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Administrator
Centers for Medicare & 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 nearly 5,000 member hospitals, health care systems, networks and other providers of care, the American Hospital Association (AHA) appreciates the opportunity to comment on Phase II of the Centers for Medicare & Medicaid Services' (CMS) final rule on physicians' referrals to health care entities with which they have financial relationships (Phase II).

Phase II implements regulations under Section 1877 of the Social Security Act (the Stark law). We are pleased that CMS has allowed for a comment period on this interim final rule. The Stark law is complex, and we believe that the hospital field can provide essential feedback to CMS on how its rules are likely to affect the delivery of health care in communities across the country.

The AHA supports many of the regulatory modifications CMS implemented 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' decision to create new regulatory exceptions, and we are pleased with the agency's efforts to clarify many ambiguous provisions.

Below we outline our most significant concerns with the Phase II rule and make related suggestions. In general, these concerns relate to:

- the exceptions for recruitment and retention;
- issues involving the strict liability nature of the Stark law and the possible imposition of sanctions that are disproportionate to the noncompliance; and
- the exception for remuneration unrelated to designated health services (DHS).

Physician Recruitment Exception

In order to meet the health care needs of their communities, hospitals must have the ability to recruit physicians to practice medicine in particular geographic areas. Hospitals typically conduct community needs assessments on a periodic basis, looking at short- and long-term needs. Through these and other methods, hospitals often are the first to recognize a shortage of needed physicians or specialties. Hospitals take into account various factors in developing their recruitment plans: the number of patients seeking primary care at the emergency departments; lack of on-call coverage in certain specialties; delays for patients in getting appointments for on-going care; and limits on the number of Medicaid or indigent patients that physicians accept in their practices.

In today's environment, the predominant practice setting for physicians is a group practice. As CMS recognized in the preamble to the new regulation, "many new or relocating physicians prefer to join existing practices rather than set up a new practice for legitimate reasons."[1] A group, rather than solo practice, offers the recruited physician mentoring, professional education, back-up coverage and economies of scale.

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' decision to exclude residents and new physicians from the relocation requirement.

However, we have significant concerns about certain requirements included in the provision for recruitment payments made through an existing practice. Specifically, as discussed in more detail below, the new provisions on income guarantees and practice restrictions (*i.e.*, noncompete 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 the time and the impediments created for meeting community need.

- ***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]

This requirement presents a significant obstacle for hospitals and group practices that wish to jointly recruit. As a practical matter, it would be difficult, if not impossible, to track "actual additional incremental costs" attributable to the recruited physician with any degree of precision. This rule would impose an unnecessary and daunting administrative and accounting burden that many physician practices are not equipped to handle. Under a literal reading of the rule, groups would be required not only to measure easily identifiable incremental costs (such as additional

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1 69 Fed. Reg. 16054, 16096 (March 26, 2004).

2 42 C.F.R. §411.357(e)(4)(iii).

staff or equipment), but also such details as additional supply costs and staff overtime that are attributable to the recruited physician. In addition, the rule would force hospitals to be aware of (and involved in) the details of the existing group's accounting practices, a requirement that is not practical or desirable for either party. Among other concerns, there is no guarantee that groups would cooperate with hospitals' attempts to audit or verify their accounting methods.

Moreover, without specific standards for measuring incremental costs, 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, this 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 full-time equivalent (FTE) physicians in the group is a fair, equitable and practical way of solving these issues. 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. A common situation that clearly would call for the use of proportional allocation would be when a recruited physician is replacing a group member who has relocated, retired or died. In those and similar "succession" scenarios, it is only equitable that the recruited physician should be allocated a proportional share of overhead and other reasonable expenses. Anything else would likely foster feelings among existing group members that the recruited physician was receiving favorable treatment.[3]

- ***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."[4] The preamble indicates that practice restrictions include noncompete agreements.[5]

Again, this provision raises significant concerns. First, other than noncompete agreements, it is unclear what would qualify as a "practice restriction" for purposes of this rule. For example, it is unclear how the following types of provisions would be treated under the regulation since they could be viewed as not affecting a practice's quality of care: a "no moonlighting" provision that applies while the physician is an employee of the group; a prohibition on soliciting patients of the group; a prohibition on soliciting employees of the group; and/or an obligation to provide on-

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3 A related alternative would be to: prohibit groups from changing their expense allocation methodology from the process they have used historically (including any process required in by-laws or other governing documents) in any manner that would increase the amount allocated to the recruited physician; and set a maximum amount that could be allocated to the recruited physician equal to the amount that would be allocated on a pro-rated basis.

4 42 C.F.R. §411.357(e)(4)(vi).

5 69 Fed. Reg. at 16096-97.

call coverage at the hospital. The lack of specificity in the rule makes it impractical and puts hospitals and physicians at unreasonable risk of violating the law.

Perhaps more importantly, the use of noncompete agreements is a standard, legitimate business practice in many communities. The threat of competition from the recruited physician may well present a real business concern for the existing group. If noncompete agreements were to be prohibited, then hospitals in some areas could have difficulty convincing groups to help them recruit needed physicians. If existing groups are not willing to take on new physicians without the safety of a noncompete agreement, then hospitals could find themselves unable to attract new physicians, and certain health care needs of their surrounding communities could go unmet. The reality of physician employment agreements is that they typically include noncompete agreements (negotiated by the parties for legitimate business reasons), and for CMS to deny that contractual right in this context could severely limit the utility of this exception (and thereby curtail important recruiting activities). [6]

Prohibiting the use of noncompete agreements is a particular problem for existing arrangements. A great number of hospitals, groups, and recruited physicians have entered into arrangements that include noncompetes. Relying in good faith on the statute and existing CMS guidance, the parties reasonably believed that such provisions would not present a problem under the Stark law. Requiring groups to renegotiate, amend or terminate these agreements would be highly disruptive and problematic. First, hospitals 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. Second, many of the existing noncompete provisions contain certain "safeguards" that are worth noting. For instance, many noncompete provisions include reasonable geographic limits associated with the practice restrictions. Also, some of the arrangements require the group to reimburse the hospital for payments made under income guarantee provisions in instances where a group exercises the noncompete.

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: continuing to fund recruitment arrangements that do not comply with the regulation; or ceasing the funding and risking a breach of contract suit from the group and/or recruited physician. Recruited physicians could be left with a substantial debt that they could not have foreseen. Finally, the breach of trust that would result between physicians in the group and the hospital would work against fostering cooperative relationships so necessary in meeting the needs of the community.

Our understanding of the rationale for this provision is that CMS is concerned that a noncompete could undermine one of the objectives of the recruitment exception, which is to assist communities that need certain types of physicians. Specifically, as we understand it, the concern is that a noncompete might force a physician to move out of the area that needed the physician in the first place. However, there are more reasonable, less restrictive ways that CMS could address this concern. For instance, instead of flatly prohibiting all noncompetes and other non-

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6 We believe it is inappropriate for CMS to regulate physician noncompete agreements. Such agreements do not relate to coverage or reimbursement, or to any other subject matter typically within the control of CMS. Moreover, noncompetes do not implicate "fraud and abuse" concerns, and therefore should not be considered a Stark law issue. They are simply commercial business terms.

quality related practice restrictions, CMS could prohibit only those practice restrictions that might interfere with the recruited physician's ability to meet his or her contractual obligation to continue practicing medicine in the community. This approach would advance CMS' objectives regarding meeting community needs, but also would give hospitals and physicians greater flexibility to negotiate competitive business terms.

- ***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."[7]

We have at least two concerns with this new requirement. First, it would 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. 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" that have the greatest need for additional physicians.

Second, we are concerned about applying 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: require the physician to relocate (again) into the defined geographic area; or terminate the arrangement. Either of these options could have dramatic negative effects on the community's health care needs. For instance, 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.

- ***Requested Action***

For the reasons outlined above, we urge CMS to amend the exception for recruitment by:

- revising the provision at §411.357(e)(4)(iii) to permit pro-rated allocation of costs among FTE physicians in the group (or as suggested in footnote 4);
- deleting the provision at §411.357(e)(4)(vi) relating to practice restrictions[8]; and
- deleting the definition of geographic area at §411.357(e)(2).

We ask that CMS take steps to ensure that existing arrangements entered in good faith reliance on the statute and prior CMS guidance are not disrupted. As described above, amending recruitment agreements to be in compliance with the provisions cited above would present major

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7 42 C.F.R. §411.357(e)(2).

8 Alternatively, as discussed above, CMS could prohibit only those practice restrictions that might interfere with the recruited physician's ability to meet his or her contractual obligation to continue to practice medicine in the community.

problems for hospitals and the communities they serve. Terminating the agreements would be equally, or more, impractical, since in many cases physicians have relocated, money has been paid and all parties have relied on prior CMS guidance that did not impose these restrictions. Consequently, if CMS is unwilling to change the regulatory conditions imposed in Phase II, then the agency should permit existing arrangements to run their course, and it should not rely on the new requirements when assessing compliance with such existing arrangements.

At an absolute minimum, we request 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:

- the existing agreement is set forth in writing and was executed prior to March 26, 2004;
- the terms of the existing agreement reflect a good faith reliance on prior guidance from CMS regarding recruitment arrangements; and
- the payment, guarantee and/or loan forgiveness aspects of the agreement will be in effect no longer than four 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.[9]

- ***Delay in Effective Date***

In the event that CMS does not act quickly on one of these alternatives, we would urge the agency to immediately delay the effective date of the new requirements in this exception. This is a reasonable short-term solution that would allow CMS time to carefully consider the issues in detail, and allow hospitals and physicians time to evaluate their current arrangements and prepare for CMS' ultimate decision, without facing the immediate prospect of an enforcement action for noncompliance.

We note that there is relevant precedent for this type of delay of a specific regulatory provision. After the publication of Phase I of the final rule (but before the rule's effective date), CMS delayed the effective date for one particular aspect of the definition of "set in advance."[10] As part of its rationale for the delay, CMS noted in the *Federal Register*: "We understand that

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9 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).

10 66 Fed. Reg. 60154 (Dec. 3, 2001).

hospitals, academic medical centers, medical foundations and other health care entities would have to restructure or renegotiate thousands of physician contracts to comply with the language in [the relevant provision]."[11] Procedurally, the issues currently causing concerns with the recruitment exception are very similar to the concerns raised with respect to the "set in advance" definition in 2001. We appreciate the flexibility CMS showed in its treatment of the "set in advance" issues, and we strongly encourage the agency to follow suit here.

Exception for Retention Payments in Underserved Areas

We support the inclusion of an exception for certain retention payments by hospitals and federally qualified health centers (FQHC). However, we are concerned that one of the requirements of this exception would greatly restrict its utility. Specifically, §411.357(t)(1)(iii) requires that the physician have a "bona fide firm, written recruitment offer from [another] hospital or federally qualified health center." In practice, hospitals often do not provide written recruitment offers to physicians. When written offers are provided, as a practical matter, the parties often already have agreed in principle on terms, and the written offer is provided merely as a formality. In that case, it is likely too late to take meaningful action to retain the physician.

Accordingly, we urge CMS to amend this requirement and delete the word "written" from the provision. With that modification, the provision still would require the existence of a bona fide offer, but the offer could be either verbal or written. This change 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 health professional shortage area (HPSA). As discussed above in the section on recruitment, outreach areas (including rural clinics) often have the greatest need to retain or recruit physicians. Whether the hospital itself is located within a HPSA should not be the relevant factor; the more important issue is whether the physician provides services in an underserved area.

Finally, we see no reason why the other recruitment offer must come from a hospital or FQHC. A bona fide offer *from any source*, including from a physician group, to employ the physician (for physician services) should be sufficient to permit a hospital to make a retention payment under this exception. We ask CMS to revise these requirements accordingly.

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.[12] The issues discussed below relate generally to the concerns caused by this unfortunate aspect of the law.

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11 *Id*. at 60155.

12 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.

- ***Exception for Temporary Noncompliance***

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.

Second, 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.[13]

Although this exception is encouraging in theory, we are concerned that many innocent and immaterial lapses will not meet all of the requirements of this exception. Because sanctions under the Stark law, as discussed above, can be so wildly disproportionate to the degree of noncompliance, we strongly urge CMS to expand the applicability of this exception. First, we ask CMS to delete the requirement that noncompliance result from reasons beyond the control of the entity. Also, we ask that the 90-day "cure period" begin on the date that noncompliance is discovered.

- ***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)). We understand that CMS believes this is necessary to comply with the statutory requirement that regulatory exceptions "not pose a risk of program or patient abuse."[14] However, there is nothing in the statute that would require CMS specifically to refer to the antikickback law in its regulations. 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.[15] There is no reason for CMS to require compliance with the antikickback law for purposes of the Stark law.

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13 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.

14 42 U.S.C. §1395nn(b)(4).

15 *See*, e.g., CMS' 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 antikickback 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 antikickback statute.") 66 Fed. Reg. 855, 860 (January 4, 2001).

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

Exception for Remuneration Unrelated to DHS

In Phase II, CMS significantly narrowed the scope of this exception. The preamble commentary even withdrew the prior interpretation that general administrative or utilization review services are not related to DHS (as stated in the 1998 proposed rule preamble). CMS apparently based its revised reading of the rule at least in part on the expansion of the Stark law in 1993 from clinical laboratory services to "designated health services," including all hospital services.[16]

This explanation is unconvincing. 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 1993, 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.[17] 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.[18] At the very least, we ask CMS to provide additional examples of when this exception could apply.

Specialty Hospital Moratorium/Reporting Requirements

In Phase II, CMS incorporated the provision in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) providing that, effective for an-18 month period beginning on December 8, 2003, the exception for ownership or investment interest in a hospital does not include ownership or investment in a specialty hospital as defined in the amendment. CMS also implemented the statutory requirements for the reporting of information to CMS or the Office of Inspector General (OIG) concerning an entity's reportable financial relationships. The required information must be retained by entities and submitted upon request within a specified time period. In general, the AHA supports the treatment of providers' reporting obligation under the Stark law.

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16 69 Fed. Reg. at 16093.

17 *Id.*

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

However, during the moratorium (or such other period as Congress may specify), any entity making an application for a Medicare provider number for the operation of a hospital should be required to submit, as part of the application process, the information required under section 411.361(c)(1)-(4). Submission of the information (the names of physicians or family members with an ownership or investment interest and the nature of the relationships, as well as the covered services furnished by the entity) will be essential to the Secretary in monitoring and enforcing the moratorium.

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The AHA 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 Maureen D. Mudron, Washington counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

Rick Pollack
Executive Vice President