



HEALTH CARE FRAUD REPORT



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Self-Referral

Phase III Regs on Physician Self-Referrals Delayed Until March 2008, CMS Rule Says

The Centers for Medicare & Medicaid Services March 20 announced it is extending the publication deadline for the third phase of the Stark II final rule restricting physician referrals to entities with which they or their family members have a financial relationship (72 Fed. Reg. 13710).

Under a previously established three-year timeline, CMS was required to respond to public comments on the Phase II interim final rule from the March 26, 2004, *Federal Register* (69 Fed. Reg. 16053), and publish the Phase III final rule no later than March 26 of this year.

The notice extends the Phase III publication deadline through March 26, 2008, and allows the Phase II regulations to remain in effect until the final rule is published.

The Phase II interim final rule, which went into effect July 24, 2004, set forth the physician self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse, CMS said in the notice.

The Phase II regulations also addressed issues that remained open after the Phase I rulemaking, published in the Jan. 4, 2001, *Federal Register* (66 Fed. Reg. 856), and responded to comments on that earlier rule

'Exceptional Circumstances.' Sections 1871(a)(3)(B) and (a)(3)(C) of the Social Security Act allow for a one-year extension of the three-year publication timeline where there are "exceptional circumstances," CMS said in the notice.

"We are not able to meet the 3-year timeline for publication because we received extensive public comments requesting clarification of and revisions to the

physician self-referral regulations," CMS said. "Further, because the physician self-referral rules are jointly enforced by CMS, the [Department of Health and Human Services] Office of Inspector General, and the Department of Justice, substantial interagency coordination has been necessary."

While the notice extends the publication deadline for the Phase III final rule to March 26, 2008, an agency spokeswoman told BNA March 21 that CMS would publish the Phase III rule "as soon as it is ready."

Among matters Phase III of the Stark rule is expected to address are the underlying statute's applicability to the Medicaid program and whether the physician recruitment exception can be expanded, attorney John T. Brennan, Crowell & Moring LLP, Washington, said March 22 at the American Health Lawyers Association's Institute on Medicare and Medicaid Payment Issues in Baltimore. Brennan said the coming rule also could contain a narrower in-office ancillary services exception.

Brennan told BNA he agreed that CMS likely would issue the rule before the new March 2008 deadline. He commented that four years appeared to be a lengthy time frame for reviewing and responding to comments on Phase II, especially given CMS's "exhaustive" review and comment periods that preceded the release of Phase II.

In addition, Brennan said, there was a general sense in the health care industry that CMS did a good job in Phase II of giving flexibility for "dealing with the contours of the Stark law."

Nevertheless, he said the additional time likely would give CMS the opportunity to consider more carefully how it would address concerns about the physician recruitment exception, the vocational criteria under the in-office ancillary exception, issues related to the exception for indirect compensation arrangements, and how purely technical violations that result in no harm to the Medicare program should be handled.