

CMS amended the definition of "physician in the group practice" to clarify when independent-contractor physicians are considered to be group physicians. The group practice and the independent contractor must satisfy two requirements for the independent contractor to be treated as a group physician. First, the group and the independent contractor must have a direct contractual relationship. Indirect contractual relationships, such as when a group contracts with a staffing agency to supply an independent contractor, are permitted, but the independent contractor would not be deemed a physician in the group practice.

Second, the independent contractor must provide services while in the group's facilities; otherwise, CMS fears that there would no true nexus to the group's medical practice. For example, if an independent contractor remotely provided the group with medical services, such as an online patient evaluation, the physician would not be considered a physician within the group practice, even if the physician had a direct contractual relationship with the group.

XIV. ALTERNATIVE DISTANCE TEST ADOPTED FOR THE INTRA-FAMILY RURAL-REFERRALS EXCEPTION

Under Phase II, CMS exempted certain referrals from a referring physician to an immediate family member or to a designated health-service entity with which either the physician or immediate family member has a financial relationship. The exception required that the patient being referred reside in a rural area and that no other person or entity is available to furnish the designated health service in a timely manner, either at the patient's residence or within 25 miles of the residence.

Under Phase III, CMS has adopted an additional, alternative test: the physician can now make this type of referral if the designated health service cannot be provided within 45 minutes transportation time from the patient's home. Physicians who choose to use this test should keep comprehensive documentation to demonstrate compliance. The records should include mileage, weather conditions, road conditions, and the patient's mode of transportation. There are free resources available to help gather the needed data. For example, www.mapquest.com generates estimated driving distances and www.weather.com provides up-to-the-minute weather reports for each zip code and highway traffic times for certain areas.

Under the alternative test, it is possible that a physician could make an intra-family referral within the 25-mile zone established in Phase II. CMS stated that this is acceptable. Extra care should be taken to document the reasons why the 45-minute rule applies. CMS may closely scrutinize the referral when the 45-minute rule is used within a 25-mile zone.

In addition, CMS clarified that physicians can treat any designated health-services entity within 25 miles or 45 minutes of the patient's residence that does not participate in Medicare as if they do not exist. For example, if there is only a single hospital that provides the designated health service within 45 minutes of the patient's

residence, but it does not participate in the Medicare program, then the physician could make the intra-family referral under this exception.

XV. PROFESSIONAL-COURTESY EXCEPTION'S NOTIFICATION REQUIREMENT ELIMINATED

CMS no longer requires designated health-service entities to notify an insurer when the courtesy involves the whole or partial reduction of any co-insurance obligation under the professional-courtesy exception. Nonetheless, it is best to continue to make such notifications because individual insurers may require them.

In addition, CMS clarified that this exception only applies to hospitals and other designated health-service entities with formal medical staffs. Suppliers, such as laboratories and durable medical-equipment companies do not qualify for this exception.

XVI. COMPLIANCE-TRAINING EXCEPTION NOW INCLUDES CME CREDIT

In response to several commenters, CMS has amended the compliance-training exception to include compliance-training programs that qualify for continuing medical-education credit, as long as the compliance training is the program's primary purpose.

XVII. OPHTHALMIC SCANS ARE "COVERED ANCILLARY SERVICES"

CMS clarified the rules pertaining to ophthalmic A-scans and B-scans made in preparation for eye surgery. It noted that under the current regulatory framework, these scans do not fall within the definition of "radiology and certain other imaging services" because they do not take place during the eye surgery or immediately after it. Nonetheless, CMS explained that these scans fall within the definition of "covered ancillary services" because they are integral to the procedure and they are performed on the same day.

XVIII. THERE ARE FEW CIRCUMSTANCES IN WHICH A PHYSICIAN COULD PERSONALLY FURNISH DURABLE MEDICAL EQUIPMENT

In Phase II, CMS excluded from the definition of "referral" any services that are personally performed by the referring physician. In this final rulemaking, it stated that there are few, if any, circumstances in which a referring physician could personally furnish durable medical equipment because the physician would need to be enrolled in Medicare as a supplier and then perform all of a supplier's duties. Although it did not foreclose the possibility, CMS believes that it is highly unlikely that a referring physician would ever meet all of the requirements when dispensing the equipment.

We recommend that any physician who claims to be a supplier and who also claims the personal-services exception maintain thorough documentation to establish

compliance with both requirements. For example, the physician should document how the physician:

(1) personally fit the item for the beneficiary;
(2) provided all necessary information and instructions concerning the use of the equipment;
(3) advised the beneficiary that he may either rent or purchase inexpensive or routinely-purchased equipment;
(4) explained the purchase option for capped-rental equipment;
(5) explained all warranties;
(6) delivered the equipment to the beneficiary at home;
(7) explained to the beneficiary at the time of delivery how to contact the physician in the capacity as the equipment supplier by telephone; and
(8) performed all other activities required of suppliers.

CONCLUSION

Phase III is meant to be the final phase in the Stark rulemaking process. All three phases are meant to be read together. Phase III grants physicians and designated health-service entities greater flexibility and eliminates several onerous restrictions from the earlier phases. There are still many unanswered questions, and the rules are still quite complex and changing. The “stand in the shoes” rule was suspended for a year as it applies to Academic Medical Centers. Although it is of little solace, Congressman Pete Stark who is responsible for the original legislation that bears his name, expressed regrets for having ever done it.

Butzel Long is committed to assisting healthcare professionals and organizations adapt their practices to these new regulations. For more information on how Butzel Long can serve you or your organization, contact the authors of this bulletin or any other member of our Healthcare Practice Group or White Collar Defense Practice Group.

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