

Highlights of the New Phase II Regulations to the Stark Law

Executive Summary

The new Phase II regulations, issued on March 26, 2004 and effective as of July 26, 2004, are lengthy and complex and can best be described as a collection of “technical corrections,” changes, supplements, and explanations with regard to the Phase I regulations and the gaps left in the regulatory scheme by the Phase I regulations. From a practical perspective, the more significant changes include:

- Incentive compensation can be paid to physicians for personally performed services regardless of practice setting and group structure, but not for “incident to” services.
- Incentive compensation is “set in advance” even if it varies based on a formula so long as that formula is agreed upon in advance.
- The “same building” rules for in-office ancillary services have been liberalized.
- The rules for mid-term lease and rental changes/terminations have been liberalized.
- The physician recruitment regulations have been liberalized, including specific authorization for recruitment payments to existing medical groups under specified conditions.

Despite more than 12 years of Stark legislation and regulations, the end is still not in sight. The Phase II regulations were expected to address how the Stark law should be extended to the Medicaid program. In the interest of “expediting publication” of the Phase II regulations, CMS has reserved the Medicaid issue for a future rulemaking. Similarly, although the Stark law requires entities that provide designated health services (“DHS”) to report information concerning their financial relationships with physicians, the new Phase II regulations specify that the information need not be reported on a regular or periodic basis, requiring instead that providers make the information available upon CMS’s request. This development leaves open, however, the possibility of still further rulemaking in the future.

Changes to Basic Stark Concepts

The basic concepts of financial relationship, referral, and designated health services (“DHS”) all receive additional detailed explanation and, in certain cases, modifications.

- *Financial Relationship:* The Phase II regulations clarify the meaning of direct and indirect ownership and affirm that common ownership of an entity does not create an ownership interest by one common investor in another; clarify the relationship between the “indirect compensation arrangements” definition and the “volume or value” and “other business generated” standards; and clarify that a referring physician may be treated as “standing in the shoes” of his wholly-owned professional corporation but not his practice group.
- *Referral:* The Phase II regulations clarify that personally performed work is not considered a “referral.” Thus, a productivity bonus based on personally performed work would not be based on the volume or value of “referrals.” CMS specifically refused to exclude services that are performed “incident to” a physician’s personally performed services or that are performed by a physician’s employees.

- *Designated Health Services:* CMS refused all requests either to exclude certain services from any of the 11 broad DHS categories or to create exceptions for financial arrangements involving specific DHS. The DHS category of “radiation therapy services and supplies” continues to exclude nuclear medicine. CMS finally concedes that lithotripsy is not DHS as an “inpatient or outpatient service” for Stark purposes “in light of [its] unique legislative history.”

Clarifications Regarding Physician Compensation

Under the Stark law, group practices are permitted to compensate physicians in the group, regardless of status as owner, employee, or independent contractor, for “incident to” services and indirectly for other DHS referrals.

The Phase II regulations clarify that independent contractor and academic medical center physicians, like their group practice and employed counterparts, can be paid on a percentage of revenues or collections for personally performed services and receive a productivity bonus on any personally performed services. Moreover, the Phase II regulations permit group practice, employed, and academic medical center physicians, like independent contractors, to participate in a physician incentive plan related to managed health plan enrollees.

- *“Set In Advance” Standard:* The Phase I regulations specified that percentage compensation arrangements did not constitute compensation that is “set in advance” if the percentage compensation were based on fluctuating or indeterminate measures or the arrangement resulted in the seller receiving different payment amounts for the same service from the same purchaser. The Phase II regulations retract this, stating that the position was “overly restrictive.” The Phase II regulations define the “set in advance” position to include variable compensation if the formula for calculating percentage compensation is established with specificity prospectively, is objectively verifiable, and does not change over the course of the agreement between the parties based on the volume or value of referrals or other business generated by the referring physician. Compensation is “set in advance” if it is set in an agreement before the services for which payment is being made are rendered.
- *“Other Business Generated” Standard:* For those exceptions that take into account “other business generated between the parties” (e.g., the exceptions for personal service arrangements, fair market value, and academic medical centers), the payments also may not take into account any other business, including non-federal health care business, generated by the referring physician. The Phase II regulations provide that the “other business generated” standard excludes personally performed professional services.

Phase II Changes to Phase I Requirements for Exceptions That Apply to Both Ownership and Compensation Interests

The Phase II regulations explain and, in certain cases, modify the interpretation of the statutory exceptions set forth in the Phase I regulations for physician services, services provided under prepaid health plans, and in-office ancillary services.

- *In-Office Ancillary Services:* The Phase II regulations substantially revise the “same building” requirement under the in-office ancillary services exception to provide greater flexibility and a clearer rule. The requirement in the statute provides that the building be one in which the referring physician (or a member of his group practice) furnishes physician services unrelated to the furnishing of DHS. The Phase II regulations develop three new alternative tests to meet this requirement that completely replace an earlier test set forth in the Phase I regulations. Only one of the three tests needs to be satisfied to meet the “same building” requirement. All three tests are available to solo practitioners as well as group practices.

New Phase II Requirements for Exceptions That Apply Only to Ownership Interests

The Phase II regulations set forth new requirements for the statutory exceptions for physician ownership interests in publicly traded securities, in “whole hospitals” in which the physician-owner is authorized to perform services, in rural providers, and in Puerto Rican hospitals.

- *Publicly Traded Securities:* The ownership interest must be in securities that are generally available to the public at the time of the DHS referral. CMS will not consider stock options received as compensation to be ownership or investment interests until the time that they are exercised.
- *“Whole Hospitals”:* “Specialty hospitals” as defined in Section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 are precluded from qualifying for the exception.

New Phase II Requirements for Exceptions That Apply Only to Compensation Interests

The Phase II regulations set forth new requirements for the statutory exceptions for the certain physician compensation interests, including:

- *Office Space/Equipment Rental:* Leases or rental agreements may be terminated with or without cause as long as no further agreement is entered into within the first year of the original lease term and any new lease fits in an exception. Month-to-month holdover leases are allowed for up to 6 months if they continue on the same terms and conditions as the original lease. The Phase II regulations revise the “exclusive use” provision to allow subleases in many cases. The “exclusive use” test will be considered met as long as the lessee (or sublessee) does not share the rented space or equipment with the lessor during the time it is rented or used by the lessee (or sublessee). A subleasing arrangement may create a separate indirect compensation arrangement between the lessor and the sublessee that would need to be evaluated under the indirect compensation rules. “Per-click” rental payments are permitted for DHS referred by the referring physician as long as the payments are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician.
- *Personal Service Arrangements:* The regulations make clear that independent contractor physicians can receive compensation that takes into account the volume or value of personally performed services and can be compensated using a percentage-based compensation methodology as long as the methodology is set in advance. Other modifications include clarifying the treatment of termination provisions, clarifying that payments from down stream subcontractors are included in the physician incentive plan exception, and easing the incorporation by reference rule.
- *Remuneration Unrelated to the Provision of DHS:* In light of the statutory history, the Phase II regulations interpret the exception to be narrow and available only if remuneration is wholly unrelated to the provision of DHS.
- *Physician Recruitment:* The Phase II regulations look to the relocation of the recruited physician’s medical practice, rather than the physician’s residence.
 - A physician will be deemed to have relocated to the hospital’s geographic area (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75% of its inpatients) if: (i) the physician has relocated the site of his or her practice a minimum of 25 miles; or (ii) at least 75% of the physician’s revenues from services provided by the physician to patients (including services to hospital inpatients) are derived from services provided to new patients.
 - Residents and physicians who have been in medical practice less than one year will not be considered to have an established practice and will therefore be eligible under the physician recruitment exception regardless of whether the physician actually moves his practice location.

- CMS has created a regulatory exception for federally qualified health centers (FQHCs) that make recruitment payments to physicians on the same basis as hospitals.
- Recruitment payments made through existing medical groups (rather than directly to the recruited physician) in connection with the recruitment of a new physician are permitted under certain conditions.
- *Isolated Transactions:* The Phase II regulations permit installment payments, provided the total aggregate payment is: (i) set before the first payment is made and (ii) does not take into account, directly or indirectly, referrals or other business generated by the referring physician. The outstanding balance must be guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment even in the event of default by the purchaser or obligated party. Post-closing adjustments that are commercially reasonable and not dependent on referrals or other business generated by the referring physician will be permitted if made within 6 months of the date of a purchase or sale transaction.

Phase II Changes to Regulatory Exceptions Established in Phase I

The Phase II regulations explain and, in certain cases, modify the regulatory exceptions set forth in the Phase I regulations for academic medical centers, implants in an ASC, fair market value, non-monetary compensation up to \$300 and medical staff incidental benefits, risk-sharing arrangements, compliance training, ESRD and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility, and preventive screening tests, immunizations, and vaccines.

- *Academic Medical Centers:* The Phase II regulations substantially revise the rule to make it easier to qualify as an academic medical center or a component of an academic medical center (e.g., by eliminating the requirements that an academic medical center include an accredited medical school and that faculty practice plans be organized as tax-exempt organizations) and clarify some of the exception's terminology. The Phase II regulations also add a "safe harbor" provision that deems any referring physician who spends at least 20% of his professional time or, in the alternative, 8 hours per week providing academic services or clinical teaching services (or a combination of academic services and clinical teaching services) as fulfilling the "substantial academic or substantial clinical teaching services" requirement.
- *Non-Monetary Compensation Up to \$300/Medical Staff Incidental Benefits:* The Phase II regulations expand the exception so that all institutional entities that have medical staffs, such as long-term care facilities, FQHCs, and other health care clinics, are permitted to provide incidental benefits to those staffs on the same terms and conditions as apply to hospitals under the exception. The exception applies only to bona fide medical staffs.
 - The \$300 aggregate limit for non-monetary compensation and the \$25 per-occurrence limit will be adjusted annually for inflation effective January 1 of each year using the increase in the Consumer Price Index-Urban All Items (CPI-U) for the 12-month period that ends the previous September 30.
 - The "on-campus" requirement in the exception is clarified to limit the exception for medical staff incidental benefits to benefits incidental to services being provided by the medical staff at the hospital, such as parking, cafeteria meals, and the like, that are customarily provided by hospitals to their medical staff. The exception is not intended to cover the provision of tangential, off-site benefits, such as restaurant dinners or theater tickets, which must comply with the exception for non-monetary compensation up to \$300. The exception does cover benefits in the form of computer and internet access that "facilitates the maintenance of up-to-date medical records and the availability of cutting edge medical information."
 - The simple listing or identification of the medical staff on a hospital's website is an incidental benefit that is excepted. However, advertising or promoting a physician's private practice on a hospital website is not covered.

- **Compliance Training:** The Phase II regulations modify the exception to include compliance training provided by any entity that furnishes DHS to a physician or a physician's office staff.

New Phase II Regulatory Exceptions

The Phase II regulations establish several additional regulatory exceptions for certain anti-kickback safe harbors, professional courtesy, charitable donations by a physician, certain arrangements involving temporary non-compliance, retention payments in underserved areas, and community-wide health information systems.

- *Anti-Kickback "Safe Harbors":* As a general matter, CMS does not believe it is feasible to except financial relationships solely because they fit in an anti-kickback "safe harbor." Nevertheless, the Phase II regulations do create two new exceptions for the anti-kickback "safe harbors" for referral services and obstetrical malpractice insurance subsidies.
- *Professional Courtesy:* The Phase II regulations create a new exception for certain services provided to a physician or his immediate family members that defines "professional courtesy" as the provision of free or discounted health care items or services to a physician or his immediate family members or office staff.
- *Physicians' Charitable Contributions:* The Phase II regulations create a new exception for bona fide charitable donations made by a physician (or immediate family member). To qualify, donations must be made to an organization exempt from taxation under the Internal Revenue Code (or to an exempt supporting organization, such as a hospital foundation). Broad-based solicitations not targeted specifically at physicians, such as sales of charity ball tickets or general fund-raising campaigns, will qualify under this exception.
- *Certain Arrangements Involving Temporary Non-Compliance:* The Phase II regulations create a new exception for certain arrangements that have fully satisfied another exception for at least 180 consecutive days, but have fallen out of compliance with the exception for reasons beyond the control of the DHS entity (e.g., conversion of publicly-traded companies to private ownership; loss of rural or HPSA designations; or delays in obtaining fully-signed copies of renewal agreements).
- *Community-Wide Information Systems:* The Phase II regulations create a new exception for the provision of information technology items and services (including both hardware and software) by a DHS entity to a physician to participate in a community-wide health information system designed to enhance the overall health of the community, so long as certain conditions are met. The health information system must be community-wide; that is, available to all providers, practitioners, and residents of the community who desire to participate. The health care system must be one that allows community providers and practitioners to access and share electronic health care records. In addition to health care records, the system may permit access to, and sharing of, complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners. The DHS entity may only provide information technology items and services that are necessary to enable the physician to participate in the health information system. In all cases, the information technology items or services furnished under the exception must principally be used by the physician as part of the community-wide health information system. The items and services may not be provided in any manner that takes into account the volume or value of referrals or other business generated by the physicians. Finally, the arrangement must not violate the anti-kickback statute and all claims and billing must comply with applicable federal and state laws and regulations.

Contact Information

If you have any questions or would like to learn more about the new Stark Phase II regulations, please contact your usual legal advisor at Ropes & Gray.