Public Comments on Medicare Program; Revisions to the Medicare
>Advantage and Part D Prescription Drug Contract Determinations,
>Appeals, and Intermediate Sanctions Processes:========
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>General Comment:I am so glad you are tring to speed program up.I
>haven't been able to work since1-
>2006 and waiting on a hearing since 8-2006.I will be 60 in aug.my
>husband has had to take his 401k to help us keep house,pay bills'and
>get rx's our children have been helping all they can.Husband
makes14.50
>an hour so we don't qualify for other programs.health ins. is $100.31
>aweek and co-pays on our rx's are 175-200 a month.husband only had
401k
>for a few years so it is all gone except for 2600.
>Again I am so happy you are trying to speed process up. thank you,
>nancy
>greathouse p.s. I had congressman Hill write a letter for me in march
>-no results yet.
>

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American Psychiatric Association

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July 31, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code CMS–4124–P
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes;" [CMS–4124–P] RIN 0938–AO78, May 25, 2007

Dear Deputy Administrator Kuhn:

The American Psychiatric Association (APA), the national medical specialty society representing more than 38,000 psychiatric physicians, appreciates the opportunity to submit these comments in response to the Centers for Medicare & Medicaid Services (CMS) proposed rule, entitled "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes;" published in the Federal Register on May 25, 2007.[1] It concerns revisions to 42 C.F.R. Parts 422 and 423, many of which appear to be beneficial to the Part D prescription drug program in a variety of ways.

We have concerns about some aspects of the proposed rule that relate to CMS' ability to hold Part D contractors and subcontractors accountable for programmatic compliance and for Part D data reporting, as outlined below. Such accountability is important to ensure that the Part D program operates for the maximum benefit of its beneficiaries.

Entities, Contracts and Compliance

[1] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes;" [CMS–4124–P] RIN 0938–AO78 [Federal Register Vol. 72, No. 101 (May 25, 2007)]

MAs and PDPs contract with CMS and must use compliance plans that ensure that they employ certain standards of training, education, communications and compliance to protect beneficiaries. The principal contracting entities, MAs and PDPs, are responsible for their subcontractors' compliance with certain standards, through contractual agreement. First tier, downstream, and related entities contract with Medicare Advantage plans (MAs) and Part D prescription drug plan sponsors (PDPs) to provide certain functions, i.e., pharmaceutical benefits management, pharmacy services, quality assurance, claims processing, etc. Therefore, the program compliance control that CMS can exert on subcontractors through the principals (MAs and PDPs) is crucial to protecting beneficiaries and ensuring consistency across plans. We commend CMS for the proposed revisions to Section 422.503 that will add a self-reporting requirement for potential fraud or misconduct to enhance uniformity of compliance plans across MAs and PDPs.[2]

Adding definitions for first tier, downstream, and related entities in 42 C.F.R. Section 422.2 is a good idea, although the term in the definitions "a written arrangement, acceptable to CMS" would benefit from further clarification. There is no definition for this term in the proposed regulations, nor is there a reference for one. The term is ambiguous; it is not the same as "approved by CMS." It suggests that this "written arrangement" may not be already approved through any particular process and that the determination of acceptability could be made *ad hoc* at some unspecified time. This is an important distinction, since it is the written arrangement between the principal entity under contract with CMS and that entity's subcontractors that invokes accountability for compliance with various programmatic obligations of the principal.

Presumably, CMS would find it advantageous to approve subcontracting arrangements in advance of the subcontractor undertaking its contractual obligations. If CMS means that it wants to approve these "written arrangements," then the regulation should be revised to reflect this. If CMS does not mean to routinely approve the "written arrangements," then the regulations should set forth criteria and the method by which CMS would consider these to be "acceptable" and in legal compliance.

The definition for "related entity" acknowledges that these may have contracts with the principal entity to fulfill various functions, although it does not require that those contracts be under "a written arrangement, acceptable to CMS." If such entities are going to be carrying out functions of MAs or PDPs, the contracts under which they operate should be viewed with the same level of scrutiny by CMS as those with first-tier and downstream entities. We suggest that the CMS approval language be added to the definition for "related entity," as well.

Price Concessions Information and Other Part D Data Reporting

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[2] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes;" [CMS–4124–P] RIN 0938–AO78 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29373.

CMS notes that it has statutory authority to obtain price concessions and other information through inspection and audits of books of MAs or PDPs, relating to the Part D program.[3] CMS states that, "(w)e 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."[4] CMS embodied this authority in a regulation requiring subcontractors to make its books and records available.[5] However, exertion of this authority requires affirmative action on the part of CMS to obtain information, cooperation of the entity who owns or controls the records, and the premise that those books that CMS locates would have the desired information in them.

CMS avoids, per Section 423.505, requiring a specified, standard process for plan vendors to submit information, once CMS has made a request for it.[6] Instead, CMS intends leave it to the MA or PDP and its subcontractor to determine the process by which information will flow to CMS. This will lead to several undesirable results that will cause an additional burden on CMS staff through delays, confusion and inefficiency: 1) the processes will vary significantly from one CMS contractor to another, making CMS' internal processes more complex to deal with those variations; 2) there will be controversies between principals and subcontractors as to who is responsible for doing

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[3] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes;" [CMS–4124–P] RIN 0938–AO78 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29373:
"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."

"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."

[4] *Ibid*, CMS–4124–P, at 29374.

[5] *Ibid*, CMS–4124–P, at 29374:
". . . 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).''

[6] *Ibid*, CMS–4124–P, at 29374:
"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.

what and when, causing CMS to resolve accountability issues; 3) there will be variations in the form and type of information provided that will make CMS analysis more difficult; 4) the timeframe to obtain the data will vary without deadlines; and 5) the date and other elements of noncompliance will be hard to establish, absent uniformly set regulatory requirements.

It is more efficient and productive for CMS to promulgate a regulation that requires the entity to affirmatively provide this information to CMS in a targeted form of a report containing the relevant data on a regular basis. CMS has the authority to require such reports and should exercise it. That will prevent CMS from the overly burdensome task of hunting for the information, sifting through extensive accounting books in order to locate the information.[7] In addition, if CMS receives standard pricing data reports from MAs and PDPs in a consistent, controlled form on a regular basis, it can analyze it more efficiently and effectively than if it goes into original accounting books and extracts scattershot data in a variety of forms.

Automatically receiving certain, targeted information at CMS and having procedures to analyze and use it would ultimately benefit the Part D program more than CMS waiting for events to sporadically occur, such as fraud and abuse complaints, that trigger CMS to request, then wait for information. CMS would also be in a position to more actively monitor red flags for fraud and abuse through data analysis, instead of passively awaiting complaints to prompt action.[8] As CMS notes, "(i)t 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."[9]

Price information is highly important and can be used in a variety of ways at CMS that may benefit beneficiaries. The ability of CMS to obtain this and other essential information should be codified in its regulations specifically to avoid controversies as to statutory construction and to shift the need and burden to take affirmative action from CMS to the MA or PDP and their subcontractors. Regulations also need to clearly set forth requirements for data reporting compliance, including deadlines for submission of information to CMS and sanctions for non-compliance.

Expedited Termination and Beneficiary Protections

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[7] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes;" [CMS–4124–P] RIN 0938–AO78 [Federal Register Vol. 72, No. 101 (May 25, 2007)], at 29374:
"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."

[8] *Ibid*, CMS–4124–P, at 29375:
"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."

[9] *Ibid*, CMS–4124–P, at 29374.

CMS proposes to revise regulations of Parts 422 and 423 to provide for CMS to make an "expedited," rather than "immediate" termination of its contract with an MA or PDP. CMS could expedite the contractual termination, where providing the contractor with the usual notice and hearing procedures would pose an imminent and serious risk to the health of those enrolled in the plan. Under the proposed revisions, CMS would be able to set the termination date to allow for sufficient time to arrange for enrollees to transfer into another plan.

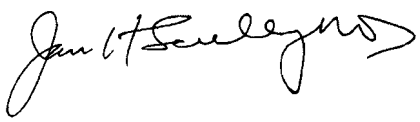
CMS is going to craft policy and procedures to manage enrollee notification and plan transfers in these situations. We would recommend that CMS design these to afford maximum protection to beneficiaries and seamless continuity of care upon termination of their plan. Auto-enrollment into the next most comparable plan might be one way to handle the situation. If the beneficiary did not affirmatively choose an alternate plan by a date certain, s/he could be automatically transferred to a comparable plan. Even if auto-enrolled in another plan, the beneficiary should be given a second period in which to opt-out and choose a different plan or remain in the plan of transfer.

CONCLUSION

APA urges CMS to revise the proposed regulatory definitions to clarify what it means by "acceptable" written arrangements between principals and subcontractors and should apply this to all such arrangements, including those with "related entities." CMS' proposed regulations should also be revised to require Medicare Advantage plans and Part D plan sponsors to affirmatively report standardized Part D information on a regular basis to CMS from their own books and those of their subcontractors. CMS should hold the principal contractors accountable for providing these reports. As with other program elements, appropriate sanctions should also be instituted for non-compliance with reporting requirements.

We recommend that CMS consider which policies and procedures to adopt that will provide the most possible protection for beneficiaries' continuity and quality of care in the event that a beneficiary's plan falls under the proposed expedited termination by CMS. Thank you for allowing the opportunity for us to communicate our concerns.

Sincerely,



James H. Scully Jr., M.D., Medical Director and C.E.O., American Psychiatric Assn.

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July 24, 2007

Ms. Leslie Norwalk
Acting Administrator
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Re: Comments on Proposed Regulation: Revisions to the Medicare Advantage and Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

Dear Ms. Norwalk:

Omnicare is one of the nation's leading providers of pharmaceutical care for the elderly, serving residents in long-term care facilities and other chronic care settings comprising approximately 1.4 million beds in 47 states and the District of Columbia. We appreciate the opportunity to comment on the proposed regulations, as published in the *Federal Register* on May 25, 2007 at 72 FR 29369. Our comments will follow the format and organization of the CMS Federal Register release for the proposed rule.

II. PROVISIONS OF THE PROPOSED REGULATIONS

C. Proposed Changes to Parts 422 and 423

Sections 422.2 and 423.4—Definitions

CMS proposes to move the definitions of "first tier entity", "downstream entity" and "related entity" from Subpart K to Subpart A of Parts 422 and 423. CMS has also provided a flowchart and description of an example of what the terms "first tier entity" and "downstream entity" are intended to refer to.

We believe that one portion of the flowchart which CMS has included should be clarified. Specifically, CMS has shown individual pharmacists as "downstream entities", below the level of pharmacies, which also are identified as downstream entities. The definition of "downstream entity" is "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."

In the typical situation under Part D, the ultimate provider of health services is the pharmacy, not the pharmacist—i.e., it is the licensed pharmacy which purchases the drug from a wholesaler or manufacturer and dispenses the drug to the beneficiary. The pharmacist is only an employee of the pharmacy. It is the pharmacy with which the patient has the legal purchaser-vendor relationship.

We acknowledge that there could be circumstances in which an individual pharmacist, which is not employed by a pharmacy, could subcontract with a pharmacy to provide administrative services for a Part D plan—e.g., medication therapy management services. In that case, the pharmacist would be a downstream entity, as the ultimate provider of administrative services.

We believe that it is important to note these distinctions; otherwise, presumably all employees of each entity involved with providing Part D services, including all employees of each Part D plan sponsor, its PBM and all providers, would constitute "downstream entities." We do not believe such an all-encompassing definition was intended by CMS, or is warranted based upon the way this term is used in the rules.

Sections 422.503 and 423.504—General Provisions

Compliance Training and Education for Downstream Entities

CMS proposes to modify subsections 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C) to provide that the compliance plans of Medicare Advantage organizations and other Part D plan sponsors must include "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."

Given the way that CMS is defining "downstream entity", this amended rule would require Part D plan training and education of pharmacies. We believe such a requirement would be overbroad and unworkable in practice. There are approximately 90 different PDP sponsors and over 400 MA-PD sponsors nationwide. For a national pharmacy provider such as Omnicare to have to subject its personnel to compliance training and education from each of these would represent an enormous burden. Moreover, given the variation between different Part D plans' compliance programs, this would likely create tremendous confusion for Omnicare staff. Even for pharmacies with only a single location, the need to receive training and education from typically 20+ PDPs and MA-PDs in that pharmacy's PDP region would create an unworkable mess. Because of these factors, imposing such requirements would not be likely to facilitate compliance. Indeed, in Omnicare's case, we have our own compliance program, to which all personnel must adhere, so this would be a completely unnecessary requirement in our case.[1]

We believe that any training and education requirements should be limited only to a Part D plan sponsor's own personnel. However, we do not object to the proposed subsection 423.504(b)(4)(vi)(D), which would require a Part D plan to have effective lines of communication between its compliance officer and downstream entities such as pharmacies. We

[1] We do not believe it would be wise to mandate that each downstream entity must have a compliance plan, as this would be impractical for small pharmacies and we see no reason why compliance plans should be mandated for Part C or D providers when they are not required of providers under traditional Medicare or state Medicaid programs.

also note that existing subsections 423.504(b)(4)(vi)(F) and (G) require procedures for effective internal monitoring and auditing, prompt responses to detected offenses, and prompt inquiries when evidence of misconduct is discovered relating to payment or delivery of prescription drug items or services. These and other similar portions of the regulations are more than adequate to appropriately promote regulatory compliance by pharmacies consistent with the real-world situation between Part D plan sponsors and pharmacies.

Mandatory Self-Reporting of Potential Violations

CMS also proposes to add a new subsection 423.504(b)(4)(vi)(G)(3) (and a corresponding change to the Medicare Advantage rules), requiring that Part D plan sponsors have procedures for "mandatory self-reporting of potential fraud or misconduct related to the Part program to the appropriate government authority." Part D sponsors would be "required to report potential fraud or misconduct related to the Part D program to the appropriate government authority."

We believe this change would be unwise and should not be made. An obligation to report any "potential" fraud or potential "misconduct" would mean that a huge number of issues involved in the day-to-day administration of the benefit would be reported to CMS, OIG and other governmental entities prior to the plan sponsor appropriately investigating and working through whether any issue really exists. Moreover, there is no concept of materiality, so the smallest "potential misconduct" would need to be reported—on a mandatory basis.

There will also typically be more than one "appropriate government entity" to which a potential violation could be reported—e.g., a local U.S. Attorney, CMS, OIG, a state Attorney General, and local police may all of have jurisdiction. A number of these would not have appropriate expertise to evaluate "potential misconduct" under a program as complex as Part D. Accordingly, any mandatory self-reporting provision should require only reporting to CMS. However, before mandating any such reporting, CMS must ensure that it has hired the additional staff which would doubtless be needed to deal with the flood of information which would be provided to it in accordance with such a mandate. We believe that in reality this would constitute a huge duplication of the administrative functions performed by Part D plans themselves, and a waste of taxpayer dollars.

We believe the existing requirements for Part D plan sponsors, including their obligations to work with MEDICs, are more than adequate to ensure appropriate detection and reporting of relevant program violations to CMS.

Sections 422.504 and 423.505—General Provisions

Requirements for Contracts with Downstream Entities

CMS proposes to add a new subsection 423.505(i)(3)(iv), which would require that all contracts between Part D sponsors and pharmacies include a provision specifying that the pharmacy (as a downstream entity) must 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.

We believe that it is inappropriate to create a potential obligation of downstream entities such as pharmacies to produce documents requested by CMS to Part D sponsors, rather than to CMS directly. Among other things, the documents and records requested by CMS may be proprietary or subject to confidentiality obligations which would be breached if they were provided to a Part D sponsor (e.g., a pharmacy's contract with a different Part D sponsor, or records which reflect transactions with other sponsors or third parties). Aside from the fact the Part D sponsor would see these materials themselves, there is nothing in the proposed rule which would require a Part D sponsor to maintain the confidentiality of the materials it would obtain pursuant to such a request.

CMS states in the preamble that whether the documents would be provided directly to the government or to the Part D sponsor would be a subject of contract negotiations, but if that is the case we do not see why there needs to be any regulatory provision relating to provisions of documents to the plan—Part D plans and their first tier/downstream entities are already free to include such provisions in their contracts, as a negotiated provision.

More generally, we believe that pursuant to Section 1860D-12(b)(3)(C) of the Social Security Act (the "Act"), any obligations to produce documents or other information to CMS must be consistent with the provisions of Section 1857(d) of the Act. Specifically, that provision provides for: (i) annual auditing of the financial records (including data relating to Medicare utilization and costs) of the plan sponsor; (ii) inspection and evaluation of the quality, appropriateness, and timeliness of services provided under the plan's contract with CMS and the facilities of the plan when there is reasonable evidence of some need for such inspection; and (iii) audit and inspection of any books and records of the plan sponsor that pertain to the ability of the sponsor to bear risk of potential financial losses, or to services performed or determinations of amounts payable under the plan's contract with CMS. Accordingly, the materials which CMS is entitled to obtain are limited by statute; consequently, CMS does not have authority to audit or otherwise obtain other materials.

As noted above, the amended rule would require disclosure by first tier and downstream entities of "any pertinent contracts, books, documents, papers and records relating to the Part D program." We believe these provisions should be modified to incorporate the statutory limitations on the types of information which may be obtained. Further, consistent with the statutory provision, any requirement to provide materials should be limited to provision of such materials to the government directly, not to a Part D sponsor.

With respect to this provision and related regulations requiring disclosure in response to a "request" from the government or its "designee", we ask that CMS clarify that the "request" for materials to which this provision applies would be only for specific materials from a specific first tier/downstream entity, and that the "designee" in such situations is not intended to include Part D plan sponsors (but rather refers to entities such as the MEDICs). We are very concerned about these regulatory provisions being interpreted by numerous Part D sponsors as authorizing them to obtain any documents they may choose to request of a given pharmacy. To date we have encountered numerous highly-burdensome requests from Part D sponsors, and entities with which they have contracted, for inappropriate or irrelevant materials. We do not understand this to be the intent of the rule, but we ask CMS to state this affirmatively.

We also note that the proposed new subsection 423.505(i)(4)(v) would require that all contracts specify "that the first tier, downstream, or related entity, or pharmacy must comply with all applicable Federal laws, regulations and CMS instructions." We believe the "CMS instructions" portion of this requirement must be deleted. In effect, it could be read to allow CMS to impose any requirement whatsoever on pharmacies or other first tier or downstream entities, regardless of whether CMS has statutory authority to do so, and without complying with the requirements of the Administrative Procedures Act relating to imposition of new agency rules of substantive effect. While CMS has authority to include in its contracts with Part D plan sponsors "such other terms and conditions not inconsistent with this part ... as the Secretary may find necessary and appropriate" (Section 1857(e)(1) of the Act, incorporated into Part D by Section 1860D-12(b)(3)(D) of the Act), this authority cannot plausibly be read to permit CMS to impose undefined and potentially unlimited obligations on providers, without even conducting a rulemaking, when Congress has not otherwise granted the agency such authority.

Finally, we note that, in addition to adding this new subsection 423.505(i)(4)(v), which uses the defined terms "first tier" and "downstream" entity, CMS has also proposed adding a new subsection 423.505(i)(3)(v), and retaining the existing subsection 423.505(i)(4)(iv), both of which contain nearly identical language to 423.505(i)(4)(v) but instead use the terms "contractor" and "subcontractor" that CMS indicates it is trying to replace. We believe these additional subsections are unnecessary and should be deleted; if retained, they should be revised consistent with our comments above (by deleting "and CMS instructions") and "contractor" and "subcontractor" should be replaced with "first tier entity" and "downstream entity".

III. COLLECTION OF INFORMATION REQUIREMENTS

We disagree with CMS's estimates of various components of the proposed rule amendments. Overall, we believe the expected changes would have economically significant effects (over $100 million per year), and as such requires a regulatory impact statement.

We believe that CMS has dramatically underestimated the cost of requiring compliance training and education for downstream entities. If implemented as drafted, the rule would require every Part D sponsor to conduct compliance program education and training with respect to every pharmacy in its network. We do not believe that the earlier version of the rule, requiring "effective training and education between the compliance officer and the organization's employees, contractors, agents, and directors", required training and education with respect to network pharmacies; certainly, CMS never indicated that it did in discussing this regulation in the proposed or final rules.

Given the many thousands of pharmacies in the United States which contract with Part D plans, and the 650 Part D plans identified by CMS at 72 FR 29382, we believe the cost of such training and education would substantially exceed $100 million on an annual basis. In this regard, it is important to take into account not just the expense of conducting the training, but the lost working time for pharmacy staff in attending it, which would in many cases require additional staff to be hired.

Similarly, we believe CMS has dramatically underestimated the cost of its proposed mandatory self-reporting provision. An obligation to report every instance of "potential" fraud or "misconduct" relating to Part D to multiple governmental entities would realistically entail

significant involvement of legal counsel to determine whether particular issues require reporting, and then follow-up and cooperation with each governmental entity to which the issue is reported. As indicated in our comments above, we believe many governmental entities will not have appropriate expertise to be able to evaluate issues under the complex Part D program, and accordingly will require Part D sponsors (as well as any entities or individuals being investigated) to expend significant resources in explaining issues. Reporting of all such "potential" violations will result in an enormous drain on all parties, since we expect a huge number of items which turn out not to be violations will be reported due to this over-broad regulatory obligation.

We also believe that CMS has underestimated the cost of its proposed provision requiring a contract provision that would require first tier and downstream entities to produce requested materials or information either directly to the Part D plan sponsor or to CMS or its designee, as negotiated by the plan sponsor and each such entity. CMS estimates one hour of attorney time for each such negotiation. However, we believe these negotiations would likely be contentious, as virtually all Part D plans would want materials provided to them, and first tier and downstream entities would stringently resist such demands out of concerns about losing confidentiality, as indicated above. We believe negotiating the types of provisions, and including the types of complex mechanisms, necessary to mitigate such concerns consistent with the terms of the rule CMS has proposed would be significant. Further, there is the potential for the failure of such negotiations to result in termination of agreements, with a consequent loss of beneficiary access to Part D drugs. While it is difficult to estimate the cost of this provision in detail, we believe that it would be significant.

Respectfully submitted,

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Public Affairs

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314-692-1991

July 24, 2007

Leslie Norwalk
Acting Administrator
Center for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

File Code: CMS-4124-P

Dear Administrator Norwalk:

Express Scripts appreciates the opportunity to submit comments in response to the Notice of Proposed Rulemaking (NPRM) with regard to revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes.

Express Scripts, Inc. is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to over 50 million patients through facilities in 13 states and Canada. Express Scripts serves thousands of client groups, including managed-care organizations, insurance carriers, third-party administrators, employers and union-sponsored benefit plans. Express Scripts is headquartered in St. Louis, Missouri.

Express Scripts has four main points that we would like to discuss within this proposed rule:

- Assumption that a "contractor" and "subcontractor" are equivalent to a "downstream entity" as defined within the current regulations.
- Mandatory self-reporting should not be a requirement of a Plan Sponsor's compliance program.
- The sensitive and proprietary nature of Part D sponsors' data and records, including PDE, rebate, and price concession information, must be preserved by CMS; and
- Mandating that any manufacturer rebate not passed completely through to the Plan by a PBM must be deducted from the "gross covered prescription drug costs" would in effect undermine a plan's ability to achieve the greatest possible savings on behalf of beneficiaries by eliminating any incentive that MA-PDs and PDPs have to fully utilize cost-savings tools.

423.504 (b)(4)(vi)(C) & (D) CMS Proposed Change - Elimination of "contractors" and "agents" and replace with "first tier, downstream, and related entities."

Express Scripts recommends keeping the original requirement of the Part D sponsor's compliance plan consisting 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. We have some concerns with the change to the term "downstream entity" instead of "contractor" and "subcontractor". The CMS definition of "downstream entity" is understandable within the current regulatory context. However, "downstream entity" is not an interchangeable term with "contractor" and "subcontractor." For example, retail pharmacies and their employees (e.g. pharmacists) are not subcontracted by the plan sponsor. They merely agree to fulfill prescriptions under an agreement with the plan sponsor who submits those claims for reimbursement. Thus, the network pharmacy and their employees are not providing a service on behalf of the plan sponsor but submitting claims to the plan sponsor for payment. The plan sponsor is really functioning as a fiscal intermediary, not a prime contractor.

We agree with the requirement that the plan sponsor performs fraud, waste and abuse procedures with respect to claims processed under the Part D benefit. However, direct fraud, waste and abuse monitoring of downstream entities is not feasible. We recommend that fraud, waste, and abuse monitoring be a condition set forth in the network agreements with the downstream entities promising to perform that task. Most fraud, waste and abuse monitoring procedures are organization-specific and would require a level of involvement by the plan sponsor in the downstream or related entities' operations that is neither feasible nor necessary. Just as with business associates under HIPAA, Part D sponsors and PBMs should be allowed to rely on contractual commitments made by downstream and related entities that they will implement reasonable and appropriate compliance activities.

Clarification of the use of the terms "first tier, downstream, and related entities", "pharmacies", "other providers", "subcontractors", "contractor".

In the proposed regulations, pharmacies and other providers are separated from first tier, downstream and related entities (proposed section 423.505(i)(3), 423.505(i)(4) & (4)(v)). This create ambiguity with respect to whether pharmacies and other providers are, or are not, first tier, downstream or related entities.

Also, "...related entity, contractor, or subcontractor..." was used without mention of "first tier" or "downstream entities." We recommend adding the terms first tier and downstream entities to the proposed regulation at section 423.505(i)(3)(v).

423.504(b)(4)(vi)(G)(3) – Proposed Mandatory Reporting Requirement

We understand the recent media reports of fraud, waste and abuse have caused concern at CMS that there may not be adequate oversight. However, a regulatory self-reporting obligation would actually have a chilling effect on the compliance programs of plans and their contractors, such as PBMs. The fundamental elements of a good compliance program

include effective lines of communication. This requires that employees at all levels trust the compliance officer and personnel, and that they are willing to discuss potential problems without the fear of retaliation. For example, the OIG stated in its Compliance Guidance for Pharmaceutical Manufacturers:

"In order for a compliance program to work, employees must be able to ask questions and report problems. Supervisors play a key role in responding to employee concerns and it is appropriate that they serve as a first line of communications. Pharmaceutical manufacturers should consider the adoption of open-door policies in order to foster dialogue between management and employees. In order to encourage communications, confidentiality and non-retaliation policies should also be developed and distributed to all employees. Open lines of communication between the compliance officer and employees are equally important to the successful implementation of a compliance program and the reduction of any potential for fraud and abuse. In addition to serving as a contact point for reporting problems and initiating appropriate responsive action, the compliance officer should be viewed as someone to whom personnel can go to get clarification on the company's policies." 68 Fed. Reg. 23731, 23741 (May 5, 2003).

Requiring a company to report any "potential fraud or misconduct" would have the opposite effect. If an employee believes there is a risk that he or she might become involved with a governmental fraud investigation or the subject of a report to CMS, there is very little chance he or she will contact the supervisor or compliance officer with questions or concerns about a particular issue. For the same reason, this chilling effect would make it very difficult for companies to satisfy other fundamental elements of good compliance programs, such as conducting internal monitoring (which requires, in large part, extensive employee cooperation).

Also, the term "potential fraud or misconduct" is vague and would be very difficult to apply. The term "fraud" refers to an act or omission that has a large subjective element absent fact-finding and proof. Moreover, it is often unknown whether the person allegedly committing fraud actually intended to mislead as opposed to having simply commited an innocent mistake. It would be unreasonable for a plan sponsor to make this type of determination and be held accountable for reporting of such a subjective incident.

CMS Proposed Section 422.504 and 423.505—General Provisions

CMS has proposed to have the ability to access to the books and records of MA Organizations or Part D plan sponsor's first tier, downstream, and related entities.

We agree that CMS currently has a right of access to information from the MA organization or Part D plan sponsor's first tier, downstream, and related entities for the purposes of providing quality care to beneficiaries and to audit fraud, waste, and abuse oversight. All claims data should be treated as confidential regardless of its origin. We recommend that the regulation be modified to clarify that assurance.

CMS Comments on pg 29374-29375 of the Federal Register concerning excluding rebates from gross covered prescription costs.

Finally, we believe mandating that any manufacturer rebate not passed completely through to the Plan by a PBM must be deducted from the "gross covered prescription drug costs" would in effect undermine a plan's ability to achieve the greatest possible savings on behalf of beneficiaries by eliminating any incentive that MA-PDs and PDPs have to fully utilize cost-savings tools.

When a Part D sponsor purchases a drug, the price it pays for the drug represents its actual cost (i.e. ingredient cost). CMS clearly accepts this when the drug is purchased from the pharmacy, even though the ingredient cost includes a pharmacy profit margin or mark-up that causes it to be higher than the pharmacy's acquisition cost for that drug. It should be no different if the Part D sponsor purchases the drug from a PBM instead of the pharmacy, and the ingredient cost includes the PBM mark-up.

There is no basis for treating PBMs any differently from any other entity in the supply chain of the drug if the PBM actually purchases the drug and sells it to the Part D sponsor. At each link along the supply chain – from the manufacturer to the wholesaler to the pharmacy to the PBM to the plan – there is a mark-up in the price of the product to account for the seller's overhead and profit in selling the product. This becomes embedded in the actual price paid for the product by the next buyer in the chain. CMS is not requiring the carve-out of this embedded mark-up for any other entity in the supply chain, and accepts that this is an integral part of the product cost to the buyer at the next level. If a PBM purchases a drug and assumes the financial risk and responsibilities of ownership of that drug, the price it charges a Part D sponsor for that drug should be treated in the exact same way as the price charged by any other entity in the supply chain.

CMS should not mandate one pricing model over any other. Part D sponsors should continue to have the broadest possible choice in designing their prescription drug benefits, in order to ensure the lowest possible cost for beneficiaries. The portion of the manufacturer rebate retained by a PBM should not be eliminated from the "gross covered prescription drug costs," which would effectively mandate pass through pricing for all plan sponsors.

In closing, we appreciate the opportunity to share our concerns with you.

Regards,

Janice Forsyth
Vice President and Deputy General Counsel
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Recd 7/23/07

July 24, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Attention: CMS-4124-P

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule, "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes" (72 FR 29368, May 25, 2007). AHIP is the national trade association representing nearly 1,300 member companies providing health coverage to more than 200 million Americans. This proposed rule would affect AHIP's member organizations, many of which participate as plan sponsors under the Medicare Advantage (MA) and Medicare Part D Prescription Drug Benefit (Part D) programs. Our comments appear below.

General Comments

- **Crosswalk.** AHIP commends CMS' development of a crosswalk of corresponding Part 422 and Part 423 provisions of the regulations. The crosswalk will promote consistency in CMS' application of similar policies across both programs and facilitate compliance by organizations participating in both the MA and Part D programs.

- **Restructuring of requirement for program to prevent and detect fraud, waste and abuse.** CMS is proposing to restructure the rule to revise the requirement for addressing prevention and detection of fraud, waste and abuse under the Part D plan sponsor's compliance program. The agency is modifying the compliance plan regulatory requirements to clarify that CMS expects such a program to be an integral part of the other elements of the sponsor's compliance plan rather than a separate element. AHIP supports this change. The language in the existing regulations lists a program to prevent and detect fraud, waste, and abuse, as a distinct element that Part D plan sponsors are required to incorporate into their compliance plans and the manner in which they are expected to implement this element in conjunction with the other elements of the plan has been unclear. We support the integrated approach reflected in the proposed rule.

- **Applicability of Part 423 provisions to Medicare cost plans.** The preamble states that the proposed rule would clarify the Medicare program provisions relating to contract determinations involving Medicare Advantage organizations and Medicare Part D prescription drug plan sponsors. The preamble is silent on which Part 423 provisions apply to cost plans that offer a Part D optional benefit. AHIP recommends that CMS identify in the preamble to the final rule which portions of Part 423 apply to Medicare cost plans that offer Part D benefits.

Specific Comments

- **Training and education (§422.503(b)(4)(vi)(C) and §423.504(b)(4)(vi)(C)).** CMS is proposing to clarify the requirements for including training and education components in compliance plans by conveying that this obligation extends to the MA and Part D plan sponsors' first tier, downstream, and related entities. AHIP is seeking clarification of CMS' expectation regarding how the organization implements this requirement for first tier and downstream contractors where a contractor may have its own compliance program for its own employees and subcontractors, and a single contractor may have relationships with a number of MA and Part D plan sponsors. AHIP raised this issue during CMS' development of Chapter 9 of the Prescription Drug Benefit Manual. When CMS finalized that chapter, CMS conveyed these responsibilities in §50.2.2.1 by stating that Part D plan sponsors are responsible for:

  > Creating and coordinating, or appropriately delegating, educational training programs to ensure that the Sponsor's officers, directors, managers, employees, and other individuals working on the Part D program are knowledgeable of the Sponsor's compliance program; its written standards of conduct, policies, and procedures; and the applicable statutory, regulatory, and other requirements.

  AHIP believes that CMS' position that the organization has the flexibility to implement the training and education requirement directly or through coordination with other organizations or delegation is important. The ability to employ a variety of strategies would permit plan sponsors to fulfill their accountability for implementation of compliance plans, while avoiding unnecessary redundancy for entities that contract with multiple MA and Part D plan sponsors and promoting efficiency for plan sponsors. For clarity, AHIP recommends that CMS confirm in the preamble to the final regulation that CMS' intends to continue this policy.

- **Self-reporting of potential fraud and misconduct (§422.503(b)(4)(vi)(G)(3) and §423.504(b)(4)(vi)(G)(iii)).**

  + **Determination of whether the "potential" standard has been met.** CMS is proposing that MA and Part D plan sponsors must self-report "potential" fraud or misconduct. When allegations of inappropriate conduct come to the attention of a plan sponsor, the sponsor typically conducts an initial investigation to verify that inappropriate conduct appears to have occurred, makes a determination of the potential nature of the inappropriate conduct (e.g., unintentional mistake, possible fraud, or other intentional misconduct), and determines the next steps in the course of further investigation. The regulations and the preamble discussion do not acknowledge that such a process would be the foundation for a determination that potential fraud or misconduct has occurred so that the reporting requirement can be met. AHIP recommends that CMS include in the preamble to the final regulations a discussion acknowledging the appropriateness of conducting such reviews prior to reporting potential fraud or misconduct.

    Our recommendation is consistent with CMS' current position regarding disclosure as reflected in Section 50.2.8.2 (Recommended Procedures for Reporting by Sponsors) of Chapter 9 of the Prescription Drug Benefit Manual. That section explains that the sponsors with appropriate resources are encouraged to investigate potentially fraudulent activity so that they can make a determination whether potential fraud or misconduct has occurred. The discussion continues by stating, after conducting a reasonable inquiry by the Sponsor, if it is determined that potential fraud or misconduct has occurred, the Sponsor should refer it to the appropriate MEDIC. AHIP recommends that CMS adopt similar language in the preamble clarifying its intention here.

  + **Definition of misconduct.** The proposed rule requires the self-reporting of potential fraud and misconduct. While the meaning of the term "fraud" is reasonably clear, we believe the term "misconduct" merits clarification. It is our understanding that misconduct arises as a result of an intentional wrongful action rather than inadvertent errors. We believe that clarification of the meaning of "misconduct" to highlight this distinction would avoid ambiguity and promote consistent implementation of the reporting requirement. Accordingly, AHIP recommends that CMS clarify in the preamble to the final rule that misconduct entails "intent."

- **Disclosure of information to CMS (§423.505(i)(3)(iv)).** CMS is proposing to add a provision to the regulations to require that contracts between Part D plan sponsors and their first tier, downstream, and related entities must contain a term providing that information requested by CMS can be submitted by these parties either through the Part

  D plan sponsor or directly to CMS. CMS explains in the preamble that, "We intend to leave it to the contracting parties to determine during their contract negotiations the process for submitting the requested information."

  We are concerned that the language of the proposed regulation could be interpreted to mean that the contract term must include two options either of which may be elected unilaterally by the first tier, downstream, or related entity. However, based upon the preamble discussion, it is our understanding that CMS intends that the manner of reporting should be resolved through negotiation that results in a mutually acceptable contract term. To avoid ambiguity, AHIP recommends that CMS modify the language of the regulation to clarify that this is the agency's intent.

- **Requirements that must be included in first tier and downstream contracts.** Because of the substantial resources and time necessary to recontract with network providers and pharmacies in order to amend contracts, AHIP is seeking clarification that to the extent that contract amendments are needed as a result of the final rule, changes may generally be made at the time of contract renewal. To mitigate disruption and administrative burden, we recommend that CMS include this clarification in the preamble to the final rule.

- **Record retention requirements (§422.503(i) and §423.505(i)).** AHIP recommends that CMS clarify the record retention requirements as they apply to first tier and downstream contractors. AHIP's understanding is that these contractors are required to retain records for a 10 year period. However, because the regulations include a provision requiring a right to inspect records through 10 years from the final date of the contract period or from the date of completion of any audit, the language of the regulations could be interpreted to extend this 10 year period to be aligned with the term of the organization's contract with CMS or the timing of audits. If CMS' intent is to define the obligation as a 10 year period from creation of the record, AHIP recommends that CMS revise §422.503(i) and §423.505(i) to convey this period. If this is not CMS' intent, we recommend that CMS amend these sections to convey more clearly the record retention obligation for first tier and downstream contractors.

- **Nonrenewal of a contract (§422.506 and §423.507).** CMS is proposing to revise the regulations to provide that the agency will notify an organization of CMS' decision not to renew an MA or Part D contract by September 1, rather than the current deadline of May 1, in order to allow additional time for CMS to evaluate plan sponsor performance. However, the existing time frame provides nonrenewal notice to organizations in advance of the bid submission deadline, so that neither they nor CMS unnecessarily invest

  significant resources in the bidding process. Further, the September 1 deadline appears to render moot the appeal right the organization has under Subpart N of Parts 422 and 423. Accordingly, if CMS does not retain the existing deadline, we recommend that in finalizing any new deadline CMS identify an earlier date no later than August 1 in order to mitigate unnecessary resource allocation, permit orderly planning, and ensure that appeal rights under Part 422 and Part 423 are preserved.

AHIP appreciates the opportunity to comment on these proposed rules. If you have questions or would like additional information about the issues we have raised, please contact me at (202) 778-3209 or cschaller@ahip.org.

Sincerely,

Candace Schaller

Candace Schaller
Senior Vice President, Federal Programs

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

George Paz
Chairman, CEO
Express Scripts, Inc.

Mark Merritt
President & CEO

July 24, 2007

Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

File Code: CMS-4124-P

Dear Acting Administrator:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Notice of Proposed Rulemaking (NPRM) with regard to revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes.

PCMA has four primary concerns with this proposed rule:

- Part D sponsors should not be responsible for education and enforcement of the fraud, waste and abuse (FWA) activities of first tier, downstream, and related entities;
- Reporting of FWA should remain voluntary;
- The sensitive and proprietary nature of Part D sponsors' data and records, including PDE, rebate, and price concession information, must be preserved by CMS; and
- The current timeline for CMS review of contracts and May 1st notification of nonrenewal should be maintained.

Our comments are as follows:

Sections 422.2 and 423.4 – Definitions

CMS proposes to apply the definitions of "downstream entity," "first tier entity," and "related entity" from Subpart K of Parts 422 and 423 to the General Provisions of the MA and Part D regulations. A "first tier entity" as defined in Subpart K is "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."

As defined, these terms are overly-broad in scope. They not only would cover any health care provider (pharmacies, pharmacists, physicians, nursing facilities, etc...) but also all contractors with whom the plan sponsor has any sort of administrative relationship. Based on the CMS-proposed definition, this could potentially include such third party contractors as printers, mailers, legal counsel, human resources firms, etc...

PCMA Recommendation: *CMS should be explicit in their definition of "first tier entity," "downstream," and "related entity" to state that these terms only cover those entities that provide a health care or administrative service directly to a Medicare beneficiary.*

Sections 422.503 and 423.504 – General Provisions

CMS states 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 "first tier, downstream, and related entities. ...*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."[1]

As with their commercial and other government clients, PCMA members are working diligently to preserve the integrity of the prescription drug benefit. Sponsors and PBMs are fully committed to have policies and procedures consistent with the list of applicable statutory, regulatory, and guidance as specified in Sections 422 and 423. This includes procedures for identification of potential fraud, waste and abuse in a Sponsor's pharmacy network, as well as a process to ensure that marketing is consistent with applicable federal and state laws as well as CMS policy.

We also presume that Sponsors are entitled to rely on the FWA programs of those multiple stakeholders in instances where the Sponsor is not in a position to identify a risk or vulnerability. For example, if a manufacturer is engaged in inappropriate relationships with physicians, a PDP or its subcontractors would not be in a position to identify those instances. Should those instances come to its attention, of course, it is clear that the PDP would take appropriate action. Similarly, if a wholesaler engaged in activities such as inappropriate documentation of pricing information, a PDP or its subcontractors would not have all the information necessary to adequately determine if fraud, waste, or abuse were present.

However, Sponsors should not be required to implement or monitor the implementation of these requirements by subcontractors and downstream entities. Most of the procedures are organization specific and would require a level of involvement in the subcontractors' operations that is neither feasible nor necessary. Sponsors expect subcontractors to comply with the requirements of the guidance – as is appropriate for their organizations – and to in turn impose the obligations on their subcontractors.

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[1] Federal Register / Vol. 72, No. 101at 29372/ Friday, May 25, 2007 / Proposed Rules

PCMA Recommendation: *Sponsors should not be responsible for implementing or monitoring FWA activities of other stakeholders such as manufacturers and wholesalers. In addition, just as with business associates under HIPAA, with respect to subcontractors and downstream entities such as pharmacists, marketing firms, claims processing firms, quality assurance companies, healthcare marketing consultants, etc..., plan sponsors should be allowed to rely on contractual commitments by subcontractors that they will implement reasonable FWA activities related to their delegated activities and appropriate to their size and sophistication: i.e. these entities should not be subject to the same full-blown FWA program as Sponsors.*

Sections 422.503(b)(4)(vi)(G)(3) and 423.504(b)(4)(vi)(G)(3)

CMS also proposes to make mandatory the self-reporting provisions that apply to Part D sponsors. Specifically, CMS states that "[t]he 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."[2]

The Part D program is only in its second year, and new guidance is issued by CMS on a frequent basis. Given that the program itself is still evolving and that guidance in many areas is still expected or in flux, there is a significant level of uncertainty in many areas. Some of these areas are Part B v. D determinations, annual enrollment reconciliation, vaccine administration, paper claims adjudication, record retention, and claims adjustments, to name only a few. As a result, there may be significant data issues, such as inaccuracies, errors from CMS and others, and inconsistent payment that make the task of monitoring and determining whether any FWA has occurred especially challenging. While plans sponsors continue to make their best good faith efforts to meet the requirements of the program and comply with program guidance, we request that CMS be cognizant of these challenges and difficulties as it monitors and audits compliance, and take into account the fact that in many areas, particularly in those dealing with Part D data and processing issues, the exact rules and requirements of the program are still in development.

While we acknowledge that there have been a select few highly-publicized cases of abuse that were not reported to CMS in a timely manner by a particular plan, we do not believe that requiring mandatory reporting of *all potential* fraud, waste, or abuse by Part D sponsors would necessarily have prevented these cases from occurring. The term "potential fraud, waste and abuse" is extremely vague and open-ended, and especially troubling when CMS proposes to make reporting under this vague and broad standard mandatory. Again, should instances of clear actual fraud and/or abuse come to a plan's attention, the plan will take appropriate action in the circumstances, such as reporting the conduct to government authorities at that time.

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[2] Federal Register / Vol. 72, No. 101 at 29393 / Friday, May 25, 2007 / Proposed Rules

The Office of the Inspector General (OIG) of Health and Human Services has established protocols for health care providers for the self-disclosure of fraud, waste, and abuse.[3] In addition the OIG has consistently applied its standard for measuring misconduct across the health care sector. OIG has advised that providers should report cases of misconduct in the following three circumstances: when the conduct (1) is a clear violation of administrative, civil, or criminal laws; (2) has a significant adverse effect on the quality of care provided to federal health care program beneficiaries; or (3) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on federal health care programs.[4]

PCMA Recommendation: *The mandatory self-reporting by plan sponsors of all potential fraud is too broad. Plan sponsors have no way of knowing what could potentially be fraudulent. Self-reporting should remain voluntary, and even then, the standard needs to be consistent across the health care sector, including plan sponsors, their first tier, and downstream entities. Similar to the circumstances identified by the OIG, or the language of the June 26, 1998 interim final rule, Part D sponsors should only have to report to CMS and/or the OIG on credible information of violations of law.*

Sections 422.504 and 423.505 – General Provisions

CMS has proposed to clarify HHS' access to the books and records of MA organizations 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. According to CMS, this includes "any pertinent contracts, books, documents, papers, and records relating to the Part D program."[5]

PCMA is in agreement with CMS that medical and prescription claims data can be used to discover potential gaps in patient care, identify trends in the care of Medicare patients, improve the quality of care for Medicare patients, and enhance the efficiency of the Medicare program. In addition, we agree that CMS has a responsibility to collect information from Part D plans and sponsors to administer, evaluate, and analyze, and make recommendations relating to the Medicare Part D program as well as to carryout its fraud monitoring activities. **However, PCMA believes that the proprietary data related to PDE records should receive the same statutory and regulatory protections as exist currently.**

PCMA Recommendation: *CMS should make clear that the books and records made available to them by first tier, downstream, or related entities in support of the agency's*

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[3] Federal Register / Vol. 63, No. 210 / Friday, October 30, 1998 / Notices P. 58399

[4] The OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; and ambulance suppliers.
http://www.oig.hhs.gov/fraud/complianceguidance.html

[5] Federal Register / Vol. 72, No. 101at 29374 / Friday, May 25, 2007 / Proposed Rules

oversight and monitoring functions will be treated as proprietary and confidential by CMS.

We offer to provide assistance in developing workable solutions to facilitate the sharing of the data for the purposes outlined in the proposed regulation through different means. PBMs are experts in working with prescription drug data and we believe this expertise could be invaluable to appropriately and effectively take advantage of this critical Part D data. Such solutions could include aggregating, de-identifying by plan, and selecting the appropriate claims data fields that provide sufficient information to carry out the goals of improving FWA monitoring set forth in the proposed rule without compromising patient privacy, or proprietary information.

We believe that CMS has previously drawn the proper distinction and balance in how they treat the following levels of data to ensure that program goals are met for beneficiaries, and that plans are fulfilling their contractual obligations to CMS:

1. **Information to determine that the program is offering the benefits intended –**

   Various types of aggregate or general program data (such as enrollment, formulary, drug price comparisons, MTMP and quality assurance data), which is collected from Part D plans and used and disseminated for program oversight, evaluation and beneficiary education purposes.

2. **Data used by CMS to perform its payment function –**

   Claim-specific data that include personal health information and are also recognized and protected as proprietary. Its use is restricted to only that necessary for CMS to perform its payment oversight role.

In the proposed regulation, CMS states that "it may be "necessary" for it to obtain more detailed rebate and other price concession information from first tier entities" and states that the objective in doing so is to "verify proper payments made to the sponsor" and to "determine what was "actually paid."[6]

A standard term of plan sponsors' contracts with PBMs includes the right to audit rebates, either directly, or through an independent third party auditor that is subject to the terms of a confidentiality agreement, which is used to ensure the confidentially of highly proprietary rebate contracts. Part D plans are sophisticated purchasers of drugs and services and have a long standing history of negotiating and contracting with PBMs in the commercial market. As such, plans ensure that they receive the full manufacturer rebates to which they are entitled through the aforementioned audits used to verify PBM compliance.

PCMA Recommendation: *In order to ensure that plan sponsors continue to receive the lowest possible price for Part D drugs, the competitive process of negotiating rebate contract terms must remain confidential, as currently is the case in the commercial*

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[6] Federal Register / Vol. 72, No. 101 at 29374 / Friday, May 25, 2007 / Proposed Rules

market. Should CMS need to verify that Part D plans are receiving the appropriate rebates, Part D plans can make available the independent auditor reports used by plan sponsors.

We note that in discussion of price concession received by the plan sponsor from PBMs, CMS refers to "administrative cost," "gross covered prescription drug costs," and "actually paid costs." PCMA has concerns with CMS's interpretation of these terms as outlined in CMS-4130-P, "Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit", and would like to reiterate those concerns here.[7]

Sections 422.506(b)(2)i) and 423.507(b)(2)i) – Nonrenewal of a Contract

CMS proposes to change the date by which they must provide notice of their decision not to authorize renewal of a contract from May 1st to September 1st. As justification, CMS states that this date change 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."[8]

Plan sponsors invest significant time and resources into preparing and submitting their bids, designing plans and formularies, as well as obtaining approval for and producing their marketing materials. Much of this activity occurs between May and September of each year. Should CMS determine that a contract will not be renewed, this significant investment made by plans will be lost. In addition, if a Part D sponsor requests a hearing on the decision to nonrenew, any favorable decision for the contract in question must be issued by July 15th for the contract to be effective on January 1st of the following year. If the decision to nonrenew is postponed until September 1st, the Part D plan effectively loses any opportunity to appeal CMS's decision for the following contract year.

PCMA Recommendation: *CMS should make no change to the May 1st deadline for issuance of notice of nonrenewal.*

On behalf of PCMA, I appreciate the opportunity to comment on proposed rule CMS-4124-P. PCMA looks forward to working with CMS to combat fraud, waste and abuse and to ensure a successful Part D benefit.

Sincerely,

Mark Merritt
President and Chief Executive Officer

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[7] See PCMA Comment on File Code CMS-4130-P

[8] Federal Register / Vol. 72, No. 101 at 29376 / Friday, May 25, 2007 / Proposed Rules

COMMENTS OF KAISER FOUNDATION HEALTH PLAN, INC.

On Proposed Rule CMS-4124-P

July 24, 2007

Kaiser Foundation Health Plan, Inc. and its subsidiary Health Plans ("Kaiser"), all of which are either Medicare Advantage organizations or Medicare Cost contractors pursuant to Section 1876 of the Social Security Act, appreciate the opportunity to comment upon the proposed rule (CMS-4124-P) published in the May 25, 2007 Federal Register. Kaiser's comments are set forth below. If readers of these comments have any questions or seek further information, they may contact any of the following Kaiser attorneys: Judith Mears (Judith.Mears@kp.org, 510 271-5964), Paula Ohliger (Paula.Ohliger@kp.org, 510 271-2325), Amy Hafey (Amy.B.Hafey@kp.org, 626 405-5494), or Anthony Barrueta (Anthony.Barrueta@kp.org, 510 271-6835).

PROVISIONS OF THE PROPOSED REGULATIONS

p. 29384 Section 422.503(b)(4)(vi)(c) General provisions.

CMS is proposing that an MAO's compliance plan must include effective training and education not only for the MAO's employees, managers and directors, but also for an MAO's "first tier, downstream and related entities." These terms have very expansive definitions, and there are more such entities participating in an MAO's Part C activities than in its Part D activities. As a result, an MAO's training and education obligations would be increased exponentially under the proposed rule. The magnitude of this task would be immense. An MAO can not possibly be responsible for training each such entity or the personnel who work for each such entity. Even if an MAO could make its compliance training available to these entities (hard copy or on-line), it would be virtually impossible for the MAO to track each such entity's completion of the compliance training.

In the final rule, we believe CMS should clarify the options available to an MA to meet this requirement and make those options consistent with existing guidance in the Fraud, Waste and Abuse Chapter of the Prescription Drug Benefit Manual. This Chapter acknowledges that it may not be reasonable for Part D sponsors to provide all of the training directly to first tier, downstream, and related entities and staff, and provides options for accomplishing the training. Downstream entities can (1) attend the sponsor's training "to the extent that it is feasible and reasonable"; (2) conduct their own Part D compliance training; or (3) use a combination of both, by supplementing their own training with sponsor-held training and education which can be available through multiple means (web-based tools, intranet sites and videotaped presentations). MAOs should have similar flexibility on the Part C side to train and/or delegate the training, so

long as the training content meets CMS guidelines. This flexibility is especially important (and necessary) when an "entity" is an off-shore contractor. Moreover, any training obligations should be applicable only to those first tiers, downstream and related entities whose functions are directly related to the MAO's Medicare business.

p. 29384 Section 422.503(b)(4)(vi)(G)(3) General provisions.

In this provision, CMS is proposing that an MAO be "required to report potential fraud or misconduct related to the MA program to the appropriate government authority." This is not the first time CMS has proposed such a requirement. In the proposed MMA rule, published in the Federal Register on August 3, 2004, CMS proposed a mandatory duty of self-reporting in the following language:

> "If the MA organization discovers from any source evidence of misconduct related to payment or delivery of health benefits under the contract, it must conduct a timely, reasonable inquiry into that misconduct. If, after reasonable inquiry, the MA organization has determined that the misconduct may violate criminal, civil or administrative law, the MA organization must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred..." (69 FR 46908)

This prior description of a mandatory self-reporting duty is more specific, and therefore more capable of being operationalized in a compliant manner by an MAO, than the very broad and general terms of the mandatory self-reporting duty CMS has included in the current proposed rule. There are, for example, no definitions in the preamble to this proposed rule, or in the proposed rule itself, for "potential" or "potential fraud" or "potential misconduct." Therefore MAOs must guess at the meaning of these terms, and guess as well at how much evidence it must have of fraud or misconduct before the mandatory duty to self-disclose begins.

We believe that any duty to self-report should begin where probable fraud or misconduct has been identified through the performance of a due diligence-level investigation by an MAO's appropriately qualified internal personnel. The issue of "potential" versus "probable" is not just a semantic argument. Instead it goes to the nature, duration and depth of the investigation that MAOs are required and permitted to conduct before self-reporting fraud or misconduct. We do not suggest that an MAO must be 100% certain that fraud or misconduct has occurred before it self-reports. At the same time, we do not believe self-reporting is warranted at a stage when an MAO only knows that there is a "possibility" or a "potential" that fraud or misconduct has occurred. CMS should preserve, whether as described in guidance in the final rule's preamble or in a change to the text of the proposed rule itself, the ability of an MAO to conduct timely preliminary investigations that solidly identify cases of probable malfeasance. Indeed, we believe that the relevant standard should require self-reporting only when an MAO has "credible, probative evidence of administrative, civil or criminal misconduct."

CMS already has many well-established procedures to monitor, accept disclosures from MAOs about, and oversee the correction of, certain mistakes made by MAOs. This

is especially true in case of errors or omissions in the reporting of membership data to CMS, the failure to pay "clean claims" on time, or the failure to observe applicable timelines in processing member appeals from coverage denials. When does such a "mistake" (routinely reported to CMS) rise to the level of reportable "misconduct"? We do not believe that CMS' existing procedures to accept reports about, and require correction of, such mistakes should be eliminated or superseded by a significant new self-reporting obligation imposed on top of them. Instead, we believe that for any misconduct to be mandatory self-reportable, the MAO must determine that the activity was intentional, or at least conducted with reckless disregard for the rules.

In addition, we believe that "misconduct" should be defined clearly and narrowly, so that it applies only to misconduct which is material to, or may threaten, the integrity of an MAO, i.e., systemic issues or patterns of misconduct, or instances where a large dollar amount of a large number of MA members is involved. Lastly, we believe that CMS should state, in its final rule, that any self-reported information is protected from disclosure to third parties under the federal Freedom of Information Act (FOIA). Such protection would incent timely and complete reporting.

p. 29385 Section 422.506 Nonrenewal of contract.

CMS is proposing to provide a notice of intent not to renew an MAO's contract by September 1 instead of the current May 1 deadline. CMS says it will give MAOs a reasonable opportunity to develop and submit a corrective action plan (CAP) before non-renewing a contract. The stated timeframes for submitting a CAP mean that if CMS wanted to observe the September 1 deadline for providing non-renewal notices, CMS would have to inform an MAO no later than June 15 that it (CMS) was likely to issue such a notice, in order to allow the MAO to submit a timely CAP. An MAO that is notified on June 15 that it is in serious danger of non-renewal and must submit a CAP would be under extreme time-pressure to produce and implement that CAP at the same time it was negotiating its bid and preparing member materials for the following year, in case its contract was renewed. Because CMS has significantly "collapsed" the time period during which an MAO can submit a successful CAP that will stave off non-renewal, CMS should commit, in the proposed rule, to notify MAOs no later than May 15 of the need for them to submit a CAP in anticipation of possible non-renewal. We believe that contract renewal is a significant penalty, injurious to both the MAO and to the MAO's enrollees, and CMS should give MAOs every good faith opportunity to avoid it.

p. 29385 Section 422.510(a) Termination of contract by CMS.

In this provision, CMS is proposing to give itself the authority to terminate an MAO's contract in a current year because of the MAO's substantial failure to carry out the terms of its contract "from the preceding contract term." We believe such authority is too broad, because an MAO that has "cured" its failures from the prior year and is, according to any reasonable CMS audit and investigation, in compliance during the current contract year, should be able to retain its MA contract. The proposed authority that would be

given to CMS here actually represents a disincentive to MAOs to improve their performance during any contract year, because, despite an MAO's best improvement efforts during that year, it will never be able to be sure that CMS will not seek, in the next contract year, to terminate its contract based not upon its current level of performance but based on the past. This is inherently unfair. CMS should conduct its oversight and enforcement activities only on a "real time" basis.

p. 29386 Section 422.660(b) Right to a hearing and burden of proof.

CMS is proposing that once it non-renews or terminates an MAO's contract, and the MAO appeals to a CMS hearing officer, the burden of proof is on the MAO "to demonstrate that it was in substantial compliance...on the earliest of the following three dates": the date the MAO was notified of the nonrenewal/termination; the date of the most recent on-site CMS audit; the date of the alleged breach of the current contract or "past substantial noncompliance as determined by CMS". Putting the burden of proof on the MAO to demonstrate its compliance gives CMS a significant (and we think unfair) advantage at such a hearing. We believe instead that before the CMS hearing officer, CMS should be required to produce evidence of the MAO's non-compliance, and then the MAO should be required to counter that showing with evidence of its own. Both parties would stand on an equal footing, both with evidentiary production obligations, before the CMS hearing officer.

If CMS is unwilling to adopt this approach, it should at least amend the proposed rule to create a rebuttable presumption of non-compliance, with the MAO assuming the burden of going forward to rebut the presumption. If the MAO submits at least colorable evidence of substantial compliance, the burden of persuasion should then shift to CMS to prove noncompliance by clear and convincing evidence. Another alternative is to copy the process outlined in the proposed new Subpart T at Section 422.106 (b)(6), which would govern comparable failures by an MAO, and is more fair.

We also believe that CMS' proposed requirement that the MAO demonstrate its compliance "as of the earliest of the...three dates" is very unfair. One the dates that could be the "earliest" date is the date of the most recent CMS site visit. Assuming the findings of the site visit are valid, there is no way an MAO could prove, after the fact, that it was in "substantial compliance" as of the date of the site visit. Another of the dates that could be the "earliest" date is the date of the alleged "breach of the current contract". When CMS selects that date, having already compiled its evidence to substantiate a breach, it would be impossible for an MAO to prove after the fact that it was in "substantial compliance" as of that date. We believe that procedural rules requiring demonstrations of compliance as of a <u>past</u> date fundamentally violate due process. Instead, the rule should permit an MAO to demonstrate to a CMS hearing officer that it has seriously and comprehensively addressed all of CMS' noncompliance findings arising from its past problems, and is currently in substantial compliance.

p. 29387 Section 422.692(b) and (c) Review by Administrator.

The proposed rule would permit an MAO to appeal, to a CMS hearing officer, CMS' decision to non-renew or terminate its MA contract, and if that hearing officer ruled in favor of CMS, the MAO could request the Administrator of CMS to review the hearing officer's ruling. However, the proposed rule would permit the Administrator to "accept or decline to review the hearing decision". If the Administrator took no action within 30 days of the MAO's request, that would be "treated as a decision to decline the request for review", and the CMS hearing officer's decision would "become final and binding." This proposal authorizes an unstructured, unrecorded exercise of the Administrator's discretion that can hide unequal (i.e., arbitrary and capricious) treatment but which itself evades review. Because the hearing officer's ruling becomes "final and binding" if the Administrator does nothing for 30 days, the MAO has effectively been deprived of a level of review that other MAOs may obtain when the Administrator decides, again without explanation or standards, to review their appeals. We strongly believe that the Administrator should review every case where his/her review is requested.

p. 29387 Section 422.752(c) Basis for imposing intermediate sanctions and civil money penalties.

CMS notes in the preamble that in some cases it could decide to impose "multiple sanctions, for example, contract termination, intermediate sanctions, or CMP, against an MA organization..." The proposed rule would require an MAO faced with multiple sanctions (presumably all arising out of the same set of facts) to appeal the CMP to an ALJ while its appeal of the the sanctions and contract termination would go to a CMS hearing officer. In defense of requiring the MAO to defend "the same underlying conduct" in these bifurcated forums, CMS blandly says: "We believe that the separate processes would result in more consistent decision making by hearing officers and ALJs." We have great difficulty understanding how requiring an MAO to proceed simultaneously in two parallel tracks, in two different forums, before two different types of adjudicators, on the same set of facts, could possibly "result in more consistent decision making". We strongly believe that an MAO facing multiple CMS sanctions arising out of the same set of facts should be able to obtain a hearing on all the proposed sanctions before one hearing officer, in one appeal.

The proposed rule also lacks any explanation of the circumstances that will warrant CMS and the OIG both imposing CMPs upon an MAO based upon the same set of facts. Surely such an extraordinary demonstration of regulatory authority (and financial punishment!) should be reserved only for the most serious, and clearly specified, wrongdoing. The proposed rule should describe the nature of such wrongdoing. Moreover, an MAO should be able to defend itself against CMPs imposed by both CMS and the OIG, when the CMPs are based on the same set of facts, in one proceeding before one hearing officer. We understand that the proposed rule does not seek to amend the

rules governing the OIG's imposition of CMPs, but we believe that CMS could and should include in its own rules a requirement that when CMS imposes CMPs on a set of facts that also subjects the MAO to CMPs imposed by the OIG, CMS must pursue the CMPs in accord with the OIG's rules, so there would only be one, combined, action against the MAO.

p. 29388 Section 422.760(a) Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

CMS has proposed, for the first time, a list of factors which it will consider when determining the appropriate amount of a CMP it will impose on an MAO. A number of these factors are, in effect, "factors in aggravation". We also believe that CMS should add to this list some "factors in mitigation", such as:

* The nature and extent to which the MAO cooperated with CMS' investigation
* The nature and extent to which the MAO mitigated any injury or damage caused by the violation
* The nature and extent to which the MAO has taken corrective action to ensure the violation will not recur

Consideration of both types of factors by CMS is important for it to reach a fair result about the amount of any CMPs it decides to impose.

p. 29393 Section 423.504 General provisions.

Because all of the Kaiser Foundation Health Plans are Part D sponsors, we have the same comments with respect to the "effective training and education" and mandatory self-reporting requirements in this proposed rule as we have stated above with respect to Section 422.503.

p. 29394 Section 423.505(i)(3)(iv) Contract provisions.

In this section, CMS notes its authority to conduct investigations and audits of Part D sponsors and their first tier, downstream or related entities. CMS is also proposing to make more explicit the requirements (a) that it and its designees have access to the books and records of Part D sponsors, and to books and records of the first tier, downstream and related entities with which the Part D sponsor does business, and (b) that sponsors must assure this access in their contracts with these entities. CMS is explicit that such books and records may include records of Part D rebates and price concessions, as well as any data used by a Part D sponsor to calculate and submit its PDE data. CMS says it expects these first tier, downstream and related entities to "produce any pertinent contracts, books, documents, papers and records related to the Part D program." CMS further states that the first tier, downstream or related entity can provide the requested information "either [to] the Part D sponsor or directly to CMS...", and that CMS will leave it to the Part D sponsor to specify in its contracts with these entities whether the

entities will furnish the requested information directly to CMS or to the Part D sponsor to give to CMS, but contracts must be clear on this point.

We believe that it is critically important for a Part D sponsor to have the contractual authority to require its first tier, downstream or related entities to provide any information requested by CMS or its designee to the sponsor to furnish to CMS, and we agree that contracts must be clear as to whether the sponsor or the entity will provide the information. However, we believe the proposed language of the applicable regulation is not as clear as it should be on this point. It requires contracts to contain:

> "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."

This language would appear to require a contract provision giving a first tier, downstream or related entity the option to furnish the information either to the Part D sponsor or to CMS (or its designees). We think this could be a problematical ambiguity. We believe the language should be revised as follow:

> "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 related to the Part D program, and a provision either requiring the entity to furnish such information to the Part D sponsor to transmit to CMS or its designees, or requiring the entity to furnish such information directly to CMS or its designees, in accord with the terms of the contract between the Part D sponsor and the entity."

Lastly, we strongly believe that this provision should include a requirement that when CMS or its designee makes a request to a Part D sponsor's "entity" to produce books, records or other documents, CMS or the designee must notify the Part D sponsor simultaneously that it had made such a request. The Part D sponsor's compliance depends essentially upon the compliance of its "entities", and therefore the Part D sponsor has a vested interest in knowing when one of its "entities" has received such a request, and in assuring that the entity will respond appropriately to the request.

p. 29394 Section 423.507 Nonrenewal of contract.

We have the same comments with respect to the nonrenewal timeframe and associated CAP requirements in this proposed rule as we have stated above with respect to Section 422.506.

p. 29395 Section 423.650 Right to a hearing and burden of proof.

We have the same comments with respect to the burden of proof requirement in this proposed rule as we have stated above with respect to Section 422.660(b).

p. 29396 Section 423.666(c) Review by Administrator.

We have the same comments with respect to the Administrator's ability to decline to review a hearing determination in this proposed rule as we have stated above with respect to Section 422.692(b) and (c).

p. 29396 Section 423.752(c) Basis for imposing intermediate sanctions and civil money penalties.

We have the same comments with respect to multiple sanctions arising out of the same set of facts, as implemented in this proposed rule as we have stated above with respect to Section 422.752(c)