On March 26, 2004, the Centers for Medicare & Medicaid Services ("CMS") published its long-awaited second phase of regulations ("Phase II"), which interpret the federal physician self-referral law known as the Stark Law.\(^1\) Published as an interim final rule, Phase II adopts, amends, and/or clarifies numerous exceptions to the Stark Law, including the physician recruitment exception. This article addresses how hospitals, physicians, and group practices can structure physician recruitment arrangements in compliance with Phase II.

I. **Background Information**

The Stark Law and its implementing regulations have a long and tortured history. Congress enacted the original Stark Law ("Stark I"), applicable only to clinical laboratory services, on December 19, 1989.\(^2\) On August 10, 1993, Congress made the Stark Law applicable to ten additional designated health services ("Stark II").\(^3\) Congress intended these statutory provisions to prevent "self-referrals," or referrals by physicians to those with whom they have too close a relationship.

The Health Care Financing Administration ("HCFA") published proposed regulations interpreting Stark I on March 11, 1992, and published final regulations

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interpreting Stark I on August 14, 1995 (the “1995 Rule”).\(^4\) HCFA published proposed regulations interpreting Stark II on January 9, 1998 (the “1998 Proposed Rule”),\(^5\) and published Phase I of the final regulations interpreting Stark II (“Phase I”) on January 4, 2001.\(^6\) The Centers for Medicare and Medicaid Services’ (“CMS”)\(^7\) March 26, 2004, publication contains Phase II of the final regulations.\(^8\)

Unless an exception applies, the Stark Law generally prohibits a physician (or a physician with an immediate family member) who has a financial relationship with an entity from referring a patient to the entity for the furnishing of designated health services (“DHS”) payable in whole or in part by the Medicare Program.\(^9\) The Stark Law also prohibits the referred-to entity from billing the Medicare Program for a prohibited referral.\(^10\) Financial relationships subject to the Stark Law referral and billing prohibitions include direct and indirect ownership and investment interests as well as compensation arrangements.\(^11\) DHS subject to the Stark Law referral and billing prohibitions include clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients,

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\(^7\) On July 1, 2001, HCFA became CMS. See Restructuring of HCFA into CMS, at http://www.cms.hhs.gov/about/reorg.asp.
\(^10\) Id. § 1395nn(a)(1)(B).
\(^11\) Id. § 1395nn(a)(2) (statutory definition of financial relationship); id. § 1395nn(h)(1) (statutory definition of compensation arrangement); 42 C.F.R. § 411.354 (2004) (regulatory definition of financial relationship).
equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health
services; outpatient prescription drugs; and inpatient and outpatient hospital services.\textsuperscript{12}

Sanctions for Stark Law violations include denial of payment, refunds of amounts collected in violation of the Stark Law, civil money penalties of $15,000 for each improper claim, civil money penalties of three times the amount improperly claimed, civil money penalties of $100,000 for each Stark Law circumvention scheme, and/or exclusion from the Medicare Program.\textsuperscript{13}

II. \textit{The Physician Recruitment Exception}

When Congress enacted Stark I in 1989, the law included a provision that protected certain physician recruitment arrangements.\textsuperscript{14} Specifically, Stark I established that a hospital may provide remuneration to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital if: (1) the physician is not required to refer patients to the hospital; (2) the amount of the remuneration is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and (3) the arrangement meets such other requirements as the Secretary of the federal Department of Health and Human Services (the “Secretary”) may impose by regulation as needed to protect against program or patient abuse.\textsuperscript{15}

\textsuperscript{12} 42 U.S.C. § 1395nn(h)(6) (statutory definition of designated health services); 42 C.F.R. § 411.351 (2004) (regulatory definition of designated health services). The most current list of CPT codes that are included within each type of designated health service is set forth in Phase II at 69 Fed. Reg. at 16143-46.

\textsuperscript{13} 42 U.S.C. § 1395nn(g)(1)-(4).


\textsuperscript{15} Id.
HCFA’s 1995 Rule incorporated the statutory exception for physician recruitment into regulations at 42 C.F.R. § 411.357(e). Using the authority delegated to it by Congress to impose additional requirements needed to protect against program or patient abuse, the 1995 Rule established two additional requirements for physician recruitment arrangements: (1) the arrangement and its terms must be in writing and signed by both parties; and (2) the physician must not be precluded from establishing staff privileges at another hospital or referring to another entity.\(^{16}\)

HCFA’s 1998 Proposed Rule would have retained the regulatory physician recruitment exception established in 1995 with minor editorial changes.\(^{17}\) In the preamble to the 1998 Proposed Rule, HCFA interpreted the exception to require the recruited physician to reside outside of the hospital’s geographic area and to actually relocate to the hospital’s geographic area.\(^ {18}\) HCFA specifically solicited comments addressing how it should define a hospital’s “geographic area.”\(^ {19}\) HCFA further suggested that recruitment payments made to residents who are living in the hospital’s geographic area as well as recruitment payments to group practices that intend to employ

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\(^{16}\) 42 C.F.R. § 411.357(e) (1996) (excepting “Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met: (1) The arrangement and its terms are in writing and signed by both parties. (2) The arrangement is not conditioned on the physician's referral of patients to the hospital. (3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital. (4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.”).

\(^{17}\) 63 Fed. Reg. at 1669 (noting that “This proposed rule would retain § 411.357(e), with a minor editorial change.”).

\(^ {18}\) 63 Fed. Reg. at 1702 (stating that “We believe that the terms of the statute dictate that this exception applies just to those situations in which a physician resides outside the geographic area and must actually relocate in order to join the hospital’s staff.”).

\(^ {19}\) 63 Fed. Reg. at 1702 (explaining that “We considered a number of ways to define the concept of a hospital’s ‘geographic area,’ including mileage requirements or the likelihood that the physician would be able to bring patients along when he or she relocates. Because we believe that what constitutes a hospital’s ‘geographic area’ may depend on a variety of circumstances, we are specifically soliciting comments on how to define this term.”).
a physician might be excepted under a new “fair market value” compensation exception also included in the 1998 Proposed Rule.

As discussed in more detail below, hospitals, physicians, and group practices should become familiar with Phase II because it modifies the requirements and interpretation of the physician recruitment exception in several ways.

a. Basic Requirements

Phase II continues to permit a hospital to provide remuneration directly to a physician in order to recruit the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital’s medical staff if the arrangement satisfies certain basic requirements. Before examining these basic requirements, it is worth noting that Phase II uses the phrase “relocate his or her medical practice” while the 1995 Rule used the phrase “relocate to the geographic area.” Phase II thus looks to the relocation of the recruited physician’s medical practice, not the recruited physician’s residence (“We are persuaded, however, that the recruited physician's practice location, not his or her residence, should be the relevant consideration.”).

Like all of the other exceptions relating to compensation arrangements, Phase II continues to require physician recruitment arrangements to satisfy several basic requirements. First, the recruitment arrangement must be set out in writing and signed by both the hospital and the recruited physician. Second, the arrangement must not be

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conditioned on the physician’s referral of patients to the hospital. Third, the hospital must not determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties. Finally, the physician must be allowed to establish staff privileges at any other hospital and to refer business to any other entity or entities (although a referrals may be restricted under a separate employment or services contract that complies with 42 C.F.R. § 411.354(d)(4)). The preamble emphasizes that recruited physicians must be allowed to establish staff privileges at other hospitals and to refer patients to other facilities even if such other facilities are competitors of the hospital. CMS clarifies, however, that “reasonable credentialing restrictions on physicians becoming competitors of a hospital” do not violate this requirement:

We have modified the proposed language requiring recruited physicians to establish staff privileges at other hospitals and to refer to other entities to make clear our original intent that recruitment payments not be used to lock physicians into using the recruiting hospital, except insofar as there may be a separate, excepted employment or contractual arrangement under which required referrals may be permitted in accordance with Sec. 411.354(d)(4). The revised language makes clear that recruited physicians

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24 Id. § 411.357(e)(ii).
25 Id. § 411.357(e)(iii).
26 42 C.F.R. § 411.354(d)(4) provides that a “physician’s compensation from a bona fide employer or under a managed care or other contract may be conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement -- (i) Is set in advance for the term of the agreement; (ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals); (iii) Otherwise complies with an applicable exception under Sec. 411.355 or Sec. 411.357; (iv) Complies with the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties; (B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a reference for a different provider, practitioner, or supplier; the patient’s insurer determines the provider, practitioner, or supplier; or the referral is not in the patient’s best medical interests in the physician's judgment; and (v) The required referrals relate solely to the physician's services covered by the scope of the employment or the contract and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation relationship. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or contract.”
must be allowed to establish staff privileges at other hospitals and, except as noted in the preceding sentence, to refer to other entities (even if the other hospital or entity is a competitor). For purposes of section 1877 of the Act, reasonable credentialing restrictions on physicians becoming competitors of a hospital would not violate this condition.27

b. “Geographic Area” and “Relocation” Requirements

Phase II clarifies that the “geographic area served by the hospital” is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients.28 Phase II further clarifies that a physician will be considered to have relocated his or her medical practice if the physician moves his or her medical practice at least 25 miles or if the physician establishes a practice with a substantial base of new patients (i.e., the physician’s new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding three years, measured on an annual (fiscal or calendar) basis).29 Phase II also clarifies that, for the initial “start up” year of the recruited physician’s practice, the 75 percent test is satisfied if there is a reasonable expectation that the recruited physician’s medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.30 In its preamble, CMS explains its belief that these regulatory provisions:

provide clear rules with sufficient flexibility to permit legitimate recruitment arrangements, while protecting against potentially abusive

29 Id. § 411.357(e)(2)(i) and (ii).
30 Id. § 411.357(e)(2)(ii).
arrangements (for example, cross-town recruitment of an established physician’s practice from a competitor hospital).31

c. Application to Residents and New Physicians

In its 1998 Proposed Rule, HCFA declined to extend the physician recruitment exception to residents participating in a program located in the hospital’s geographic area as well as new physicians located in the hospital’s geographic area, reasoning that “the terms of the statute dictate that this exception applies just to those situations in which a physician resides outside the geographic area and must actually relocate in order to join the hospital's staff.”32 However, both the 1998 Proposed Rule33 and Phase I34 left open the possibility that another exception, the fair market value compensation exception, might protect some recruitment incentives provided to residents and new physicians. In Phase II, CMS reverses its earlier position and provides that the physician recruitment exception (but not the fair market value exception)35 applies to recruitment arrangements involving residents and new physicians. Phase II specifically provides that residents and physicians who have been in practice for one year or less are not subject to the relocation requirement; however, the recruited resident or physician must establish his or her medical practice in the geographic area served by the hospital.36 The preamble to Phase II explains:

32 63 Fed. Reg. at 1702.
33 Id. (“If a hospital makes recruitment payments to physicians who are living in the hospital’s geographic area (for example, to retain residents) or to a group practice that intends to employ the physician and contracts with the hospital, these payments might be excepted under the new compensation-related exception that we have included in § 431.357(l).”).
34 66 Fed. Reg. at 919 (“Physician recruitment arrangements might be covered by the fair market value exception or the physician recruitment exception, depending on the specific facts involved.”).
35 69 Fed. Reg. at 16095 (“Recruitment payments to community or other local physicians who do not meet the relocation requirement will not fit in the fair market value exception in Sec. 411.357(1), which requires fair market value payments for services rendered.”); id. at 16096 (“Upon further consideration, we do not believe that recruitment incentives can fit in the fair market value exception in Sec. 411.357(l).”).
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 or not the physician actually moves his or her practice location. . . . 37

[and]

Comment: Many commenters objected to treating residents and new physicians as residing in the hospital's service area. These commenters argued that these physicians have not yet established a medical practice, so hospitals should be permitted to recruit them. Other commenters pointed out that for many hospitals with residency programs, the residents were the most likely physicians to stay in the community.

Response: We agree and have modified the regulation to provide that hospital residents, as well as physicians who have been in practice one year or less, will not be subject to the relocation requirement. In our view, these physicians do not have an established practice to relocate. However, the recruited physician must establish his or her medical practice in the geographic area served by the hospital to be eligible for recruitment payments under the exception.38

CMS believes that these provisions will benefit small rural hospitals, which often experience difficulty in recruiting physicians.39

d. Recruitment to Existing Group Practices

Although the Stark Law permits certain payments made by a hospital to a physician, the Stark Law does not address the permissibility of hospital payments to a group practice that contracts with the hospital and wishes to recruit the physician. Because many new and relocating physicians prefer to join existing group practices (rather than establish their own practices) in order to save costs and labor and to benefit from cross-coverage, professional expertise, shared-call, and peer review, Phase II is

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38 Id. at 16095.
39 Id. at 16122.
significant because it addresses such arrangements. With respect to recruitment to existing group practices, CMS explains in its preamble that:

We are concerned that a recruitment arrangement involving direct or indirect payments to an existing physician practice might be used improperly to pay for referrals from the existing physician practice, in essence creating an improper financial relationship between the hospital and the existing physician practice. However, we have concluded that some narrowly tailored accommodation for recruitment into existing groups would be appropriate under the recruitment exception and have sought to create criteria that would preclude abuse of the exception.40

Phase II thus establishes a relatively narrow exception that protects hospital payments to a physician either indirectly through payments made to another physician or physician practice, or directly to a physician who joins a physician practice, if the arrangement satisfies seven additional requirements.41 First, the written agreement must be signed by the third party to whom the payments are directly made.42 Second, except for actual costs incurred by the physician or physician practice in recruiting the new physician, the remuneration must be passed directly through to, or must remain with, the recruited physician.43

Third, in the case of an income guarantee made by the hospital to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or practice to the recruited physician must not exceed the actual additional incremental costs attributable to the recruited physician.44 This requirement may be one of the most significant restrictions for joint recruiting arrangements that include income guarantees. The physician group will be required to identify costs incurred as a result of adding the

40 Id. at 16096.
42 Id. § 411.347(e)(4)(i).
43 Id. § 411.357(e)(4)(ii).
44 Id. § 411.357(e)(4)(iii).
new physician to the group, and allocations of general overhead, or per-capita cost allocations, to the recruited physician may be questioned. The end result is that the group practice only will receive an income guarantee payment if the actual additional incremental costs attributed to the recruited physician exceed the recruited physician’s collections.

Fourth, the parties must maintain records of the actual costs and the passed-through amounts for a period of at least five years, and the parties must make these records available to the Secretary upon request.\footnote{Id. § 411.357(e)(4)(iv).} Fifth, the remuneration from the hospital must not be determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.\footnote{Id. § 411.357(e)(4)(v).}

Sixth, the physician or practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care.\footnote{Id. § 411.357(e)(4)(vi).} Because some group practices impose practice restrictions on their members, including covenants not to compete ("non-competes"), this requirement may be an obstacle for such groups. CMS’ main concern is that hospital payments should not benefit the physician group. Stated another way, the goal of the recruiting arrangement must be to add the recruited physician to the community, not to protect the group practice’s business and financial interests in the community.

\begin{footnotes}
\item[45] Id. § 411.357(e)(4)(iv).
\item[46] Id. § 411.357(e)(4)(v).
\item[47] Id. § 411.357(e)(4)(vi).
\end{footnotes}
Finally, the arrangement must not violate the federal anti-kickback statute or any other federal or state law or regulation that governs billing or claims submission.\textsuperscript{48} With respect to this last requirement, CMS explains:

if there is any intent unlawfully to reward or induce referrals from the physician practice whose recruitment the hospital chose to underwrite, the anti-kickback statute would be violated and the exception would not apply.\textsuperscript{49}

e. **Application to Payments by Federally Qualified Health Centers and other Non-Hospital Institutional Providers**

The physician recruitment exceptions set forth in the Stark Law and the 1995 Rule permit certain recruitment payments to physicians by hospitals, but do not appear to permit payments by other types of non-hospital institutional providers such as skilled nursing homes and home health agencies.\textsuperscript{50} Some individuals have requested CMS to expand the physician recruitment exception to protect payments by non-hospital institutional providers. In Phase II, CMS extends the physician recruitment exception to permit federally qualified health centers (“FQHCs”) to recruit physicians, but does not allow other non-hospital institutional providers to recruit physicians.\textsuperscript{51} The preamble to Phase II explains that:

The statutory exception is expressly limited to recruitment payments made by hospitals, and we are not persuaded that a wholesale extension to other DHS entities is warranted. Under our authority in section 1877(b)(4) of the Act to create additional exceptions, we are extending the exception to cover federally qualified health centers (FQHCs) that recruit physicians to join their medical staffs. We believe that FQHCs should be able to recruit physicians to join their medical staffs under the same terms and conditions applicable to hospitals. This extension is consistent with the statutory

\textsuperscript{48} Id. § 411.357(e)(4)(vii).
\textsuperscript{49} 69 Fed. Reg. at 16097.
\textsuperscript{50} 42 U.S.C. § 1395nn(e)(5) (“In the case of remuneration which is provided by a hospital to a physician . . . ” (emphasis added); 42 C.F.R. § 411.357(e) (1996) (“Remuneration provided by a hospital to recruit a physician . . . ”) (emphasis added).
\textsuperscript{51} 69 Fed. Reg. at 16094-95 (“We have created a regulatory exception for federally qualified health centers (FQHCs) that make recruitment payments to physicians on the same basis as hospitals.”).
intent and scheme and will help ensure that the statute does not impede efforts by FQHCs, which provide substantial services to underserved populations, to recruit adequate staffs. We are not persuaded that the exception should similarly be extended to other DHS entities, such as nursing homes or home health agencies, that may want to recruit physicians into their service areas. These kinds of recruitment arrangements could pose a risk of abuse. . . .\textsuperscript{52}

Phase II thus includes the following provision within the physician recruitment exception:

This paragraph (e) applies to remuneration provided by a federally qualified health center in the same manner as it applies to remuneration provided by a hospital, so long as the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.\textsuperscript{53}

In summary, hospitals, physicians, and physician groups that have already entered into physician recruitment arrangements, as well as those contemplating such arrangements, must ensure that they comply with the restrictions imposed by Phase II including, but certainly are not limited to, limitations relating to income guarantees and non-competes. As noted above, CMS published Phase II as an interim final rule with comment period. The deadline for submitting written comments to CMS was June 24, 2004, and the effective date of Phase II is July 26, 2004.

\textsuperscript{52} Id. at 16095.
\textsuperscript{53} 42 C.F.R. § 411.357(e)(5) (2004).