* * * * *

[FR Doc. 04–55504 Filed 4–5–04; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 424

[CMS–1810–CN]

RIN 0938–AK67

Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Correction

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

ACTION: Correction of interim final rule with comment period.

SUMMARY: This document corrects a technical error in the interim final rule with comment period published in the **Federal Register** on March 26, 2004, entitled "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II).''

EFFECTIVE DATE: This correction is effective July 26, 2004.

FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer (410) 786–4620.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 04–6668 of March 26, 2004 (69 FR 16054), there was a technical error that we are identifying and correcting in the Correction of Errors section below. (The provisions in this correction are effective as if they were included in the document published March 26, 2004.)

We inadvertently omitted two sections from the preamble of the document, "Section IX. Reporting Requirements'' and "Section X. Sanctions.'' We are publishing the omitted sections in this correction.

II. Correction of Errors

In FR Doc. 04–6668 of March 26, 2004 (69 FR 16054), make the following correction—

On page 16099, column three, before the fourth paragraph, add "Section IX. Reporting Requirements'' and "Section X. Sanctions'' to read as follows:

IX. Reporting Requirements (Section 1877(f) of the Act; Phase II; § 411.361)

[If you choose to comment on issues in this section, please include the caption "Reporting Requirements'' at the beginning of your comments.]

Existing Law: Section 1877(f) of the Act sets forth certain reporting requirements for all entities providing covered items or services for which payment may be made under Medicare. Under section 1877(f) of the Act, each entity must report to the Secretary information concerning the entity's ownership, investment, and compensation arrangements, including—

(1) The covered items and services provided by the entity, and

(2) The names and unique physician identification numbers (UPINs) of all physicians who have an ownership or investment interest in, or a compensation arrangement with, the entity, or whose immediate relatives have such an ownership or investment interest in, or compensation relationship with, the entity.

The requirements do not apply to DHS provided outside the United States or to entities that the Secretary determines provide services for which payment may be made under Medicare very infrequently.

The required information must be provided in a form, manner, and at such times that the Secretary specifies. Section 1877(g)(5) of the Act provides that any person who is required, but fails, to meet one of these reporting requirements is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made.

The August 1995 final rule with comment period (60 FR 41914), which applied only to referrals for clinical laboratory services, addressed the provisions of sections 1877(f) and (g)(5) of the Act in § 411.361. Section 411.361 stated that the reporting requirements applied to all entities furnishing items or services for which payment may be made under Medicare, except for entities that provide 20 or fewer Part A and Part B services during a calendar year or DHS provided outside the United States. Entities were required to submit information to us concerning any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act. We specified that the information submitted must include at least the following:

(1) The name and UPIN of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician with an immediate relative (as then defined in § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under (1) and (2), the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by us).

Section 411.361 of the August 1995 final rule provided that the required information must be submitted on a form prescribed by us within the time period specified by the servicing carrier or intermediary. Entities were given at least 30 days from the date of the carrier's or intermediary's request to provide the information. Thereafter, the entity must provide updated information within 60 days of the date of any change in the submitted information. This section required the entity to retain documentation sufficient to verify the information provided on the forms and, upon request, to make that documentation available either to us or to the Office of the Inspector General (OIG). Information furnished under § 411.361 was subject to public disclosure in accordance with the provisions of 42 CFR part 401.

Proposed Rule: The January 1998 proposed rule stated that we were in the process of developing a procedure and form for implementing the reporting requirements and that we planned to notify affected parties about the procedures at a later date (63 FR 1703). We stated that, until then, physicians and entities were not required to report to us. We also noted that the 60-day timeframe for reporting updated information could be onerous and thus, we proposed to modify § 411.361 to require entities to report annually to us updated information regarding their financial relationships with physicians.

The proposed rule also noted in § 411.361(d) that a reportable financial relationship was defined as "any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.'' Under that definition, we were concerned that an entity could decide that it fell within one of the exceptions and thus report no information to us. As a result, we would have no opportunity to scrutinize the entity's financial arrangements to determine if that assessment was correct. We proposed to modify § 411.361(d) to include those relationships excepted in the statute.

We also proposed that the information that an entity must acquire, retain, and submit to us if requested, for each physician identified in the rule, include the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or any compensation arrangement).

Final Rule: The final rule generally requires entities to retain reportable information and furnish it upon request. For reasons set out in more detail in the responses to comments that follow, we have reconsidered some of the proposed provisions regarding reporting requirements.

We have modified the proposed definition of "reportable financial relationship'' in § 411.361(d). While we are still including in the definition those relationships excepted under § 411.355 through § 411.357, we are specifically excluding from that definition ownership or investment interests in publicly-traded securities and mutual funds if such interests satisfy the exceptions in § 411.356(a) or § 411.356(b), respectively. This exclusion from the definition of reportable financial relationships for publicly-traded securities and mutual funds is limited to shareholder information; contractual arrangements concerning these ownership or investment interests are reportable financial relationships.

We are also modifying § 411.361(c)(4) to specify that the information required is only that information that the entity knows or should know in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with Internal

Revenue Service and Securities and Exchange Commission rules and other rules under the Medicare and Medicaid programs.

We do not intend to develop any forms for the submission of information. We are requiring that records be retained for the length of time specified by the applicable regulatory requirements for the information, including the Internal Revenue Service, the Securities and Exchange Commission, and the Medicare and Medicaid programs and be made available upon request. We have dropped the requirement to report updated information every 12 months.

Comment: Most commenters were concerned that the proposed reporting requirements were unduly burdensome.

Response: We believe we have significantly reduced the burden on entities with the modifications we have made to the proposed rule.

Comment: Several organizations requested that we limit the reporting requirements to only those financial relationships that do not meet a Stark exception. Of those, half of the commenters asked that we specifically exempt publicly-traded securities and mutual funds.

Response: We do not agree that all excepted financial relationships should be exempt from the reporting requirements. We are still concerned that an entity could decide that one or more of its financial relationships falls within an exception, fail to retain data concerning those financial relationships, and thereby prevent the government from reviewing the arrangements to see if they qualify for an exception. However, we are persuaded that, in the case of shareholder information for ownership interests in publicly-traded securities and mutual funds that satisfies the exceptions in § 411.356(a) or § 411.356(b), respectively, the burden of collecting, retaining, and reporting shareholder information outweighs the benefit of reviewing it, and the potential for abuse is minimal. Therefore, we are providing that shareholder information for ownership interests in publicly-traded securities and mutual funds need not be reported. Nevertheless, entities must report other financial relationships with referring physicians who are shareholders, such as personal services arrangements.

Comment: Several commenters were of the opinion that the reporting requirements exceeded those in the statute and thus, we were without statutory authority to impose them.

Response: As explained in the January 2001 final rule, we believe that the statute allows us to gather information on all financial relationships without regard to whether the relationships qualify for an exception. Section 1877(f) of the Act states that each entity providing any covered items or services for which payment may be made under Medicare shall provide the Secretary with information concerning the entity's ''ownership, investment, and compensation arrangements, *including* * * * the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described subsection (a)(2)(B)), in the entity. * * *'' (emphasis added). Thus, we believe the statute allows us to gather data on financial relationships, *including, but not limited to,* financial relationships that do not qualify for an exception under sections 1877(a)(2)(A) or 1877(a)(2)(B) of the Act.

Comment: Several commenters suggested that we confine our requests for information to records that an entity is already required to retain under Internal Revenue Service, Securities and Exchange Commission, and Medicare and Medicaid requirements.

Response: We agree with the commenters that these records should be retained to provide information, upon request, concerning an entity's financial relationships. However, we are also requiring that entities retain, and provide upon request, other records that they know or should know about in the course of prudently conducting business and that would evidence the nature of the financial relationships (including the extent and/or value of the ownership or investment interest or compensation arrangement).

Comment: Three organizations believed that the ''knows or should know'' standard was too vague to provide guidance concerning which records should be retained.

Response: We disagree with the commenters. Entities are required to discern which records they know or should know about in the course of prudently conducting business on a daily basis. We are only requiring retention of those records that entities would retain in the prudent conduct of their business. We are not requiring that any additional records be created specifically to comply with the requirements of this rule. We have defined the scope of the required information and the reportable financial relationships with sufficient specificity to allow an entity to determine what information should be retained.

Comment: Two associations believed that 30 days was not enough time in which to respond to a request for information.

Response: The regulation states that entities must submit the required information within the time period specified in the request, but will be given at least 30 days from the date of the request to provide the information. Since the records requested will already be retained in the course of conducting business, in most cases 30 days should be sufficient to collect them in response to a request. In addition, the rule states that the entity will be given at least 30 days, leaving open the possibility of a greater period of time if reasonably necessary.

Comment: Two commenters felt that the information requested should be confidential.

Response: We are bound to comply with the Freedom of Information Act (FOIA), (5 U.S.C. § 552), as implemented by the Department's regulations at 45 CFR part 5 and our own regulations as 42 CFR part 401. To the extent we are obligated to disclose records that we have received pursuant to the physician self-referral reporting requirements, we cannot maintain these records as confidential. However, because § 411.361(e) requires information to be disclosed to CMS or the OIG, we are modifying § 411.361(g) to provide that information furnished to either CMS or the OIG will be subject to public disclosure in accordance with 42 CFR part 401. Nevertheless, to the extent that reported information is protected from disclosure under the Privacy Act of 1974 (December 31, 1974, Pub. L. 93–579), the information will not be disclosed in response to a FOIA request.

X. Sanctions (Section 1877(g) of the Act; Phase II; § 411.353)

[If you choose to comment on issues in this section, please include the caption ''Sanctions'' at the beginning of your comments.]

Violations of the physician self-referral prohibition are subject to the following sanctions: (i) Nonpayment of claims for DHS furnished as a result of a prohibited referral, and (ii) the obligation to refund amounts collected as a result of submitting claims for DHS performed pursuant to a prohibited referral. These sanctions are addressed in section III.B of the January 1998 proposed rule (63 FR 1695), in section III. A of the Phase I preamble (66 FR 864), in section II.A of this Phase II preamble, and in the regulations at § 411.353. We are making no changes to the sanction provisions in § 411.353. Under section 1877(g)(3) and (g)(4), individuals and entities that knowingly violate the prohibition are subject to civil monetary penalties (CMPs). The CMP sanctions set forth in section 1877(g)(3) and (g)(4) are enforced by the OIG in accordance with the regulations at 42 CFR part 1003.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a notice take effect. We can waive this procedure, however, if we find good cause that notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the finding and the reasons for it into the notice issued.

We believe that it is unnecessary to subject the correction identified above to public comment because it merely provides preamble language that was inadvertently omitted from the regulation preamble. For this reason, and because the public will have an opportunity to comment on this section with the interim final rule with comment period, we find it unnecessary to provide separately the opportunity for comment on the technical correction made in this notice. Therefore, we find good cause to waive notice and comment procedures.

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

Dated: March 31, 2004.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 04–7716 Filed 4–1–04; 11:57 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1380–IFC]

RIN 0938–AN05

Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period will implement the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) related to the calculation and submission of manufacturer's average sales price (ASP) data on certain Medicare Part B drugs and biologicals to CMS by manufacturers.

DATES: Effective date: These regulations are effective on April 30, 2004.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 7, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1380–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* or to *http://www.regulations.gov.* Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1380–IFC, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (410) 786–0548.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1380–IFC and the specific "issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call telephone number: (410) 786–7197.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND'' at the beginning of your comments.]

Section 303(c) of the MMA amends Title XVIII of the Social Security Act (the Act) by adding new section 1847A. This new section establishes the use of the ASP methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. For calendar quarters beginning on or after January 1, 2004, the statute requires manufacturers to report manufacturer's ASP data to CMS for Medicare Part B drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act. Manufacturers are required to submit their initial quarterly ASP data to us beginning April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter. The types of Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act include drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

All Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act are subject to the ASP reporting requirements. Certain drugs and biologicals, for example, radiopharmaceuticals, are not paid under these sections of the Act and will not be subject to the ASP reporting requirements.

We are issuing this interim final rule with comment period in order to allow us to implement the manufacturer ASP reporting requirement of section 303(i)(4) of the MMA within the time frames established by the MMA. Therefore, effective April 30, 2004, this interim final rule with comment period will provide implementation guidelines for manufacturers to submit their ASP data to us. We expect to publish a proposed rule on the 2005 ASP based payment system later this year.

II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption "Provisions of the Interim Final Rule'' at the beginning of your comments.]

In this interim final rule with comment period, we are adding a new subpart J (Submission of Manufacturer's Average Sales Price Data) to Part 414 that implements section 1927(b)(3)(A)(iii) of the Act by specifying the requirements for submission of a manufacturer's ASP data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1847A, 1842(o)(1)(D), or 1881(b)(13)(A)(ii) of the Act.