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Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

**Medicare Program; Revisions to the
Medicare Advantage and Part D
Prescription Drug Contract
Determinations, Appeals, and
Intermediate Sanctions Processes; Final
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 422 and 423**

[CMS-4124-FC]

RIN 0938-AO78

Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period.

SUMMARY: This rule with comment period finalizes the Medicare program provisions relating to contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors, including eliminating the reconsideration process for review of contract determinations, revising the provisions related to appeals of contract determinations, and clarifying the process for MA organizations and Part D plan sponsors to complete corrective action plans. In this final rule with comment period, we also clarify the intermediate sanction and civil money penalty (CMP) provisions that apply to MA organizations and Medicare Part D prescription drug plan sponsors, modify elements of their compliance plans, retain voluntary self-reporting for Part D sponsors and implement a voluntary self-reporting recommendation for MA organizations, and revise provisions to ensure HHS has access to the books and records of MA organizations and Part D plan sponsors' first tier, downstream, and related entities. Although we have decided not to finalize the mandatory self-reporting provisions that we proposed, CMS remains committed to adopting a mandatory self-reporting requirement. To that end, we are requesting comments that will assist CMS in crafting a future proposed regulation for a mandatory self-reporting requirement.

DATES: *Effective date:* These regulations are effective on January 4, 2008, except for the amendments to §§ 422.503, 422.504, 423.504, and 423.505, which are effective January 1, 2009.

Comment Period: We will consider comments on the mandatory self-reporting provisions discussed in section II of this final rule with comment period at the appropriate

address, as provided below, no later than February 4, 2008.

ADDRESSES: In commenting, please refer to file code CMS-4124-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-4124-FC, P.O. Box 8020, Baltimore, MD 21244-8020.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-4124-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Christine Reinhard, (410) 786-2987.

Kevin Stansbury, (410) 786-2570.

Stephanie Kaisler, (410) 786-0957, for issues regarding voluntary self-reporting, access to records, and compliance.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on mandatory self-reporting to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-4124-FC and "self-reporting."

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Abbreviations

Because of the many terms to which we refer by abbreviation in this final rule with comment period, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ALJ	Administrative Law Judge
BBA	Balanced Budget Act of 1997
CAP	Corrective Action Plan
CMP	Civil Money Penalty
CMS	Centers for Medicare & Medicaid Services
DAB	Departmental Appeals Board
FWA	Fraud, Waste, and Abuse
HHS	U.S. Department of Health and Human Services
MA	Medicare Advantage
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
M+C	Medicare + Choice
OIG	Office of the Inspector General

PBM Pharmaceutical Benefit Manager
PDE Prescription Drug Event

I. Background

On May 25, 2007, we published a proposed rule in the **Federal Register** (72 FR 29368, hereafter referred to as the proposed rule), setting forth the proposed provisions relating to contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors, intermediate sanction and civil money penalty (CMP) provisions, compliance plans, mandatory self-reporting, and provisions to ensure the Department of Health and Human Services (HHS) has access to the books and records of MA organizations and Part D plan sponsors' first tier, downstream, and related entities. In this final rule with comment period we are finalizing the majority of the provisions of the proposed rule, with some clarifications in response to public comments. At this time, we are not finalizing the proposed provision for mandatory self-reporting of potential fraud and abuse, but we intend to issue future rulemaking on this topic, as discussed below in section II.

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) into law on December 8, 2003. The MMA established the Medicare prescription drug benefit program and renamed the Medicare+Choice (M+C) program the Medicare Advantage (MA) program. In accordance with the MMA, we revised the existing Medicare regulations applicable to the MA program at 42 CFR part 422 and published regulations governing the prescription drug benefit program at 42 CFR part 423.

As we have gained more experience with MA organizations and Part D prescription drug plan sponsors, we proposed clarifications to the Medicare program provisions relating to contract determinations involving MA organizations and Medicare Part D prescription drug plan sponsors, including eliminating the reconsideration process for review of contract determinations; revising the provisions related to appeals of contract determinations and clarifying the process for MA organizations and Part D plan sponsors to complete corrective action plans. We proposed clarifications to the intermediate sanction and civil money penalty (CMP) provisions that apply to MA organizations and

Medicare Part D prescription drug plan sponsors. We also proposed changes in both programs to clarify elements of the compliance plan requirements, such as training and education, and changes to clarify our access to the books and records of a MA organization or Part D sponsor's first tier, downstream, and related entities. Finally, we proposed a self-reporting requirement as part of both MA organization and Part D sponsor's compliance plans. We have decided at this time not to finalize the provision requiring mandatory self-reporting of potential fraud and misconduct. Until such time as such a provision is finalized, we have chosen to retain voluntary self-reporting for Part D sponsors and implement a recommendation for voluntary self-reporting for MA Organizations.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) established the M+C program. Under section 1851(a)(1) of the Social Security Act (the Act), every individual with Medicare Parts A and B, except for individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where the beneficiary lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices.

The Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), amended the M+C provisions of the BBA. Further amendments were made to the M+C program by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), enacted December 21, 2000.

The President signed the MMA into law on December 8, 2003. Title I of the MMA added new sections 1860D-1 through 1860D-42 to the Act creating the Medicare Prescription Drug Benefit program, a landmark change to the Medicare program since its inception in 1965.

Sections 201 through 241 of Title II of the MMA made significant changes to the M+C program. As directed by Title II of the MMA, we renamed the M+C program the MA program. We also revised our regulations to include new payment and bidding provisions based largely on risk, to recognize the addition of regional Preferred Provider Organization (PPO) plans, to address the provision of prescription drug benefits

under the Medicare Part D regulations, and to make other changes.

The MMA, at section 1860D-12(b)(3) of the Act, directed that specific aspects of the MA contracting requirements apply to the prescription drug plan benefit program. Consequently, the processes for contract determinations and the administrative appeal rights in the two programs are virtually identical.

We published the regulations implementing the MA and prescription drug benefit regulations separately, though their development and publication were closely coordinated. On August 3, 2004, we published proposed rules for the MA program (69 FR 46866) and prescription drug benefit program (69 FR 46632). The final regulations implementing both the MA and prescription drug programs were published on January 28, 2005 (70 FR 4588 and 70 FR 4194, respectively). We revised some of our proposed provisions in the final rules in response to public comments. For further discussion of the revisions we made to our proposed rules, see the final rules cited above. We have not issued previous guidance, other than regulatory requirements regarding contract determinations, corrective action plans, contract determination appeals, intermediate sanctions, or CMPs. However, we have published guidance on how to develop an effective fraud, waste and abuse (FWA) prevention program. This guidance is found in Chapter 9 of the Prescription Drug Benefit Manual entitled "Part D Program to Control Fraud, Waste and Abuse." This rule makes further revisions to the MA and prescription drug regulations.

II. Summary of the Provisions of the Proposed Rule and Analysis of and Response to Public Comments

In response to the publication of the May 25, 2007 proposed rule, we received 58 timely items of correspondence from the public. We received numerous comments from various trade associations and health insurance providers. Comments also originated from other providers, suppliers, and practitioners, health care consulting firms, and private citizens.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the impact analysis), and our responses to the comments are set forth below. Comments related to the paperwork burden and the impact analysis are addressed in the Collection of Information and Impact Analysis Sections in this preamble.

A. General Comments on the Proposed Rule

Comment: We received a question related to the applicability of the Part 423 provisions to Medicare cost contractors who offer Part D plans.

Response: Cost plans, per 42 CFR 417.440(b)(2)(ii), which offer a Part D prescription drug program as an optional supplemental benefit, must offer the benefits “in accordance with applicable requirements under Part 423.” The current proposed revisions do not change the existing regulations. Therefore, the Part 423 regulations would continue to apply to cost plans just as they have prior to the publication of this rule.

B. Proposed Changes to the Medicare Advantage Program and the Prescription Drug Benefit Program

Our experience involving contract determinations, appeals, intermediate sanctions, and CMPs since the enactment of the BBA of 1997 led us to propose changes to our regulations. In the proposed rule, we proposed to simplify the procedures for contract determinations; to clarify the procedures regarding submission and review of corrective action plans; to clarify the procedures for imposition of intermediate sanctions and CMPs; and to clarify the procedures to appeal CMPs imposed under the MA and Part D programs.

In addition, we proposed revisions to the appeal procedures for all types of contract determinations, which would make these procedures identical for decisions not to contract, nonrenewals,

and terminations. We proposed to provide for enhanced beneficiary protections when we decide to terminate a plan on an expedited basis.

In the proposed rule, we also proposed changes and clarifications to Subpart K, contract requirements under the MA and Part D programs. We proposed changes to clarify HHS’ access to the books and records of a MA organization or Part D sponsor’s first tier, downstream, and related entities. We also proposed changes to clarify that certain elements of the compliance plan apply to first tier, downstream, and related entities. We also proposed mandatory self-reporting in both the MA and Part D programs, but we are not finalizing the provision at this time.

Below, we set forth the final regulatory changes, and corresponding final implementation dates:

Regulation change	Implementation date
Incorporation of Fraud, Waste, and Abuse Prevention Measures into Compliance Plan	1/1/2009
Requirement to apply Compliance Plan’s training and communication requirements to first tier, downstream, and related entities	1/1/2009
Voluntary procedures for MA organizations for self-reporting potential fraud and misconduct	1/1/2009
Requirement to obtain access to Part D sponsor’s first tier, downstream, and related entity’s books and records through contractual arrangements	1/1/2009
Elimination of CMS’ requirement to inform organization of renewal	1/4/2008
Change date of CMS’ notification of non-renewal from May 1 to August 1	1/4/2008
Provide for same administrative appeal rights (including Corrective Action Plans (CAPs)) for all contract determinations (non-renewal, expedited termination, termination)	1/4/2008
Change regarding CAP process may be provided prior to notification of termination, and the imposition of time limits on Corrective Action Plans	1/4/2008
Change immediate termination to expedited termination with CMS setting the effective date of termination	1/4/2008
Elimination of Reconsideration Step for contract determination appeals	1/4/2008
Implementation of Burden of Proof for contract determinations	1/4/2008
Ability for a hearing officer to issue summary judgment	1/4/2008
Request for Administrator review, submission of information, and timeframe associated with Administrator review	1/4/2008
Settlement of Civil Money Penalties	1/4/2008
Appeal procedures for Civil Money Penalties	1/4/2008

We did not receive any comments on the implementation dates we proposed and are generally finalizing the implementation dates as we proposed, with minor modification to reflect that certain provisions will be effective on January 4, 2008. However, since we are not implementing the proposed mandatory self-reporting requirement at this time, we have only included a

reference to an implementation date for the voluntary self-reporting recommendation for MA organizations in the above chart. We are retaining the existing voluntary self-reporting recommendation for Part D sponsors so that recommendation is currently in effect and will remain in effect in the future.

C. Distribution Table

The following crosswalk table references the changes we are making to the prescription drug and the MA programs. We proposed making the same changes to 42 CFR parts 422 and 423 with minimal differences. The crosswalk lists the section headings, for parts 422 and 423, and indicates if the section is being deleted.

TABLE 1.—CROSSWALK OF PART 422 AND PART 423 CFR SECTIONS

Section heading	Section references in part 422	Section references in part 423
Definitions	422.2	423.4
Compliance Plan	422.503(b)(4)(vi)	423.504(b)(4)(vi)
Access to Facilities and Records	422.504(e) and 422.503(d)(2)(iii).	423.505(e)
Contract Provisions	422.504(i)	423.505(i)
Effective Date and Term of Contract	422.505	423.506
Non-renewal of contract	422.506	423.507

TABLE 1.—CROSSWALK OF PART 422 AND PART 423 CFR SECTIONS—Continued

Section heading	Section references in part 422	Section references in part 423
Termination of contract by CMS	422.510	423.509
Notice of contract determination	422.644	423.642
Effect of contract determination	422.646	423.643
Reconsideration: applicability	422.648 (delete)	423.644 (delete)
Request for reconsideration	422.650 (delete)	423.645 (delete)
Opportunity to submit evidence	422.652 (delete)	423.646 (delete)
Reconsidered determination	422.654 (delete)	423.647 (delete)
Notice of reconsidered determination	422.656 (delete)	423.648 (delete)
Effect of reconsidered determination	422.658 (delete)	423.649 (delete)
Right to a hearing and burden of proof	422.660	423.650
Request for hearing	422.662	423.651
Postponement of effective date of a contract determination when a request for a hearing with respect to a contract determination is filed timely.	422.664	423.652
Time and Place of Hearing	422.670	423.655
Discovery	422.682	423.661
Prehearing and Summary Judgment	422.684	423.662
Review by the Administrator	422.692	423.666
Reopening of initial contract determination or intermediate sanction or decision of a hearing officer or the Administrator.	422.696	423.668
Effect of revised determination	422.698 (delete)	423.669 (delete)
Types of intermediate sanctions and civil money penalties	422.750	423.750
Basis for imposing intermediate sanctions and civil money penalties	422.752	423.752
Procedures for imposing intermediate sanctions and civil money penalties	422.756	423.756
Collection of civil money penalty imposed by CMS	422.758	423.758
Determinations regarding the amount of civil money penalties and assessment imposed by CMS.	422.760	423.760
Settlement of penalties	422.762	423.762
Other applicable provisions	422.764	423.764
Basis and scope	422.1000	423.1000
Definitions	422.1002	423.1002
Scope and applicability	422.1004	423.1004
Appeal rights	422.1006	423.1006
Appointment of representatives	422.1008	423.1008
Authority of representatives	422.1010	423.1010
Fees for services of representatives	422.1012	423.1012
Charge for transcripts	422.1014	423.1014
Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.	422.1016	423.1016
Notice and effect of initial determinations	422.1018	423.1018
Request for hearing	422.1020	423.1020
Parties to the hearing	422.1022	423.1022
Designation of hearing official	422.1024	423.1024
Disqualification of Administrative Law Judge	422.1026	423.1026
Prehearing conference	422.1028	423.1028
Notice of prehearing conference	422.1030	423.1030
Conduct of prehearing conference	422.1032	423.1032
Record, order, and effect of prehearing conference	422.1034	423.1034
Time and place of hearing	422.1036	423.1036
Change in time and place of hearing	422.1038	423.1038
Joint hearing	422.1040	423.1040
Hearing on new issues	422.1042	423.1042
Subpoenas	422.1044	423.1044
Conduct of hearing	422.1046	423.1046
Evidence	422.1048	423.1048
Witnesses	422.1050	423.1050
Oral and written summation	422.1052	423.1052
Record of hearing	422.1054	423.1054
Waiver of right to appear and present evidence	422.1056	423.1056
Dismissal of request for hearing	422.1058	423.1058
Dismissal for abandonment	422.1060	423.1060
Dismissal for cause	422.1062	423.1062
Notice and effect of dismissal and right to request review	422.1064	423.1064
Vacating a dismissal of request for hearing	422.1066	423.1066
Administrative Law Judge's decision	422.1068	423.1068
Removal of hearing to Departmental Appeals Board	422.1070	423.1070
Remand by the Administrative Law Judge	422.1072	423.1072
Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.	422.1074	423.1074
Request for Departmental Appeals Board review	422.1076	423.1076
Departmental Appeals Board action on request for review	422.1078	423.1078
Procedures before Departmental Appeals Board on review	422.1080	423.1080

TABLE 1.—CROSSWALK OF PART 422 AND PART 423 CFR SECTIONS—Continued

Section heading	Section references in part 422	Section references in part 423
Evidence admissible on review	422.1082	423.1082
Decision or remand by the Departmental Appeals Board	422.1084	423.1084
Effect of Departmental Appeals Board decision	422.1086	423.1086
Extension of time for seeking judicial review	422.1088	423.1088
Basis, timing, and authority for reopening an Administrative Law Judge or Board decision	422.1090	423.1090
Revision of reopened decision	422.1092	423.1092
Notice and effect of revised decision	422.1094	423.1094

We did not receive any comments on the crosswalk distribution table and have made no substantial changes to it. We are finalizing the table as proposed.

D. Proposed Changes to Part 422—Medicare Advantage Program and Part 423—Medicare Prescription Drug Benefit Program

Sections 422.2 and 423.4—Definitions

We proposed to correct a technical oversight in both regulations by including the definitions of “downstream entity,” “first tier entity,” and “related entity,” in the overall definitions sections of both the MA and Part D regulations at § 422.2 and § 423.4 to ensure that these terms are used consistently throughout both programs. Since these three terms are only defined in Subpart K of parts 422 and 423, we proposed to add them to Subpart A, General Provisions at § 422.2 and § 423.4.

Please see page 29372 of the proposed rule for a flow chart that provides examples of, and describes the relationships between, Part D sponsors, and first tier, downstream, and related entities.

Comment: A few commenters requested more explicit definitions of first tier, downstream, and related entities. They asked us to provide clarification for the terms record retention, administrative services,

written arrangements, acceptable to CMS, CMS instructions, and directors. We also received a request that we clarify the phrase “a written agreement, acceptable to CMS,” found in the definition of “downstream entity,” and a request that we clarify which entities are involved in such an arrangement.

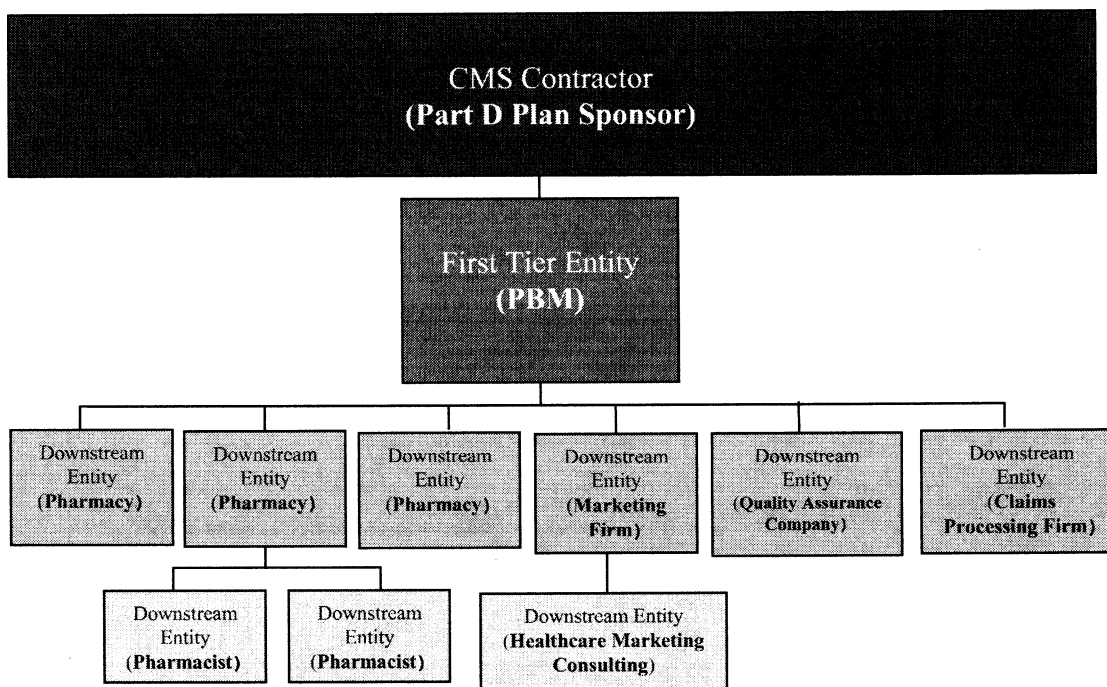
Response: The terms “first tier entity,” “downstream entity,” and “related entity” are already defined in Subpart K of parts 422 and 423, and we are only including them in Subpart A, General Provisions at § 422.2 and § 423.4 for clarity, since these terms were originally defined in only Subpart K. Examples of downstream entities include, but are not limited to, pharmacy benefit managers, mail order pharmacies, retail pharmacies, firms providing agent/broker services, agents, brokers, marketing firms, and call center firms. We are neither providing definitions nor clarifications for the terms “record retention,” “administrative services,” “written arrangements,” “acceptable to CMS,” “CMS instructions,” or “directors,” since these terms are longstanding terms used by us and the industry. We are finalizing the definitions of “first tier entity” and “related entity” as proposed.

Based upon an unintentional oversight in the proposed regulation, we are revising the definition of

“downstream entity” for improved clarity, as described below. The definition of a Part D “downstream entity” at § 423.4 states that a “[d]ownstream entity means any party that enters into a written arrangement acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity.” In response to this comment, we are modifying the proposed definition to address with whom the entity is entering into a written arrangement. The definition is revised to read: “Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.” We are making similar changes to the definition of “downstream entity” in the MA regulation at § 422.2.

Comment: One commenter questioned whether a pharmacist is a downstream entity.

Response: As illustrated in the sample flowchart provided on p. 29372 of the proposed rule, and below, a pharmacist would be considered a downstream entity as defined in the regulation.



Sections 422.503 and 423.504—General Provisions

The current regulations at § 423.504 include a requirement that a Part D sponsor's compliance plan consist of training and education, and effective lines of communication between the compliance officer, and the organization's employees, contractors, agents, directors, and managers. The terms "contractor" and "agent" are not defined in the current regulations, and it has been unclear to the industry which entities are subject to the training and education, and the effective lines of communication requirements. In response to industry concerns and to eliminate the confusion associated with using the term "contractor", currently used in those sections, we proposed to revise paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D) of § 423.504. The proposed revision clarified that a compliance plan must consist of training and education, and effective lines of communication between the compliance officer and the Part D sponsor's employees, managers, and directors, as well as the Part D sponsor's "first tier, downstream, and related entities" which are defined at 422.500 and 423.501. This change clarifies that Part D plan sponsors need to apply these training and communication requirements to all entities they are partnering with to provide benefits or services in the Part D program, not just to their direct employees within their organizations.

Pursuant to our authority under § 1856(b)(1) of the Act to establish MA

standards by regulation, we also proposed to make the same changes in the MA program. We similarly proposed to require MA organizations to apply their training and education and effective lines of communication requirements to their first tier, downstream, and related entities, in an effort to make the compliance plan requirements uniform across MA organizations, Medicare Advantage Prescription Drug Plans (MA-PDs), and other Part D sponsors. Additionally, we proposed clarifying paragraph (b)(4)(vi) in § 422.503 and § 423.504 by removing what we believe to be a duplicative and confusing "final element" of the compliance plan—a comprehensive "fraud, waste, and abuse plan to detect, correct, and prevent fraud, waste, and abuse," at paragraph (b)(4)(vi)(H) of both regulations. We proposed to remove this element because since the Part D program's inception, we received feedback from many Part D sponsors indicating that it was not clear whether we were requiring a fraud, waste, and abuse (FWA) plan separate and distinct from a compliance plan.

In April 2006, we issued Chapter 9 of the Prescription Drug Benefit Manual ("Part D Program to Control Fraud, Waste and Abuse," hereafter referred to as "Chapter 9") as best practices guidance for Part D sponsors to develop an FWA plan. We intend for Chapter 9 to be similar to the type of best practices guidance issued by the Office of the Inspector General (OIG) in its Compliance Program Guidance for drug manufacturers and health care

providers. While we clarified in Chapter 9 that Part D sponsors could choose whether to incorporate FWA measures in a compliance plan, we believe the final element continues to cause potential confusion to the industry, and therefore, proposed to remove this element from (b)(4)(vi) of § 422.503 (for MA-PDs) and § 423.504 (for Part D sponsors).

We continue to believe an effective compliance plan includes procedures and policies for preventing fraud, waste, and abuse, and so proposed changes to the introductory clause of § 423.504(b)(4)(vi) that reflect our policy stance. Congress mandated that Part D sponsors have a "program to control fraud, waste, and abuse." See § 1860D-4(c)(1)(D) of the Act. Therefore, we are also clarifying that if Part D plan sponsors develop an effective compliance plan that incorporates measures to detect, prevent, and correct fraud, waste, and abuse, this compliance plan would also satisfy the statutory requirement that sponsors have a FWA plan in place. Part D sponsors should continue to look to Chapter 9 as recommended guidance for the types of measures we recommend in detecting and preventing fraud, waste, and abuse. Chapter 9 can be viewed at: http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.

We recognize that Chapter 9 was specifically developed for Part D sponsors and is not applicable for MA organizations that do not offer a prescription drug benefit. In the interim,

MA organizations should refer to Chapter 9 as a reference regarding how to incorporate fraud, waste, and abuse detection and prevention into their compliance plans. We plan to develop separate guidelines for MA organizations for implementation by January 1, 2009.

Pursuant to our authority under section 1856(b)(1) of the Act, we also proposed to make the same change to the introductory clause of § 422.503(b)(4)(vi), so that the compliance plan requirements for MA organizations will be identical to those for Part D sponsors. We proposed that MA organizations must include “measures to detect, correct, and prevent fraud, waste, and abuse” throughout the 7 elements of the compliance plan requirement. Before this proposed change, only MA-PDs were explicitly required to include detection and prevention of fraud, waste, and abuse into their compliance plans. However, it has always been our expectation that fraud, waste, and abuse would be addressed through the implementation of all 7 elements in a MA organization’s compliance plan, enumerated at paragraphs (A) through (G) of § 422.504(b)(4)(vi). It has been our longstanding policy that an effective MA compliance plan addresses the detection, correction, and prevention of fraud, waste, and abuse in the MA program, and we believe that our proposed change makes this policy explicit in our regulations. As previously stated in this final rule with comment period, MA organizations may refer to Chapter 9 in the interim, and further guidance on the types of measures we recommend in detecting and preventing fraud, waste, and abuse will be developed specifically for MA organizations.

Comment: A number of respondents requested further clarification regarding who must provide training and education under the compliance plan and who must be trained and educated.

Response: We did not intend to imply that MA organizations and Part D sponsors are required to directly provide Part D compliance training and education to all of their first tier, downstream, and related entities. Instead, we seek to reaffirm the role and responsibilities of the MA organization and Part D sponsor in this area. To the extent that aspects of the compliance plan are delegated, it is important to remember that the MA organization’s or Part D sponsor’s compliance officer must maintain appropriate oversight of those delegated activities. The Part D sponsor and the MA organization maintain ultimate responsibility

regardless of whether training has been delegated to the first tier, downstream, or related entities. In accordance with the Part D and MA applications, the Part D sponsor or MA organization must attest it will implement a compliance plan that includes effective training and education between the compliance officer, organization employees, contractors, agents and directors. In addition, as part of plan audits, CMS will verify that all necessary training has been provided. Therefore, CMS would expect that a Part D sponsor and MA organization would have training logs and copies of attestations from the first tier, downstream or related entities to comply with this requirement. As previously stated in this final rule with comment period, MA organizations may refer to Chapter 9 in the interim, and further guidance will be developed for MA organizations.

Comment: A few commenters questioned “who would be responsible” for implementing the compliance program’s fraud, waste, and abuse detection and prevention efforts related to Part D.

Response: The MA organization or Part D sponsor is ultimately responsible for meeting the compliance plan requirement to implement measures for detecting and preventing fraud, waste, and abuse. However, we realize that each MA organization and Part D sponsor has a unique business model and structure, and that some will choose to perform certain functions themselves while some MA organizations and Part D sponsors will subcontract certain functions and rely on the expertise and operations that first tier, downstream, and related entities offer. The job of the compliance officer cannot be delegated. But MA organizations and Part D sponsors have the flexibility to determine how, and to what extent, they will delegate their compliance activities, which may include training and education to control fraud, waste, and abuse. MA organizations and Part D sponsors have the flexibility to determine how and to what extent they will delegate other aspects of their contractual requirements. To the extent that any compliance activities are delegated to first tier, downstream, and related entities, MA organizations and Part D sponsors are ultimately responsible for compliance plan oversight, including monitoring training and education, and complying with all statutory and regulatory requirements, as well as any additional guidance identified by us. One option MA organizations and Part D sponsors may choose is to contractually require their first tier, downstream, and related

entities to train their own workforce on delegated activities and establish lines of communication to the appropriate managers in those entities. We recommend that Part D sponsors review chapter 9 of the Prescription Drug Benefit Manual for further guidance regarding accountability and oversight of first tier, downstream, and related entities. As previously stated in this final rule with comment period, MA organizations may refer to Chapter 9 in the interim, and further guidance will be developed specifically for MA organizations.

MA organizations and Part D sponsors should consider requiring that any first tier, downstream, and related entities performing activities on behalf of the MA organization or Part D sponsor, provide their own training in accordance with § 422.504(b)(4)(vi)(C) or § 423.504(b)(4)(vi)(C) respectively, or where there are sufficient organizational similarities, the MA organization or sponsor may choose to make its training programs available to these entities. This will allow the first tier, downstream, and related entities the choice of accessing the MA organization or Part D sponsor’s training and education materials, or providing proof to them of their compliance with the training and education requirement. For further guidance, please refer to chapter 9 of the Prescription Drug Benefit Manual.

Employees with specific responsibilities in Medicare Part D business areas should receive specialized training on issues posing compliance risks based on their job function (for example, pharmacist, statistician, and so on), upon initial hire, when requirements change, or when an employee works in an area previously found to be noncompliant with program requirements or associated with past misconduct. Such training should also be required at least annually thereafter as a condition of employment. Specialized training content may be developed by the sponsor or employees may attend professional education courses that help meet this objective. Further discussion related to this subject may be found in Chapter 9.

In Chapter 9, we discuss how delegation of training would be applicable, if deemed appropriate by the sponsor, for General Compliance Training and Specialized Compliance Training. We did not make any changes to our proposed provisions as a result of this comment.

Comment: We received some comments suggesting that we should work with the industry to develop a

standardized training and communication plan applicable to all stakeholders, and make it available on the internet. This way, stakeholders would receive one comprehensive training and communication package.

Response: We believe this to be a valuable suggestion, and we will take it under consideration.

Comment: Some commenters requested that we conduct certifications to verify that training and education had been completed for Part D plans and their first tier, downstream, and related entities.

Response: At this time, we do not require a certification process but rather, through our audit and review process, will determine whether or not the training and education requirements were fulfilled. We hold the Part D sponsor or MA organization responsible for fulfilling this requirement regardless of whether first tier, downstream, and related entities certify to that effect. We may revisit the idea of certification in the future.

Comment: One respondent questioned who downstream entities should contact with "compliance concerns."

Response: We have contracted with program integrity contractors who will use innovative techniques to monitor and analyze data to help identify and prevent fraud, waste, and abuse. Any person or entity at a first tier, downstream, or related entity level that wishes to report potential fraud or misconduct may contact a program integrity contractor and/or the MA organization or the Part D sponsor, depending on the type of violation.

Comment: Another respondent questioned who would be responsible for reporting potential prescription drug fraud.

Response: The Part D sponsor or MA organization maintains ultimate responsibility regardless of whether oversight duties have been delegated. To the extent that any of the compliance activities for Parts C or D are delegated, it is important that the MA or Part D compliance officer maintain appropriate oversight of those duties that have been delegated. The compliance officer is responsible for determining whether voluntary self-reporting of any potential fraud or misconduct related to the MA or Part D program is appropriate. In addition, first tier, downstream, and related entities are encouraged to report fraud, waste, or abuse to the program integrity contractor and/or the MA organization or the Part D sponsor.

Sections 422.503(b)(4)(vi)(G)(3) and 423.504(b)(4)(vi)(G)(3)—Mandatory Self-Reporting

At § 422.503(b)(4)(vi)(G)(3) and § 423.504(b)(4)(vi)(G)(3), we proposed mandatory self-reporting of potential fraud or misconduct in both the MA and Part D programs. We believe that it is important for the government to have information on potential fraud or misconduct as soon as possible. The comments we received on the May 25, 2007, proposed rule highlighted the challenges in establishing the parameters of a mandatory self-reporting process in the context of MA and PDP plans. Commenters expressed several concerns during the public comment period, including the need for us to better define what constitutes "potential" fraud and misconduct, the process for reporting, and the need to be consistent with other agencies' guidance regarding self-reporting. After reviewing these comments, we determined that additional analysis needs to be undertaken and additional information sought before implementing a mandatory self-reporting requirement.

In the meantime, we believe that self-reporting is a valuable component of an MA organization's or Part D sponsor's compliance plan. Therefore, in an effort to make the compliance plan requirements uniform across MA organizations, Medicare Advantage Prescription Drug Plans (MA-PDs), and other Part D sponsors, we will amend proposed paragraph (b)(4)(vi)(G)(3) of both §§ 422.503 and 423.504 to read: A MA organization or Part D sponsor "should have procedures for voluntary self-reporting of potential fraud or misconduct * * *." We are essentially retaining the voluntary self-reporting recommendation for Part D sponsors, but merely moving it within the regulatory text to accommodate other regulatory changes we are making, and implementing a voluntary self-reporting recommendation for MA organizations. We are strongly recommending that, if after conducting a reasonable inquiry, it is determined that potential fraud or misconduct has occurred, the conduct should be promptly referred to the program integrity contractor for further investigation. While we are not requiring mandatory self-reporting in this final rule with comment period, there may be instances under federal criminal and fraud and abuse statutes where MA organizations and Part D sponsors are potentially subject to prosecution if certain issues are not properly addressed. We further note that our decision not to amend the existing MA and PDP requirements further at

this time does not mean that organizations may not be liable under other Federal laws or regulations if they fail to disclose a violation they have discovered.

We wish to call attention to the existing guidance we provide on self-reporting. Key documents include Chapter 9 of the Prescription Drug Benefit Manual, concerning fraud, waste, and abuse (at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf) and the Medicare Part D Reporting Requirements for Contract Year 2007 (at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_CurrentYear.pdf). While these documents are not codified rules, the guidance they contain provides clear direction to plans as to our expectations. We will periodically revise these guidelines to reflect additional guidance on ways to improve reporting of fraud, waste, and abuse.

We are committed to implementing mandatory self-reporting and we intend to issue a proposed rule. Finally, we believe that it would be valuable to obtain additional input at this time, in order to inform our evaluative, analytic, and guidance efforts. Accordingly, we are asking for additional public comments on this issue. Specifically, we ask for comments regarding the following:

- We proposed requiring MA organizations and Part D sponsors to report potential "fraud or misconduct." We seek guidance as to how to define what kinds of offenses would constitute fraud and misconduct for purposes of this reporting requirement. We seek specific examples of what constitutes potential fraud and misconduct.
- Alternatively, we seek input as to whether there is an alternate formulation, rather than "fraud or misconduct" that would better describe the categories of offenses that should be reported to CMS (for example violations of administrative, civil and/or criminal authorities).
- Who are the entities that would be responsible for reporting to CMS (sponsor, first tier, downstream entities)?
- At what point would CMS require that a MA or Part D plan report a potential issue that could fall into the category of offenses that would require self-reporting (for example, upon initial discovery or after an opportunity for reasonable inquiry or due diligence)?
- How should this information be reported to CMS (through the MEDICs, disclosure to the CMS plan manager, or

CMS central office)? Please provide a discussion of the advantages or disadvantages of any of these or other reporting mechanisms.

- In addition to the specific questions raised above, please provide us with any other comments or constructive feedback that might assist us in crafting a mandatory self-reporting requirement.

Sections 422.504 and 423.505—General Provisions

We proposed to clarify which entities under contract to MA organizations and Part D sponsors are subject to the contract provisions in the MA and Part D programs. Currently, the contract provisions at 422.504 and 423.505 refer to such entities as the MA organization or Part D sponsor's "contractors" and "subcontractors," which as we described in the proposed rule, are undefined terms in the statute and regulations. We proposed, where applicable, to delete the term "contractor," because of potential confusion and redundancy, and replace the term "subcontractor" with the terms "first tier entity" and "downstream entity" in 422.504(e) and (i), to clarify which entities are subject to the contract provisions at 422.504.

We also proposed, where applicable, to delete the term "contractor," and replace the term "subcontractor" with the terms "first tier entity" and "downstream entity" in the Part D contract provisions at 423.505(e) and (i) for the same reasons. We believed using "first tier and downstream, entities" instead of "subcontractor" would lessen the potential for confusion in the Part D program. Please see page 29372 of the proposed rule for examples of first tier, downstream, and related entities.

Comment: We received a number of technical comments concerning the definitions of "contractor" and "subcontractor."

Response: Based on these comments, we are correcting a few typographical errors in § 423.505(i)(3)(v) by replacing the phrase "related entity, contractor or subcontractor" with the phrase "first tier, downstream, and related entities" to be consistent with the other parts of the regulation. In §§ 423.505(i)(3), and §§ 423.505(i)(3)(ii), (i)(4), and (i)(4)(v), we are deleting the term "pharmacy" as it was included in error and is redundant. Section 423.505(i)(4) will now read: "If any of the Part D plan sponsor's activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, and related entity," and § 423.505(i)(4)(v) will read: "All contracts or written arrangements must

specify that the first tier, downstream, or related entity must comply with all applicable Federal laws, regulations, and CMS instructions." We also are making similar corrections to § 422.504(i)(3), (i)(3)(ii), and (i)(4) where the term "provider" was left in the regulations unintentionally. All references to "provider" have been deleted in the final regulations.

We proposed to add a provision to the contracts and written arrangements between sponsors and their first tier, downstream, and related entities at § 423.505(i)(3)(iv) to clarify that this information can be provided to either the Part D sponsor to give to CMS, or can be provided directly to CMS or its designees. We discussed in the proposed rule at page 29373 our existing authority under section 1860D–12(b)(3)(c) of the Act and § 422.504(e) and § 423.505(e) to inspect and audit any books, contracts, requests, and records of a Part D sponsor or MA organization relating to the Part D program. Because of the proposed contract provision, we also proposed to redesignate § 423.505(i)(3)(iv) as § 423.505(i)(3)(v). We are finalizing these changes as proposed.

Comment: A few commenters questioned our authority to access the books and records of first tier, downstream and related entities. One commenter suggested a need for more formal rulemaking on this topic.

Response: We have existing authority under section 1860D–12(b)(3)(c) of the Act and § 422.504(e)(2) and § 423.505(e)(2) to inspect and audit any books, contracts, and records of a Part D sponsor or MA organization and its first tier, downstream, and related entities that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of accounts payable under the contract or as the Secretary may deem necessary to enforce the contract. Therefore, it is not necessary, as the commenters suggested, to propose a more formal regulation and offer another public comment period.

These third party disclosure requirements were finalized in the final MA and Part D rules and were approved under the Paperwork Reduction Act approval under OMB #0938–1004 (Part C) and OMB #0938–1000 (Part D). Additionally, in the preamble to the Part D proposed rule, published on January 28, 2005 (70 FR 4194), we clearly stated our inspection and audit rights with respect to a Part D sponsor and its contractors, subcontractors, and related entities under the section entitled "Access to Facilities and Records" (69 FR 46632–46712). In this regulation, we have further clarified that our access

rights apply to "first tier, downstream, and related entities," and not "contractors, subcontractors, and related entities."

The limited rebate and other price concession information provided to the Part D sponsor by its contracting entities may provide some payment information to us, but it may not be enough for us to determine in all cases whether appropriate payments have been made to the sponsor. Therefore, it may be necessary for us to rely on our authority to access books and records to obtain more detailed rebate and other price concession information in order to verify proper payments were made to the Part D sponsor.

Comment: We received a number of comments questioning whether books and records must be made available to us directly or through the Part D sponsor.

Response: We have chosen not to be prescriptive regarding whether first tier, downstream, and related entities must make their books and records available to us directly or through the Part D Sponsor. It is our opinion that this is considered to be part of the negotiation process between the Part D sponsor and its first tier, downstream, and related entities. The provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to us (or our designee(s)), or submitted directly to us (or our designee(s)). The parties could also decide to have such books and records made directly available to us, or our designee(s), through onsite access. The Part D sponsor must be prepared to submit evidence of this agreed upon provision in its executed contracts to us. To clarify, the "designee" either refers to entities under a program integrity contract with us, or entities, such as law enforcement, working in collaboration with us to fight fraud, waste and abuse in the Medicare Part D program.

HHS, the Comptroller General, or its designees have the authority to collect any information from the first tier, downstream, or related entities that is related to the Medicare Part D prescription drug transaction. Examples of the type of information collected are provided at § 423.505(e)(2).

In addition to proposing a new contract provision at § 423.505(i)(4)(iv), we also proposed minor regulatory changes which clarify the Part D sponsor's CMS contractual requirements. While we continue to believe our regulations clearly state our authority to access the books and records of a Part D sponsor's first tier, downstream, and related entities, we proposed to add language about these

partnering entities to § 423.505(b)(10), and proposed to consolidate § 423.505(e)(2) and (3) into one provision at (e)(2). We proposed these revisions to make explicit the Part D plan sponsor's contractual obligation to ensure HHS, the Comptroller General, or their designees have access to any books and records related to the Part D program, including those of a sponsor's first tier, downstream, and related entities. These revisions do not impose any new requirements on Part D sponsors or its partnering entities. We are finalizing these proposed provisions without change.

Comment: A few commenters noted that the proposed revision to § 422.504 and § 423.505 has not prescribed "typical" data sets to be reported within the context of our request for books and records of first tier, downstream, and related entities. Another commenter indicated that the information that could be collected is too broad.

Response: We want to clarify that the "books and records" we are entitled to access do not make up a typical data set included in the Medicare Part D Reporting Requirements. There is no report form to be defined, as the format will be dependent upon the information being requested and the unique circumstances upon which the request is based. The scope of the information collected will be based on the type of audit being performed. If upon review of the information submitted we, or our designee(s), determine that additional information or clarification is warranted, the scope of the review may be expanded.

Comment: A commenter suggested that we should rely on subpoena authority, regulation, provider contracts, or some other method to collect books and records in connection with investigations.

Response: We do not have subpoena authority; however, our law enforcement partners such as OIG and DOJ do. The government may use a variety of methods to obtain records and books from entities under contract with MA organizations and/or Part D sponsors. There may be instances where we may need to see books and records without involving law enforcement. These provisions at § 422.504 and § 423.505 only clarify one method we may employ to do so.

We clarified in the preamble to the proposed rule that HHS, the Comptroller General, or their designees have the authority under the statute to request records from MA organizations and Part D sponsors or their first tier, downstream, or related entities. MA organizations and Part D plan sponsors

must maintain, as required by § 423.505(d), "books, records, documents and other evidence of accounting procedures and practices," pertaining to determinations of amounts payable under the contract, agreements, contracts, and subcontracts. Since Part D sponsors have delegated many Part D functions to their first tier entities, we are aware that many of these records reside with first tier and downstream entities, such as pharmaceutical benefits managers (PBMs). We are taking the opportunity again, in this final rule with comment period, to make explicit that we have the authority to request for verification of payment purposes, any records relating to rebates and any other price concessions between PBMs and manufacturers that may impact payments made to sponsors in the Part D program.

Comment: We received a comment addressing the 10-year record retention requirement.

Response: This requirement was implemented in a prior regulation and is outside the scope of this final rule with comment period.

Comment: A number of commenters expressed concern that information submitted by first tier, downstream, and related entities, especially proprietary information, would not be kept confidential by us.

Response: As an agency, we are subject to various Federal disclosure laws, such as the Trade Secrets Act, the Privacy Act, and the Freedom of Information Act (FOIA) (5 U.S.C. 552). We are also subject to confidentiality and disclosure regulations at 42 CFR Part 401 Subpart B. In addition, sections 1860D-15(d)(2)(B) and (f)(2) of the Act place restrictions on the Secretary's disclosure of certain payment data collected in the Part D program to anyone outside of HHS. Therefore, we believe there are sufficient legal restrictions to protect the disclosure of such proprietary data outside of the agency.

Comment: One commenter questioned our need to gather information about rebate agreements between potential first tier and downstream entity contracted partners.

Response: Our proposal to obtain rebate and price-concession related records is supported by statute. Sections 1860D-15(d)(2) and 1860D-15(f)(1)(A) of the Act authorize us to request any information "necessary" to carry out the payment provisions in section 1860D-15 of the Act, which include payments of direct subsidies, reinsurance, and risk corridor costs to sponsors. While the rebate and other price concession information reported by the sponsors

may provide some payment information, it may not be enough for us to determine in all cases whether appropriate payments have been made to the sponsor. It may be "necessary" for us to obtain more detailed rebate and other price concession information from first tier, downstream, and related entities in order to verify proper payments made to the sponsor. For example, we must receive accurate and complete rebate and other price concession information in order to determine what was "actually paid" and to clearly reflect what was a gross prescription drug covered cost, which excludes administrative costs.

As stated in the CMS 2007 Prescription Drug Sponsor Call Letter, "CMS must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of the Part D sponsors then the direct payment the sponsor pays the PBM for its services will be less, that is, the sponsor receives a price concession from the PBM." If the rebates are passed completely through to the Plan then the charge from the PBM to the Plan would be an administrative cost that will need to be deducted from the "gross covered prescription drug costs" which along with the "actually paid costs" are a basis for CMS payment to the plans.

In addition, such rebate and other price concession information is critical to our oversight efforts in curbing fraud, waste, and abuse in the Part D program. Under section 1860D-2(d)(3) of the MMA, Congress granted us the right to conduct periodic audits of a sponsor's financial statements, books, and records "to protect against fraud and abuse and to ensure proper disclosure and accounting" in the Part D program.

Given the history of rebate reporting problems the government has encountered with PBMs in administering the Medicaid Drug Rebate Act, we believe we must have the ability to evaluate and inspect records relating to Part D rebates and other price concessions in order to fulfill our statutory duty of protecting beneficiaries from fraud and abuse and to ensure the financial integrity of the Part D program. Therefore, we are restating in this final rule with comment period that we reserve the right to request records relating to Part D rebates and price concessions from the sponsor's first tier entities, downstream, and related entities when appropriate.

Comment: A commenter questioned whether certain contracted partners are considered to be downstream entities.

Response: In Exhibit 1 of the proposed rule, on p. 29372, and in this final rule with comment period, we

provided examples of first tier and downstream entities. We encourage you to contact the CMS staff listed at the beginning of this final rule with comment period if you have any questions as to whether a contracted partner is a downstream entity.

Sections 422.505 and 423.506—Effective Date and Term of Contract

We proposed removing § 422.505(c)(1) and § 423.506(c)(1), which state that contracts with MA organizations or Part D plan sponsors are only renewed if CMS informs the MA organization or Part D sponsor that it has authorized a renewal. Section 1857(c)(1) of the Act provides that the contract renews automatically, unless CMS or the organization notifies the other party of its intent to terminate the contract at the end of the existing contract term. Therefore, we proposed to revise § 422.505(c) and § 423.506(c) to state that in accordance with § 422.506 and § 423.507, contracts are renewed annually only if the MA organization or Part D plan sponsor has not provided us with a notice of intent not to renew and we have not provided the MA organization or Part D plan sponsor with a notice of intent not to renew. This change better aligns the regulations with the statute and we are finalizing the provision as proposed.

Comment: One commenter asked whether contracts needing amendment as a result of this final rule with comment period could be made at the time of contract renewal.

Response: As indicated in the proposed rule and finalized here, the implementation date of this provision is January 1, 2009. Therefore, all revised contracts need to be in place by that date. We did not make any changes based on this comment and are finalizing the provision as proposed.

Sections 422.506 and § 423.507 Nonrenewal of a Contract

We proposed revising the introductory text for § 422.506(b)(2) and § 423.507(b)(2). In addition, we proposed revising § 422.506(b)(2)(i) and § 423.507(b)(2)(i). The existing provisions require us to provide plans with notice of both renewal and nonrenewal decisions by May 1. We proposed that a notice only be provided if we decide not to renew an MA organization or a Part D plan sponsor's contract with us. As discussed in the proposed rule, Section 1857(c)(1) of the Act provides for an automatically renewable contract and does not require us to provide notice when we decide to renew a plan or sponsor's contract with us.

We proposed revising the § 422.506(b)(2) introductory text and the § 423.507(b)(2) introductory text to clarify that we must provide notice of our decision not to authorize renewal of a contract. In addition, we proposed to revise § 422.506(b)(2)(i) and § 423.507 (b)(2)(i) to require that we provide such notice by September 1 of the contract year, rather than May 1. If an MA organization or Part D sponsor receives a nonrenewal notice from CMS, we will not provide information regarding the MA or Part D plans that the organization or sponsor offers in certain hard copy materials, such as the "Medicare & You" handbook. Information regarding the plans would continue to be available on the CMS Web site. For purposes of this final rule with comment period, a nonrenewal would take effect on January 1 of the following contract year (unless a nonrenewal is being appealed through the administrative appeals process and the appeals process is ongoing, or additional time is required to comply with our requirements with respect to providing notice to beneficiaries of the nonrenewal, in which case the nonrenewal may become effective during the following calendar year), whereas a termination may take effect at any time during the contract year. Our proposed provisions make contract renewal automatic, without notice, unless we notify the MA organization or Medicare Part D plan sponsor of our intent to nonrenew the contract by September 1 of the current contract year. Please see the proposed rule for our rationale for changing the nonrenewal notification date to a date later than May 1.

Comment: We received several comments concerning the proposed September 1 nonrenewal notification date. Several commenters believed that plans will have to incur significant expenditures prior to September 1 to prepare for the following calendar year, and that a September 1 date would require plans to incur expenditures that would not have been incurred before the existing May 1 nonrenewal notification date, in the event that we take action to nonrenew a plan.

Response: We understand that MA organizations and Part D sponsors expend effort in preparing for the following contract year. Therefore, while we will not retain the existing May 1 nonrenewal notification date, we are revising our proposal and finalizing a notification date of August 1, instead of our proposed September 1 notification date.

We understand that MA organizations and Part D sponsors expend effort in

preparing for the following contract year. Therefore, while we will not retain the existing May 1 nonrenewal notification date, we are responding to commenters' concerns and revising our proposal and finalizing a notification date of August 1, instead of our proposed September 1 notification date. We believe that this is an appropriate compromise. While we appreciate commenters' concerns, we believe we have a significant countervailing interest in moving the current May 1 nonrenewal notification date to later in the calendar year. As we explained in the preamble to the proposed rule, these additional months will allow us to have access to significantly more information about plan performance, which will allow for more informed and educated decisions about MA organizations and Part D sponsors that have serious compliance problems and may be the subject of a nonrenewal determination. We believe that allowing for the opportunity to access this data will benefit both CMS and the MA organizations and Part D sponsors.

Comment: Another commenter said that the September 1 date would not provide for enough time for beneficiary notification.

Response: As explained above, we are finalizing a nonrenewal notification date of August 1, rather than September 1 as we proposed. We believe this change is more likely to result in administrative appeals of CMS nonrenewal actions being completed in time to allow for 90 days notice of the nonrenewal to be provided to members and the general public prior to the end of the calendar year.

Comment: One commenter requested clarification as to whether deficiencies could be cured after receiving the notice of an intent to nonrenew. The commenter stated that a September 1 date would not give enough time for an organization to make necessary changes to come into compliance for the next contract year. This commenter also expressed concern about the inability of a plan to participate in the program for the following year because of the timeframes associated with Corrective Action Plans (CAPs) and appeal rights, potentially rendering a plan's appeal rights moot.

Response: We believe comments related to plan participation in the following calendar year based on CAP submission dates reflect a misunderstanding of our proposals in the proposed rule. We clarified in our proposed rule that we will offer plans an opportunity to submit an acceptable CAP prior to notifying them of our intent to nonrenew or terminate their

contract. If an acceptable CAP is submitted to us, we will not take action to nonrenew or terminate the sponsor or organization's contract. Once a sponsor or organization receives a nonrenewal notification from us (or a termination notice), the sponsor or organization is not entitled to an additional opportunity to submit another CAP. We will not be required to provide any additional time for a MA organization or Part D sponsor to come into compliance or cure deficiencies once we have notified a sponsor or organization of our intent to nonrenew (or terminate) its contract. We proposed this clarification in an effort to streamline the CAP and nonrenewal process. We have added additional language at § 422.506, § 422.510, § 423.507, and § 423.509 to expressly clarify that the opportunity to submit an acceptable CAP is afforded to a MA organization or Part D sponsor prior to our decision to nonrenew or terminate a contract.

With respect to the comment regarding ongoing administrative appeals, if a MA organization or Part D sponsor is in the process of appealing a nonrenewal or termination, and the appeal process has not been concluded, the organization will be able to participate in the program the following calendar year until such time during the following calendar year as the appeals process is concluded and appropriate notice is provided to beneficiaries. Therefore, appeal rights will not be moot.

Comment: Several commenters believed that the September 1 date would place an undue burden on pharmacies to join plan provider networks and the commenters recommended that we provide some sort of contingent renewal notice for organizations and sponsors to send to providers for the following year.

Response: MA organizations and Part D sponsors who have not received a request for a CAP from us as a result of deficiencies are not in jeopardy of receiving a nonrenewal notification, making the need for a contingent nonrenewal notice unnecessary. Furthermore, as explained above, we are changing the proposed September 1 nonrenewal notification date to August 1, affording pharmacies an additional month to make network decisions.

We proposed redesignating § 422.506(b)(3) as § 422.506(b)(4) and redesignating § 423.507(b)(3) as § 423.507(b)(4). We proposed adding a new paragraph at § 422.506(b)(3) and § 423.507(b)(3) which would clarify the CAP process for nonrenewals. The Act requires us to provide MA organizations and Part D plan sponsors with a

reasonable opportunity to develop a CAP prior to terminating a contract, either through the termination process or the nonrenewal process. The CAP process for nonrenewals would be the same process as we proposed for terminations. We proposed a more defined process than currently exists and we proposed a process and timeframes for the submission and review of CAPs. Our proposal clarified that, in the future, once we issue a nonrenewal notice or a termination notice, the MA organization or Part D plan sponsor will not be entitled to an opportunity to submit a CAP. We will provide that opportunity to organizations and sponsors prior to issuing a notice of intent to nonrenew or terminate a contract. MA organizations and Part D plan sponsors should take very seriously any request from us to develop and implement a CAP since a failure to fully comply may result in a nonrenewal or termination action.

Comment: One commenter questioned whether the termination and CAP process applied to all contract years and if the termination would be retroactive to the beginning of a plan contract.

Response: The most recent finding of deficiencies and the request for a CAP would be relied upon to support a termination or other contract determination. Prior CAPs may provide additional information to us and support for our action if the MA organization or Part D sponsor has had continued compliance problems that have not been resolved, but would not be the basis of a contract determination if the prior CAPs have been accepted by us and implemented to our satisfaction. A termination action would affect the existing contract with us. Given that we have already adopted automatically renewable multi-year contracts, failure to substantially carry out a contract term necessarily would apply to the entire term of the contract (that is, the life of the contract). Part D and MA contracts are evergreen, so the existing contract is not just the current calendar year's contract, but is a continuing contract that existed during prior calendar years (assuming the Part D sponsor or MA organization participated in the program in prior calendar years).

We proposed time limits at § 422.506(b)(3) and § 423.507(b)(3) for the development and implementation of a CAP. We proposed to provide the MA organization or Part D plan sponsor 45 days in which to submit a CAP to us. If we find that the CAP is unacceptable, the MA organization or Part D plan sponsor would have an additional 30 days to revise and resubmit the CAP. If

we then find the CAP acceptable, we would provide the MA organization or Part D plan sponsor with a deadline by which the CAP must be implemented. If we find that the second version of the CAP is unacceptable, we would be under no obligation to accept further revisions to the CAP and would have the discretion to proceed directly to issuing a notice of nonrenewal to the MA organization or Part D plan sponsor.

Comment: One commenter requested clarification on whether the timeframe is measured in business or calendar days. The commenter requested that we leave open lines of communication with organizations with respect to working to develop acceptable CAPs. The commenter was concerned that there would only be one chance to provide an acceptable CAP.

Response: We are clarifying here, and at §§ 422.506(3) and 423.507(3), that the CAP timeframes are measured in calendar days. We will provide MA organizations and Part D sponsors two opportunities to submit acceptable CAPs. Prior to requesting a CAP, or simultaneous with a request for a CAP, we will inform the MA organization or Part D sponsor about the deficiencies that must be addressed and corrected. If the first CAP submission is unacceptable to us, we will inform the MA organization or Part D sponsor as to what is unacceptable. The MA organization or Part D sponsor will then have a second opportunity to submit an acceptable CAP.

It is our intent to assist plans in submitting acceptable CAPs, while implementing a limit on the number of CAP submissions in order to bring some closure to this process when Part D sponsors or MA organizations are unable or unwilling to bring their organizations into compliance with our requirements. Aside from the clarification explained above regarding the use of calendar days, we are finalizing our proposed processes and timeframes for the submission and review of CAPs as proposed.

Sections 422.510 and 423.509— Termination of Contract by CMS

We proposed revising § 422.510(a)(1) and § 423.509(a)(1) to clarify one of the bases for contract termination. The existing provision states that we may terminate an MA organization or Part D plan sponsor's contract with us if the MA organization or Part D plan sponsor "failed substantially to carry out the terms of its contract with CMS." We proposed language to clarify that we may terminate an MA organization or Part D plan sponsor's contract if the organization substantially failed to carry

out the terms of its contract with us during the current calendar year or for a prior calendar year. This clarification is consistent with section 1857(c)(1) of the Act, which states that a contract must be for a period of at least 1 year with the contract being automatically renewable from term to term (that is, calendar year to calendar year), absent notice from either party of an intent to terminate the contract at the end of the current term. Given that we have already adopted automatically renewable multi-year contracts, failure to substantially carry out a contract term necessarily would apply to the entire term of the contract (that is, the life of the contract).

We have made a minor change to the regulatory text at §§ 422.510(a)(1) and 423.509(a)(1) to clarify our proposal. The change is a technical edit to accurately reflect the multi-year nature of our contracts with MA organizations and Part D sponsors.

We proposed revising § 422.510(b) and § 423.509(b) introductory text and revising the paragraph heading for § 422.510(b)(2) and § 423.509(b)(2) to delete the term “immediate” and replace it with “expedited”. In addition, we proposed revising § 422.510(b)(2)(i) and § 423.509(b)(2)(i) to state that an expedited termination would take effect on a date specified by us. According to the existing regulations, an immediate termination takes effect once the MA organization or Part D plan sponsor receives notice that we intend to immediately terminate the plan’s contract with us and a plan’s enrollees are automatically disenrolled from the plan on the date such notice is received. The proposed change will provide greater protection for Medicare beneficiaries because we would have time between notifying a plan of an expedited termination decision and the actual date of termination to provide enrollees of the MA or Part D plan with enough information to enroll in another plan. We are finalizing this proposal without change.

Comment: We received a recommendation that we auto-enroll beneficiaries into another plan for seamless continuity of care, provided the beneficiary was able to make another health care choice. Another commenter felt that the effective date should be made in consultation with the terminated plan to better meet the needs of beneficiaries.

Response: We will take actions to ensure beneficiaries are protected and that continuity of care is a priority in our planning for all termination actions. We are not addressing beneficiary auto-enrollment in regulation since it is an

operational issue. We have considered the suggestion that we involve the terminated plan in determining the effective date of the termination but believe that we are in the best position to determine the effective date of the termination. Determining the effective date of an expedited termination is a decision that should be made solely by us. We are finalizing the provision as proposed.

Comment: A few commenters did not believe we should be able to terminate a contract based on deficiencies during prior years. Commenters also stated that deficiencies that have been cured should not be the basis for a contract termination.

Response: We clarify here that failure to carry out contract terms means the MA organization or Part D sponsor is not currently in compliance. The failure to be in compliance currently may be a continuation of a failure to be in compliance in the previous year and/or the result of an incident(s) that occurred during the prior year or years. For example, a notice of intent to terminate provided to an organization in February of the current year might be based on the organization failing to provide an acceptable CAP for an audit that occurred in December of the previous year. In addition, the deficiencies found in December of the previous year may be unresolved deficiencies from a prior audit, never having been cured. We need the ability to look into previous contract terms for uncured deficiencies. We proposed the ability to terminate a contract based on current, open deficiencies, no matter how long they have been open deficiencies. It is not our intent to terminate a contract based on deficiencies that have been, and remain, cured.

Comment: One commenter recommended an expedited hearing process for expedited terminations.

Response: The current regulations provide for a hearing process to occur after an immediate, proposed expedited, termination has occurred. Current regulations do not provide for an expedited appeals process. Our proposed changes to the appeals process do not provide for an expedited appeals process. We do not believe an expedited appeals process is warranted. However, we note that eliminating the reconsideration process for all contract determinations, as we have proposed and are finalizing, will have the effect of accelerating the appeals process for all contract determinations. We are finalizing this provision as proposed.

Comment: One commenter requested guidance or examples of what we

consider to be “imminent and serious risk to enrollees.”

Response: We do not wish to provide examples of what “imminent and serious risk to enrollees” might entail because of the complexities of each and every expedited termination that may take place. Each case is different and we do not feel that past examples will necessarily help plans in preventing future expedited terminations.

We also proposed to clarify that we are able to invoke the expedited termination process when a determination regarding an MA organization is made according to § 422.510(a)(5). The existing regulations state that we invoke the current immediate termination process when a determination is made according to § 422.510(a)(4) for the MA program and § 423.509(a)(4) or (a)(5) for the Medicare Part D program. By adding (a)(5) as a basis for an expedited termination for MA organizations, the grounds for expedited terminations would be identical for the MA and Part D programs. The addition of § 422.510(a)(5) would provide consistency between the Part C regulations and the Part D regulations.

Comment: One commenter did not agree that expedited terminations should be based on instances where an MA organization or Part D sponsor provides “false” data without any fraudulent intent or knowledge that false data was provided. The commenter believes that expedited terminations should be reserved for instances of beneficiary harm and intentional fraud.

Response: We proposed in the Part C regulations, at 422.510, that the submission of false data may serve as the basis for an immediate termination (proposed name change to expedited termination) to correlate with existing Part D regulations. Our ability to immediately terminate based on the submission of false data has already been subject to notice and comment during the comment period for the existing Part D regulations. We now proposed this change to the Part C regulations to ensure that the Part C and Part D regulations mirror each other where appropriate. We believe that this change is necessary to ensure the integrity of the Part C program and to continue to ensure that conduct under both the Part C and Part D programs is handled similarly. Therefore, we are finalizing our proposal without modification.

We proposed to amend our procedures at § 422.510(c) and § 423.509(c) to more clearly define the process for the submission and review of CAPs prior to a termination action.

The Act requires us to provide MA organizations and Part D plan sponsors with a reasonable opportunity to develop and implement a CAP before we terminate the organization or sponsor's contract. The CAP process we proposed is the same process for nonrenewals outlined above and which we proposed at § 422.506 and § 423.507, providing for a more structured process and timeframes for the development and implementation of a CAP. We received comments concerning CAPs as applied to terminations, and have addressed them above in §§ 422.506 and 423.507, given that the CAP process is identical for nonrenewals and terminations.

Subpart N—Medicare Contract Determinations and Appeals

We proposed revisions to subpart N of 42 CFR part 422 and 42 CFR part 423 to coordinate and improve the contract determination and appeals processes for MA organizations and Part D plan sponsors. We proposed eliminating the reconsideration process for appeals of all types of contract determinations. We also proposed to make the appeals process consistent for all three types of contract determinations (terminations, nonrenewals, and decisions by us not to enter into a contract with an applicant). In addition, we proposed that the MA organization or Part D plan sponsor have the burden of proof in appealing a contract determination. Please see the proposed rule for a more detailed explanation of our proposals.

Sections 422.644 and 423.642—Notice of Contract Determination

We proposed to make conforming changes to § 422.644(b)(2) and § 423.642(b)(2) as a result of the changes we are making to the immediate termination process. Consistent with the proposed revisions we have previously described, we proposed to revise § 422.644(c) and § 423.642(c) to state that we would determine the effective date of an expedited termination. We also proposed adding § 422.510(a)(4) as a basis for which we may undertake an expedited termination. We are finalizing these provisions as proposed.

We also proposed to revise the provisions at § 422.644(d) and § 423.642(d) to conform to the proposed change previously described whereby we would provide notice of nonrenewal to MA organizations or Part D plan sponsors by September 1, rather than the current May 1. Please see above for a discussion of nonrenewal notification dates. We are finalizing these proposals with a modification to reflect the fact that we are finalizing the nonrenewal

notification date as August 1, rather than September 1 as we proposed.

Sections 422.646 and 423.643—Effect of Contract Determination

We proposed making conforming changes to the provisions at § 422.646 and § 423.643 to reflect our proposal to eliminate the reconsideration process. The current regulations state that a contract determination is final unless an MA organization or Part D plan sponsor requests reconsideration. Since we proposed eliminating the reconsideration process, we also proposed a conforming change to indicate that a contract determination would be a final decision unless a timely request for a hearing is filed.

Comment: One commenter felt that eliminating a step for “informal collaboration” with us would create a process that is not in the best interest of beneficiaries. The commenter stated that by eliminating the reconsideration process, we appear to be eliminating opportunities to remedy potential problems prior to taking a formal contract action.

Response: We have reviewed the comment and have decided to finalize our proposal without modification. The commenter seems to be under the impression that the existing reconsideration process is an informal, collaborative process which provides the organization with another opportunity to come into compliance with our requirements. The commenter is misinformed about the nature of the current reconsideration process. The reconsideration is the first formal step in the administrative appeals process for organizations. The time for informal collaboration is prior to the commencement of an appeal, and prior to the seeking of reconsideration.

Sections 422.660 and 423.650—Right to a Hearing and Burden of Proof

We proposed conforming changes to the provisions at § 422.660(a) and 423.650(a) to reflect our proposal to eliminate the reconsideration process. These provisions would state that if we determine that an applicant is not qualified to enter into a contract with us and the applicant chooses to appeal the determination, a hearing before a CMS hearing officer would be the first step in the appeal process. We proposed to make similar conforming changes to § 422.660(b) and § 423.650(b), to indicate that a hearing before a CMS hearing officer would be the first step in appealing a nonrenewal determination or a termination decision. We did not receive any comments on these

provisions and are revising them as proposed.

We proposed to add a new provision at § 422.660(c) and at § 423.650(c) to clarify that the burden of proof would be on the MA organization or Part D plan sponsor at a hearing appealing a CMS contract determination. The MA organization or Part D plan sponsor must demonstrate that they were in compliance at the stated time by a preponderance of the evidence. We believe case law supports our decision to place the burden of proof on the affected party in an administrative hearing on a contract determination involving a Part D plan sponsor or MA organization. See *Hillman Rehabilitation Center*, DAB No.1611 (1999), aff'd *Hillman Rehabilitation Center v. U.S.* No.98-3789 (GEB) (D.N.J. May 13, 1999).

Comment: We received comments related to our effort to clarify that burden of proof is on the MA Organization or Part D sponsor. Commenters stated that the burden of proof should be on us, and not the organization or sponsor, since we are taking the contract action and that imposing the burden of proof on the organization or sponsor is contrary to traditional principles of jurisprudence and is unfair. One commenter suggested that if the burden is on the organization or sponsor, then there should be a rebuttable presumption of non-compliance with the organization or sponsor assuming the burden of proof to rebut the presumption on a going forward basis. The commenter stated that if the organization or sponsor submits at least colorable evidence of substantial compliance the burden of persuasion should shift to CMS to prove non-compliance by clear and convincing evidence.

Another commenter stated that putting the burden of proof on the organization or sponsor effectively removes the organization or sponsor's ability to self-regulate and come into compliance once the compliance issue has been identified. The commenter stated that the date of compliance must allow for entities to fix identified deficiencies and cure the deficiencies.

Response: We have considered these comments and have determined that the proposed provision should be finalized without modification. Plans, following an audit, receive a report notifying the plan of any non-compliance. Following the report, plans have an opportunity to dispute the findings. For those compliance issues not related to formal audits, we continue to notify the plan about deficiencies of which we become aware, giving the plan an opportunity to

dispute the allegation. Whenever a plan is found to be non-compliant, we will request a CAP to cure the deficiencies. We are finalizing regulations that will provide a MA organization of Part D sponsor with an opportunity to submit an acceptable CAP before we decide to take contract action. It is important to understand that the date we notify an organization of our intent to take a termination or nonrenewal action is not the first time the organization learns that it is out of compliance with our requirements.

In addition, we also proposed that the MA organization or Part D sponsor must demonstrate substantial compliance with the relevant MA or Part D plan requirements as of the earliest of the following dates: (1) The date the organization or sponsor received written notice of the contract determination; (2) the date of the most recent on-site audit conducted as the basis of the termination; (3) or the date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

Comment: We received a comment stating that the date of compliance should be the hearing date, not the earliest of the three dates proposed in the regulation. The commenter stated that using the earliest of the three dates violates due process.

Response: We have reviewed the comment and do not believe requiring compliance at the earliest of the three dates violates due process. MA organizations and Part D sponsors are required to be in compliance at all times. If we used the hearing date as the date by which we measured compliance, we would have absolutely no way of disputing a MA organizations or Part D sponsor's assertion that they are currently in compliance. Under no circumstance do we believe that the date for determining compliance should be after the date of termination notification. We are finalizing the proposal without modification.

Sections 422.662 and 423.651—Request for a Hearing

We proposed to revise § 422.662(b) and § 423.651(b) to conform to our proposed change to eliminate the reconsideration process. These provisions specify that a request for a hearing must be filed within 15 days after the date of the initial determination. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.664 and 423.652—Postponement of Effective Date of a Contract Determination When a Request for a Hearing Is Filed Timely

We proposed to revise § 422.664 and § 423.652 to postpone the effective date of a contract determination when an MA organization or Part D sponsor timely requests a hearing to appeal the contract determination. However, the postponement would not override the requirement that any final decision in favor of the plan or sponsor must be issued by July 15 for an initial contract to be effective for the upcoming year. Thus, if an organization's application is not approved and the hearing officer's decision is not provided until August, the applicant would not be able to have a contract for the next year. This is consistent with our current process. We do not currently postpone the effective date of termination in cases of immediate termination, and did not propose any change in policy with respect to expedited terminations. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.670 and 423.655—Time and Place of Hearing

We proposed revising § 422.670(a) and § 423.655(a), to require the hearing officer to send written notice to the parties specifying the general and specific issues to be resolved at the hearing, outlining the burden of proof and providing any information about the hearing procedures. In addition, the notice would inform the parties that they may conduct formal discovery. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.682 and 423.661—Discovery

We proposed revising § 422.682 and § 423.661, to clarify the scope of permissible discovery, and to require the hearing officer to conclude discovery and provide all documents to both the hearing officer and the opposing party at least 10 days prior to the hearing. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.684 and 423.662—Prehearing and Summary Judgment

We proposed to amend the provisions at § 422.684 and § 423.662 (and revise the section heading accordingly) to permit the hearing officer to rule on a motion for summary judgment filed by either of the parties to the hearing. In ruling on such a motion, we propose that the hearing officer would be bound

by CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.692 and 423.666—Review by the Administrator

The existing regulations only explicitly permit Administrator review of a hearing officer's decision in appeals of a contract termination. We clarify that this review is available for all appeals of CMS contract terminations, including decisions not to contract with an applicant and nonrenewals.

We proposed revising the provisions at § 422.692(a) and § 423.666(a) to allow us to request Administrator review of a hearing officer's decision regarding a contract determination. The existing regulations permit only the MA organization or Part D sponsor to request Administrator review. In addition, we proposed to amend the same provisions to permit both the parties to submit written arguments to the Administrator.

Comment: One commenter did not feel that we should be able to request an appeal to the Administrator.

Response: We believe that we should have the right to request a review by the Administrator. We feel that appeal rights should be provided to both parties to provide for an equal opportunity to be heard by the Administrator. Therefore, we are not making any changes to the proposed regulations based on these comments.

We proposed revising the provisions at § 422.692(b) and § 423.666(b), to permit the Administrator, upon receipt of a request for Administrator review, to accept or decline to review the hearing decision. The existing regulations require the Administrator to review the decision when a request for review is received. We believe that providing the Administrator with the discretion to accept or decline the request for review would lead to a more expeditious resolution of appeals of contract determinations.

Comment: We received a comment stating that the Administrator failing to take action within 30 days authorizes an unstructured, unrecorded exercise of the Administrators decision that can hide unequal treatment which evades review. The commenter stated that the Administrator taking no action does not afford the plan the level of review of other plans in which the Administrator reviews the appeal.

Response: We believe the Administrator has the authority to either

accept to review Hearing Officer decisions or to decline to review Hearing Officer decisions. This right is well-founded in current Provider Reimbursement Review Board policy. We are not making any changes to the proposed regulation as a result of this comment.

We proposed redesignating § 422.692(c) as § 422.692(e) and redesignating § 423.666(c) as § 423.666(e). We proposed adding a new § 422.692(c) and § 423.666(c), to require the Administrator to make a determination as to whether to accept or decline the request for review within 30 days of the request of the review. The failure of the Administrator to make a determination within 30 days of the request would be treated as a decision to decline the request for review. We believe that providing this timeline assists all parties in reaching a final decision in an expeditious manner. We did not receive any comments on this provision and are adopting it as proposed.

In addition, we proposed amending our existing regulations to add a new paragraph at § 422.692(d) and § 423.666(d) which specifies that Administrator review is based on the hearing record and any written arguments submitted by the parties. However, review would not be based on any new evidence, such as evidence that was not before the hearing officer. We believe the specified sources provide a sufficient basis for the Administrator to make a determination.

Comment: A commenter stated that Administrator review should not be limited to the record but should accept additional evidence.

Response: The Administrator review does allow for each party to submit additional arguments, but the current regulation does not provide for additional evidence to be submitted. We feel that the hearing record is sufficient, with enough information provided for the Administrator to make a determination. Therefore, we are not making any changes to the proposed regulations based on these comments.

Sections §§ 422.696 and 423.668—Reopening of Initial Contract Determination or Intermediate Sanction or Decision of a Hearing Officer of the Administrator

We proposed to revise the section headings for § 422.696 and § 423.668 from “Reopening of a contract or reconsidered determination or decision of a hearing officer or the Administrator” to “Reopening of an initial contract determination or decision of a hearing officer or the

Administrator” to conform to our proposed elimination of the reconsideration process described above. We did not receive any comments on this provision and are adopting it as proposed.

Sections §§ 422.698 and 423.669—Effect of Revised Determination

We proposed a conforming change to reflect our proposed elimination of the reconsideration process by removing in its entirety § 422.698 and § 423.669, “Effect of revised determination.” We did not receive any comments on this provision and are adopting it as proposed.

Subpart O—Intermediate Sanctions

We proposed several changes to our regulations in Subpart O—Intermediate Sanctions in 42 CFR Part 422 and 42 CFR Part 423, to clarify our policies and procedures for imposing intermediate sanctions and Civil Money Penalties (CMPs) on MA organizations and Part D sponsors. Specifically, we proposed to modify the appeals procedures for intermediate sanctions and clarify which set of procedures affected parties should use to appeal a CMP.

General Comments:

Comment: We received a few comments concerning bifurcated hearings for intermediate sanctions and/or CMPs. The commenters felt that one hearing should be used for both CMS imposed intermediate sanctions or CMPs and OIG imposed CMPs.

Another commenter expressed concern that there is no explanation as to when both CMS and OIG may impose CMPs based upon the same set of facts. The commenter stated that only in the most egregious cases should both CMS and the OIG impose CMPs.

Response: Appeals of CMS intermediate sanctions or CMPs and OIG imposed CMPs are governed by different regulatory processes and therefore cannot be combined in one hearing. In addition, CMS and OIG may impose sanctions/CMPs under different and independent authorities. The regulations currently provide for both OIG and CMS to impose sanctions on the same set of facts. We have considered the comment and are not making any changes to the regulations.

Sections §§ 422.750 and 423.750—Types of Intermediate Sanctions and Civil Monetary Penalties

We proposed reorganizing § 422.750 and § 423.750, to distinguish the three different types of intermediate sanctions from CMPs. We also proposed to clarify that each of the three intermediate

sanctions, (suspension of enrollment, suspension of payment, and suspension of marketing) would remain in effect until we are satisfied that the reasons for the initial suspensions have been corrected and are not likely to reoccur. This revision reflects our current policy and practice.

Comment: We received a comment stating that the suspension of all marketing activities is too severe for “noncompliant behavior.” The commenter stated that the suspension should only be for the particular MA or Part D plan that is non-compliant.

Response: We are revising § 422.750(a) and § 423.750(a) to clarify that the marketing sanctions will be imposed only on CMS-specified plans. We did not intend to expand the scope of the sanction with our proposed change. Therefore, we have changed the proposed regulatory language to be consistent with the existing provisions.

For clarity, we proposed specifying at § 422.750(b) and § 423.750(b) that we may impose CMPs in the dollar amounts specified in § 422.760 and § 423.760. We proposed to remove the prior reference at § 422.750(a)(1) and § 423.750(a)(1) to the range of CMPs because it is confusing. We did not receive any comments on this provision and are adopting it as proposed.

Sections §§ 422.752 and 423.752—Basis for Imposing Intermediate Sanctions and Civil Money Penalties

At § 422.752 and § 423.752, we proposed to reorganize the regulation to clarify the breakdown of responsibility between CMS and the OIG for imposing intermediate sanctions and CMPs based on the type of violation involved. Specifically, we clarify that CMS may impose a suspension of enrollment, payment, or marketing on an MA organization or Part D sponsor for violations specified in § 422.752(a)(1) through (a)(8) and for violations specified in § 423.752(a)(1) through (a)(6).

As part of the reorganization to the regulation, we also proposed to add a new § 422.752(c) and § 423.752(c), to clarify that in addition to the intermediate sanctions, we continue to have authority to impose CMPs for contract determinations made under § 422.510(a) and § 423.509(a). However, as specified in § 422.752(c)(2) and § 423.752(c)(2), OIG would continue to have sole authority to impose CMPs for any determinations concerning the MA organization or the Part D sponsor committing or participating in false, fraudulent, or abusive activities affecting the Medicare program, including the submission of false or

fraudulent data, as stated in § 422.510(a)(4) and § 423.509(a)(4). We did not receive any comments on this provision and are adopting it as proposed.

**Sections §§ 422.756 and 423.756—
Procedures for Imposing Intermediate
Sanctions and Civil Money Penalties**

At § 422.756 and § 423.756, we proposed to eliminate the existing informal reconsideration process used for review of a decision by CMS to impose an intermediate sanction, and allow an MA organization or Part D sponsor to proceed directly to a hearing, pursuant to the same procedures used to appeal contract determinations in Subpart N. (See § 422.660 through § 422.698 and § 423.650 through § 423.669.) We believe it would be more efficient and effective to allow the MA organization or Part D sponsor to proceed to a hearing in appealing an intermediate sanction. We note that a request to appeal an intermediate sanction before a hearing officer does not delay the intermediate sanction from taking effect on the date specified in the sanction notice. We did not receive any comments on this provision and are adopting it as proposed.

Because we proposed to eliminate the informal reconsideration process, we proposed that an MA organization or Part D sponsor have an opportunity to present information to us that may affect our decision to impose an intermediate sanction prior to the sanction taking effect. We recognize there may be occasions when we receive information that we previously did not have when making a decision to impose an intermediate sanction. Therefore, we proposed that MA organizations and Part D sponsors have an opportunity to submit a written rebuttal statement as specified at § 422.756(a)(2) and § 423.756(a)(2), and to require the rebuttal statement be provided to us within ten (10) calendar days after the MA organization or sponsor receives notice of the intermediate sanction. The 10 calendar days begin the day after the notice of intermediate sanction is mailed to the plan. A notice of intermediate sanction is sent by overnight mail and by e-mail or fax.

In some cases we may decide to take multiple actions, for example, contract termination, intermediate sanction, or CMP, against an MA organization or Part D sponsor. We proposed to have the appeals of CMPs go to an ALJ while the appeals of other actions, such as an intermediate sanction or a termination, will be before a CMS hearing official. Although the same underlying conduct may be the basis for both actions we

believe that the separate processes would result in more consistent decision making by hearing officers and ALJs. We did not receive any comments on this provision and are adopting as proposed.

In addition, in preparing this final rule with comment period, we recognized that we inadvertently omitted some corresponding revisions to the existing regulatory text. These changes are necessary to implement the policies that we articulated in the proposed rule and are finalizing here. Specifically, we are revising § 422.756(c) and § 423.756(c) to reflect the fact that we have eliminated the reconsideration process and that an intermediate sanction imposed by CMS will go into effect on the date specified in the notice (15 days after the date of notification) and a reconsideration, or now an appeal to a hearing officer, will not delay the effective date of the sanction. See page 29379 of the proposed rule. We are also revising §§ 422.756(d) and 423.756(d) to reflect the fact that we have eliminated the reconsideration process, that an appeal will not delay the effective date of the sanction, and that where the exception at § 422.756(d)(2) or § 423.756(d)(2) applies, CMS may make the sanction effective on a specified date prior to 15 days after the date of notification. The changes to § 422.756(d)(2) and § 423.756(d)(2) are consistent with our existing authority. We interpret the existing provisions to allow us to make a sanction effective at any time when there is a serious threat to an enrollee's health and safety, including prior to 15 days after notification. It is critical that we continue to have the ability to protect the interests of Part C and D enrollees by taking immediate action in some cases.

In addition, upon review, we realized that some typographical corrections to the proposed regulatory text at § 423.756(f) were necessary. Specifically, in the proposed rule, we realized that we had typographical errors at § 423.756(f)(2) and (f)(2)(v). We have corrected the cross-reference to § 423.509(c)(1) and replaced it with a cross-reference to § 423.752(c)(1). We have also replaced the reference at (f)(2)(v) to § 423.650 with a reference to Subpart T since those are now the appeals provisions that govern appeals of CMPs.

**Sections §§ 422.758 and 423.758—
Collection of Civil Money Penalties
Imposed by CMS**

At § 422.758 and § 423.758 we proposed to revise the section heading "Maximum amount of civil money

penalties imposed by CMS" to read "Collection of civil money penalties imposed by CMS." In addition, we proposed to revise § 422.758 and § 423.758. Specifically, we proposed that we would initiate collection of the CMPs if the MA organization or Part D sponsor does not timely request a hearing, or if our decision to impose a CMP is upheld by an ALJ. We did not receive any comments on this provision and are adopting as proposed.

**Sections §§ 422.760 and 423.760—
Determinations Regarding the Amount
of Civil Money Penalties and
Assessment Imposed By CMS**

We proposed redesignating the existing § 422.760 as § 422.764 and redesignating the existing § 423.760 as § 423.764 because in this rule we have explicitly outlined the CMP appeals procedures in proposed subpart T in parts 422 and 423.

We proposed adding a new § 422.760 and § 423.760 to clarify that we use the statutory factors in section 1128(A) of the Act in determining the appropriate amount of civil money penalties or assessments to impose on an MA organization or Part D sponsor. These factors, if applicable, include the nature of the conduct, the degree of culpability, the prior history of offenses, the financial condition of the MA organization or Medicare Part D sponsor presenting the claims, and other matters as fair administration may require. These factors are based on the same statutory factors used in other Medicare enforcement programs, including the nursing facility enforcement context.

We also proposed to clarify, in § 422.760(b) and § 423.760(b), the amounts that may be assessed for CMPs that we impose.

Comment: We received a comment stating that we should provide for additional mitigating factors that would affect the penalty determination as a result of the MA organization or Part D sponsor's noncompliance/deficiencies. The commenter suggested that we review mitigating factors such as the corrective action that the organization has taken and the nature and extent to which the organization has cooperated with CMS.

Response: We have reviewed the comment and believe that consideration of mitigating factors is already included in the proposed provision. We state that factors that may be reviewed include the degree of culpability of the MA organization, the history of the prior offenses by the organization and other matters as justice may require. We believe these proposed factors provide sufficient opportunity for us to adjust

sanctions as warranted. We are finalizing our proposal without modification.

Sections §§ 422.762 and 423.762—Settlement of Penalties

We proposed to add a new § 422.762 and § 423.762 to clarify that in accordance with section 1128A(f) of the Act, we have the authority to settle CMPs imposed by us. This provision would make it explicit that the parties may agree to settle the dispute instead of litigating an appeal. We did not receive any comments on this provision and are adopting as proposed.

Sections §§ 422.764 and 423.764—Other Applicable Provisions

We proposed to redesignate § 422.760 and § 423.760 as § 422.764 and § 423.764 respectively to conform to the changes proposed at the new § 422.760 and § 423.760. No substantive changes to the text were proposed. We did not receive any comments on this provision and are adopting it as proposed.

Subpart T—Appeal Procedures for Civil Money Penalties

We proposed to reserve subparts P, Q, R, and S in Part 422. In addition, we proposed to add a new subpart T in Part 422 and Part 423, respectively. These new subparts would outline the CMP appeal procedures for MA organizations and Part D sponsors.

Our current MA and Part D regulations do not specify which procedures an MA organization or Part D sponsor must use to appeal a CMS-imposed penalty under either of these two programs. The regulations at 42 CFR part 422.760 and 42 CFR part 423.760 state only that the provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to CMPs under this subpart to the same extent that they apply to a CMP or procedure under section 1128A of the Act. Nor have we issued any guidance directing parties to the appropriate appeals procedures for MA and Part D CMPs.

Therefore, to ensure a consistent approach in this area, we proposed incorporating appeals procedures for parties to use when appealing a CMP imposed under the MA or Part D program in a new subpart T in Parts 422 and 423 respectively.

Based on certain statutory requirements and policy considerations, we proposed to adopt CMP appeals procedures almost identical to those in part 498 of Title 42, which are used by certain Medicare providers and suppliers to challenge adverse agency enforcement decisions. Part 498 sets forth the rules for administrative and

judicial review of CMS determinations that affect participation in the Medicare and Medicaid programs for a wide array of medical providers of services. These rules, issued on June 12, 1987 (52 FR 22446), have been used by CMS for more than 20 years and provide established appeals procedures for various types of adverse agency determinations, including civil money penalties imposed on nursing facilities. For numerous reasons laid out in the proposed rule, we believe the part 498 appeals procedures are the most appropriate procedures to use for hearing disputes involving a wide range of violations. We did not receive any comments on this provision and are generally adopting it as proposed. We are making a technical revision to remove proposed paragraphs § 422.1004(a)(2) and (a)(3), and § 423.1004(a)(2) and (a)(3) because they were inadvertently retained from the part 498 procedures.

While the statute authorizing CMPs in the MA and Part D programs requires the provisions of section 1128A of the Act, (except for subsections (a) and (b)), to apply to MA and Part D CMP proceedings, it does not require that section 1128A's provisions apply to other CMP appeals procedures in the exact same manner, or without some consideration for the MA or Part D program's unique characteristics. In fact, section 1857(g)'s "same manner" language appears throughout the Act and serves as the statutory basis for several different types of CMP enforcement and appeals procedures. Because program violations may vary by the type and nature of the violation, we have modified our CMP appeal procedures when necessary. Since the MA and Part D programs differ from the nursing facility program, we proposed modifying certain sections of part 498 to take into account some of these differences.

For example, we proposed removing the reconsideration step in the MA and Part D CMP appeals procedures since this step in part 498 only applies to initial determinations made for prospective providers entering the Medicare or Medicaid program and is not applicable to CMP appeals. Removing the reconsideration step in subpart T would also help expedite the CMP appeals process.

Since it is not clearly stated in part 498's regulations, we proposed to make explicit in our regulations that in a hearing of a CMP appeal before an ALJ or the Departmental Appeals Board (DAB), the ultimate burden of persuasion would rest on the MA organization or Part D sponsor. See the

proposed rule for instances when the DAB has held that in a provider termination proceeding by the Secretary, the facility bears the ultimate burden of proving it is in compliance with program requirements (Hillman Rehabilitation Center, DAB No.1611 (1999), aff'd *Hillman Rehabilitation Center v. U.S.* No.98-3789 (GEB) (D.N.J. May 13, 1999)). We believe the administrative caselaw supports our decision to place the burden of proof on the affected party in an administrative hearing on the imposition of MA and Part D CMPs. We did not receive any comments on this provision and are finalizing it as proposed.

III. Provisions of the Final Rule With Comment Period

In this final rule with comment period, we are adopting the provisions as set forth in the May 25, 2007 proposed rule with the following revisions:

Amend § 422.2, "Definitions," by—

- Revising the proposed definition of the term "downstream entity" to read as follows: *Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Amend § 422.503 "General Provisions" by—

- Revising proposed paragraph (b)(4)(vi)(G)(3) to read as follows: The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

Amend § 422.504 "Contract provisions" by—

- Revising proposed paragraph (e)(2) for clarity.

- Revising proposed paragraph (i)(2)(i) for clarity.

- Revising paragraphs (i)(3) introductory text, (i)(3)(ii), and (i)(3)(iii) for clarity, and by deleting the term "providers."

- Revising paragraph (i)(4) introductory text by deleting the phrase "provider or."

Amend § 422.506 by—

- Revising proposed paragraph (b)(2)(i) to make the date of notice of nonrenewal by CMS August 1.

- Revising proposed paragraph (b)(3)(i) to clarify that a MA organization will have an opportunity to submit a corrective action plan (CAP) prior to

CMS providing a notice of intent to nonrenew.

- Revising proposed paragraphs (b)(3)(i) and (b)(3)(ii) to clarify that CAP submission deadlines are measured in calendar days.

Amend § 422.510 “Termination of contract by CMS” by—

- Revising proposed paragraph (a)(1) for clarity.

- Revising proposed paragraph (c)(1) to clarify that MA organizations will have the opportunity to submit a CAP before CMS notifies them of an intent to terminate.

Amend § 422.644 by—

- Revising proposed paragraph (d) to clarify that a CMS notice of an intent to nonrenew will be sent to a MA organization by August 1.

Amend § 422.750 by—

- Revising proposed paragraph (a)(3) to clarify that suspension of all marketing activities to Medicare beneficiaries by an MA organization applies only to specified MA plans.

Amend § 422.752 by—

- Revising proposed paragraph (c)(2) to reference section 1003 of chapter V of this title.

Amend § 422.756 by—

- Revising paragraph (c) to reflect the fact that we have eliminated the reconsideration process, and that an intermediate sanction imposed by CMS will go into effect on the date specified by the notice, and that an appeal will not delay the effective date of the sanction.

- Revising paragraph (d) to reflect the fact we have eliminated the reconsideration process, that an appeal will not delay the effective date of the sanction, and that where the exception at § 422.756(d)(2) applies, CMS may make the sanction effective on a specified date prior to 15 days after the date of notification.

Amend § 422.1004 by—

- Deleting proposed paragraphs (a)(2) and (a)(3).

- Redesignating paragraph (a)(1) as paragraph (a).

Amend § 422.1070, “Removal of hearing to Departmental Appeals Board,” by—

- Revising paragraph (a) to correct a typographical error. The revised paragraph now reads: “At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.”

Amend § 423.4, “Definitions,” by—

- Revising the proposed definition of the term “downstream entity” to read as follows: *Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the

Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Amend § 423.504, “General Provisions” by—

- Revising paragraph (b)(4)(vi)(C) for clarity.

- Revising proposed paragraph (b)(4)(vi)(G)(3) to read: The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

Amend § 423.505, “Contract Provisions,” by—

- Revising proposed paragraph (e)(2) for clarity.

- Revising proposed paragraph (i)(2)(i) for clarity.

- Revising proposed paragraph (i)(3) introductory text to read as follows: All contracts or written arrangements between Part D sponsors and first tier, downstream, and related entities must contain the following:

- Revising proposed paragraph (i)(3)(ii) to read as follows: Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity, only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

- Revising proposed paragraph (i)(3)(iv) to read as follows: A provision requiring the Part D sponsor’s first tier, downstream, and related entities to produce upon request by CMS or its designees any books, contracts, records, including medical records and documentation of the MA organization, relating to the Part D program to either the sponsor to provide to CMS, or directly to CMS or its designees.

- Revise proposed paragraph (i)(3)(v) to read as follows: All contracts or written arrangements must specify that the first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

- Revise proposed paragraph (i)(4) introductory text and paragraph (i)(4)(v) to remove the word pharmacy.

Amend § 423.507 “Nonrenewal of Contract” by—

- Revising proposed paragraph (b)(2)(i) to make the date of notice of nonrenewal by CMS August 1.

- Revising proposed paragraph (b)(3) to clarify that a Part D sponsor will have an opportunity to submit a CAP prior to receiving a letter of intent to nonrenew.

- Revise proposed paragraphs (b)(3)(ii) and (b)(3)(iii) to clarify that CAP submission deadlines are measured in calendar days.

Amend § 423.509 “Termination of contract by CMS” by—

- Revising proposed paragraph (a)(1) for clarity.

- Correcting a typographical error in paragraph (a)(9) by replacing the reference to § 423.128 with a reference to § 423.50.

- Revising proposed paragraph (b) introductory text for clarity.

- Revising paragraph (c)(1) to clarify that before providing an intent to terminate, CMS will provide a Part D sponsor with an opportunity to submit a CAP.

- Correcting a typographical error in paragraph (c)(1) by replacing the term “MA organization” with the term “Part D plan sponsor.”

Amend § 423.642 by—

- Revising proposed paragraph (d) to clarify that a CMS notice of an intent to nonrenew will be sent to a MA organization by August 1.

Amend § 423.750 by—

- Revising proposed paragraph (a)(3) to clarify that suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor applies only to specified Part D plans.

Amend § 422.752 by—

- Revising proposed paragraph (c)(2) to reference section 1003 of Chapter V of this title.

Amend § 423.756 by—

- Revising paragraph (c) to reflect the fact that we have eliminated the reconsideration process, and that an intermediate sanction imposed by CMS will go into effect on the date specified by the notice, and that an appeal will not delay the effective date of the sanction.

- Revising paragraph (d) to reflect the fact we have eliminated the reconsideration process, that an appeal will not delay the effective date of the sanction, and that where the exception at § 423.756(d)(2) applies, CMS may make the sanction effective on a specified date prior to 15 days after the date of notification.

- Revising paragraph (f) to correct typographical errors.

Amend § 423.1004 by—

- Deleting proposed paragraphs (a)(2) and (a)(3).

- Redesignating paragraph (a)(1) as paragraph (a).

Amend § 423.1070, “Removal of hearing to Departmental Appeals Board,” by—

- Revising paragraph (a) to correct a typographical error. The revised paragraph now reads: “At any time

before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.”

IV. Collection of Information Requirements

We received no public comments concerning the collection of information requirements of the proposed rule. Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following information collection requirements included in this proposed rule and their associated burdens are subject to the PRA.

We solicited public comment on each of the issues for the following sections of this document that contain information collection requirements and are not currently approved by the OMB.

Section § 422.503 General Provisions

Sections 422.503(b)(4)(vi)(C) and (b)(4)(vi)(D) require a MA organization to have a compliance plan, which includes measures to detect, correct, and prevent fraud, waste, and abuse. The compliance plan shall include effective training and education between the compliance officer and the MA organization's employees, managers and directors, the MA organization's first tier, downstream, and related entities; and, effective lines of communication between the compliance officer, members of the compliance committee, the MA organization's employees, managers and directors, and the MA organization's first tier, downstream, and related entities.

The burden associated with this requirement is the time and effort put forth by the MA organization to prepare a compliance plan that meets the requirements of this section. While this requirement is subject to the PRA, it is

currently approved under OMB #0938–1004.

Section 422.503(b)(4)(vi)(G)(3) recommends a MA organization to have procedures in place for voluntary self-reporting of potential fraud or misconduct related to the MA program to the appropriate government authority. We recommend that the MA organization report potential fraud or misconduct related to the MA program to the appropriate government authority.

The burden associated with this recommendation is the time and effort put forth by the MA organization to implement procedures for voluntary self-reporting. We estimate it would take one MA organization 40 hours to fulfill this recommendation. The total number of MA organizations affected by this recommendation is 393. The total one-time burden for this recommendation would be 15,720 hours. We cannot anticipate how many plans will report any potentially fraudulent activities to CMS. However, based on historical evidence, we believe that less than 10 MA organizations will self-report potential fraud or misconduct related to the MA program. While this burden is subject to the PRA, we expect that less than 10 entities will be affected. Therefore, we believe these collection recommendations are exempt as specified at 5 CFR 1320.3(c)(4).

Section 422.504 Contract Provisions

Section 422.504(e)(2) requires MA organizations to agree to allow HHS, the Comptroller General, or their designees to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the MA organization, its first tier, downstream, related entity, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

The burden associated with this requirement is the time and effort put forth by the MA organization to maintain appropriate records and documentation. While this requirement is subject to the PRA, it is currently approved under OMB #0938–1004.

Section 422.504(i)(2) requires the MA organization to require all first tier, downstream, and related entities to agree that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the first tier, downstream, and related entities involving transactions related to

CMS' contract with the MA organization.

The burden associated with this requirement is the time and effort put forth by the MA organization's first tier, downstream, and related entities to maintain appropriate records and documentation. While the burden associated with this requirement is subject to the PRA, it is currently approved under OMB #0938–1004.

Section 422.505 Effective Date and Term of Contract

Section 422.505(c) requires MA organizations who wish not to renew their contract to submit a notice of intent to CMS.

The burden associated with this requirement is the time and effort put forth by the MA organization to prepare the notice and submit it to CMS. While this requirement is subject to the PRA, it is currently approved under OMB #0938–0753.

Section 422.506 Nonrenewal of Contract

Section 422.506 provides a MA organization an opportunity to develop and submit a CAP to correct the deficiencies that are the basis of the termination decision. The MA organization must submit the CAP within 45 days of receiving notice of termination.

The burden associated with this requirement is the time and effort it would take for the MA organization to develop and submit a CAP. While this requirement is subject to the PRA, we expect less than 10 entities will be affected by receiving a notice of intent to nonrenew. Therefore, we believe these collection requirements are exempt as specified at 5 CFR 1320.3(c)(4).

Section 423.504 General Provisions

Sections 423.504(b)(4)(vi)(C) and (b)(4)(vi)(D) require Part D Sponsors to have a compliance plan, which includes measures to detect, correct, and prevent fraud, waste, and abuse. The compliance plan shall include effective training and education between the compliance officer and the Part D sponsor's employees, managers and directors, and the Part D plan sponsor's first tier, downstream, and related entities; and, effective lines of communication between the compliance officer, members of the compliance committee, the Part D sponsor's employees, managers and directors, and the Part D sponsor's first tier, downstream, and related entities.

The burden associated with this requirement is the time and effort put

forth by the Part D sponsor to prepare a compliance plan that meets the requirements of this section. While this requirement is subject to the PRA, it is currently approved under OMB #0938-1000.

Section 423.504(b)(4)(vi)(G)(3) recommends a Part D sponsor have procedures in place for voluntary self-reporting of potential fraud or misconduct related to the Part D program to the appropriate government authority. We recommend that the Part D sponsor report potential fraud or misconduct related to the Part D program to the appropriate government authority.

The burden associated with this recommendation is the time and effort put forth by the Part D sponsor to implement procedures for voluntary self-reporting. We estimate it will take one Part D sponsor 40 hours annually to fulfill this recommendation. The total number of Part D sponsors affected by this recommendation is 91. The total one-time burden would be 3,640 hours. We cannot anticipate how many plans will report any potentially fraudulent activities to CMS. However, in the event a Part D sponsor self-reports potential fraud or misconduct related to the Part D sponsor the total burden would be 5 hours annually. If every sponsor reports potential fraud or misconduct, the total burden would be 455 annual hours.

Section 423.505 Contract Provisions

Section 423.505(e)(2) requires Part D sponsors to make available its premises, physical facilities, equipment, and records that relate to its Medicare enrollees, and any additional relevant information that CMS may require. The Part D sponsor also agrees to make available any books, contracts, records, including medical records and documentation of its first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to make available records that relate to its Medicare enrollees. The burden associated with this requirement is currently approved under OMB #0938-1000.

Section 423.505(i)(2) requires the Part D sponsor to require all first tier, downstream, and related entities to agree that HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any books, contracts, records, including medical records and documentation of the first tier, downstream, and related

entities involving transactions related to CMS' contract with the Part D sponsor.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor's first tier, downstream, and related entities to maintain appropriate records and documentation. While this requirement is subject to the PRA, it is currently approved under OMB #0938-1000. However, we have prepared the following analysis of the costs and burden associated with our proposal to require sponsors to include a provision in their contracts requiring their first tier and downstream entities to produce or make available their books and records.

In the January 28, 2005 final rule that implemented the Medicare Prescription Drug Program (70 FR 4194), we noted that "The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information, dissemination, appeals processes, pharmacy network negotiations, and contracting. The other factor taken into account when developing our estimate is that Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs) will likely incur slightly higher administrative costs during the initial few years of the Part D benefit due to start-up costs related to implementation and initial operation for a new benefit." The narrative explains that the average administrative costs associated with insurance products are typically expressed as a percentage relative to net standard benefit expenses and that the administrative load is expected to decline slightly over time. For purposes of this analysis, the impact is presented in burden hours and broken out into requests for purposes of:

1. Provision in contracts;
2. BI Audit; and
3. Investigation of complaints.

1. Provision in Contracts

Ultimately, this additional provision would have to be discussed like all other provisions of a contract between a Part D sponsor and its first tier, downstream, and related entities. Since we have the authority to request this information and the Part D sponsor has attested to providing this data, we do not believe that this issue would be contentious or constitute negotiation discussion. We believe that, at the most, this provision would require 1 hour of attorney time to draft and discuss the provision.

2. BI Audit

Currently, there are a total of 650 Part D contracts (90 of those contracts represent PDPs and the remainder, 560 contracts, represents MA-PDs and employer groups). A further breakdown of those numbers out to the plan level would be: 4,927 total MA-PDs and PDP plans (including employer groups). We note that if employer groups are excluded, the actual number drops to 4,191.

Based on this information, it is believed that 16 percent of the plans will be audited during the course of a contract year. Of the plans audited, it is estimated that approximately 10 percent of the plans will be required to produce evidence or other supporting documentation related to "first tier, downstream and other related entities." It is further asserted that the labor hours required to produce the required documentation for those entities would be estimated at 10 hours per plan. Therefore, based on the number of Part D plans, the percentage of organizations that might be required to produce documentation for "first tier, downstream, and other related entities" and the number of labor hours required to produce this documentation we expect that the total impact would be 140 hours in administrative costs. The following table summarizes our calculation of the burden estimate for Part D plans:

Total number of Part D plans (PDP, MA-PD & Employer Groups)	650
Percentage of plans to be audited (16%)	104
Percentage of plans audited that would be required to produce additional documentation for "first tier, downstream and related entities" (10%)	10
Burden hours required to assemble documentation and submit to CMS (10 hours/plan)	100

3. Investigation of Complaints

Based on the past 18 months, we assume that investigation of complaints that require contacting a Part D plan to request documentation from first tier, downstream, and related entities would be approximately six instances. In the following table, we show our estimate of burden hours for downstream entities:

Total number of Part D plans (PDP, MA-PD & Employer Groups)	650
Percentage of plans to be audited (16%)	104

Percentage of plans audited that would be required to produce additional documentation for "first tier, downstream and related entities" (10%)	10
Average number of "downstream entities" (e.g. pharmacy network):	
Retail	55,000
Mail Order	1
Home Infusion	150
Long Term Care	593
I/T/U	329
Total burden hours required for downstream entities to assemble and submit documentation to the Part D organizations (hours/organization at 3 hrs/downstream entity ...	166,440

Section 423.506 Effective Date and Term of Contract.

This section states that an entity is determined qualified to renew its

contract annually only if the Part D sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D sponsor with a notice of intention not to renew.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to prepare a notice of intent not to renew and submit it to CMS. While this requirement is subject to the PRA, it is currently approved under OMB #0938-0964.

Section 423.507 Nonrenewal of Contract.

Section 423.507 provides a Part D Plan Sponsor an opportunity to develop and submit a corrective action plan (CAP) to correct the deficiencies that are the basis of the termination decision.

The Part D Sponsor must submit the CAP within 45 days of receiving notice of termination.

The burden associated with this requirement is the time and effort it would take for the Part D Sponsor to develop and submit a CAP. While this requirement is subject to the PRA, we expect less than 10 entities will be affected by receiving a notice of an intent to nonrenew; therefore, we believe these collection requirements are exempt as specified at 5 CFR 1320.3(c)(4).

As reflected in the table that follows, the aggregate annual burden associated with the collection of information section totals 73,236 hours.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden
0938-1004	422.503(b)(4)(vi)(C) and (b)(4)(vi)(D), 422.504(e)(2) & 422.504(i)(2).	393	96 hours	12,576 hours (based on 131 responses per year).
None-requesting OMB approval.	422.503(b)(4)(vi)(G)(3)	393	40 hours	15,720 hours (based on every plan reporting fraud or misconduct).
0938-0753	422.505(c)	5-10	2 hours per notice	20 hours (estimated using 10 respondents).
None/Exempt	422.506	Less than 10	N/A	N/A.
0938-1000 *	423.504(b)(4)(vi)(C) and (b)(4)(vi)(D), 423.505(e)(2), & 423.505(i)(2).	430	96 hours	41,280 hours.
None-requesting OMB approval.	423.504(b)(4)(vi)(G)(3)	91	40 hours	3,640 hours.
Exemption mentioned in 0938-0964.	423.506	Less than 10	N/A	N/A.
None/Exempt	423.507	Less than 10	N/A	N/A.
Total Annual Burden				73,236 hours.

* This package will be revised to reflect new respondent numbers & annual burden, which are previously discussed in this section (166,440 hours). The total annual burden of 73,236 hours includes 19,360 new hours, which added to 166,440 gives a total new burden of 185,800 hours which have not previously been approved.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: Melissa Musotto, CMS-4124-F, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, (CMS-4124-P), carolyn_lovett@omb.eop.gov. Fax (202) 395-6974.

V. Regulatory Impact Statement

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 provisions of this final rule with comment period would require MA and Part D sponsors to spend a total of approximately 186,000 additional hours on the functions addressed in this proposed rule. This includes our reestimates of burden. The details behind these estimates are presented in the preceding Paperwork Reduction Act section.

Assuming an average cost to plans and downstream entities of \$37.50¹ an

¹ The hourly rate of \$37.50 for the burden requirement was developed using the Department of Labor May 2006 National Average wage for management analysts. The May 2006 rate for this

hour for staff time spent on auditing and related functions covered by this final rule with comment period, the total net incremental cost of this proposal would be approximately \$7 million (\$37.50 × 185,000 hours), far below the \$100 million threshold for a major rule. This cost will be spread more or less evenly across participating plans, and hence would impose negligible burden on any plan in relation to existing administrative costs.

In the Regulatory Impact Analysis of the January 28, 2005 final rule that implemented the Medicare Prescription Drug Program (70 FR 4194), we noted that “The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information, dissemination, appeals processes, pharmacy network negotiations, and contracting.” This estimate included audit and related costs. The estimate was that administrative costs would constitute about one tenth of the cost of the program, or about \$5 billion a year. (Similar estimates were prepared for the Medicare Advantage program’s final rule.) Accordingly, the estimated cost of this final rule with comment period adds negligibly to the total administrative costs of these programs.

With respect to economic benefits, we have no reliable basis for estimating the effects of these proposals. It is important to understand that MA and Part D sponsors—not the government—bear the direct consequences of all their program costs, including unnecessary costs created by downstream entities. These plans are paid on a capitated basis and the amounts paid are not adjusted for realized costs. Hence, these plans already have strong incentives to prevent all forms of waste, including fraud and abuse. Accordingly, we estimate the benefits of these proposals as likely to be small, though larger than the costs involved. These benefits will accrue primarily to the plans themselves and, over time, to the participants who pay lower premiums as a result of plans’ cost-reducing incentives.

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 jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues

occupation was \$37.15. The \$37.50 rate accounts for an increase of approximately 1%.

of \$6 million to \$29 million in any 1 year. For details, see the Small Business Administration’s regulation that set forth the current size standards for health care industries (65 FR 69432). Individuals and States are not included in the definition of a small entity. As explained above, this final rule with comment period will not impose consequential costs on affected entities. Accordingly, we have determined that this final rule with comment period will not have a significant economic impact on a substantial number of small entities, and are not preparing an initial regulatory flexibility analysis.

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 whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This rule will have no consequential effect on State, local, or tribal governments 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.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare,

Penalties, Privacy, Reporting and recordkeeping.

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

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Section 422.2 is amended by adding the definitions “Downstream entity”, “First tier entity”, and “Related entity” to read as follows:

§ 422.2 Definitions.

* * * * *

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.

* * * * *

Related entity means any entity that is related to the MA organization by common ownership or control and

(1) Performs some of the MA organization’s management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than \$2,500 during a contract period.

* * * * *

Subpart K—Contracts With Medicare Advantage Organizations

■ 3. Amend § 422.503 by—

■ A. Revising paragraph (b)(4)(vi) introductory text.

■ B. Revising paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D).

■ C. Adding paragraph (b)(4)(vi)(G)(3).

■ D. Removing paragraph (b)(4)(vi)(H).

The revisions and additions read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *
(4) * * *

(vi) A compliance plan, which must include measures to detect, correct, and prevent fraud, waste, and abuse, shall include the following elements:

* * * * *

(C) Effective training and education between the compliance officer and the MA organization's employees, managers and directors, and the MA organization's first tier, downstream, and related entities.

(D) Effective lines of communication between the compliance officer, members of the compliance committee, the MA organization's employees, managers and directors, and the MA organization's first tier, downstream, and related entities.

* * * * *

(G) * * *

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

* * * * *

■ 4. Amend § 422.504 by—

■ A. Republishing paragraph (e) introductory text.

■ B. Revising paragraph (e)(1) introductory text.

■ C. Revising paragraph (i) heading and (i)(1).

■ D. Revising paragraph (i)(2) introductory text.

■ E. Revising paragraph (i)(2)(i).

■ F. Revising paragraph (i)(3) introductory text.

■ G. Revising paragraph (i)(3)(ii).

■ H. Revising paragraph (i)(3)(iii).

■ I. Revising paragraph (i)(4) introductory text.

The revisions and additions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) *Access to facilities and records.* The MA organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection, audit, or other means—

* * * * *

(2) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the MA organization, its first tier, downstream, related entity(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or

as the Secretary may deem necessary to enforce the contract.

* * * * *

(i) *MA organization relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The MA organization agrees to require all first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the MA organization.

* * * * *

(3) All contracts or written arrangements between MA organizations and first tier, downstream, and related entities must contain the following:

* * * * *

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a first tier, downstream, or related entity, in a manner consistent with the requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, or related entity in accordance with a contract or written agreement are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any first tier, downstream and related entity:

* * * * *

■ 5. Amend § 422.505 by revising paragraph (c) to read as follows:

§ 422.505 Effective date and term of contract.

* * * * *

(c) *Renewal of contract.* In accordance with § 422.506, contracts are renewed annually only if the MA organization has not provided CMS with a notice of intention not to renew and CMS has not provided the MA organization with a notice of intention not to renew.

* * * * *

■ 6. Amend § 422.506 by—

■ A. Revising paragraph (b)(2) introductory text.

■ B. Revising paragraph (b)(2)(i).

■ C. Redesignating paragraph (b)(3) as (b)(4).

■ D. Adding a new paragraph (b)(3).

The revisions and additions read as follows:

§ 422.506 Nonrenewal of contract.

* * * * *

(b) * * *

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the MA organization by August 1 of the contract year.

* * * * *

(3) *Corrective action plan.*

(i) Before providing a notice of intent to non-renew the contract, CMS will provide the MA organization with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(ii) The MA organization must develop and submit the CAP within 45 calendar days of receiving a request for a CAP.

(iii) If CMS determines the CAP is unacceptable, CMS will provide the MA organization with an additional 30 calendar days to submit a revised CAP.

(iv) If CMS determines the CAP is acceptable, CMS will notify the MA organization of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(v) Failure to develop and implement a CAP within the timeframes specified in paragraphs (b)(3)(i) through (b)(3)(iii) of this section may result in the non-renewal of the MA contract.

* * * * *

■ 7. Amend § 422.510 by—

■ A. Republishing paragraph (a) introductory text.

■ B. Revising paragraph (a)(1).

■ C. Revising paragraph (b) introductory text.

■ D. Revising paragraph (b)(2) heading.

■ E. Revising paragraph (b)(2)(i).

■ F. Revising paragraph (c).

The revisions read as follows:

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons:

(1) The MA organization has failed substantially to carry out the terms of its current or previous contract terms with CMS.

* * * * *

(b) *Notice.* If CMS decides to terminate a contract for reasons other than the grounds specified in

§ 422.510(a)(4) or § 422.510(a)(5), it gives notice of the termination as follows:

* * * * *

(2) Expedited termination of contract by CMS.

(i) For terminations based on violations prescribed in § 422.510(a)(4) or § 422.510(a)(5), CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

* * * * *

(c) Corrective action plan.

(1) General. Before providing a notice of an intent to terminate a contract for reasons other than the grounds specified in paragraphs (a)(4) or (a)(5) of this section, CMS will provide the MA organization with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(i) The MA organization must develop and submit the CAP within 45 days of receiving a request for a CAP.

(ii) If CMS determines the CAP is unacceptable, CMS will provide the MA organization with an additional 30 days to submit a revised CAP.

(iii) If CMS determines the CAP is acceptable, CMS will notify the MA organization of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(iv) Failure to develop and implement a CAP within the timeframes specified in paragraphs (c)(1)(i) through (c)(1)(iii) may result in the termination of the MA contract.

(2) Exceptions. If a contract is terminated under § 422.510(a)(4) or § 422.510(a)(5), the MA organization will not have the opportunity to submit a CAP.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

- 8. Amend § 422.644 by—
- A. Republishing paragraph (b) introductory text.
- B. Revising paragraph (b)(2).
- C. Revising paragraph (c).
- D. Revising paragraph (d).

The revisions read as follows:

§ 422.644 Notice of contract determination.

* * * * *

(b) The notice specifies—

* * * * *

(2) The MA organization’s right to request a hearing.

(c) For CMS-initiated terminations, CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination. For terminations based on determinations described at § 422.510(a)(4) or § 422.510(a)(5) CMS notifies the MA organization of the date that it will terminate the organization’s MA contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organization by August 1 of the current contract year.

■ 9. Section 422.646 is revised to read as follows:

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under § 422.662.

§ 422.648 [Removed]

■ 10. Section 422.648 is removed.

§ 422.650 [Removed]

■ 11. Section 422.650 is removed.

§ 422.652 [Removed]

■ 12. Section 422.652 is removed.

§ 422.654 [Removed]

■ 13. Section 422.654 is removed.

§ 422.656 [Removed]

■ 14. Section 422.656 is removed.

§ 422.658 [Removed]

■ 15. Section 422.658 is removed.

■ 16. Revise § 422.660 to read as follows:

§ 422.660 Right to a hearing and burden of proof.

(a) The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act pursuant to § 422.501.

(2) An MA organization whose contract has been terminated pursuant to § 422.510.

(3) An MA organization whose contract has not been renewed pursuant to § 422.506.

(4) An MA organization who has had an intermediate sanction imposed pursuant to § 422.752(a) through (b).

(b) The MA organization bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the MA program on the earliest of the following three dates:

(1) The date the organization received written notice of the contract determination or intermediate sanction.

(2) The date of the most recent on-site audit conducted by CMS.

(3) The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

(c) Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

■ 17. Amend § 422.662 by revising paragraph (b) to read as follows:

§ 422.662 Request for hearing.

* * * * *

(b) Time for filing a request. A request for a hearing must be filed within 15 calendar days from the date CMS notifies the MA organization of its determination.

* * * * *

■ 18. Revise § 422.664 to read as follows:

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) Hearing. When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at § 422.641 until a hearing decision is reached and affirmed by the Administrator following review according to § 422.692 in instances where an MA organization or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) Exceptions: (1) If a final decision is not reached on CMS’ determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 422.510(a)(4) or § 422.510(a)(5) will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

■ 19. Amend § 422.670 by revising paragraph (a) to read as follows:

§ 422.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 calendar days from the receipt of request for the hearing, and sends written notice to the parties. The notice informs the parties of—

(1) The general and specific issues to be resolved, the burden of proof, and information about the hearing procedure, and

(2) The ability to conduct formal discovery.

* * * * *

■ 20. Revise § 422.682 to read as follows:

§ 422.682 Discovery.

(a) Either party may make a request to another party for the production of documents for inspection and copying which are relevant and material to the issues before the hearing officer.

(b) The hearing officer will provide the parties with a reasonable time for inspection and reproduction of documents, provided that discovery is concluded at least 10 calendar days prior to the hearing.

(c) The hearing officer's order on discovery matters is final.

■ 21. Revise § 422.684 to read as follows:

§ 422.684 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.

■ 22. Amend § 422.692 by—

- A. Revising paragraph (a).
- B. Revising paragraph (b).
- C. Redesignating paragraph (c) as paragraph (e).
- D. Adding a new paragraph (c).
- E. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 422.692 Review by Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision regarding a contract determination may request review by the Administrator within 15 calendar days of receiving the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing decision in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within

30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified.

* * * * *

■ 23. Amend § 422.696 by—

- A. Revising the section heading.
- B. Revising paragraph (a).

The revisions read as follows:

§ 422.696 Reopening of an initial contract determination or decision of a hearing officer or the Administrator.

(a) *Initial determination.* CMS may reopen and revise an initial determination upon its own motion.

* * * * *

§ 422.698 [Removed]

■ 24. Section 422.698 is removed.

Subpart O—Intermediate Sanctions

■ 25. Revise § 422.750 to read as follows:

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to reoccur:

- (1) Suspension of enrollment of Medicare beneficiaries.
- (2) Suspension of payment to the MA organization for Medicare beneficiaries who are enrolled in the MA plan.
- (3) Suspension of all marketing activities to Medicare beneficiaries by an MA organization for specified MA plans.

(b) CMS may impose civil money penalties as specified in § 422.760.

- 26. Amend § 422.752 by—
- A. Revising the section heading.
- B. Revising paragraph (a) introductory text.
- C. Revising paragraph (b).
- D. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions as specified in § 422.750(a) on

any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

* * * * *

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 422.510(a), CMS may impose the intermediate sanctions at § 422.750(a)(1) and (a)(3).

(c) *Civil Money Penalties.*

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in § 422.760 for any of the determinations at § 422.510(a), except § 422.510(a)(4).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

- (i) Violations listed at § 422.752(a).
- (ii) Determinations made pursuant to § 422.510(a)(4).

■ 27. Amend § 422.756 by—

- A. Revising the section heading.
- B. Revising paragraph (a).
- C. Revising paragraph (b).
- D. Revising paragraph (c).
- E. Revising paragraph (d).
- F. Revising paragraph (f).

The revisions read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond.*

(1) *Notice of intent.* Before imposing the intermediate sanction, CMS—

- (i) Sends a written notice to the MA organization stating the nature and basis of the proposed intermediate sanction and the MA organization's right to a hearing as specified in paragraph (b) of this section; and
- (ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the MA organization 10 calendar days from receipt of the notice to provide a written rebuttal. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* The MA organization may request a hearing before a CMS hearing officer. A written request must be received by CMS within 15 calendar days of the MA organization receiving the notice of intent to impose an intermediate sanction. A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective. The MA organization must follow the right to a

hearing procedure as specified at § 422.660 through § 422.684.

(c) If CMS determines that a MA organization has acted or failed to act as specified in § 422.752, CMS may—

(1) Require the MA organization to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned MA plan during the sanction period;

(2) In the case of a violation under § 422.752, suspend payments to the MA organization for Medicare beneficiaries enrolled in the sanctioned MA plan during the sanction period; and

(3) Require the MA organization to suspend all marketing activities for the sanctioned MA plan to Medicare enrollees.

(d) Effective date and duration of sanctions. (1) Effective date. Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 calendar days after the date that the organization is notified of the decision to impose the sanction.

(2) Exception. If CMS determines that the MA organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

* * * * *

(f) Notice to impose *civil money penalties*.

(1) *CMS notice to OIG*. If CMS determines that an MA organization has failed to comply with a requirement as described in § 422.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon an MA organization as specified at § 422.752(c)(2).

(2) *CMS notice of civil money penalties to MA organizations*. If CMS makes a determination to impose a CMP as described in § 422.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The MA organization's right to a hearing under subpart T of this part.

(vi) Information about where to file the request for hearing.

■ 28. Revise § 422.758 to read as follows:

§ 422.758 Collection of civil money penalties imposed by CMS.

(a) When an MA organization does not request a hearing, CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in Subpart T of this part.

(b) If an MA organization requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

§ 422.760 [Redesignated as § 422.764]

■ 29. Amend § 422.760 by—

■ A. Redesignate § 422.760 as § 422.764.

■ B. Add a new § 422.760 to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty*. In determining the amount of penalty imposed under § 422.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the MA organization;

(3) The harm which resulted or could have resulted from the conduct of MA organization;

(4) The financial condition of the MA organization;

(5) The history of prior offenses by the MA organization or principals of the MA organization; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty*. CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees—up to \$25,000 for each determination.

(2) For each week that a deficiency remains uncorrected after the week in which the MA organization receives CMS' notice of the determination—up to \$10,000.

(3) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under § 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—\$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or \$100,000, whichever is greater.

■ 30. Add a new § 422.762 to read as follows:

§ 422.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

Subpart P [Added and Reserved]

■ 31. Subpart P is added and reserved.

Subpart Q [Added and Reserved]

■ 32. Subpart Q is added and reserved.

Subpart R [Added and Reserved]

■ 33. Subpart R is added and reserved.

Subpart S [Added and Reserved]

■ 34. Subpart S is added and reserved.

■ 35. A new subpart T is added to read as follows:

Subpart T—Appeal Procedures for Civil Money Penalties

Sec.

- 422.1000 Basis and scope.
- 422.1002 Definitions.
- 422.1004 Scope and applicability.
- 422.1006 Appeal rights.
- 422.1008 Appointment of representatives.
- 422.1010 Authority of representatives.
- 422.1012 Fees for services of representatives.
- 422.1014 Charge for transcripts.
- 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.
- 422.1018 Notice and effect of initial determinations.
- 422.1020 Request for hearing.
- 422.1022 Parties to the hearing.
- 422.1024 Designation of hearing official.
- 422.1026 Disqualification of Administrative Law Judge.
- 422.1028 Prehearing conference.
- 422.1030 Notice of prehearing conference.
- 422.1032 Conduct of prehearing conference.
- 422.1034 Record, order, and effect of prehearing conference.
- 422.1036 Time and place of hearing.
- 422.1038 Change in time and place of hearing.
- 422.1040 Joint hearings.
- 422.1042 Hearing on new issues.
- 422.1044 Subpoenas.
- 422.1046 Conduct of hearing.
- 422.1048 Evidence.
- 422.1050 Witnesses.
- 422.1052 Oral and written summation.
- 422.1054 Record of hearing.
- 422.1056 Waiver of right to appear and present evidence.
- 422.1058 Dismissal of request for hearing.
- 422.1060 Dismissal for abandonment.
- 422.1062 Dismissal for cause.
- 422.1064 Notice and effect of dismissal and right to request review.
- 422.1066 Vacating a dismissal of request for hearing.
- 422.1068 Administrative Law Judge's decision.
- 422.1070 Removal of hearing to Departmental Appeals Board.
- 422.1072 Remand by the Administrative Law Judge.
- 422.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

- 422.1076 Request for Departmental Appeals Board review.
- 422.1078 Departmental Appeals Board action on request for review.
- 422.1080 Procedures before the Departmental Appeals Board on review.
- 422.1082 Evidence admissible on review.
- 422.1084 Decision or remand by the Departmental Appeals Board.
- 422.1086 Effect of Departmental Appeals Board Decision.
- 422.1088 Extension of time for seeking judicial review.
- 422.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.
- 422.1092 Revision of reopened decision.
- 422.1094 Notice and effect of revised decision.

Subpart T—Appeal procedures for Civil Money Penalties

§ 422.1000 Basis and scope.

(a) *Statutory basis.*

(1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857(g) of the Act provides that, for MA organizations out of compliance with the requirements in part 422 specified remedies may be imposed instead of, or in addition to, termination of the MA organization's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on MA organizations.

(b) [Reserved]

§ 422.1002 Definitions.

As used in this subpart—

Affected party means an MA organization impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part. For this definition, “*party*” means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

MA organization has the meaning given the term in § 422.2.

§ 422.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with

respect to the imposition of civil money penalties in accordance with part 422, subpart O.

§ 422.1006 Appeal rights.

(a) *Appeal rights of MA organizations.*

(1) Any MA organization dissatisfied with an initial determination as specified in § 422.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) MA organizations may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 422.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 422.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 422.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 422.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

§ 422.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination.*—CMS, as required under § 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to a hearing, and information about where to file the request for hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 422.1020 Request for hearing.

(a) *Manner and timing of request.*

(1) An MA organization is entitled to a hearing as specified in § 422.1006 and may file a request for a hearing with the Departmental Appeals Board office specified in the initial determination.

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from

receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that the finding or conclusion of law is incorrect.

§ 422.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 422.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, “ALJ” includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 422.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ’s decision or providing a new hearing before another ALJ.

§ 422.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may

adjourn the prehearing conference and reconvene at a later date.

§ 422.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 422.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 422.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.*

(1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 422.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 422.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 422.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 422.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.*

(1) Unless the affected party waives its right to appear and present evidence,

notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 422.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 422.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 422.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to

disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil money penalty exists, as specified in § 422.752, the administrative law judge may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 422.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 422.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 422.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 422.1016.

§ 422.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 422.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for

good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 422.1060.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 422.1016.

§ 422.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 422.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a “show cause” notice, with a showing of good cause.

§ 422.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata*. There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing*. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed*. The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 422.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 422.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 422.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 422.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content*. As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect*. A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 422.846, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 422.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 422.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 422.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 422.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing*. (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review*. A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 422.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS*. The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party*. The Board may deny or grant the affected

party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal*. The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel*. If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 422.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 422.1016.

§ 422.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 422.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 422.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 422.862.

(b) *Right to judicial review.* Section 422.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special Rules:* Civil Money Penalty—Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision

(or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

§ 422.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 422.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 422.1092 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.*

(1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 422.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect—(1) ALJ revised decision.*

An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 422.858.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 36. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart A—General Provisions

■ 37. Section 423.4 is amended by adding the definitions of “Downstream entity”, “First tier entity”, and “Related entities” to read as follows:

§ 423.4 Definitions.

* * * * *

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

* * * * *

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

* * * * *

Related entity means any entity that is related to the Part D sponsor by common ownership or control and

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or
(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Subpart K—Application Procedures and Contracts With Part D Plan Sponsors

- 39. Amend § 423.504 by—
 - A. Revising paragraph (b)(4)(vi) introductory text.
 - B. Revising paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D).
 - C. Adding paragraph (b)(4)(vi)(G)(3).
 - D. Removing paragraph (b)(4)(vi)(H).
- The revisions and additions read as follows:

§ 423.504 General provisions.

(b) * * *
(4) * * *
(vi) A compliance plan, which must include measures to detect, correct, and prevent fraud, waste, and abuse, shall include the following elements:

(C) Effective training and education between the compliance officer and the Part D plan sponsor's employees, managers and directors, and the Part D plan sponsor's first tier, downstream, and related entities.

(D) Effective lines of communication between the compliance officer, members of the compliance committee, the Part D plan sponsor's employees, managers and directors, and the Part D plan sponsor's first tier, downstream, and related entities.

(3) The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

- 40. Amend § 423.505 by—
- A. Republishing paragraph (b) introductory text.
- B. Revising paragraph (b)(10).
- C. Republishing paragraph (e) introductory text.
- D. Revising paragraph (e)(1) introductory text.
- E. Revising paragraph (e)(2).
- F. Revising paragraph (i) heading and (i)(1).
- G. Revising paragraph (i)(2) introductory text.
- H. Revising paragraph (i)(2)(i).
- I. Revising paragraph (i)(3) introductory text.

- J. Revising paragraph (i)(3)(ii).
- K. Revising paragraph (i)(3)(iii).
- L. Adding paragraphs (i)(3)(iv) and (v).
- M. Revising paragraph (i)(4) introductory text.
- N. Revising paragraph (i)(4)(iv).

The revisions and additions read as follows:

§ 423.505 Contract provisions.

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor and its delegated first tier, downstream and related entities, that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q of this part.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through audit, inspection, or other means—

(2) The Part D plan sponsor agrees to make available to HHS, the Comptroller General, or their designees, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. The Part D plan sponsor also agrees to make available any books, contracts, records and documentation of the Part D plan sponsor, first tier, downstream and related entity(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(i) *Relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D sponsor agrees to require all first tier, downstream, and related entities to agree that—

(ii) HHS, the Comptroller General, or their designees have the right to audit,

evaluate, and inspect any books, contracts, records including medical records, and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor.

(3) All contracts or written arrangements between Part D sponsors and first tier, downstream, and related entities, must contain the following:

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, first tier, downstream, and related entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(iv) A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS or its designees any books, contracts, records, including medical records and documentation of the MA organization, relating to the Part D program to either the sponsor to provide to CMS, or directly to CMS or its designees.

(v) All contracts or written arrangements must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, and related entity:

(iv) All contracts or written arrangements must specify that the first tier, downstream, or related entity must comply with all applicable Federal laws, regulations, and CMS instructions.

- 41. Amend § 423.506 by revising paragraph (c) to read as follows:

§ 423.506 Effective date and term of contract

(c) *Qualification to renew a contract.* In accordance with § 423.507, an entity is determined qualified to renew its contract annually only if the Part D plan sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D

organization with a notice of intention not to renew.

* * * * *

- 42. Amend § 423.507 by—
- A. Revising paragraph (b)(2) introductory text.
- B. Revising paragraph (b)(2)(i).
- C. Redesignating paragraph (b)(3) as (b)(4).
- D. Adding a new paragraph (b)(3).

The revisions and additions read as follows:

§ 423.507 Nonrenewal of contract.

* * * * *

(b) * * *

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the Part D plan sponsor by August 1 of the contract year.

* * * * *

(3) *Corrective action plan.* (i) Before providing a notice of an intent to nonrenew a contract, CMS will provide the Part D sponsor with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(ii) The Part D sponsor must develop and submit the CAP within 45 calendar days of receiving a request for a CAP.

(iii) If CMS determines the CAP is unacceptable, CMS will provide the Part D sponsor with an additional 30 calendar days to submit a revised CAP.

(iv) If CMS determines the CAP is acceptable, CMS will notify the Part D sponsor of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(v) Failure to develop and implement a CAP within the timeframes specified in paragraphs (b)(3)(i) through (b)(3)(iii) of this section may result in the nonrenewal of the Part D contract.

* * * * *

- 43. Section 423.509 is amended by—
- A. Revising paragraph (a)(1).
- B. Revising paragraph (a)(9).
- C. Revising paragraph (b) introductory text.
- D. Revising paragraph (b)(2)(i).
- E. Revising paragraph (c).

The revisions read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

(1) The Part D plan sponsor has failed substantially to carry out the terms of its current or previous contract terms with CMS.

* * * * *

(9) Substantially fails to comply with the marketing requirements in § 423.50;

* * * * *

(b) *Notice.* If CMS decides to terminate a contract for reasons other

than the grounds specified in § 423.509(a)(4) or § 423.509(a)(5), it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.* (i) For terminations based on violations prescribed in § 423.509(a)(4) or § 423.509(a)(5), CMS notifies the Part D plan sponsor in writing that its contract will be terminated on a date specified by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

* * * * *

(c) *Corrective action plan—*(1) General. Before providing an intent to terminate a contract for reasons other than the grounds specified in paragraphs (a)(4) or (a)(5) of this section, CMS will provide the Part D plan sponsor with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(i) The Part D plan sponsor must develop and submit the CAP within 45 calendar days of receiving a request for a CAP.

(ii) If CMS determines the CAP is unacceptable to CMS, the Part D plan sponsor will have an additional 30 calendar days to submit a revised CAP.

(iii) If CMS determines the CAP is acceptable, CMS will notify the Part D plan sponsor of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(iv) Failure to develop and implement a CAP within the timeframes specified in paragraphs (c)(1)(i) through (c)(1)(iii) of this section, may result in the termination of the Part D contract.

(2) *Exceptions.* If a contract is terminated under § 423.509(a)(4) or § 423.509(a)(5), the Part D plan sponsor will not have the opportunity to submit a CAP.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

- 44. Amend § 423.642 by—
- A. Republishing paragraph (b) introductory text.
- B. Revising paragraph (b)(2).
- C. Revising paragraph (c).
- D. Revising paragraph (d).

The revisions read as follows:

§ 423.642 Notice of contract determination

* * * * *

(b) The notice specifies the—

* * * * *

(2) The Part D sponsor's right to request a hearing.

(c) For CMS-initiated terminations, CMS mails notice to the Part D sponsor 90 calendar days before the anticipated effective date of the termination. For terminations based on determinations described at § 423.509(a)(4) or § 423.509(a)(5), CMS notifies the Part D sponsor of the date that it will terminate the organization's Part D contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the Part D sponsor by August 1 of the current contract year.

■ 45. Section 423.643 is revised to read as follows:

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under § 423.651.

§ 423.644 [Removed]

■ 46. Section 423.644 is removed.

§ 423.645 [Removed]

■ 47. Section 423.645 is removed.

§ 423.646 [Removed]

■ 48. Section 423.646 is removed.

§ 423.647 [Removed]

■ 49. Section 423.647 is removed.

§ 423.648 [Removed]

■ 50. Section 423.648 is removed.

§ 423.649 [Removed]

■ 51. Section 423.649 is removed.

■ 52. Revise § 423.650 to read as follows:

§ 423.650 Right to a hearing and burden of proof.

(a) The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS pursuant to § 423.503.

(2) A Part D sponsor whose contract has been terminated pursuant to § 423.509.

(3) A Part D sponsor whose contract has not been renewed pursuant to § 423.507.

(4) A Part D sponsor who has had an intermediate sanction imposed according to § 423.752(a) and § 423.752(b).

(b) The Part D sponsor bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the Part D program on the earliest of the following three dates:

(1) The date the sponsor received written notice of the contract determination or intermediate sanction.

(2) The date of the most recent on-site audit conducted by CMS.

(3) The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

(c) Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

■ 53. Amend § 423.651 by revising paragraph (b) to read as follows:

§ 423.651 Request for hearing.

* * * * *

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days from the date CMS notifies the Part D sponsor of its determination.

* * * * *

■ 54. Revise § 423.652 to read as follows:

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at § 423.641 until a hearing decision is reached and affirmed by the Administrator following review pursuant to § 423.666 in instances where a Part D sponsor or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 423.509(a)(4) or § 423.509(a)(5) will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

■ 55. Amend § 423.655 by revising paragraph (a) to read as follows:

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 calendar days from the receipt of request for the hearing, and sends written notice to the parties. The notice informs the parties of—

(1) The general and specific issues to be resolved, the burden of proof, and information about the hearing procedure, and

(2) The ability to conduct formal discovery.

* * * * *

■ 56. Revise § 423.661 to read as follows:

§ 423.661 Discovery.

(a) Either party may make a request to another party for the production of documents for inspection and copying which are relevant and material to the issues before the hearing office.

(b) The hearing officer will provide the parties with a reasonable time for inspection and reproduction of documents, provided that discovery concluded at least 10 calendar days prior to the hearing.

(c) The hearing officer's order on discovery matters is final.

■ 57. Revise § 423.662 to read as follows:

§ 423.662 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing, may ask the hearing officer to rule on a motion for summary judgment.

■ 58. Amend § 423.666 by—

- A. Revising paragraph (a).
- B. Revising paragraph (b).
- C. Redesignating paragraph (c) as paragraph (e).
- D. Adding a new paragraph (c).
- E. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 423.666 Review by Administrator.

(a) *Request for review by Administrator.* CMS or a Part D sponsor that has received a hearing decision regarding a contract determination may request review by the Administrator within 15 calendar days of receiving the hearing decision as provided under § 423.665(b). Both the Part D sponsor and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing determination in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within

30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the Part D sponsor or CMS, whether the determination should be upheld, reversed, or modified.

* * * * *

■ 59. Amend § 423.668 by—

- A. Revising the section heading.
- B. Revising paragraph (a).

The revisions read as follows:

§ 423.668 Reopening of an initial contract determination or decision of a hearing officer or the Administrator.

(a) *Initial determination.* CMS may reopen and revise an initial determination upon its own motion.

* * * * *

§ 423.669 [Removed]

■ 60. Section 423.669 is removed.

Subpart O—Intermediate Sanctions

■ 61. Revise § 423.750 to read as follows:

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to reoccur.

(1) Suspension of enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries who are enrolled in the Part D plan.

(3) Suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor for specified Part D plans.

(b) CMS may impose civil money penalties as specified in § 423.760.

■ 62. Amend § 423.752 by—

- A. Revising the section heading.
- B. Revising paragraph (a) introductory text.
- C. Revising paragraph (b).
- D. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one, or more, of the

sanctions as specified in § 423.750(a) on any Part D plan sponsor that has a contract in effect. The Part D plan sponsor may also be subject to other applicable remedies available under law.

* * * * *

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may impose the intermediate sanctions at § 423.750(a)(1) and (a)(3).

(c) *Civil Money Penalties.* (1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in § 423.760, for any of the determinations at § 423.509(a), except § 423.509(a)(4).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at § 423.752(a).

(ii) Determinations made pursuant to § 423.509(a)(4).

■ 63. Amend § 423.756 by—

■ A. Revising the section heading.

■ B. Revising paragraph (a).

■ C. Revising paragraph (b).

■ D. Revising paragraph (c).

■ E. Revising paragraph (d).

■ F. Revising paragraph (f)

The revisions read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanctions, CMS—

(i) Sends a written notice to the Part D plan sponsor stating the nature and basis of the proposed intermediate sanction, and the Part D plan sponsor's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D plan sponsor 10 calendar days from receipt of the notice to provide a written rebuttal. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* The Part D sponsor may request a hearing before a CMS hearing officer. A written request must be received by CMS within 15 calendar days of the Part D sponsor receiving the notice of intent to impose an intermediate sanction. A request for a hearing under § 423.650 does not delay the date specified by CMS when the

sanction becomes effective. The Part D sponsor must follow the right to a hearing procedure as specified at § 423.650 through § 423.662.

(c) If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned Part D plan during the sanction period;

(2) In the case of a violation under § 423.752, suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned Part D plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned Part D plan to Medicare enrollees.

(d) *Effective date and duration of sanctions.* (1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 calendar days after the date that the organization is notified of the decision to impose the sanction.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

* * * * *

(f) *Notice to impose civil money penalties.* (1) *CMS notice to OIG.* If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement as described in § 423.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon a Part D sponsor as specified at § 423.752(c)(2).

(2) *CMS notice of civil money penalties to Part D plan sponsors.* If CMS makes a determination to impose a CMP described in § 423.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The Part D sponsor's right to a hearing as specified under Subpart T of this part.

(vi) Information about where to file the request for hearing.

■ 64. Revise § 423.758 to read as follows:

§ 423.758 Collection of civil money penalties imposed by CMS.

(a) When a Part D plan sponsor does not request a hearing CMS initiates collection of the civil money penalty

following the expiration of the timeframe for requesting an ALJ hearing as specified in Subpart T.

(b) If a Part D sponsor requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

■ 65. Amend § 423.760 by—

■ A. Redesignating § 423.760 as § 423.764.

■ B. Adding a new § 423.760 to read as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under § 423.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the Part D sponsor;

(3) The harm which resulted or could have resulted from the conduct of the Part D sponsor;

(4) The financial condition of the Part D sponsor;

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees—up to \$25,000 for each determination.

(2) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to \$10,000.

(3) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under § 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, \$250 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or \$100,000, whichever is greater.

■ 66. Add a new § 423.762 to read as follows:

§ 423.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

■ 67. A new subpart T is added to read as follows:

Subpart T—Appeal Procedures for Civil Money Penalties

- Sec.
- 423.1000 Basis and scope.
- 423.1002 Definitions.
- 423.1004 Scope and applicability.
- 423.1006 Appeal rights.
- 423.1008 Appointment of representatives.
- 423.1010 Authority of representatives.
- 423.1012 Fees for services of representative.
- 423.1014 Charge for transcripts.
- 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.
- 423.1018 Notice and effect of initial determinations.
- 423.1020 Request for hearing.
- 423.1022 Parties to the hearing.
- 423.1024 Designation of hearing official.
- 423.1026 Disqualification of Administrative Law Judge.
- 423.1028 Prehearing conference.
- 423.1030 Notice of prehearing conference.
- 423.1032 Conduct of prehearing conference.
- 423.1034 Record, order, and effect of prehearing conference.
- 423.1036 Time and place of hearing.
- 423.1038 Change in time and place of hearing.
- 423.1040 Joint hearings.
- 423.1042 Hearing on new issues.
- 423.1044 Subpoenas.
- 423.1046 Conduct of hearing.
- 423.1048 Evidence.
- 423.1050 Witnesses.
- 423.1052 Oral and written summation.
- 423.1054 Record of hearing.
- 423.1056 Waiver of right to appear and present evidence.
- 423.1058 Dismissal of request for hearing.
- 423.1060 Dismissal for abandonment.
- 423.1062 Dismissal for cause.
- 423.1064 Notice and effect of dismissal and right to request review.
- 423.1066 Vacating a dismissal of request for hearing.
- 423.1068 Administrative Law Judge's decision.
- 423.1070 Removal of hearing to Departmental Appeals Board.
- 423.1072 Remand by the Administrative Law Judge.
- 423.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.
- 423.1076 Request for Departmental Appeals Board review.
- 423.1078 Departmental Appeals Board action on request for review.
- 423.1080 Procedures before the Departmental Appeals Board on review.
- 423.1082 Evidence admissible on review.
- 423.1084 Decision or remand by the Departmental Appeals Board.
- 423.1086 Effect of Departmental Appeals Board Decision.
- 423.1088 Extension of time for seeking judicial review.
- 423.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

- 423.1092 Revision of reopened decision.
- 423.1094 Notice and effect of revised decision.

Subpart T—Appeal Procedures for Civil Money Penalties

§ 423.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857 (g) of the Act provides that, for Part D sponsors found to be out of compliance with the requirements in part 423, specified remedies may be imposed instead of, or in addition to, termination of the Part D sponsor's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on Part D sponsors.

(b) [Reserved]

§ 423.1002 Definitions.

As used in this subpart—
Affected party means any Part D sponsor impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part, and “*party*” means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

Part D sponsor has the meaning given the term in § 423.4.

§ 423.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart O.

§ 423.1006 Appeal rights.

(a) *Appeal rights of Part D sponsors.* (1) Any Part D sponsor dissatisfied with an initial determination as specified in § 423.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) Part D sponsors may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 423.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 423.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 423.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 423.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 423.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding

of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 calendar days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

§ 423.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination—(1) General rule.* CMS, as required under 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, the party's right to a hearing, and information about where to file the request for a hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

- (1) The affected party requests a hearing; or
- (2) CMS revises its decision.

§ 423.1020 Request for hearing.

(a) *Manner and timing of request.* (1) A Part D sponsor is entitled to a hearing as specified in § 423.1006 and may file a request with the Departmental Appeals Board office specified in the initial determination.

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

- (1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and
- (2) Specify the basis for each contention that a CMS finding or conclusion of law is incorrect.

§ 423.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 423.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate, designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 423.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 423.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 423.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 423.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

- (1) Facts that are not in controversy.
- (2) Questions that have been resolved favorably to the affected party after the determination in dispute.
- (3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

- (1) The witnesses that will be present to testify at the hearing.
- (2) The qualifications of those witnesses.
- (3) The nature of other evidence to be submitted.

§ 423.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.*

(1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.*

(1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 423.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 423.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 423.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 423.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.*

(1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 423.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if

appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 423.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

- (1) Identify the witnesses or documents to be produced;
- (2) Describe their addresses or location with sufficient particularity to permit them to be found; and
- (3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 423.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by

a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an ALJ finds that the basis for imposing a civil money penalty exists, as specified in § 423.752, the ALJ may not—

- (1) Set a penalty of zero or reduce a penalty to zero, or
- (2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 423.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 423.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 423.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 423.1016.

§ 423.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 423.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 423.1058.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 423.1016.

§ 423.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 423.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a “show cause” notice, with a showing of good cause.

§ 423.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected

party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 423.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ’s dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 423.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 423.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 423.1068 Administrative Law Judge’s decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 423.1076, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Department Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 423.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 423.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 423.1074 Right to request Departmental Appeals Board review of Administrative Law Judge’s decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ’s decision or dismissal order, and the parties are so informed in the notice of the ALJ’s action.

§ 423.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ’s decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 423.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party’s request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration,

hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 423.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 423.1016.

§ 423.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 423.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 423.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 423.1092.

(b) *Right to judicial review.* Section 423.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty.* Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-calendar day period for seeking judicial review.

§ 423.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 423.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 423.1092 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.*

(1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect—(1) ALJ revised decision.* An ALJ revised decision is binding

unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 423.858.

(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: September 14, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 26, 2007.

Michael O. Leavitt,

Secretary.

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