

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Part 414
[CMS-1385-F2]
RIN 0938-AO65

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations (§414.50)

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

ACTION: Final rule.

SUMMARY: This final rule delays until January 1, 2009 the applicability of the anti-markup provisions in §414.50, as revised at 72 FR 66222, except with respect to the technical component of a purchased diagnostic test and with respect to any anatomic pathology diagnostic testing services furnished in space that: is utilized by a physician group practice as a “centralized building” (as defined at §411.351 of this chapter) for purposes of complying with the physician self-referral rules; and does not qualify as a “same building” under §411.355(b)(2)(i) of this chapter.

EFFECTIVE DATE: The provisions of this final rule are effective January 1, 2008. However, the date of applicability of the provisions of §414.50, as revised at 72 FR 66222, with respect to certain services furnished in certain locations, as described herein, are delayed until January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Donald Romano, (410) 786-1401.

SUPPLEMENTARY INFORMATION:

I. Background

The final rule with comment period, entitled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions,” that appeared in the November 27, 2007 Federal Register (72 FR 66222), amended the anti-markup provisions for certain diagnostic tests in §414.50.

II. Provisions of the Final Regulations

As amended, the anti-markup provisions in §414.50 will apply to the technical and professional components of diagnostic tests covered under section 1861(s)(3) of the Social Security Act (the Act) and paid for under part 414 (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act). If a physician or other supplier bills for the technical component or

professional component of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control) and the diagnostic test is either purchased from an outside supplier or performed at a site other than the office of the billing physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the technical component or professional component of the diagnostic test may not exceed the lowest of the following amounts:

- The performing supplier's net charge to the billing physician or other supplier.
- The billing physician or other supplier's actual charge.
- The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

In revised §414.50(a)(2)(iii), we define the "office of the billing physician or other supplier" as medical office space where the physician or other supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined at §411.351 of this chapter), the "office of the billing physician or other supplier" is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally. Subsequent to the publication of the final rule with comment period, we received informal comments from various stakeholders who allege that the application of the rule is unclear with respect to whether certain types of space arrangements meet the definition of the "office of the billing physician or other supplier." Further, some of these stakeholders assert that patient access may be significantly disrupted due to the alleged inability of physician groups to render services in a cost-effective manner if medical office space that satisfies the "same building" test in §411.355(b)(2)(i) of this chapter for purposes of the physician self-referral rules in Part 411, Subpart J of this chapter and other medical office space in which patients are seen and that complies with the physician self-referral rules are subject to the anti-markup provisions in revised §414.50. That is, physician groups allege that, in situations in which they are subject to the anti-markup provisions and are limited to billing Medicare for the amount of the net charge imposed by the performing supplier, because they will not be able to realize a profit and will not be able to recoup their overhead costs, they will not be able to continue to provide diagnostic testing services to the same extent that they are currently providing such services.

We are concerned that the definition of "office of the billing physician or other supplier" may not be entirely clear and could have unintended consequences. Accordingly, in order for us to study the issues further, we are delaying until January 1, 2009, the applicability of the revised anti-markup provisions in §414.50, except for anatomic pathology diagnostic testing services furnished in space that : (1) is utilized by a physician group practice as a "centralized building" (as defined at §411.351 of this chapter) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a "same building" under §411.355(b)(2)(i) of this chapter. During the next 12 months, we plan to issue clarifying guidance as to what constitutes the "office of the billing physician or other supplier" or propose additional rulemaking, or both. Because anatomic pathology diagnostic testing arrangements precipitated our proposal for revision of the anti-markup provisions and remain our core concern, we are not delaying the date

of applicability with respect to anatomic pathology diagnostic testing services furnished in space that: (1) is utilized by a physician group practice as a “centralized building” (as defined at §411.351 of this chapter) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a “same building” under §411.355(b)(2)(i) of this chapter. In addition, we are not delaying the applicability of the revised anti-markup rule with respect to the technical component of any purchased diagnostic test. The anti-markup prohibition with respect to the technical component of purchased diagnostic tests is longstanding and was incorporated into the expanded and revised provision of §414.50. Accordingly, it will remain applicable to the technical component of any purchased diagnostic test.

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 effective date of a final rule, but we are not required to do so if the rule is procedural or interpretive. Where a delayed effective date is required, this requirement may be waived for good cause. We set forth below our finding of good cause for the waiver of notice and comment rulemaking and the waiver of a delayed effective date.

Our implementation of this action without opportunity for public comment and without a delayed effective date 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 and contrary to the public interest. We are implementing this delay of effective date as a result of our review of the informal comments on the final rule with comment period from various stakeholders. As discussed above, we understand from those comments that patient access for common diagnostic tests may be significantly disrupted unless we delay the effective date of revised §414.50 with respect to anatomic pathology diagnostic testing services furnished in space that: (1) is utilized by a physician group practice as a “centralized building” (as defined at §411.351 of this chapter) for purposes of complying with the physician self-referral rules; and (2) does not qualify as a “same building” under §411.355(b)(2)(i) of this chapter. Likewise, if we do not make this final rule effective upon publication, patient care may be significantly disrupted during the interim period between the issuance of the rule and a delayed effective date.

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 January 1, 2009, the majority of billing suppliers affected by the revised §414.50 do not have to comply with the revised requirements in §414.50.

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

Dated: _____

Kerry Weems,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Approved: _____

Michael O. Leavitt,
Secretary

BILLING CODE 4120-01-P