

June 23, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201



Re: CMS-1810-IFC – Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) (69 Federal Register 16054)

Dear Dr. McClellan:

On behalf of our over 130 member hospitals and health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to comment on Phase II of the Centers for Medicare and Medicaid Services’ (CMS) final rule on physicians’ referrals to health care entities with which they have financial relationships (Phase II), which implements regulations under Section 1877 of the Social Security Act (the Stark Law).

We support many of the regulatory modifications implemented by CMS in Phase II. In particular, we appreciate the agency’s efforts to balance the need for flexibility in the rules with the need for “bright line” tests. We also support CMS’s use of its statutory authority to create new regulatory exceptions, and we are pleased with CMS’s efforts to clarify many ambiguous provisions. In addition, we strongly support the Phase II treatment of providers’ reporting obligations under the Stark Law.

Below we outline our most significant concerns with the Phase II rulemaking and make related suggestions. In general, these concerns relate to: 1) the exceptions for recruitment and retention; 2) issues involving the strict liability nature of the Stark Law and the possible imposition of sanctions that are disproportionate to the noncompliance; and 3) the exception for remuneration unrelated to DHS.

1. Physician Recruitment Exception¹

Phase II made significant modifications to the physician recruitment exception. We agree with the clarification that relocation of a physician’s medical practice is more relevant than the physician’s residence, and we also support CMS’s decision to exclude residents and new physicians from the relocation requirement.

The ability to recruit physicians to practice medicine in particular geographic areas, particularly in underserved areas of Wisconsin, is of critical importance to hospitals in meeting the health care needs of their communities. However, the new provisions on income

¹ 42 C.F.R. §411.357(e).

guarantees and practice restrictions (*i.e.*, non-compete agreements) present major problems with respect to hospital recruiting efforts. Our primary concerns relate to the application of these new provisions to existing arrangements entered into in good faith reliance on the law and guidance at that time, and the potential inability in some underserved areas of Wisconsin to meet community need.

a. *Income Guarantees*

The relevant new provision in Phase II states: “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 physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician.”²

As a practical matter, without specific standards for measuring incremental costs it would be very difficult, if not impossible, to track “actual additional incremental costs” attributable to the recruited physician with any degree of precision. Furthermore, because no specific standards for measuring incremental costs are provided, a group’s calculation methodology invariably would be open to question (and methodologies undoubtedly would vary from group to group). In light of the strict liability nature and enormous penalties associated with the Stark Law, the Phase II requirement leaves physicians and health care entities vulnerable to draconian potential liability despite their best intentions to comply.

Permitting groups to allocate costs on a pro-rated basis among the total number of FTE physicians in the group is a fair, equitable, and practical way of solving this issue. This type of proportional allocation is probably the most common method of cost allocation used today by group practices, and it would be difficult to imagine a situation in which proportional allocation would result in the kind of abusive cost-shifting about which CMS is concerned.

b. *Practice Restrictions*

The relevant new provision in Phase II states: “The physician or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to the quality of care.”³ The preamble indicates that practice restrictions include non-compete agreements.⁴

This provision raises significant concerns. First, other than non-compete agreements, it is unclear what would qualify as a “practice restriction” for purposes of this rule. The lack of specificity in the rule makes it impractical and puts hospitals and physicians at unreasonable risk of violating the law.

The new provision also presents a particular problem in the context of existing arrangements. Relying in good faith on the statute and existing CMS guidance, a great number of hospitals, groups, and recruited physicians have entered into arrangements that include non-compete agreements. Requiring groups to renegotiate, amend, or terminate these agreements would be highly disruptive and problematic. An even more difficult situation for hospitals is that

² 42 C.F.R. §411.357(e)(4)(iii).

³ 42 C.F.R. §411.357(e)(4)(vi).

⁴ 69 Fed. Reg. at 16096-97.

they may not be party to agreements between groups and recruited physicians, and therefore have limited ability to affect (or even to know the details of) those arrangements.

Finally, in cases where groups declined to revise their agreements to comply with the new regulatory requirements, hospitals would be in the difficult position of either: 1) continuing to fund recruitment arrangements that do not comply with the regulation; or 2) ceasing the funding and risking a breach of contract suit from the group and/or recruited physician. In subsection (d) below, we suggest a way to address this problem.

c. Geographic Area

Another area of concern in this exception involves the new regulatory definition of the hospital's geographic area. The relevant provision in Phase II states: "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."⁵

We have at least two concerns with this new requirement. First, it could prevent hospitals from recruiting into "outreach areas" (areas outside of the new definition of geographic area, but still within the hospital's service area), where the community need for physicians may be greater than in areas closer to the hospital. Wisconsin's rural clinics and other sites not proximate to the hospital may be the ones most affected by this new restriction. Often it is these "outreach areas" of Wisconsin that have the greatest need for additional physicians.

Our other concern involves the application of this provision to existing arrangements that do not meet the new definition. For hospitals that have recruited physicians into what was reasonably considered to be the hospital's geographic area, but where such area does not qualify under the Phase II definition, the apparent options for the parties are not appealing: 1) require the physician to relocate (again) into the defined geographic area; or 2) terminate the arrangement. Either of these options could have dramatic negative effects on an underserved community's health care needs as the requirement could result in moving physicians away from areas where they are currently serving patients and meeting a community need. As long as the arrangement satisfied the requirements of this exception that were in place at the time of the recruitment agreement, the parties should not be forced to make either of the choices noted above. Again, we suggest a way to remedy this situation below in subsection (d).

d. Requested Action

For the reasons outlined above, we urge CMS to amend the exception for recruitment by: 1) revising the provision at §411.357(e)(4)(iii) to permit pro-rated allocation of costs among FTE physicians in the group; 2) deleting the provision at §411.357(e)(4)(vi) relating to practice restrictions; and 3) deleting the definition of geographic area at §411.357(e)(2).

Alternatively, we ask that CMS take steps to ensure that existing arrangements, which the parties entered in good faith relying on the statute and prior CMS guidance, are not disrupted. Consequently, if CMS is unwilling to change the regulatory conditions imposed in Phase II, then it should permit existing arrangements to run their course, and it should not take into account the new requirements when assessing compliance with such existing arrangements.

⁵ 42 C.F.R. §411.357(e)(2).

At an absolute minimum, we ask CMS to permit certain existing arrangements to continue at least for a limited period of time even if they do not meet all of the requirements imposed in Phase II. Specifically, we would ask that CMS make clear that the new requirements in the physician recruitment exception will not apply to arrangements that meet all of the following criteria:

- 1) the existing agreement is set forth in writing and was executed prior to March 26, 2004;
- 2) the terms of the existing agreement reflect a good faith reliance on prior guidance from CMS regarding recruitment arrangements;
- 3) the recruited physician has relocated and started work pursuant to the recruitment agreement; and
- 4) the payment, guarantee, and/or loan forgiveness aspects of the agreement will be in effect no longer than four [4] years from the effective date of the agreement.

To do anything less is to effectively deny these arrangements any opportunity to come into compliance. If the regulation were to be implemented as currently drafted, hospitals would find many of their arrangements to be outside of the exception, despite having entered into such arrangements based on a good faith reliance on the law and CMS guidance that existed at the time. As a result, under the Stark Law, they would not be entitled to bill Medicare or Medicaid for necessary care. This result is contrary to good public policy and past practice.⁶

2. Exception for Retention Payments in Underserved Areas⁷

We support the inclusion of an exception for certain retention payments by hospitals and federally qualified health centers. However, we are concerned that §411.357(t)(1)(iii) which requires that the physician have a “bona fide firm, written recruitment offer from [another] hospital or federally qualified health center,” greatly restricts the exception’s utility. In practice, hospitals often do not provide written recruitment offers to physicians, and if they do, the written offer is often provided merely as a formality. In either case, it is likely too late to take meaningful action to retain the physician.

Accordingly, we urge CMS to amend §411.357(t)(1)(iii) to delete the word “written” from the provision. With that modification, the provision still would require the existence of a bona fide offer but would better reflect the realities of physician employment and recruitment.

In addition, we urge CMS to revise the requirement that the hospital be located in a HPSA. Whether the hospital itself is located within a HPSA should not be the relevant factor; the more important issue is whether the physician is located in an underserved area. We ask CMS to revise this requirement accordingly.

⁶ We note that CMS has included similar “grandfathering” provisions in agency regulations in the past. Most recently, as part of the Hospital Inpatient PPS proposed rule, CMS included a “grandfathering” provision with respect to common ownership of hospitals within hospitals. See 69 Fed. Reg. 28195, 28326 (May 18, 2004).

⁷ 42 C.F.R. §411.357(t).

3. Disproportionate Penalties (and Related Issues)

The strict liability nature of the Stark Law can lead to disproportionate penalties, potentially imposing significant liability for even “minor” or “technical” violations. For instance, a personal services agreement between a hospital and a physician for \$500 (e.g., for consulting services), if unsigned or otherwise not in compliance with every technical requirement of an exception, could result in an obligation by the hospital to repay the total value of all services furnished to patients admitted or referred to the hospital by the contracting physician.⁸ The issues discussed below relate generally to the concerns caused by this unfortunate aspect of the law.

a. Exception for Temporary Noncompliance⁹

We are pleased that CMS has addressed this issue, to a certain extent, with the new exception for certain arrangements involving temporary non-compliance. However, we have concerns about the strict limitations on its applicability as currently drafted. First, non-compliance must result from “reasons beyond the control of the entity.” This phrase is unclear, and the examples provided in the preamble (including the conversion of publicly-traded companies to private ownership and the loss of rural or HPSA designation) are highly unusual.

Further, according to the rule, the problem must be rectified within 90 days of the date on which the arrangement became noncompliant with an exception. We agree that 90 days is a reasonable period of time, but for the exception to have any significant value for providers, the relevant starting point must be the date on which the noncompliance was discovered (or reasonably should have been discovered).¹⁰

b. Compliance with Antikickback Law

Many of the regulatory exceptions include a requirement that the arrangement not violate the antikickback law (42 U.S.C. §1320a-7b(b)). As CMS itself frequently points out, the antikickback law is an entirely separate statute with which providers must assure compliance wholly apart from Stark Law considerations.¹¹ There is no reason for CMS to require compliance with the antikickback law for purposes of the Stark Law.

Significantly, by including this requirement, CMS effectively negates the “bright line” nature of the tests that it otherwise tried to achieve in Phase II. The antikickback law is an intent-based statute, and interposing this degree of subjectivity in the Stark regulations potentially leaves physicians and health care entities with a great deal of uncertainty about their

⁸ Moreover, in this situation, there is no question about the medical necessity for the service, or about the fact that the service was actually provided.

⁹ 42 C.F.R. §411.353(f).

¹⁰ This would be consistent, for example, with standard disclosure provisions included in OIG Corporate Integrity Agreements. Those provisions typically require entities to report certain events (e.g., findings of violations of laws) within a certain number of days after *making the determination that the reportable event exists*. Although the context obviously is different, this analogous situation presents a more reasonable and practical approach than currently exists in the Phase II regulation discussed above.

¹¹ See, e.g., CMS’s preamble commentary to the Phase I rulemaking (“Congress only intended section 1877 of the Act to establish a minimum threshold for acceptable financial relationships, and that potentially abusive financial relationships that may be permitted under section 1877 of the Act could still be addressed through other statutes that address health care fraud and abuse, including the anti-kickback statute (section 1128B(b) of the Act). In some instances, financial relationships that are permitted by section 1877 of the Act might merit prosecution under section 1128B(b) of the Act. Conversely, conduct that may be proscribed by section 1877 of the Act may not violate the anti-kickback statute.”) 66 Fed. Reg. 855, 860 (January 4, 2001).

compliance under the Stark Law. We strongly urge CMS to remove the references to the antikickback law as an element of the regulatory exceptions.

4. Exception for Remuneration Unrelated to DHS ¹²

In Phase II, CMS significantly narrowed the scope of this exception. CMS apparently based its revised reading of the rule at least in part on the expansion of the Stark Law in 1995 from clinical laboratory services to “designated health services,” including all hospital services.¹³

This explanation is unconvincing. First, if such a reading were necessitated by the statutory history, then presumably CMS would have adopted this narrow interpretation in the proposed rule in 1998. Also, when Congress expanded the Stark Law in 1995, it specifically retained this exception. Clearly, Congress could have decided to delete the provision if it had so chosen. Although the provision remains in the statute, CMS has narrowed the rule so extensively in Phase II as to make it practically useless. In fact, the only example CMS provided in the preamble regarding the applicability of this exception involves a hospital’s “rental of residential property” from a physician.¹⁴ Needless to say, this is a rare occurrence and not likely the totality of what Congress had in mind.

We strongly urge CMS to reconsider its position on this exception. Specifically, we recommend that CMS adopt the interpretation taken in the 1998 proposed rule, including the examples included in the preamble to that rule.¹⁵ At the very least, we ask CMS to provide additional examples of when this exception could apply.

* * *

WHA appreciates the opportunity to comment on the Phase II interim final rule. Thank you for your consideration of these comments. If you or your staff have any questions regarding our comments please feel free to contact Laura Leitch or Matthew Stanford at 608-274-1820.

Sincerely,



Stephen F. Brenton
President

¹² 42 C.F.R. §411.357(g).

¹³ 69 Fed. Reg. at 16093.

¹⁴ *Id.*

¹⁵ See 63 Fed. Reg. 1659, 1702 (January 9, 1998).