

on canola will remain regionally restricted and time-limited because of a concern for avian toxicity. The use is extended for the 1996 growing season only. The Agency expects to register an alternative chemical in late 1995 for early season control of the flea beetle. This may be available in limited quantities for the 1996 growing season, and fully available thereafter.

The Interregional Research Project No. 4 (IR-4) plans to submit a petition for a permanent tolerance for carbofuran on canola in late 1995 or early 1996. However, because of the known hazard of carbofuran to birds and wildlife, EPA will not establish a permanent tolerance until the Agency has fully evaluated risks to wildlife.

The data submitted on the proposal and other relevant material have been evaluated and discussed in the proposed rule of November 8, 1994 (59 FR 55605). Based on that data and information considered, the Agency concludes that extension of the time-limited tolerance will continue to protect the public health. Therefore, the time-limited tolerance is extended for an additional 1-year period.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [OPP-300406] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall 1B2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 30, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 180.254 [Amended]

2. In § 180.254 *Carbofuran; tolerances for residues*, by amending paragraph (c) in the introductory text by changing the date "February 22, 1997" to read "February 22, 1998".

[FR Doc. 95-30115 Filed 12-6-95; 4:03 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 411

[BPD-850-F]

Medicare Program; Physician Self-Referral Regulations: Change in Date for Submission of Group Attestation Statement

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule—Technical amendment.

SUMMARY: This final rule changes (delays) the date by which a group of

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: Patricia Snyder (attestation issues) (410) 786-5991, Betty Burrier (other physician referral issues) (410) 786-4649.

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.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This rule merely makes a technical amendment to delay the due date for the submission, by a group of physicians that wishes to be identified as a "group practice," of a statement attesting that it meets certain conditions. For this reason, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR part 411 is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATION ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 411.360, paragraph (e) is revised to read as follows:

§ 411.360 Group practice attestation.

* * * * *

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

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

Dated: November 21, 1995.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Dated: November 29, 1995.

Donna E. Shalala,
Secretary.

[FR Doc. 95-30064 Filed 12-8-95; 8:45 am]

BILLING CODE 4120-01-P

42 CFR Part 424

[BPD-838-FC]

RIN 0938-AH19

Medicare Program; Additional Supplier Standards

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment.

SUMMARY: This final rule with comment period conforms our regulations to changes made to section 1834 of the Social Security Act (the Act) by section 131 of the Social Security Act Amendments of 1994. Section 1834(j) of the Act requires that suppliers meet additional standards related to compliance with State and Federal licensure requirements, maintaining a physical facility on an appropriate site, and proof of appropriate liability insurance. This final rule retains existing regulatory standards and incorporates the three additional standards specifically cited from the statute.

DATES: Effective Date: This rule is effective January 1, 1996.

Comments: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 9, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-838-FC, P.O. Box 26676, 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 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code

BPD-838-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Larry Bonander, (410) 786-4479.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

The Medicare Part B program is a voluntary program that pays all or part of the costs for physicians' services, outpatient hospital services, certain home health services, services furnished by rural health clinics, ambulatory surgical centers, and comprehensive outpatient rehabilitation facilities, and certain other medical and hospital health services not covered by Medicare Part A.

Medicare services are furnished by two types of entities, that is, providers and suppliers. The term "provider" as defined in our regulations at 42 CFR 400.202, means a hospital, a rural primary care hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare. A clinic, a rehabilitation agency, or a public health agency that has a similar agreement to furnish outpatient physical therapy or speech pathology services, or a community mental health center with a similar agreement to furnish partial hospitalization services, is also considered a provider (see sections 1861(u) and 1866(e) of the Social Security Act (the Act)).

In general, suppliers are individuals or entities that furnish certain types of medical and other health services under part B. There are different definitions of the term supplier and specific regulations governing different types of suppliers. Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) encompasses the types of items included in the definition of "medical equipment and supplies" found at section 1834(j)(5) of the Act. In