

action no less often than every five years following initiation of that remedial action to ensure that human health and the environment are being protected. EPA has determined as a matter of policy that such reviews will also be conducted if a removal action leaves hazardous substances on site above levels that allow for unlimited use and unrestricted exposure and no remedial action has taken or will take place. Since ground water contamination remains at the Site above levels that allow for unlimited use and unrestricted exposure, EPA will use the five-year review process to ensure protection of human health and the environment. EPA completed the first five-year review of the Site on September 30, 2002. In that five-year review, EPA determined that the immediate threats have been addressed and the actions taken have been protective of human health and the environment. EPA plans to complete the next five year review prior to September 30, 2009.

E. Community Involvement

Public participation activities have been satisfied as required in CERCLA Section 113(k), 42 U.S.C. 9613(k), and CERCLA Section 117, 42 U.S.C. 9617. Documents in the deletion docket which EPA relied on for recommendation of the deletion from the NPL are available to the public in the information repositories.

V. Deletion Action

The EPA, with the concurrence of the Commonwealth of Pennsylvania, has determined that all appropriate responses under CERCLA have been completed, and that no further response actions, under CERCLA, other than O&M of the existing treatment system which will be completed under the 1984 PADER Agreement and five-year reviews, are necessary. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective February 14, 2005 unless EPA receives adverse comments by January 13, 2005 on a parallel notice of intent to delete published in the Proposed Rule section of today's **Federal Register**. If adverse comments are received within the 30-day public comment period on the proposal, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and the deletion will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete

and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: October 26, 2004.

Richard J. Kampf,

Acting Regional Administrator, Region III.

■ For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended by removing the site name “York County Solid Waste and Refuse Authority, Hopewell Township, PA.”

[FR Doc. 04–27168 Filed 12–13–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1003

RIN 0991–AB30

Medicare and State Health Care Programs; Fraud and Abuse: **OIG Civil Money Penalties Under the Medicare Prescription Drug Discount Card Program**

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: In accordance with section 1860D–31 of the Social Security Act, this rule finalizes OIG's new authority for imposing civil money penalties (CMPs) against endorsed sponsors under the Medicare prescription drug discount card program that knowingly engage in false or misleading marketing practices; overcharge program enrollees; or misuse transitional assistance funds.

DATES: The interim rule amending 42 CFR part 1003 became effective on June 18, 2004.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of External Affairs, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

I. Background

A. *OIG Civil Money Penalties*

In 1981, Congress enacted the civil money penalty statute, section 1128A of the Social Security Act (the Act) (42 U.S.C. 1320a–7a), as one of several administrative remedies to combat increases in fraud and abuse. The civil money penalty (CMP) law authorized the HHS Secretary and the Inspector General to impose CMPs and program exclusions on individuals and entities whose wrongdoing caused injury to HHS programs or their beneficiaries. Since 1981, the CMP provisions have been expanded to apply by reference to numerous types of fraudulent and abusive activities.

B. *The Medicare Prescription Drug, Improvement, and Modernization Act*

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, as enacted by Public Law 108–173 and codified in section 1860D–31 of the Act, provides for a voluntary prescription drug discount card program for Medicare beneficiaries entitled to benefits, or enrolled, under Part A or enrolled under Part B, excluding beneficiaries entitled to medical assistance for outpatient prescription drugs under Medicaid, including section 1115 waiver demonstrations. Eligible beneficiaries may access negotiated prices on prescription drugs by enrolling in drug discount card programs offered by Medicare-endorsed sponsors.¹ The Medicare drug discount card program is intended to serve as a transitional program providing immediate assistance to Medicare beneficiaries with prescription drug costs during calendar years 2004 and 2005 while preparations are made for implementation of the Medicare drug benefit under Medicare Part D in 2006.

The implementing regulations establishing the requirements for the MMA program were published in the **Federal Register** as an interim final rule with comment period by the Centers for

¹ Eligible beneficiaries may enroll in the Medicare drug discount card program beginning no later than 6 months after the date of enactment of MMA and ending December 31, 2005. After December 31, 2005, beneficiaries enrolled in the program may continue to use their drug discount card during a short transition period beginning January 1, 2006 and ending upon the effective date of a beneficiary's outpatient drug coverage under Medicare Part D, but no later than the last day of the initial open enrollment period under Part D.

Medicare & Medicaid Services (CMS) on December 15, 2003 (68 FR 69840).²

1. Eligibility Procedures and Enrollment

Sections 1860D–31(b)(1) and (2) of the Act, and 42 CFR 403.810(a) and (b) of the CMS regulations, establish the eligibility criteria for the Medicare drug discount card program and for transitional assistance. Section 1860D–31(f)(1)(A) of the Act directs the Secretary to specify the procedures for determining a beneficiary's eligibility for the Medicare drug discount card program or transitional assistance, and section 1860D–31(c)(1) directs the Secretary to establish a process for eligible beneficiaries enrolling in, and disenrolling from, an endorsed program. These provisions have been codified, respectively, in 42 CFR 403.810 and 403.811 of the CMS regulations.

2. Endorsed Sponsors

Section 1860D–31(a)(1)(A) of the Act requires the Secretary to endorse qualified applicants seeking to offer endorsed discount card programs to Medicare beneficiaries. MMA sets forth specific requirements that applicants must satisfy to be eligible for endorsement and that endorsed sponsors must meet to retain their endorsement. The obligations of endorsed sponsors related to eligibility determinations and enrollment are specifically set forth in section II.C.6. of the preamble to the interim final rule.

3. Transitional Assistance

Under MMA, certain low-income Medicare beneficiaries enrolled in the Medicare drug discount card program are eligible to receive transitional assistance of up to \$600 per year, which may be applied toward the cost of covered discount card drugs obtained under the program. Section 1860D–31(h)(1)(C) of the Act requires endorsed sponsors to administer the transitional assistance on behalf of CMS and to demonstrate to the Secretary that they have satisfactory arrangements to account for the transitional assistance provided to transitional assistance enrollees. These requirements are codified in 42 CFR 403.806(e).

4. Information and Outreach

Section 1860D–31(d)(2)(A) of the Act requires that each prescription drug card endorsed sponsor that offers an endorsed discount card program make available to beneficiaries eligible for the

discount card program—through the internet and otherwise—information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs, including information on enrollment fees and negotiated prices for covered discount card drugs. In addition, section 1860D–31(h)(7)(A) of the Act limits drug card endorsed sponsors to providing under their endorsements only products and services directly related to covered discount card drugs, or discounts on over-the-counter drugs; and section 1860D–31(h)(7)(B) prohibits endorsed sponsors from marketing, under their endorsements, any products and services other than those described in section 1860D–31(h)(7)(A). The requirements for information to be included in materials are contained in the CMS regulations at 42 CFR 403.806(g).

C. Civil Money Penalties Under Public Law 108–173

Section 1860D–31(i)(3) of the Act authorizes the imposition of CMPs against endorsed sponsors that knowingly engage in conduct that violates the requirements of section 1860D–31 of the Act or engage in false or misleading marketing practices. Section 403.820(b) of the CMS regulations interpreted this to mean that those endorsed sponsors that knowingly engage in conduct that violates the conditions of their endorsement agreement with the Department or that constitutes false or misleading marketing practices may be subject to CMPs.

The Department has divided the sanction authority between CMS and OIG. Where CMP authority is shared between CMS and OIG, the Department has assigned sanction authority to OIG for those violations that concern *misleading or defrauding* a beneficiary. The Department also assigned sanction authority to OIG for misuse of transitional assistance funds.³ On the other hand, CMS has the authority to impose CMPs in those instances where the endorsed sponsor's conduct constitutes *non-compliance with an operational requirement* not directly related to beneficiary protection. (Section 403.820(b)(2) of the CMS regulations sets forth a full listing of the CMS CMP authorities related to the

Medicare prescription drug card program.)

As a result, in accordance with CMS's Medicare prescription drug discount card implementing regulations (68 FR 69787; December 15, 2003), in addition to or in place of sanctions that CMS may impose, as set forth in 42 CFR 403.820(a), OIG has been authorized to impose CMPs against an endorsed sponsor whom it determines knowingly (as defined in 42 CFR 1003.102(e)):

- Misrepresented or falsified information in outreach material or comparable material provided to a program enrollee or other person;
- Charged a program enrollee in violation of the terms of the endorsement contract; or
- Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

OIG may impose CMPs of no more than \$10,000 for each of these violations. A violation is deemed to occur in each instance when an endorsed sponsor (1) provides misleading information to a program enrollee or other person; (2) overcharges a program enrollee; or (3) misuses the transitional assistance funds of a program enrollee. Appeal rights will be afforded in accordance with the appeal procedures set forth in 42 CFR parts 1003 and 1005.

II. Summary Provisions of the Interim Final Rule With Comment Period

On May 19, 2004, we published in the **Federal Register** (69 FR 28842) an interim final rule with comment period to address these new OIG civil money penalty authorities. The interim final rule amended 42 CFR part 1003 as follows:

- In § 1003.100, Basis and purpose, we revised paragraphs (a) and (b) to state the broad purpose of these new CMP authorities.
- In § 1003.101, Definitions, we added a definition for the term “transitional assistance,” consistent with the definition in 42 CFR 403.802.
- In § 1003.102, Basis for CMPs and assessments, we added new paragraphs (b)(17), (b)(18) and (b)(19) to cross-reference the implementing CMS regulations and OIG's authority to impose penalties for violations.
- In § 1003.103, Amount of penalty, we added a new paragraph (k) to address the \$10,000 maximum penalty amounts for each of these violations.

The interim final rule noted that in addition to the CMPs set forth above, a card sponsor's misuse of the Medicare name or emblem may subject them to CMPs in accordance with 42 U.S.C.

² Section 902 of MMA has established timelines for the publication of the Medicare rules under section 1871(a) of the Act. This provision requires CMS to publish a final rule within 3 years of the publication of the interim final rule.

³ Transitional assistance, as defined in § 403.802 of the CMS regulations, refers to the subsidy funds that transitional enrollees may apply toward the cost of covered discount card drugs in the manner described in § 403.808(d).

1320b–10 and OIG regulations at § 1003.102(b)(7), which prohibit the misuse of the Medicare name and emblem. In general, in accordance with the statute and the implementing regulations, OIG may impose penalties on any person who misuses the term “Medicare,” or other names associated with DHHS in any item constituting a communication in a manner which the person knows or should know gives the false impression that the item is approved, endorsed, or authorized by the Department. Violators are subject to fines of up to \$5,000 per violation or, in the case of a broadcast or telecast violation, \$25,000.

III. Analysis of and Responses to Public Comments

We received no public comments in response to the May 19, 2004 interim final rule.

IV. Provisions of the Final Regulations

The provisions of this final rule are identical to the provisions of the May 19, 2004 interim final rule with comment period.

V. Regulatory Impact Statement

A. Regulatory Analysis

We have examined the impacts of this rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

1. Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any given year). This is not a major rule as defined at 5 U.S.C. 804(2), and it is not economically significant since it would not have a significant effect on program expenditures and there would be no additional substantive cost to implement the resulting provisions. OIG has significant experience in enforcing CMPs for a wide variety of violations and fraudulent conduct. Over the past three fiscal years (FYs), total CMPs levied by OIG for various violations and fraudulent conduct has averaged about \$2.2 million annually (\$1.1 million in FY 2001; \$2.4 million in FY 2002; and \$3.1 million in FY 2003). In addition, the revisions to 42 CFR part 1003 set

forth in this rule are designed to further clarify statutory requirements, and hence the economic effect of these regulatory provisions should impact only those limited few endorsed sponsors that would perhaps engage in prohibited behavior in violation of the statute. Given OIG's enforcement history and the nature of the entities subject to CMPs, we do not believe that these regulations will result in a significant economic impact or have an appreciable effect on the economy or on Federal or State expenditures.

2. Regulatory Flexibility Act

The RFA, and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered to be small entities by having revenues of \$6 million to \$29 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered to be small entities. In addition, section 1102(b) of the Social Security 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 providers. This analysis must conform to the provisions of section 604 of the RFA.

Because of the requirements to be an endorsed sponsor, we anticipate that few, if any, endorsed sponsors will be small entities and none will be rural providers. However, even if some sponsored entities are small entities, we believe that the aggregate economic impact of this rulemaking is minimal since it is the nature of the conduct and not the size or type of the entity that would result in a violation of the statute and the regulations. As a result, we have concluded that this rulemaking rule should not have a significant impact on the operations of a substantial number of small or rural providers, and that a regulatory flexibility analysis is not required for this rulemaking.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. As indicated, these proposed revisions comport with congressional and statutory intent and

clarify the Department's legal authorities against those who defraud or otherwise act improperly against the Federal and State health care programs. As a result, we believe that there are no significant expenditures required by these revisions that would impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of \$110 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

4. Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

The Office of Management and Budget (OMB) has reviewed this final rule in accordance with Executive Order 12866.

B. Paperwork Reduction Act

The provisions of this rulemaking impose no express new reporting or recordkeeping requirements on health care providers or endorsed sponsors.

List of Subjects in 42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties, Social security.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ Accordingly, the interim final rule with comment period amending 42 CFR part 1003, which was published on May 19, 2004 in the **Federal Register** at 69 FR 28842–28846 is adopted as a final rule without change.

Dated: August 23, 2004.

Lewis Morris,

Chief Counsel to the Inspector General.

Approved: November 9, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04–27341 Filed 12–13–04; 8:45 am]

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