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Part II

Department of Health and Human Services

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;
Proposed Rules**

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

[CMS-4124-P]

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:** Proposed rule.

SUMMARY: This proposed rule would clarify 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. This proposed rule would 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, 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.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 24, 2007.

ADDRESSES: In commenting, please refer to file code CMS-4124-P. 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-P, P.O. Box 8012, Baltimore, MD 21244-8012.

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-P, 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 Perenich, (410) 786-2987.

Kevin Stansbury, (410) 786-2570.

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

Rita Wurm, (410) 786-1139, for issues regarding access to records and compliance.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-4124-P and the specific "issue identifier" that

precedes the section on which you choose to comment.

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 proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ALJ	Administrative Law Judge
BBA	Balanced Budget Act of 1997
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999
CAP	Corrective Action Plan
CMP	Civil Money Penalty
CMS	Centers for Medicare & Medicaid Services
DAB	Departmental Appeals Board
ESRD	End-Stage Renal Disease
FWA	Fraud, Waste, and Abuse
HHS	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
PPO	Preferred Provider Organization

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

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 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 are proposing clarifications to the Medicare program provisions relating to contract determinations involving Medicare Advantage 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. This proposed rule would clarify the intermediate sanction and civil money penalty (CMP) provisions that apply to MA organizations and Medicare Part D prescription drug plan sponsors. We have also proposed changes to clarify the compliance plan requirements and our access to the books and records of an MA organization or Part D sponsor's first tier, downstream, and related entities.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established the Medicare+Choice (M+C) program. Under section 1851(a)(1) of 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 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. CMS has not issued previous guidance, other than regulatory requirements regarding contract determinations, corrective action plans, contract determination appeals, intermediate sanctions or civil money penalties. However, CMS has 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 proposes further revisions to the MA and prescription drug regulations and we welcome your comments on our proposed regulations.

II. Provisions of the Proposed Regulations

[If you choose to comment on issues in this section, please include the caption “PROVISIONS OF THE PROPOSED REGULATIONS” at the beginning of your comments.]

A. Overview of 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 Balanced Budget Act of 1997 have led us to propose changes to our regulations. In this rule, we propose 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 propose revisions to the appeal procedures for all types of contract determinations, which would make these procedures identical for decisions not to contract, for nonrenewals, and for terminations. We propose to provide for enhanced beneficiary protections when we decide to terminate a plan on an expedited basis.

In this rule, we are also proposing changes and making clarifications to Subpart K, contract requirements under the MA and Part D programs. We have 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, including records relating to Part D rebates and price concessions and any underlying PDE records. We have also proposed changes to clarify that certain elements of the compliance plan apply to first tier, downstream, and related entities.

The proposed changes would ensure that both the MA and Medicare Part D prescription drug benefit programs may operate as efficiently as possible within the guidelines of the statute.

Below, we set forth the proposed regulation changes and corresponding proposed implementation dates:

Proposed regulation change	Proposed 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
Mandatory procedures 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	1/1/2008
Change date of CMS' notification of non-renewal from May 1 to September 1	1/1/2008
Provide for same administrative appeal rights (including CAP) for all contract determinations (non-renewal, expedited termination, termination)	1/1/2008
Change regarding CAP process may be provided prior to notification of termination, and the imposition of time limits on Corrective Action Plans	1/1/2008
Change immediate termination to expedited termination with CMS setting the effective date of termination	1/1/2008
Elimination of Reconsideration Step for contract determination appeals	1/1/2008
Implementation of Burden of Proof for contract determinations	1/1/2008
Ability for a hearing officer to issue summary judgment	1/1/2008
Request for Administrator review, submission of information, and timeframe associated with Administrator review	1/1/2008
Settlement of Civil Money Penalties	1/1/2008
Appeal procedures for Civil Money Penalties	1/1/2008

B. Distribution Table

The following crosswalk table references the changes we propose to

make to the prescription drug and the MA programs. We propose to make the same changes to 42 CFR Parts 422 and 423 with minimum 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.
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.

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

Section heading	Section references in part 422	Section references in part 423
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.
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.

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

Sections 422.2 and 423.4—Definitions

We are proposing 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 are proposing to add them to Subpart A, General Provisions at § 422.4 and § 423.4. The definitions are as follows:

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

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D sponsor or 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.

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

control and (1) Performs some of the Part D sponsor or 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 Part D sponsor or MA organization at a cost of more than \$2,500 during a contract period.

Below is a flow chart that provides examples of, and describes the relationships between, Part D sponsors, and first tier, downstream, and related entities. In accordance with the proposed changes above, we are removing the term “subcontractor” from this previously published flowchart. The original flowchart was published in the final version of Chapter 9 of the Part

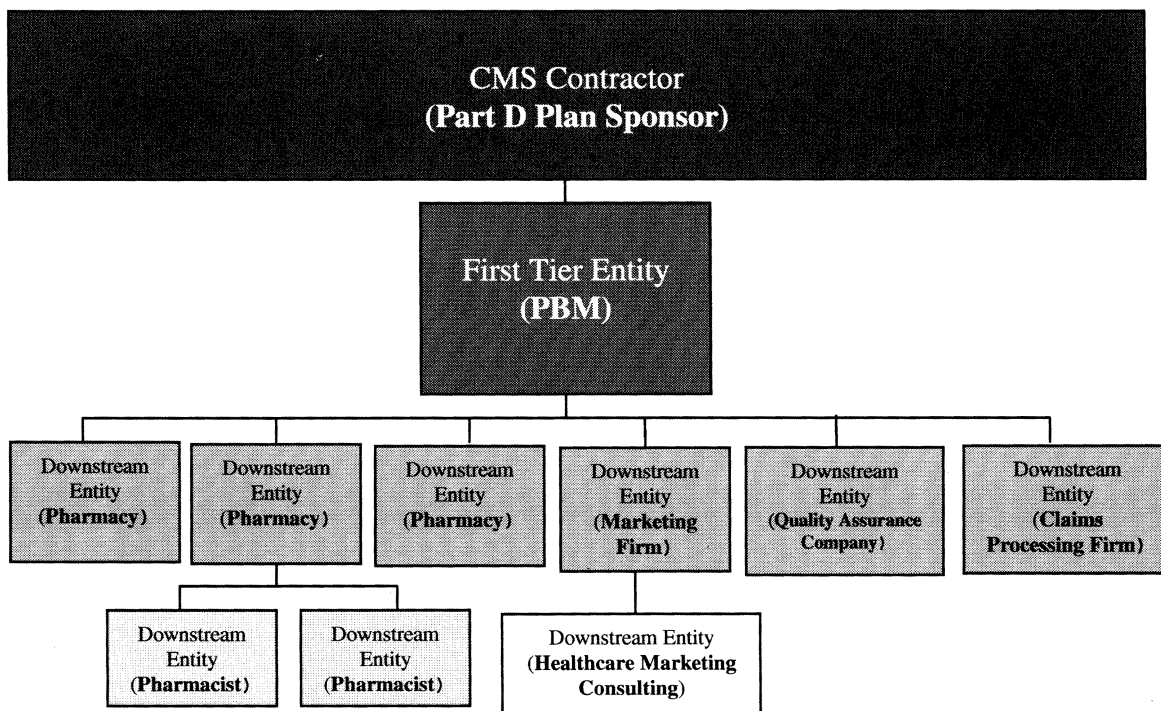
D Manual last year. We will make conforming changes to the manual at a

later date. After the flowchart we have provided examples of first tier and

downstream entities for MA organizations.

Exhibit 1: Example of Stakeholder Relationship

Flow Chart



An example of a first tier entity for MA organizations would be a provider group that contracts with the MA organization to provide health care services to MA members. An example of a downstream entity for MA organizations would be an individual provider who contracts with a provider group that contracts with the MA organization to provide health care services to MA members.

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 as well as 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 current regulation, 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 are proposing to revise paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D) of § 423.504 to clarify that a compliance plan must consist of training, 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 proposed change would clarify 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 their direct employees within their organizations.

Pursuant to our authority under section 1856(b)(1) of the Act to establish Medicare Advantage standards by regulation, we are also proposing to require MA organizations to apply their training and education and effective lines of communication requirements to their first tier, downstream, and related entities. Since many MA-PDs, as Part D sponsors, have already been required to

apply these requirements to the entities they contract with to deliver the Part D benefit, we are taking this opportunity to make the compliance plan requirements uniform across MA organizations, MA-PDs, and other Part D sponsors.

Additionally, we propose 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 are proposing to remove this element because we received feedback from many Part D sponsors indicating that it was not clear whether CMS was requiring a fraud, waste, and abuse (FWA) plan separate and distinct from a compliance plan. In fact, we believe that a compliance plan that meets the compliance plan requirements in the regulations already has a “comprehensive fraud, waste, and abuse plan to detect, correct, and prevent fraud, waste, and abuse.”

In April 2006, we issued Chapter 9 of the Part D Manual (“Part D Program to Control Fraud, Waste and Abuse”) as “best practices” guidance for Part D sponsors to develop a FWA plan. We intended 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 or develop a separate, stand-alone FWA plan, we believe the final element continues to cause potential confusion to the industry and therefore, are proposing to remove this element from (b)(4)(vi) of 422.503 and 422.504.

We continue to believe an effective compliance plan includes procedures and policies for preventing fraud, waste, and abuse and have proposed changes to the introductory clause of § 423.504(b)(4)(vi) that reflect our policy stance. Since Congress mandated that Part D sponsors have a “program to control fraud, waste, and abuse” (section 1860D–4(c)(1)(D) of the Act), we also are 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 for sponsors to have a FWA plan. Part D sponsors should 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.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.

Also pursuant to our authority under section 1856(b)(1) of the Act, we are proposing 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 propose that MA organizations must include “measures to detect, correct, and prevent fraud, waste, and abuse” throughout the 7 elements of the compliance plan requirement. While the existing MA compliance plan requirement does not explicitly refer to the prevention of fraud, waste, and abuse, it has always been our expectation that fraud, waste, and abuse would be addressed through the implementation of each of the 7 elements in a 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 our proposed change would make this policy explicit in our regulations. We welcome your comments on this proposal.

Since we are proposing to remove § 423.504(b)(4)(vi)(H), we are proposing to add paragraph (b)(4)(vi)(G)(3) to § 423.504 to include a provision on self-reporting of potential fraud or misconduct, which was addressed in § 423.504(b)(4)(vi)(H). Pursuant to our authority under section 1856(b)(1) of the Act we also propose to add paragraph (b)(4)(vi)(G)(3) to § 422.503 to add a self-reporting provision to the MA regulations as well, in order to make the compliance plan requirements uniform across MA organizations and Part D sponsors.

We note that when the original Part C regulations were issued in a June 26, 1998 interim final rule establishing a new part 422, they included a self-reporting requirement at § 423.501(b)(4)(vi)(H). (See 63 FR 35100.) Unlike the current Part D self-reporting provision, this original paragraph (H) required that compliance plans have an “adhered-to-process for reporting to [CMS] and/or the OIG credible information of violations of law by the [MA] organization * * *.” In a June 29, 2000 final rule responding to comments on the June 26, 1998 interim final rule, this mandatory self-reporting requirement was eliminated. (See 65 FR 40264–40265, 40299.)

We believe that the decision to eliminate a mandatory self-reporting requirement has contributed to some highly publicized cases in which we have first found out about a major MA organization compliance issue when it appeared in the press. We have expressed our concerns in such situations that the matter was not promptly reported to us when it came to the attention of the MA organization in question. We believe that it is important for the government to have information on possible fraud or misconduct as soon as possible in order to determine whether any actions would be appropriate. We therefore are proposing to restore a mandatory self-reporting requirement for MA organizations, and to make the self-reporting provision that applies to Part D sponsors mandatory. The language in the new proposed § 423.504(b)(4)(vi)(G)(3) and new proposed § 422.503(b)(4)(vi)(G)(3) accordingly provides for mandatory self-reporting. We welcome your comments on all of these changes.

Sections 422.504 and 423.505—General Provisions

We are proposing 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 above, are undefined terms in the statute and regulations. We are proposing, where applicable, to delete the term “contractor” and replace the term “subcontractor” with the terms “first tier and downstream entity” in 422.504(e) and (i) to clarify which entities are subject to the contract provisions at 422.504.

We are also proposing, 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 believe using “first tier and downstream entity” instead of “subcontractor” would lessen the potential for confusion in the Part D program. To clarify, under the Part D program, an example of a “first tier entity” is a pharmaceutical benefit manager (PBM) under contract to a Part D sponsor to provide all or some aspect of the Part D benefit on behalf of the sponsor. An example of a “downstream entity” in the Part D program is a pharmacy under contract to such a PBM. As discussed above, we are proposing to use the definitions of “first tier entity” and “downstream entity” (as well as “related entity”) set forth at § 423.501 to lessen any potential confusion in both programs. We welcome your comments on these proposed changes to the contract provisions.

We have 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. In the preamble to the Part D proposed rule, published on January 28, 2005 (70 FR 4194), describing these provisions, 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). 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). The information collection section of this preamble also references the OMB approval numbers.

In addition, we note that the solicitation for a Part D application already requires that a Part D sponsor's contract or letter of agreement with each subcontractor "contain language ensuring that the subcontractor will make its books and other records available in accordance with 42 CFR 423.505(i)(2)."

Under this established legal authority, HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit the books and other records of Part D sponsors and their first tier, downstream, and related entities. These rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later. However, based on industry feedback and our own varied experience with accessing Medicare payment-related records from subcontracting entities, we believe we need to provide clarity to both the Part D sponsors and their first tier, downstream, and related entities regarding our expectation for complying with this disclosure requirement. Our expectation is that the first tier, downstream, and related entities will, upon CMS' or our designees' request, produce any pertinent contracts, books, documents, papers, and records relating to the Part D program.

We are proposing in this rule 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 or directly to CMS or our designees. We do not intend this new contract provision to explicitly require first tier, downstream, or related entities to produce their books and records directly to the Part D sponsor. Instead, we propose to leave it to the contracting parties to determine during their contract negotiations the process for submitting the requested information to CMS or our designees. The provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to CMS, or submitted directly to CMS or our designees. The parties could also decide to have such books and records made directly available to CMS or our designees through onsite access. The Part D sponsor should be prepared to submit evidence of this agreed upon provision in its executed contracts to CMS.

Because of the proposed contract provision, we are also proposing to redesignate § 423.505(i)(4)(iv) as § 423.505(i)(4)(v).

In accessing Part D-related books and records, 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 this type of information include, but are not limited to: Policies and procedures; compliance plans; statements of conflict of interest; proof of beneficiary identification; documentation of the quantity and frequency of drugs being received by the beneficiary; evidence of the prescriber of the Part D drugs and the individual who signs for the drugs; and documentation relating to the drug's history and origin. This information is critical to our ability to effectively oversee and monitor the Part D benefit, with the ultimate goal of protecting the Medicare Trust Fund and those beneficiaries enrolled in Part D. The information provided will be used to conduct investigations and audits of the Part D sponsors and their first tier, downstream, or related entities, to ensure compliance with Medicare Part D requirements, and to address potential fraud, waste, and abuse in the Part D benefit.

CMS or our designees will make information requests as necessary to support any Part D investigations and audits. There is no continuous reporting requirement under sections 423.505(e) and (i), but rather requests are dependent upon the nature and severity of the complaint and the extent to which the investigation relies on supporting data from the first tier, downstream, and related entities.

In addition to proposing a new contract provision at § 423.505(i)(4)(iv), we are also proposing minor regulatory changes which clarify the sponsor's CMS contractual requirements. While we continue to believe our regulations clearly state our authority to access the books and records of a sponsor's first tier, downstream, and related entities, we are proposing to add language about these partnering entities to § 423.505(b)(10) and proposing to consolidate § 423.505(e)(2) and (3) into one provision at (e)(2). We are proposing 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

proposed revisions do not impose any new requirements on Part D sponsors or its partnering entities.

We are also proposing to clarify, without specific regulatory change in this rule that HHS, the Comptroller General, or their designees have the authority under the statute to request records relating to Part D rebate and any other price concessions information from Part D sponsors or their first tier, downstream, or related entities. These records would include, for example, copies of rebate agreements between PBMs and manufacturers and any records reflecting discounts, price concessions, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced price services, grants or other price concessions or similar benefits offered to some or all purchasers.

Part D plan sponsors must maintain, as required by § 423.505(d), financial records, books and records pertaining to "determinations of amounts payable under the contract," agreements, contracts, and subcontracts, and "all prescription drug claims for the current period and 10 prior periods." Since Part D sponsors have delegated many Part D functions to their first tier entities, many of these records reside with first tier entities, such as PBMs. We are taking this opportunity in this proposed rule 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.

We believe our proposal to obtain rebate and price-concession related records is supported by the statute. Sections 1860D–15(d)(2) and 1860D–15(f)(1)(A) of the Act give us authority 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 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 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. Congress granted us, under section 1860D-2(d)(3) of the Act, 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 propose when appropriate, to reserve the right to request records relating to Part D rebates and price concessions from the sponsor's first tier entities.

To the extent information necessary to verify payment would be collected under the auspices of section 1860D-15 of the Act, the restrictions on using such information under 1860D-15(f) and (d) of the Act would also apply. Thus, the information collected to verify payment would be used only in carrying out the provisions of section 1860D-15 of the Act, and would not be used for other purposes.

We are also clarifying in this proposed rule that in instances of suspected improper payment or potential fraud, we may obtain the actual records used by a Part D sponsor to submit its prescription drug event (PDE) data for payment, whether such records are with the sponsor or its first tier, downstream, or related entities. Sections 1860D-15(d)(2)(A) and 1860D-15(f)(1) of the Act require the sponsor to

disclose or provide "such information as the Secretary determines is necessary" to verify appropriate payments made to the Part D sponsor and to do so in a "form and manner" specified by the Secretary. The Secretary has also delegated to CMS inspection and audit rights under section 1860D-15(f)(1)(B) of the Act to ensure proper payments to sponsors.

Based on these authorities, we are clarifying in the preamble of this proposed rule that we have the ability to access any records used by a Part D plan sponsor to calculate and submit its PDE data, including any records with the sponsor's first tier, downstream, or related entities, for purposes of verifying payment. In order to verify accurate payments to the Part D plan sponsor, we may need at times to evaluate the records which comprised the basis for the PDE submission to ensure there are no inconsistencies, inaccuracies, or mistakes contained in these records which could have resulted in inappropriate or inaccurate determinations of payment. Moreover, we may need to review the underlying records of the PDE submission for purposes of investigating allegations of misconduct such as data tampering, fraudulent misrepresentation, or omissions of data which could have affected whether appropriate and accurate payments were made to the sponsor.

In such instances of suspected fraud or improper payment, we may request from the sponsor, or its first tier, downstream, and related entities, records that include for example, the prescription drug claim or transaction record submitted by a pharmacy to a PBM. We are soliciting comment on what types of records should be subject to this access requirement. Again, to the extent such information would be provided under the authority of 1860D-15 of the Act, the restrictions on use in that section would also apply.

We note that any failure or omission by a first tier, downstream, or related entity to provide information requested by us, or to allow HHS access to its books and records relating to payment, would constitute a violation by the MA organization or Part D plan sponsor of its contract with us and a violation of the MA and Part D regulations. Such a failure would provide the basis for any applicable adverse actions, including potentially, the imposition of intermediate sanctions, civil money penalties, or contract termination against the Part D sponsor or MA organization. We welcome comments on these proposed changes.

Sections 422.505 and 423.506—Effective Date and Term of Contract

We propose 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 propose 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 proposed change would better align the regulations with the statute.

Sections 422.506 and § 423.507—Nonrenewal of a Contract

We propose revising the introductory text for § 422.506(b)(2) and § 423.507(b)(2). In addition, we propose 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 propose 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 above, 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 propose 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 propose to revise § 422.506(b)(2)(i) and § 423.507(b)(2)(i) to require that we provide notice by September 1 of the contract year, rather than May 1. If an MA organization or Part D sponsor receives a non-renewal 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 website. For purposes of this proposed rule, a non-renewal would take effect on January 1 of the following contract year, whereas a termination may take effect at any time during the

contract year. Our proposed provisions would 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. We welcome comments on these proposed changes.

Changing the notification deadline to September 1 would provide us with additional time to make a determination as to whether an MA organization or Part D plan sponsor is in compliance with our requirements and should have its contract renewed for the following contract year. It has been our experience that the May 1 deadline does not provide us with enough time to obtain accurate up-to-date information in order to make a decision about contract renewals. This change would provide more time for us to make an accurate determination concerning contract non-renewals.

We propose redesignating § 422.506(b)(3) as § 422.506(b)(4) and redesignating § 423.507(b)(3) as § 423.507(b)(4). We propose 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, in this case, a nonrenewal. The CAP process for nonrenewals would be the same process as we propose for terminations. We propose a more structured process which outlines the processes and timeframes for CAPs. Since we have the discretion to provide plans with the opportunity to develop and implement a CAP either prior to, or after, sending out a notice of intent to nonrenew, we would provide an MA organization or Part D plan sponsor with an opportunity to develop and implement a CAP prior to sending the sponsor or organization a notice of intent to nonrenew. This proposal marks a divergence from our past practice with respect to the CAP process as we have previously asked sponsors or organizations to develop CAPs subsequent to notifying them of a nonrenewal or termination decision. Our proposal clarifies that, in the future, once we issue a notice of nonrenewal or a notice of termination, the MA organization or Part D plan sponsor would not have an opportunity to submit a CAP. We would provide that opportunity to organizations and sponsors prior to issuing a notice of intent to nonrenew or a notice of intent to terminate. 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 comply may result in a nonrenewal or termination action. We welcome comments on these proposed changes.

We propose time limits at § 422.506(b)(3) and § 423.507(b)(3) for the development and implementation of a CAP. Our experience with the CAP process is that plans may attempt to draw out the process indefinitely in the absence of a time limit. We do not believe that the statute intends for this process to go on indefinitely. We propose 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. We welcome comments on these proposed changes.

Sections 422.510 and 423.509— Termination of Contract by CMS

We propose 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 propose 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 for the current term or its contract from a previous term. This clarification would be 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, 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 all years of the contract.

We propose 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 propose 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. Our proposed change would 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 welcome comments on these proposed changes.

These changes are supported by section 1857(h)(2) of the Act which permits us to terminate a contract with an MA organization or Part D plan sponsor without providing the plan with an opportunity to submit a CAP and without notice and opportunity for a hearing, where the notice and hearing procedures required by section 1857(h)(1) of the Act would pose an imminent and serious risk to the health of enrollees in the plan. Section 1857(h)(2) of the Act is silent on the specifics of this alternate termination process and does not require "immediate" termination; merely that the procedures at section 1857(h)(1) of the Act shall not apply.

We would also clarify that we would be 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.

We propose to amend our procedures at § 422.510(c) and § 423.509(c) to provide more structure to the process for the submission and review of CAPs. 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 are proposing is the same process for nonrenewals outlined above and which we are proposing at § 422.506 and § 423.507, providing for a more structured process and timeframes for the development and implementation of a CAP.

Subpart N—Medicare Contract Determinations and Appeals

We propose 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 propose removing the reconsideration process for appeals of all types of contract determinations. We also propose 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 propose that the MA organization or Part D plan sponsor have the burden of proof in appealing a contract determination. Below is a more detailed explanation of our proposals.

We propose removing the provisions regarding the reconsideration process for appeals of contract determinations at § 422.648, § 422.650, § 422.652, § 422.654, § 422.656, § 422.658, § 423.644, § 423.645, § 423.646, § 423.647, § 423.648, and § 423.649. Section 1857(h) of the Act requires only that we provide an organization with notice and an opportunity for a hearing before terminating a contract. The reconsideration process is not required by statute. Eliminating the reconsideration process would expedite the appeals process which would benefit MA organizations and Part D plan sponsors as well as CMS. We welcome comments on the proposal to eliminate the reconsideration process for appeals or contract determinations.

Sections 422.644 and 423.642—Notice of Contract Determination

We are proposing 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 propose to revise § 422.644(c) and § 423.642(c) to state that we would determine the effective date of an expedited termination. We also propose adding the reference § 422.510(a)(4) as a basis for which we may undertake an expedited termination.

We also propose 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. We welcome comments on the proposal to shift the date of the notice of nonrenewal from May 1 to September 1.

Sections 422.646 and 423.643—Effect of Contract Determination

We propose 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 have proposed eliminating the reconsideration process, we are proposing a conforming change to indicate that a contract determination would be a final decision unless a timely request for a hearing is filed.

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

We also propose making 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 then 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 propose 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 propose 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. 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. The DAB has previously held that in a termination proceeding by the Secretary, the facility bears the ultimate burden of proving it is in compliance with program requirements. (See *Hillman Rehabilitation Center*, DAB No. 1611 (1990), aff'd *Hillman Rehabilitation Center v. United States*, No. 98–3789 (GEB)(D.N.J. May 13, 1999).) We require that MA

organizations and Part D sponsors are in compliance with our program requirements during the entire contract period. When we provide a notice of nonrenewal or termination, the basis for the notice is noncompliance with contractual and regulatory provisions. Once we have determined that the MA organization or Part D plan sponsor is out of compliance, the MA organization or Part D plan sponsor has the burden to prove it was in compliance. In addition, we also propose to specify that the MA organization or Part D plan 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. We welcome comments on these proposed changes.

Based on our experience with appeals of contract determinations, we have found the current regulations do not provide hearing officers with a particular “compliance date” to use as a reference point in issuing a ruling. This creates the potential for inconsistency in the decisions issued by hearing officers. We believe our proposal to provide a framework for hearing officers to use in establishing a compliance date as a reference point will lessen the potential for such inconsistency. By requiring the compliance date to be the earliest of the three possible dates, the hearing will reflect that circumstances may differ on a case by case basis. For example, where an onsite audit was conducted or where a significant breach occurred, we think it is appropriate for us to base our decision to terminate a plan's contract on the date of either the audit or the breach. However, where an onsite audit did not occur, or where the basis of our termination decision is not one major breach, we think it is appropriate to use the date we notified the MA organization or Part D sponsor of our intent to terminate as a reference point. Without a specific date as a reference point for evaluating compliance, the hearing officer lacks the information necessary to arrive at a determination. We welcome comments on these proposed changes.

Sections 422.662 and 423.651—Request for a Hearing

We propose to revise § 422.662(b) and § 423.651(b) to conform to our proposed

change to eliminate the reconsideration process. These provisions would specify that a request for a hearing must be filed within 15 days after the date of the initial determination.

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

We propose 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 we are not proposing any change in policy with respect to expedited terminations.

**Sections 422.670 and 423.655—Time
and Place of Hearing**

We propose 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.

**Sections 422.682 and 423.661—
Discovery**

We propose 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. It has been our experience that such a deadline, which is not set out in the existing regulations, is necessary to provide enough time for the parties or the hearing officer to review documents prior to the hearing. We welcome comments on these proposed changes.

**Sections 422.684 and 423.662—
Prehearing and Summary Judgment**

We propose 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. This would be more efficient and cost effective for both parties when no factual dispute exists. We welcome comments on these proposed changes.

**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 propose 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 propose to amend the same provisions to permit both the parties to submit written arguments to the Administrator.

We propose 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.

We propose redesignating § 422.692(c) as § 422.692(e) and redesignating § 423.666(c) as § 423.666(e).

We propose 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 would assist all parties in reaching a final decision in an expeditious manner. We welcome comments on these proposed changes.

In addition, we propose 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.

If the Administrator declines to review the hearing officer's decision, the decision of the hearing officer would become final and binding.

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

We propose 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.

**Sections 422.698 and 423.669—Effect of
Revised Determination**

We propose making 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."

Subpart O—Intermediate Sanctions

We are proposing 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 propose to modify the appeals procedures for intermediate sanctions and clarify which set of procedures affected parties should use to appeal a CMP. We are soliciting public comment on our proposed changes to subpart O.

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

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

For clarity, we propose 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 propose to remove the prior reference at § 422.750(a)(1) and § 423.750(a)(1) to the range of CMPs because it is confusing.

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

At § 422.752 and § 423.752, we are proposing 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 are proposing 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).

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

At § 422.756 and § 423.756 we propose 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 welcome comments on these proposed changes.

Because we propose to eliminate the informal reconsideration step, we propose 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 propose 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 impose multiple sanctions, for example, contract termination, intermediate sanction, or CMP, against an MA organization or Part D sponsor. We propose to have the CMP appeal process go to an ALJ while the other actions such as an intermediate sanction or a termination go to 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.

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

At § 422.758 and § 423.758 we propose 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 propose to revise § 422.758 and § 423.758. Specifically, we propose 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.

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

We propose redesignating the existing § 422.760 as § 422.764 and redesignating the existing § 423.760 as § 423.764 because in this rule we have made explicit which provisions of section 1128A of the Act apply to CMP appeals procedures in proposed subpart T in parts 422 and 423.

We propose 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 those in the nursing facility enforcement context.

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

Sections 422.762 and 423.762—Settlement of Penalties

We propose 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 what the parties may agree to settle the dispute instead of litigating an appeal. We welcome comments on these proposed changes.

Sections 422.764 and 423.764—Other Applicable Provisions

We propose 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 have been made.

Subpart T—Appeal Procedures for Civil Money Penalties

We propose to reserve subparts P, Q, R, and S in Part 422. In addition, we propose 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 civil money penalties under this subpart to the same extent that they apply to a civil money penalty 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 are proposing 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 are proposing 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 almost 20 years and provide established appeals procedures for various types of adverse agency determinations, including civil money penalties imposed on nursing facilities. We welcome comments on the proposed changes to adopt most aspects of 42 CFR 498 into the 42 CFR 422 and 42 CFR 423 proposed regulations.

The statute authorizing CMPs in the MA and Part D programs require the provisions of section 1128A of the Act, (except for subsection (a) and (b)), to apply to MA and Part D CMP proceedings, in the "same manner" as such provisions apply to other CMPs imposed under section 1128A. (See section 1857(g)(4) of the Act.) CMPs imposed on nursing facilities are also authorized under section 1128A of the Act. (See section 1819(h)(2)(B)(ii) of the Act (SNFs) and section 1919(h)(3)(C)(ii) of the Act (NFs), which state that "[t]he provisions of the section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty[] in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).") Based on this common statutory basis, we believe using the Part 498 procedures to hear CMP appeals in

the MA and Part D programs is consistent with Congress' intent.

We also believe that relying on Part 498 appeals procedures for CMP appeals in the MA and Part D programs make sense for policy reasons. We have substantial experience using these procedures and they provide an established infrastructure and well-vetted process for hearing CMP appeals. The bases on which we may impose CMP in the MA and Part D programs are also somewhat similar to those used in the nursing facility context. For example, CMPs can be imposed on MA organization and Part D sponsors for a wide range of regulatory and/or contractual violations, which may be brought to the agency's attention based on audit findings. We believe the part 498 appeals procedures are the most appropriate procedures to use for hearing disputes involving a wide range of violations. We welcome your comments on our proposal to adopt the part 498 procedures as our CMP appeals 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. In the past, we have used our discretion to tailor certain hearing procedures to the particular type when developing other CMP appeals proceedings. Since the MA and Part D programs differ from the nursing facility program, we are proposing modifying certain sections of part 498 to take into account some of these differences.

For example, we have 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 are proposing 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. The DAB has previously 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. (See *Hillman Rehabilitation Center*, DAB No. 1611 (1990), aff'd *Hillman Rehabilitation Center v. United States*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).) The DAB has also held that the same allocation of the burden of proof is appropriate where a CMP has been imposed on a nursing facility participating in Medicare. (See *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004).) 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. As discussed above, noncompliance with requirements for MA and Part D organizations who participate in Medicare is analogous to noncompliance by providers (including nursing facilities) who participate in the program. Moreover, like the providers in the cited cases, an MA or Part D organization is party in possession of the most complete evidence of the state of its compliance. Thus, placing the ultimate burden of persuasion on the organization is fair.

III. Collection of Information Requirements

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 are soliciting 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) would require a MA organization to have procedures in place for mandatory self-reporting of potential fraud or misconduct related to the MA program to the appropriate government authority. The MA organization would be required to report potential fraud or misconduct related to the MA program to the appropriate government authority.

The burden associated with this requirement is the time and effort put forth by the MA organization to implement procedures for mandatory self-reporting. We estimate it would take one MA organization 40 hours to fulfill this requirement. The total number of MA organizations affected by this requirement is 393. The total one-time burden for this requirement would be 15,720 hours. We cannot anticipate how many plans will need to report any potentially fraudulent activities to CMS. However, based on historical evidence, we believe that less than 10 MA organizations would be required to 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 requirements 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, or inspect any books, contracts, medical records, patient care documentation, and other records 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 inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records 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 requires an MA organization 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; 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) would require a Part D sponsor to have procedures in place for mandatory self-reporting of potential fraud or misconduct related to the Part D program to the appropriate government authority. The Part D sponsor would be required to report potential fraud or misconduct related to the Part D program to the appropriate government authority.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to implement procedures for mandatory self-reporting. We estimate it would take one Part D sponsor 40 hours annually to fulfill this requirement. The total number of Part D sponsors affected by this requirement is 91. The total one-time burden would be 3,640 hours. We cannot anticipate how many plans will need to report any potentially fraudulent activities to CMS. However, in the event a Part D sponsor needed to self-report potential fraud or misconduct related to the Part D sponsor the total burden would be 5 hours annually. If every sponsor had to report 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, medical records, patient care documentation, and other records of the Part D sponsor, first tier, downstream and related entity(s), or its transferee.

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 pertinent contracts, books, documents, papers, and records 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
IT/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 requires a Part D Plan Sponsor 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; 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-P, 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.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed

with a subsequent document, we will respond to the comments in the preamble to that document.

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 proposed rule 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 \$37.50 an hour for staff time spent on auditing and related functions covered by this proposed rule, the total net incremental cost of this proposal would be approximately \$7 million (\$37.50 x 185,000 hours), far below the \$100 million threshold for a major rule. This cost would 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 proposed rule 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 of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. As explained above, this proposed rule will not impose consequential costs on affected entities. Accordingly, we have determined that this proposed rule 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 603 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 would amend 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, 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 must have procedures for mandatory self-reporting of potential fraud or misconduct related

to the MA program to the appropriate government authority. The MA organization is required to report potential fraud or misconduct related to the MA program to the appropriate government authority.

* * * * *

4. Amend § 422.504 by—

A. Republishing paragraph (e) introductory text.

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

C. Revising paragraph (i) introductory text 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 may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records 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.

* * * * *

(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 inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records 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 providers, related entities, first tier and downstream entities must contain the following:

* * * * *

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, 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 related entity, first-tier, or downstream 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 provider or 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 September 1 of the contract year.

* * * * *

(3) *Corrective action plan.* (i) Before nonrenewing a 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 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 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 (3)(i) through (3)(iii) of this section may result in the nonrenewal 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—
(i) Its current contract term with CMS, or

(ii) Its contract with CMS from the preceding contract term.

* * * * *

(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 terminating 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—

(1) * * *

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

(c) For CMS-initiated terminations, CMS mails notice to the MA organization 90 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 September 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 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 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 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 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 all 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 section 1003 of this chapter, 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 (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); 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.

* * * * *

(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.

(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.

(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.

29. Amend § 422.760 by—

A. Redesignating § 422.760 as § 422.764.

B. Adding 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. Adding 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—[Reserved]

31. Subpart P is reserved.

Subpart Q—[Reserved]

32. Subpart Q is reserved.

Subpart R—[Reserved]

33. Subpart R is reserved.

Subpart S—[Reserved]

34. Subpart S is 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 hearing.
- 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 of this title.

§ 422.1004 Scope and applicability.

(a) *Scope.* (1) This subpart sets forth procedures for reviewing initial determinations that CMS makes with

respect to the matters specified in paragraph (b) of this section.

(2) The determinations listed in this section affect participation in the Medicare program.

(3) The following provisions in this subpart specify the applicability of the provisions of part 422, subpart O to civil money penalties or remedies imposed on the indicated entities on MA organizations and MA-Part DD organizations.

(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) in Subpart O, 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 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 days to file objections to the order.

(3) After the 10 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 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), 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 or reconsidered 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 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 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 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 itself from 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 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-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.*

(1) 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-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 ALJ or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 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, 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 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.

* * * * *

(G) * * *

(3) The Part D plan sponsor must have procedures for mandatory self-reporting of potential fraud or misconduct related to the Part D program to the appropriate government authority. The Part D sponsor is required to report potential fraud or misconduct related to the Part D program to the appropriate government authority.

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) introductory text 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).
 - O. Redesignating (i)(4)(iv) as (i)(4)(v).
- 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.
 - (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, medical records, patient care documentation, and other records 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—
 - (i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records 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 pharmacies or other providers, related entities, first tier and downstream entities must contain the following:
 - (ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a pharmacy, first tier, downstream, and 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 pertinent contracts, books, documents, papers, and records relating to the Part D program to either the sponsor or directly to CMS or its designees.
 - (v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor 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, or pharmacy:
 - (v) All contracts or written arrangements must specify that the first tier, downstream, or related entity, or pharmacy 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 of this subpart, 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) *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 September 1 of the contract year.
 - (3) *Corrective action plan.* (i) Before nonrenewing 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 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 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 (3)(i) through (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 (b) introductory text.
 - C. Revising paragraph (b)(2).
 - D. 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—

(i) Its current contract term with CMS, or

(ii) Its contract with CMS from the preceding contract term.

* * * * *

(b) *Notice.* If CMS decides to terminate a contract for reasons other than the grounds specified § 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 terminating 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 Part D plan sponsor must develop and submit the CAP within 45 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 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—

(1) * * *

(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 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 September 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 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's 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 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 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 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 all 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 section 1003 of this chapter, 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 (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 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.

* * * * *

(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 monetary 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 § 423.509(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 § 423.650.

(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's 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. Adding 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.

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423.1002 Definitions.

423.1004 Scope and applicability.

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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 a 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.* (1) This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b).

(2) The determinations listed in this section affect participation in the Medicare program.

(3) The following provisions in this subpart specify the applicability of the provisions of part 423, subpart O to civil money penalties or remedies imposed on the indicated entities on Part D sponsors

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart T.

§ 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 ALJ 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.

§ 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) An 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 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 days to file objections to the order.

(3) After the 10 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 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 or reconsidered 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), 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), 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 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 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 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 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 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-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-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-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 ALJ or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board

decision may be reopened, within 60 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)

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Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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Michael O. Leavitt,

Secretary.

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