DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1810–F2]

RIN 0938–AK67

Medicare Program; Delay of the Date of Applicability for Certain Provisions of Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule delays the date of applicability of certain specified compensation arrangements only, until December 4, 2008.

DATES: *Effective Date:* The provisions of this final rule are effective December 4, 2007 as specified in the September 5, 2007 final rule (72 FR 51012). However, the date of applicability of the provisions of § 411.354(c)(1)(ii), § 411.354(c)(2)(iv), and § 411.354(c)(3) with respect to certain compensation arrangements involving physician organizations and academic medical centers or integrated section 501(c)(3) health care systems, as described herein, are delayed until December 4, 2008.

FOR FURTHER INFORMATION CONTACT: Lisa Ohrin, (410) 786–4565.

SUPPLEMENTARY INFORMATION:

I. Background

The final rule, entitled ''Medicare Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III),'' published in the **Federal Register** on September 5, 2007 (72 FR 51012), interpreted and implemented certain provisions of section 1877 of the Social Security Act (the Act). Under section 1877 of the Act, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services (DHS) payable under the Medicare program, and the entity may not bill for the services, unless an exception applies.

II. Provisions of the Final Regulations

The Phase III final rule includes provisions under which referring physicians will be treated as ''standing in the shoes'' of their physician organizations for purposes of applying the rules that describe direct and indirect compensation arrangements in § 411.354 (72 FR 51026 through 51030). A ''physician organization'' is defined at § 411.351 as ''a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352.'' Therefore, for purposes of determining whether a direct or indirect compensation arrangement exists between a physician and an entity to which the physician refers Medicare patients for DHS, the referring physician stands in the shoes of: (1) Another physician who employs the referring physician; (2) his or her wholly-owned professional corporation; (3) a physician practice (that is, a medical practice) that employs or contracts with the referring physician; or (4) a group practice of which the referring physician is a member or independent contractor. The referring physician is considered to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization in whose shoes the referring physician stands.

Subsequent to the publication of Phase III, we received informal comments on the Phase III ''stand in the shoes'' provisions from affected industry stakeholders. These comments addressed the application of the Phase III ''stand in the shoes'' provisions in the academic medical center (AMC) setting or similar settings (such as a nonprofit integrated health care system in which each affiliated organization qualifies for exemption from federal income taxation under section 501(c)(3) of the Internal Revenue Code (for purposes of this final rule, referred to as an ''integrated section 501(c)(3) health care system'')) where ''support payments'' or other similar monetary transfers are common. The commenters asserted that, under Phase III, support payments that previously did not trigger application of the physician self-referral law will need to satisfy the requirements of an exception if, for example, a DHS entity component (for example, a hospital) of an AMC transfers funds to the faculty practice plan component of the AMC. Specifically, in the situation where a physician stands in the shoes of his or her faculty practice plan, the compensation arrangement between the AMC component providing the support payment and the faculty practice plan will be considered to be a direct compensation arrangement between the component and the physician. If the component making the support payment is a DHS entity to which the physician refers Medicare patients, the arrangement between the component and the faculty practice plan would need to satisfy the requirements of a direct compensation arrangement exception if the physician were to continue referring Medicare patients to the component for DHS. A similar analysis applies in the case of an integrated section 501(c)(3) health care system that includes both a hospital affiliate and a nonprofit physician practice affiliate. According to the commenters, it is unlikely that the requirements of any available exception could be satisfied given the nature of support payments (that is, support payments usually are not tied to specific items or services provided by the faculty practice plan (or nonprofit group practice within the health system), but rather are intended to support the overall mission of the AMC or nonprofit integrated health system).

We understand the commenters' concerns and intend to review the application of the Phase III ''stand in the shoes'' provisions in the situations described above. In addition, we are cognizant of the special nature of AMCs and nonprofit integrated health care systems, specifically with respect to their community service and teaching missions. In order to evaluate fully the impact of the Phase III ''stand in the shoes'' provisions on remunerative relationships within AMCs and nonprofit integrated health care systems that, prior to Phase III, did not trigger application of the physician self-referral laws, we are delaying the date of applicability of the provisions in § 411.354(c)(1)(ii), § 411.354(c)(2)(iv), and § 411.354(c)(3) for 12 months after the effective date of Phase III (that is, until December 4, 2008) as to the following compensation arrangements between the following physician organizations and entities ONLY:

- With respect to an AMC as described in § 411.355(e)(2), compensation arrangements between a faculty practice plan and another component of the same AMC; and
- With respect to an integrated section 501(c)(3) health care system, compensation arrangements between an affiliated DHS entity and an affiliated physician practice in the same integrated section 501(c)(3) health care system.

We note that, in a prior rulemaking (Phase I), in response to a comment that compensation arrangements between organizations regulated under the IRS rules pose minimal risk of program or patient abuse, we indicated that regulation under IRS rules, though

beneficial, is not necessarily sufficient to prevent fraud or abuse (66 FR 917). Our action delaying the date of applicability of the Phase III provisions in § 411.354(c)(1)(ii), § 411.354(c)(2)(iv), and § 411.354(c)(3) with respect to integrated section 501(c)(3) health care systems should not be read as a reversal of our previous position. As stated above, we are delaying the date of applicability of these provisions in a targeted manner in order to evaluate any unintended impact of the Phase III ''stand in the shoes'' provisions.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking and invite public comment on the proposed rule. The notice and comment rulemaking procedure is not required, however, if the rule is interpretive or procedural in nature, and it may be waived if there is good cause that it is impracticable, unnecessary, or contrary to the public interest and we incorporate in the rule a statement of such a finding and the reasons supporting that finding. Likewise, we ordinarily provide for a delayed date of applicability of a final rule, but we are not required to do so if the rule is procedural or interpretive. Where a delayed date of applicability is required, this requirement may be waived for good cause. Although we believe that this rule is procedural in nature and, therefore, prior notice and comment and a delayed date of applicability are not necessary, to the extent that it could be considered to be a substantive rule, we set forth below our finding of good cause for the waiver of notice and comment rulemaking and the waiver of a delayed date of applicability.

Our implementation of this action without opportunity for public comment and without a delayed date of applicability is based on the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and (d), respectively. We find that seeking public comment on this action is impracticable, unnecessary, and contrary to the public interest. We are implementing this delayed date of applicability as a result of our review of the informal comments on the Phase III ''stand in the shoes'' provisions from various stakeholders. As discussed above, we understand from those comments that, unless we delay the date of applicability of § 411.354(c)(1)(ii), § 411.354(c)(2)(iv), and § 411.354(c)(3) with respect to the compensation arrangements described herein only, compensation arrangements that previously did not trigger application of the physician self-referral law may need to satisfy the requirements of an exception, requiring renegotiation of a large number of contracts, or the restructuring of many common arrangements involving AMCs and integrated 501(c)(3) health care systems, potentially causing significant disruption within the health care industry. We are concerned that the disruption could unnecessarily inconvenience Medicare beneficiaries or interfere with their medical care and treatment. Likewise, if we do not make this final rule effective upon publication, arrangements described herein that have been in compliance may fall temporarily out of compliance.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Regulatory Impact Statement

We do not believe that this delay in the date of applicability will result in any significant economic impact on any small entity. Until the effective date of the provisions of § 411.354(c)(1)(ii), § 411.354(c)(2)(iv), and § 411.354(c)(3) with respect to the types of compensation arrangements described herein as subject to the delayed date of applicability, physicians, AMCs, and certain nonprofit integrated health care systems do not have to comply with the requirements of the ''stand in the shoes'' provisions of the Phase III final rulemaking and may continue to rely on whichever appropriate exceptions they used before the creation of the new provisions.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 2, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: November 6, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–5655 Filed 11–9–07; 2:46 pm]

BILLING CODE 4120–01–P