III. Waiver of Proposed Rulemaking and 30-day Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a rule take effect. We can waive this procedure, however, if we find good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of finding and its reasons for it into the correcting amendment issued (5 U.S.C. (b)(B)).

We find for good cause that it is unnecessary to undertake notice and public comment procedures because this correcting amendment does not make any substantive policy changes. This document makes technical corrections and conforming changes to the August 4, 2003 final rule. Therefore, for good cause we waive the notice and public comment procedures.

Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendment:

The authority citation for part 409 continues to read as follows:

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

I. Background

In FR Doc. 03–19677 of August 4, 2003 (68 FR 46036), there was a technical error we are identifying and correcting in the “Correction of Errors” section II of this final rule. Specifically, the August 4, 2003 final rule made a number of technical corrections to the regulations, including the revision of a cross-reference that appears in the regulations text at § 409.20(c). However, in republishing the introductory portion of paragraph (c) of § 409.20, we inadvertently used the paragraph heading for the preceding paragraph instead (paragraph (b)(2), “Services not generally provided by (or under arrangements made by) SNFs”). Therefore, we are publishing this final rule to restore the correct paragraph heading (“Terminology”) for paragraph (c) of § 409.20. The provisions in this final rule are effective July 26, 2004.

II. Correction of Errors

In FR Doc. 03–19677 of August 4, 2003 (68 FR 46036), make the following correction:

On page 46070, in the second column, the heading for paragraph (c) of § 409.20 should read, “Terminology.”
the entity may not bill for the services, unless an exception applies. Many of the exceptions that apply to compensation relationships require that the amount of compensation be “set in advance.” Section 411.354(d)(1) defines the term “set in advance.”

Section 411.354(d)(1) was first published in the Federal Register on January 4, 2001 (66 FR 856) in a final rule with comment period that is commonly referred to as the “Phase I” physician self-referral final rule. The last sentence of §411.354(d)(1), as originally published in Phase I stated that—“Percentage compensation arrangements do not constitute compensation that is ‘set in advance’ in which the percentage compensation is based on fluctuating or indeterminable measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.” Many of the comments we received regarding Phase I final rule opposed this language. The comments indicated that physicians are commonly paid for their professional services on a percentage compensation basis and that hospitals, academic medical centers (AMCs), medical foundations, and other health care entities would have to restructure or renegotiate thousands of physician contracts to comply with the language in §411.354(d)(1) regarding percentage compensation arrangements. To give the agency additional time to reconsider the matter, we published a 1-year delay of the effective date of the last sentence in §411.354(d)(1) in the Federal Register on December 3, 2001 (66 FR 60154).

Through a series of subsequent rules, we further delayed the effective date of this provision until July 7, 2004 (see 67 FR 70322, 68 FR 20347, and 68 FR 74491). We indicated in those rules that we intended to definitively address the percentage compensation issue in the “Phase II” physician self-referral final rule.

We published the Phase II interim final rule with comment period on March 26, 2004. In Phase II, we modified our interpretation of “set in advance” to permit some percentage compensation if the methodology for calculating the compensation is set in advance and does not change over the course of the arrangement in any manner that reflects the volume or value of referrals or other business generated by the referring physician. Accordingly, we removed the last sentence of §411.354(d)(1) and otherwise modified the provision to reflect this interpretation. Phase II becomes effective on July 26, 2004, 19 days after the expiration of the most recent delay in effective date for the last sentence of the Phase I “set in advance” definition.

II. Provisions of This Final Rule

To avoid regulatory conflict and unnecessary disruption to existing contractual arrangements in the health care industry, we are further postponing for an additional 19 days, until July 26, 2004, the effective date of the last sentence of §411.354(d)(1) as published in Phase I. This delay is intended to coincide with the effective date of the Phase II physician self-referral interim final rule. Accordingly, on July 26, 2004, §411.354(d)(1) of Phase I will automatically be superseded by the revised §411.354(d)(1), as published in Phase II. In the meantime, compensation that is required to be “set in advance” for purposes of compliance with section 1877 of the Act may continue to be based on percentage compensation methodologies, including those in which the compensation is based on a percentage of a fluctuating or indeterminate measure. We note that the remaining provisions of the Phase I §411.354(d)(1) will still apply and that all other requirements for exceptions must be satisfied (including, for example, the fair market value and “volume and value” requirements.)

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking and invite public comment on the proposed rule. This procedure can be waived, however, if an agency finds good cause that the notice and comment rulemaking procedure is impracticable, unnecessary, or contrary to the public interest and if the agency incorporates in the rule a statement of such a finding and the reasons supporting that finding.

We do not believe that a delay in effective date is subject to notice and comment procedures when the regulatory provision at issue has never become effective. Nevertheless, for the benefit of the public, we set forth below the reasons why our implementation of this action without opportunity for public comment satisfies the good cause exception in 5 U.S.C. 553(b). We find that seeking public comment on this action would be impracticable and unnecessary.

We believe public comment is unnecessary because we are implementing this additional delay of effective date as a result of our review of the public comments that we received on the January 4, 2001 physician self-referral final rule. We do not believe that it is necessary to offer yet another opportunity for public comment on the same issue in the limited context of whether to delay this sentence of the regulation.

In addition, we find that seeking public comment on this delay in effective date will be impracticable and contrary to the public interest because it would implement, for 19 days, a statutory interpretation that we have rejected in a recent interim final rule. Even a brief implementation of the rejected statutory interpretation carries the potential for significant disruption in the health care industry. As discussed above, we understand from public comments and the comments we received on the December 3, 2001 interim final rule that, unless we further delay the effective date of the last sentence of §411.354(d)(1), many physician contracts with hospitals, AMCs, and other entities furnishing DHS will not be in compliance with the physician self-referral prohibition. Consequently, these physicians will be unable to refer to the hospitals, AMCs, and other DHS entities to whom they are contractually obligated to provide professional or other services, and these DHS entities will be prohibited from billing Medicare for any services furnished as a result of a prohibited referral. We are concerned that this would unnecessarily disrupt the practice of medicine, inconvenience Medicare beneficiaries, or interfere with beneficiary medical care and treatment.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)


Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: June 17, 2004.

Tommy G. Thompson,
Secretary.

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