

physicians that wishes to be identified as a group practice for purposes of the physician self-referral regulations (42 CFR 411.350 through 411.361) must file a statement attesting that it meets certain specified conditions.

DATES: These regulations are effective on December 11, 1995.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On August 14, 1995, we published, at 60 FR 41914, a final rule with comment period entitled, "Medicare program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements." That rule specified that, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of clinical laboratory services under the Medicare program except under specified circumstances. Under the rule, being designated as a group practice may enable a group of physicians to meet the conditions that would qualify it for an exception to the prohibition on referrals. Specifically, the rule required, at § 411.360 (a) and (b), that a group of physicians that intends to be identified as a group practice (as defined at § 411.351) submit a written statement to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period), 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group. In the case of a newly formed group practice, the group would submit a statement to attest that during the next calendar year, fiscal year, or 12-month period, it expects to meet the 75-percent standard. The rule further required, at § 411.360(e), that the attestation be submitted to the appropriate Medicare carrier by December 12, 1995.

II. Provisions of This Rule

This rule changes the above submittal date to require that the attestation statement be submitted no later than 60 days after receipt of instructions from the carrier.

We have been in the process of developing a method for groups to

provide us with their attestation statements. However, we have come to realize that those individuals who would be completing the attestation statement need to be offered more guidance than we had originally anticipated providing in the attestation instructions. The attestation instructions will not be available early enough to give the respondents sufficient time to submit the statement by the deadline stated in the regulations. Therefore, this final rule revises § 411.360(e) to require that the attestation be submitted no later than 60 days after receipt of the attestation instructions from the carrier. In the interim, a group of physicians can regard itself as a group practice if it believes it meets the definition of group practice that was incorporated in our regulations, at § 411.351, by the August 14 rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide a 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. Therefore, we are soliciting public comment on each of these issues for the information collection requirement discussed below.

Section 411.360 contains a requirement concerning those groups of physicians attempting to be identified as a "group practice." It specifies that the group must attest that, in the aggregate, 75 percent of total patient care services furnished by all physician members are (or, in the case of a newly formed group, are expected to be) furnished through the group and billed under a billing number assigned to the group. This information collection requirement was established by the August 14, 1995 rule discussed earlier. As stated in the August 14, 1995 rule, public reporting burden for this collection of information

is estimated to be 1 hour per response. Organizations and individuals were given an opportunity to comment on the information collection requirements at the time the August 14 rule was published. However, because this rule changes the date by which the attestation must be submitted, we are again soliciting public comment on this requirement and providing the 60-day notice. As also stated in the August 14 rule, a document will be published in the Federal Register after Office of Management and Budget approval is obtained.

Organizations and individuals desiring to submit comments on these information collection and recordkeeping requirements should mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-850-F, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21224-1850.

IV. Waiver of Proposed Rulemaking and Delay in Effective Date

As required by the Administrative Procedure Act, we generally provide notice and opportunity for comment on regulations and provide that final rules are not effective until 30 days after the date of publication unless we can find good cause for waiving the notice-and-comment procedure and delayed effective date as impracticable, unnecessary, or contrary to the public interest.

Unless the requirement at § 411.360(e) is revised before December 12, 1995, the regulations would contain a requirement that, through no fault of their own, groups of physicians would be unable to meet. Therefore, we find good cause to waive the notice-and-comment procedure as being contrary to the public interest. We also find good cause to waive the delay in effective date.

V. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all physicians are considered to be small entities.