

package, including a Responsiveness Summary in the Site repositories.

DATES: The direct final action published on July 7, 2005, at 70 FR 129, is withdrawn as of September 1, 2005.

ADDRESSES: Comprehensive information on the Site, as well as the comments that were received during the comment period are available through the public docket contained at: U.S. Environmental Protection Agency, Region 2, Superfund Records Center, 290 Broadway, 20th Floor, New York, New York 10007-1866, (212) 637-4308. Hours: 9 a.m. to 5 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Isabel Rodrigues, Remedial Project Manager, U.S. EPA Region 2, 290 Broadway, 20th Floor, New York, New York 10007-1866, (212) 637-4248; Fax Number (212) 637-4284; E-mail address: Rodrigues.Isabel@EPA.GOV.

SUPPLEMENTARY INFORMATION:

Comprehensive information about the Site is available for viewing and copying at the Site information repositories located at:

U.S. Environmental Protection Agency, Region 2, Superfund Records Center, 290 Broadway, Room 1828, New York, New York 10007-1866, (212) 637-4308. Hours: 9 a.m. to 5 p.m., Monday through Friday; by appointment

and,

Hyde Park Free Public Library, 2 Main Street, Hyde Park, NY 12538. Hours: 9 a.m. to 8 p.m., Monday and Tuesday; 12 to 8 p.m., Wednesday and Thursday; 9 a.m. to 2 p.m., Saturday.

List of Subjects in 40 CFR Part 300

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

Dated: August 19, 2005.

Dore Laposta,

Acting Regional Administrator, Region II.
[FR Doc. 05-17435 Filed 8-31-05; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS-4063-F]

RIN 0938-AN97

Medicare Program; Medicare Prescription Drug Discount Card; Revision of Marketing Rules for Endorsed Drug Card Sponsors

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

ACTION: Final rule.

SUMMARY: This final rule will revise the current limitations prohibiting an endorsed drug card sponsor from marketing its Part D plans to its drug card enrollees. This revised rule will give the current drug card sponsors the ability to market to their enrollees Part D plans that are either offered by the same endorsed drug card sponsor or an affiliated organization of the same endorsed drug card sponsor. We are making these changes after considering the public comments received regarding the need to ensure a smooth transition from the drug card to the Medicare Prescription Drug Benefit.

DATES: *Effective Date:* These regulations are effective on October 1, 2005.

FOR FURTHER INFORMATION CONTACT: Jennifer Shapiro, (410) 786-7407.

SUPPLEMENTARY INFORMATION:

Availability of Final Rule

Electronic Copies: An electronic copy of this document may be downloaded using a modem and suitable communications software. Internet users may reach CMS's Web page at

- <http://www.cms.hhs.gov/regulations>;
- <http://www.regulations.gov>; or
- <http://www.gpoaccess.gpo/nara/index.html>.

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I. Background

The Medicare drug discount card program was established by section 101, subpart 4, of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and is codified in section 1860D-31 of the Social Security Act (the "Act"). On December 15, 2003, in accordance with section 105(c)(1)(C) of the Act, we published the interim final rule with comment period (hereafter referred to as "interim final rule") for the Medicare drug discount card program on December 15, 2003 (68 FR 69840).

The interim final rule at § 403.813(a) addresses marketing limitations applicable to endorsed discount card sponsors in accordance with section 1860D-31(h)(7)(B) of the Act. Under these marketing limitations, an endorsed sponsor may only market those products and services offered under its endorsed program that are inside the scope of endorsement and permitted under the HIPAA Privacy Rule.

After considering the public comments on these issues we agree with the commenters that this policy does not comply with the intent of the Medicare Modernization Act which directs the Secretary to facilitate efficient enrollment into Part D plans. This final rule allows an endorsed card sponsor to market information to its Medicare drug card enrollees concerning its Part D plans offered by the endorsed card sponsor or an affiliated organization. This change will increase Medicare beneficiaries' awareness and knowledge of Part D plans, thereby facilitating a smooth transition from the Medicare Prescription Drug Discount Card Program to the Medicare Prescription Drug Benefit.

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires, in part, that the Secretary, in consultation with the Director of the Office of Management and Budget establish and publish timelines for the publication of Medicare final regulations based on the previous

publication of a Medicare proposed or interim final regulation. Section 902(a)(1) of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

Therefore, we believe that the final rule is in accordance with the Congress's intent to ensure timely publication of final regulations.

II. Discussion of the Provisions of the Final Rule

A. Provision of the Interim Final Rule

Section 403.813(a)(1) of the December 15, 2003 interim final rule provides that an endorsed sponsor may only market those products and services offered under its endorsed program that are inside the scope of endorsement as defined in § 403.806(h) and permitted under § 403.812(b) (pertaining to the HIPAA privacy requirements). Section 403.806(h)(2) defines products and services inside the scope of the Medicare endorsement as products and services that are: (1) Directly related to covered discount card drugs or discounts for over-the-counter drugs; and (2) offered for no additional fee (other than the enrollment fee).

Section 403.813(a) of the interim final rule provides that an endorsed sponsor may not request that a drug card enrollee or an individual seeking to enroll in its endorsed discount card program authorize the endorsed sponsor to use or disclose individually identifiable health information for marketing other products or services not otherwise allowed under § 403.813(a)(1) (§ 403.813(a)(2)); that an endorsed sponsor may not commingle any materials related to the marketing of products or services allowed under § 403.813(a)(1) with other marketing materials (§ 403.813(a)(3)); and that following termination of an endorsed sponsor's endorsement under § 403.820(c), (d) or (e) or termination of the Medicare Drug Discount Card and Transitional Assistance Program, a drug card enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for purposes of marketing any product or service (§ 403.813(a)(4)).

These provisions on marketing limitations are based on section 1860D-31(h)(7)(B) of the Act, which states that an endorsed sponsor may market a product or service under the program only if the product or service is directly related to a covered discount card drug or a discount price for a non-

prescription drug, and on section 1860D-31(h)(8) of the Act, which charges us with protecting and promoting the interests of discount card eligible individuals.

In addition to the specific requirements of the Act that the product or services be directly related to a covered discount card drug or a discount on a non-prescription drug, § 403.806(h)(2) of the interim final regulation further requires that products and services inside the scope of endorsement are limited to products or services offered for no additional charge because, as we stated in the preamble, we were concerned that beneficiaries would be unable to access negotiated prices and transitional assistance, as intended by the Congress, if endorsed sponsors required that they pay additional fees for optional products and services. Further, we believed that permitting endorsed sponsors to charge additional fees could be confusing to beneficiaries. Also, if we were to allow endorsed sponsors to charge additional fees, we believe beneficiaries might, in effect, be charged annual enrollment fees higher than the \$30 limit mandated by section 1860D-31(c)(2)(B) of the Act, especially if endorsed sponsors were to condition enrollment in their endorsed programs on beneficiaries paying these additional fees.

III. Analysis of and Response to Public Comments

A. Overview of Comments

We received 49 public comments concerning the Medicare drug discount card program. Of these comments, 8 timely comments were received that addressed issues on marketing and information and outreach in two separate areas. A summary of the major issues and our responses are as follows:

Comment: Of the 8 comments related to marketing, 4 of the comments expressed the need to minimize the potential for beneficiary confusion and encouraged us to allow sponsors to provide enrollees with valuable health education and other information. One commenter encouraged us to ensure that the regulation reflect the intent of the conferees that there be a seamless transition between the drug card program and the Medicare Prescription Drug Benefit. The other commenters encouraged us to create guidelines concerning marketing materials and fairness in marketing. None of the comments were opposed to us issuing additional guidelines.

Response: We agree with the commenters' concerns regarding the need to minimize beneficiary confusion

by allowing endorsed sponsors to distribute certain important and valuable information to beneficiaries, including information which will promote a smoother transition for drug card enrollees from the Medicare-approved prescription drug discount card program to the Medicare Prescription Drug Benefit. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report clearly articulates this intent where the report discusses the history of the drug card program and its original purpose as an interim step toward prescription drug coverage for Medicare beneficiaries. Furthermore, a separate discussion appearing in the Conference Report addressing Part D emphasizes the need to facilitate outreach to beneficiaries to ensure participation in Medicare prescription drug coverage and to reduce barriers associated with marketing to minimize the potential for confusion and to facilitate enrollment into the Medicare Prescription Drug Benefit.

We agree with the commenter that encouraged us to ensure that the regulation reflect the intent of the conferees that there be a seamless transition between the drug card program and the Medicare Prescription Drug Benefit. As we move toward implementation of the Medicare Prescription Drug Benefit, it has become evident that certain aspects of the interim final rule are creating unintended consequences for Medicare beneficiaries and endorsed card sponsors. Specifically the marketing limitations at § 403.813(a) contradict Congressional intent for the Medicare prescription drug discount card program to serve as a transitional program to the Medicare Prescription Drug Benefit. As previously mentioned, the provisions in the interim final rule prevent an endorsed drug card sponsor from marketing its Part D plans to its drug card enrollees. Moreover, we agree that clarifications and modifications to the marketing limitation rules would reduce beneficiary confusion as the drug card program concludes and the Medicare Prescription Drug Benefit begins. Finally, it is crucial that Medicare beneficiaries have complete and accurate information on the forthcoming Medicare Prescription Drug Benefit. We agree with all comments that expressed an important aspect of ensuring that beneficiaries receive this information is by allowing a beneficiary's drug card sponsor, an entity with which the beneficiary is familiar and has an existing relationship to provide educational and related information

about the transition to the Medicare prescription drug benefit and the Part D plans that will be offered by the endorsed sponsor or its affiliated organizations. Allowing endorsed sponsors to provide information to their members about certain Part D plans available to them is a component of the Secretary's strategy for meeting his obligation under sections 1851(d)(1) and 1860D-1(c) of the Act to promote an active, informed selection by beneficiaries among their Medicare coverage options.

As a result, this final rule amends § 403.813(a)(1) to allow an endorsed card sponsor to market to its drug card enrollees not only items and products offered within the scope of endorsement, but also Part D plans offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

Section 1860D-31(h)(7)(B) of the Act provides that endorsed sponsors may only market products or services "under the program" if they directly relate to either a covered discount card drug or discount prices available for over-the-counter drugs. We believe products or services marketed "under the program" include not only those within the scope of endorsement, but also Part D plans. Because information about Part D plans offered by an endorsed sponsor or its affiliated organizations would reinforce the purpose of the Medicare prescription drug discount card program to serve as a transitional program to the Medicare prescription drug benefit, we believe marketing of such Part D plans constitutes marketing of a product or service under the Medicare prescription drug discount card program. In addition, we believe Part D plans are directly related to covered discount card drugs, as evidenced by the fact that the statutory definition of a covered drug under section 1860D-31(a)(4)(a) of the Act cross-references the definition of covered Part D drug under section 1860D-2(e) of the Act, and thus is identical to the definition of covered Part D drug.

Therefore, we amend the marketing limitations in § 403.813(a)(1) by explicitly stating that Part D plans offered by an endorsed sponsor or its affiliated organization may be directly marketed by the endorsed sponsor to its enrollees. We will not otherwise change the marketing limitation provisions of the interim final rule because we maintain that section 1860D-31(h)(8) of the Act charges us with protecting and promoting the interests of Medicare beneficiaries who may be unable to access negotiated prices and transitional assistance, as intended by the Congress,

if endorsed sponsors require that they pay additional fees for optional products and services, such as Part B supplies. Furthermore, permitting endorsed sponsors to charge additional fees for products and services outside the scope of the endorsement could be confusing to beneficiaries. Also, if we were to allow endorsed sponsors to charge additional fees, we believe beneficiaries might, in effect, be charged annual enrollment fees higher than the \$30 limit mandated by section 1860D-31(c)(2)(B) of the Act, especially if endorsed sponsors were to condition enrollment in their endorsed programs on beneficiaries paying these additional fees. The amendment to allow marketing of Part D plans makes sense in this instance because in this context it does not negate the intent or practice of the original restriction (for example, regarding Part B supplies). We believe that this amendment is consistent with the intent of the Congress, which would reduce confusion and facilitate a smooth transition to the Medicare Prescription Drug Benefit which protects and promotes interests of all Medicare beneficiaries. Also, this exception will not affect the enrollment fee.

We will require information and outreach (marketing) materials discussing Part D plans that are disseminated by endorsed drug card sponsors or their affiliated organizations to the endorsed sponsors' drug card enrollees to be approved through the Medicare Prescription Drug Benefit review process as described under § 423.50 as opposed to the drug card review process. This change addresses comments that CMS should create guidelines concerning marketing materials and fairness in marketing, and comments that we should endeavor to reduce beneficiary confusion. Using a single review process, with consistent guidelines specifically developed for Part D materials, is the optimal process for ensuring adherence to guidelines and reducing beneficiary confusion. Therefore, we are amending § 403.806(g)(5) to state that all materials related to Part D plans being offered by the same endorsed sponsor or its affiliated organization must comply with the requirements described in § 423.50.

We are cognizant that constraints and clarifications must be made about whose products an endorsed card sponsor may provide marketing materials about to its drug card enrollees. An endorsed drug card sponsor may market a Part D plan offered by it or its affiliated organization. By allowing an endorsed card sponsor to market Part D plans

offered by an affiliated organization of the endorsed sponsor, we are treating Part D plans offered by an affiliated organization of the endorsed sponsor as a product or service under the program. Allowing such treatment gives practical effect to the Congressional intent of a smooth transition between the drug card program and the Medicare Prescription Drug Benefit because it recognizes that rather than offer Part D plans through the same legal entity, organizations may have legitimate business and legal reasons for offering Part D plans through another legal entity, or may offer Part D plans through different legal entities based on geography (for example, Part D plans in region A offered through legal entity A, Part D plans in region B offered through legal entity B). We do not want to constrain an organization's ability to offer its Part D plans through the legal entities that make the most sense given other business and legal considerations. A Part D Plan is not offered under the program, however, if the plan is offered by an organization that is not the endorsed sponsor or an affiliated organization of the endorsed sponsor.

Therefore, we are adding a definition of affiliated organization to § 403.802. This definition would allow an endorsed drug card sponsor to market to its enrollees a Part D plan of an affiliated organization if the organization is legally separate and at least one of the following conditions is met:

(1) Both the affiliated organization and the endorsed drug card sponsor are under common control (common control exists if another entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of the affiliated organization and the endorsed drug card sponsor);

(2) The affiliated organization is under the control of the endorsed drug card sponsor or the affiliated organization controls the endorsed drug card sponsor (control exists if an entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of another entity); or

(3) The affiliated organization possesses an ownership or equity interest of 5 percent or more in the endorsed drug card sponsor on both: The date on which the endorsed drug card sponsor markets the affiliated organization's Part D plan; and the date on which the endorsed drug card sponsor signed its endorsement contract with us. This is to ensure that the entity is currently affiliated with the endorsed sponsor and ensures that a Part D plan does not acquire a drug card sponsor

after publication of this rule in order to gain access to the sponsors' drug card enrollees.

We will not permit endorsed sponsors to market to their drug card enrollees Part D plans offered by unaffiliated third parties (as described by this new section) because an endorsed sponsor's marketing of a Part D plan offered by a third party generally is prohibited by the HIPAA privacy rule absent authorization from the individual.

As important, information that is provided by a drug card sponsor about its or its affiliate's Part D plan will, we believe, be more likely to promote a smoother transition to Part D since the beneficiary is familiar with the endorsed sponsor, and we anticipate that there will be similarities between the Medicare drug discount card and the Part D plan (for example, similar pharmacy network, similar formulary).

Furthermore, under certain circumstances, HIPAA may prohibit an endorsed sponsor's marketing of Part D plans offered by certain affiliated entities. Thus, any use or disclosure of enrollee's protected health information by an endorsed card sponsor must comply with all Federal laws, including the HIPAA Privacy Rule.

IV. Provisions of the Final Regulations

Except as mentioned below, this final rule incorporates the marketing and information and outreach provisions of the interim final rule. This rule creates a definition at section 403.802 pertaining to the requirements that must be met before an organization will be considered an affiliated organization to an endorsed drug card sponsor.

We are also revising § 403.813 to permit an endorsed card sponsor to market to its drug card enrollees a Part D plan offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

We will require information and outreach (marketing) materials provided by an endorsed drug card sponsor that are discussing Part D plan offerings to be approved through the Medicare Prescription Drug Benefit review process as described under § 423.50.

V. 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).

VI. Regulatory Impact

We have examined the impact of this rule as required by Executive Order 12866 September 1993, Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is 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 (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the 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 hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule will have no consequential effect on the

governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1359b-3 and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. In Subpart H, § 403.802 is amended by adding in alphabetical order the definitions of "Affiliated organization" and "Part D plan" to read as follows:

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

§ 403.802 Definitions.

* * * * *

Affiliated organization means an organization that is a legally separate entity from the endorsed drug card sponsor and meets one of the following conditions:

(1) The organization and the endorsed drug card sponsor are under common control. Common control exists if another entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of the organization and the endorsed drug card sponsor.

(2) The organization is under the control of the endorsed drug card sponsor or the organization controls the endorsed drug card sponsor. Control exists if an entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of another entity.

(3) The organization possesses an ownership or equity interest of 5 percent or more in the endorsed drug card sponsor on both the date on which the endorsed drug card sponsor markets the organization's Part D plan, and the date on which the endorsed drug card sponsor signed its endorsement contract with CMS.

* * * * *

Part D plan has the meaning given the term at § 423.4.

* * * * *

■ 3. Section 403.806(g)(5) is amended by—

- A. Revising paragraph (g)(5)(i).
- B. Revising paragraph (g)(5)(iii).
- C. Adding paragraph (g)(5)(vi).

The revisions and addition read as follows:

§ 403.806 Sponsor requirements for eligibility for endorsement.

* * * * *

(g) * * *

(5) * * *

(i) Comply with the Information and Outreach Guidelines published by CMS except as provided in paragraph (g)(5)(vi) of this section.

* * * * *

(iii) If CMS does not disapprove the initial submission of information and outreach materials within 30 days of receipt of these materials, the materials are deemed approved under paragraph (g)(5)(ii) of this section.

* * * * *

(vi) All materials related to products and services that are Part D plans must comply with the requirements specified in § 423.50 of this chapter.

* * * * *

■ 4. Section 403.813 is amended by revising paragraph (a)(1) to read:

§ 403.813 Marketing limitations and record retention requirements.

(a) *Marketing limitations.* (1) An endorsed sponsor may only market the following:

(i) Those products and services offered under the endorsed program that are inside the scope of endorsement defined in § 403.806(h) and permitted under § 403.812(b).

(ii) A Part D plan offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: July 8, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 10, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–17424 Filed 8–29–05; 11:58 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4069–F3]

RIN 0938–AN06

Medicare Program; Establishment of the Medicare Advantage Program

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

ACTION: Final rule; correcting amendment; partial stay of effectiveness.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on January 28, 2005 entitled “Establishment of the Medicare Advantage Program.” It also stays several amendments made in the previous rule.

EFFECTIVE DATES: This final rule is effective March 22, 2005. Sections 422.152(a)(1) and (c), 422.156(b)(7), 422.316, and 422.527 are stayed from September 1, 2005 until January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Christopher McClintick, (410) 786–4682.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 05–1322 of January 28, 2005 (70 FR 4588), there were several errors that we identify in the “Summary of Errors” section and correct in the “Correction of Errors” section below. The provisions in this correcting amendment are effective as if they were included in the final rule published January 28, 2005. Accordingly, the corrections are effective retroactive to March 22, 2005, the effective date of most of the provisions of the January 28, 2005 final rule, except for those provisions that are specifically designated in the **EFFECTIVE DATES** section as being stayed effective September 1, 2005 until January 1, 2006.

II. Summary of Errors

In the January 28, 2005 final rule, on page 4588, we inadvertently omitted from the list of provisions that will become effective January 1, 2006, the following provisions relating to changes in the quality improvement provisions in subpart D: §§ 422.152(a)(1) and (c), and 422.156(b)(7). These provisions implement changes to section 1852(e) of the Social Security Act (the Act) that, under section 722(c) of the MMA, apply to contract years beginning on and after January 1, 2006. Sections 422.152(a)(1) and (c) concern the requirement that an MA organization must have a chronic care improvement program for each plan it offers. In order to clarify that these provisions of the quality improvement requirements do not apply to contracts previous to contract periods beginning January 1, 2006, and to comply with the Act, we are staying the effective dates of §§ 422.152(a)(1) and (c) until January 1, 2006. We are also staying § 422.156(b)(7), a quality improvement provision concerning deemable requirements and Part D prescription drug programs offered by MA programs. We also inadvertently omitted from the list of provisions that will become effective January 1, 2006, the following provisions relating to arrangements with federally qualified health centers: §§ 422.316 and 422.527. Section 237(c) of the MMA provides that these changes apply to services provided on or after January 1, 2006, and contract years beginning on or after that date. In order to clarify the effective dates of these provisions and to bring our regulations into conformance with the statute, we are also staying the effective dates of §§ 422.316 and 422.527 until January 1, 2006.

On page 4676, we clarify that an MA organization and not a practitioner is responsible for providing a written notice to the beneficiary when an adverse decision is made in an office setting. In other words, if an enrollee requests an explanation of a practitioner's denial of an item or service, in whole or in part, the MA organization is responsible for giving the enrollee a written notice. We are making a corresponding change to § 422.568(d) of the regulation text.

On page 4681, we inadvertently specified 72 hours as the timeline for the expedited grievance process MA organizations must establish for complaints involving certain procedural matters in the appeals process. In that discussion, we were referring to 42 CFR 422.564(d), which we redesignated in the final rule as § 422.564(f), but did not otherwise change. The timeline, as