CMS-4124-P-1 **Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes**

Submitter : Thomas Campbell **Date & Time:** 06/07/2007

Organization : Gateway Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

RE: (Pages 12, 19-21): Compliance plan training and communications requirements to first tier, downstream, related entities: The proposed timeframe for implementation appears to be too aggressive.
RE: (page 40): Change to the date of notice to the plan of intent to not renew contract: This date would not allow sufficient time to notify beneficiaries, in order to allow proper plan change and coordination of care.
RE: (Pages 43-44): CAP deadline: it is proposed that a termination will apply to all years of a contract. Does that propose that terminations may be retroactive to the beginning of a plan contract?
RE: Pages 69-70): Self-reporting: need clear articulation of timeframe for a plan to conduct an investigation. Many times investigations can be time consuming due to the time that has elapsed since the event.

#2

CMS- 4124-P

Because the referenced comment number does not pertain to the subject matter for CMS-4124-P, it is not included in the electronic public comments for this regulatory document.

CMS-4124-P-3 **Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes**

Submitter : Mr. Justin Carangelo **Date & Time:** 07/10/2007

Organization : MVP Healthcare, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

d. Legal Issues with Self-Reporting

i. We are concerned that the proposed self-reporting requirement could violate an entity s Fifth Amendment right against self-incrimination. Considering the nature of what might have to be reported, criminal liability could result. Federal courts have consistently held that when criminal liability is at stake, or when a civil penalty is so punitive as to make it decisively penal in nature, the rights against self-incrimination apply. SEC v. Radio Hill Mines Co., 479 F.2d 4 (2d Cir. 1973).

ii. The Fifth Amendment can also apply in non-criminal cases. The United States Supreme Court held in United States v. Ward, 448 U.S. 242 (U.S. 1980) that when a regulatory requirement imposes a civil or criminal penalty that is sufficiently punitive, the protections provided by the Fifth Amendment against compulsory self-incrimination are triggered. United States v. Ward, 448 U.S. 242 (U.S. 1980).

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

III. Implementation Time Frame

a. It is our belief that requiring notice of non-renewal on September 1 has the effect of preventing plans from participating in the next calendar year. We hope that an earlier notice date is being considered.

b. Requiring notice on 9/1 results in a defacto eliminations of the plan without due process of the law because the various dates for notice (9/1), CAP (10/1), CMS review (11/15 after 45 day review), and marking notification (10/31) are too inconsistent. Under such a requirement, the last possible date a plan could use for terminations notice would be 7/15 (resulting in 8/15, 10/1) as possible dates which allow the plan to stay in business for the next calendar year.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

1. Training and Education

a. Clarification of expectations

i. We wish to clarify CMS expectations for training and education of first tier and downstream entities. Under the proposed regulation, it is unclear to us what specific actions would be required on the part of an MAO to meet CMS expectations for training and education. The burden of providing direct training to the large number of downstream entities such as pharmacies, pharmacists and all contracted providers is an unreasonable burden for small to middle sized organizations to bear. More specifically, in light of the multiple relationships that downstream providers maintain with organizations, to whom will plans be required to provide detailed compliance plans? The rule as proposed would likely produce less clarification and understanding of compliance requirements despite increased training costs.

ii. It is also unclear whether downstream entities will contact the associated plan directly with any compliance concerns instead of relying on their own established, internal resources. If so, interoperation and cooperation between both organizations will likely result in an overlapping of duties, and confusion over when action is required by either respective entity.

II. Mandatory Self-Reporting

a. As a plan, we are also concerned about the scope of the self-reporting requirement. For example, if a plan becomes aware of fraud on the part of a provider, should the plan report the provider to the OIG? Or is the self-reporting requirement limited to potential violations by the MAO only?

b. We have similar concerns about the parameters surrounding potential fraud or misconduct. At what point in the investigation of potential fraud should the MAO self-report? If the MAO s internal investigation of potential fraud determines that the report is unsubstantiated, would the plan be required to self-report the investigation? Is there any dollar amount threshold for potential fraud that would trigger a self-report? For example, should a report of potential prescription drug fraud in the amount of $50.00 be reported to a MEDIC? Which entity would be responsible for reporting potential prescription drug fraud? We understand that self-reports of prescription drug fraud should be directed to MEDICs. For the reporting of Part C fraud, would the appropriate government authority be the OIG?

c. The Efficiency of Self-Reporting

i. Previous proposals regarding self-reporting have been met with objections that the reporting requirements were too vague, the requirements only regulated plans and not other health care entities, and that it was unclear as to what information should be reported. These concerns seem to remain valid. The intent of the proposed reporting requirement is for CMS to be kept abreast of any potential fraud or misconduct relating to MA plans so that the government may respond at the earliest possible date to any allegations of misconduct. However, according to a CMS estimate, only ten (10) out of the three hundred and ninety three (393) organizations affected will experience an incident of misconduct or fraud. Accepting the CMS estimate as accurate, roughly 2.5% of the entire MA plan population will be driving all plans to implement new requirements that are vague and unnecessary.

ii. The current system of voluntary reporting works well, and there is no reason to believe that the voluntary system is inefficient, or that it fails to provide CMS with the necessary information to investigate incidents of fraud or misconduct. As recently as 2005, CMS indicated that despite the elimination of the mandatory self-reporting requirement, Plans that self-report violations will continue to receive the benefits of voluntary self- reporting found in the False Claims Act and Federal sentencing guidelines. 70 FR 4588, 4681.

CMS-4124-P-3-Attach-1.DOC

CMS-4124-P-3-Attach-1.DOC

MVP HEALTH CARE

Preferred care

#3

To: Center for Medicare and Medicaid Services, Office of Strategic Operations, and Regulatory Affairs, Regulations Development Group; Office of Information and Regulatory Affairs, Office of Management and Budget

From: Justin Carangelo
MVP/Preferred Care-Associate Counsel

Date: July 9, 2007

Re: Proposed Rules Affecting MA and Part D Programs (File Code: CMS-4124-P)

PROVISIONS OF THE PROPOSED REGULATIONS

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

Sections 422.503 and 423.501-General Provisions

I. Training and Education

a. Clarification of expectations

i. We wish to clarify CMS' expectations for training and education of first tier and downstream entities. Under the proposed regulation, it is unclear to us what specific actions would be required on the part of an MAO to meet CMS' expectations for training and education. The burden of providing direct training to the large number of downstream entities such as pharmacies, pharmacists and all contracted providers is an unreasonable burden for small to middle sized organizations to bear. More specifically, in light of the multiple relationships that downstream providers maintain with organizations, to whom will plans be required to provide detailed compliance plans? The rule as proposed would likely produce less clarification and understanding of compliance requirements despite increased training costs.

ii. It is also unclear whether downstream entities will contact the associated plan directly with any compliance concerns instead of relying on their own established, internal resources. If so, interoperation and cooperation between both organizations will likely result in an overlapping of duties, and confusion over when action is required by either respective entity.

II. Mandatory Self-Reporting

a. As a plan, we are also concerned about the scope of the self-reporting requirement. For example, if a plan becomes aware of fraud on the part of a provider, should the plan report the provider to the OIG? Or is the self-reporting requirement limited to potential violations by the MAO only?

b. We have similar concerns about the parameters surrounding "potential fraud or misconduct." At what point in the investigation of potential fraud should the MAO self-report? If the MAO's internal investigation of potential fraud determines that the report is unsubstantiated, would the plan be required to self-report the investigation? Is there any dollar amount threshold for potential fraud that would trigger a self-report? For example, should a report of potential prescription drug fraud in the amount of $50.00 be reported to a MEDIC? Which entity would be responsible for reporting potential prescription drug fraud? We understand that self-reports of prescription drug fraud should be directed to MEDICs. For the reporting of Part C fraud, would the "appropriate government authority" be the OIG?

c. <u>The Efficiency of Self-Reporting</u>

   i. Previous proposals regarding self-reporting have been met with objections that the reporting requirements were too vague, the requirements only regulated plans and not other health care entities, and that it was unclear as to what information should be reported. These concerns seem to remain valid. The intent of the proposed reporting requirement is for CMS to be kept abreast of any potential fraud or misconduct relating to MA plans so that the government may respond at the earliest possible date to any allegations of misconduct. However, according to a CMS' estimate, only ten (10) out of the three hundred and ninety three (393) organizations affected will experience an incident of misconduct or fraud. Accepting the CMS estimate as accurate, roughly 2.5% of the entire MA plan population will be driving all plans to implement new requirements that are vague and unnecessary.

   ii. The current system of voluntary reporting works well, and there is no reason to believe that the voluntary system is inefficient, or that it fails to provide CMS with the necessary information to investigate incidents of fraud or misconduct. As recently as 2005, CMS indicated that despite the elimination of the mandatory self-reporting requirement, "Plans that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines." 70 FR 4588, 4681.

d. Legal Issues with Self-Reporting

i. We are concerned that the proposed self-reporting requirement could violate an entity's Fifth Amendment right against self-incrimination. Considering the nature of what might have to be reported, criminal liability could result. Federal courts have consistently held that when criminal liability is at stake, or when a civil penalty is so punitive as to make it decisively penal in nature, the rights against self-incrimination apply. *SEC v. Radio Hill Mines Co.*, 479 F.2d 4 (2d Cir. 1973).

ii. The Fifth Amendment can also apply in non-criminal cases. The United States Supreme Court held in *United States v. Ward*, 448 U.S. 242 (U.S. 1980) that when a regulatory requirement imposes a civil or criminal penalty that is sufficiently punitive, the protections provided by the Fifth Amendment against compulsory self-incrimination are triggered. *United States v. Ward*, 448 U.S. 242 (U.S. 1980).

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

III. Implementation Time Frame

a. It is our belief that requiring notice of non-renewal on September 1 has the effect of preventing plans from participating in the next calendar year. We hope that an earlier notice date is being considered.

b. Requiring notice on 9/1 results in a defacto eliminations of the plan without due process of the law because the various dates for notice (9/1), CAP (10/1), CMS review (11/15 after 45 day review), and marking notification (10/31) are too inconsistent. Under such a requirement, the last possible date a plan could use for terminations notice would be 7/15 (resulting in 8/15, 10/1) as possible dates which allow the plan to stay in business for the next calendar year.

Thank you for your time and attention in this matter.

Sincerely,

Justin B.Carangelo | Associate Counsel
MVP Health Care/Preferred Care
625 State Street | Schenectady, NY 12305
Tel: (518) 388-2680 | Fax: (518) 388-2311

#4

CMS- 4124-P

Because the referenced comment number does not pertain to the subject matter for CMS-4124-P, it is not included in the electronic public comments for this regulatory document.

CMS-4124-P-5 **Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes**

Submitter : **Date & Time:** **07/19/2007**

Organization : **Delmarva Health Integrity**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-5-Attach-1.DOC

#5

Medicare Program: Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes. 42 CFR Parts 422 and 423 (CMS-4124-P)

Comments' Submitter: Delmarva Health Integrity, SE MEDIC
Date: July 19, 2007

General Provisions
P. 22
D/HI strongly supports the CMS proposed requirement for flow down of training and compliance program requirements to plan subcontractors. Lack of plan oversight affects D/HI's ability to operate effectively. We support the strengthening of accountability for training and performance by Part D plan sponsors.

P.23. D/HI applauds CMS' "removing what we believe to be a duplicative and confusing "final element" of the compliance plan—a "comprehensive fraud, waste and abuse plan to detect, correct and prevent fraud, waste and abuse" and supports the idea that a comprehensive compliance program includes this element by definition.

P. 27
D/HI strongly supports CMS "proposing to restore mandatory self-reporting requirements for MA organizations, and to make the self reporting provision that applies to Part D sponsors mandatory. Reporting would trigger CMS and the MEDICs to respond quickly to scams to detect patterns of fraud and abuse that may not be as visible from inside a single plan sponsor.

P.30
D/HI strongly supports the CMS ruling that the Comptroller General or his designees have the right to inspect, evaluate, and audit the books and other records of Part D sponsors and their first tier, downstream and related entities. Furthermore, we agree that the data can be submitted directly to CMS or to CMS designees. D/HI supports the concept that the data contained in these books and records are necessary to uncover Part D fraud, waste and abuse.

P.31

CMS proposes that "The provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to CMS, or submitted directly to CMS or our designees."

D/HI believes that the down stream entity should provide its data to the Part D sponsor, which should in turn provide it to CMS or its designee for two reasons:
1. The Part D sponsors should exert appropriate management and control over their down stream entities.
2. The audit process would be facilitated if materials were provided from a single source.

P. 69
D/HI supports the CMS ruling that MA plans have compliance plans that include measures to detect, correct and prevent fraud, waste and abuse.

D/HI also supports the CMS requirement that an MA organization have procedures in place for mandatory self reporting of potential fraud or misconduct related to the MA program to the appropriate government authority.

CMS-4124-P-6 **Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes**

Submitter : Mr. Peter Weidenheim **Date & Time:** 07/19/2007

Organization : Security Health Plan of Wisconsin Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4124-P-6-Attach-1.DOC

#6

Proposed Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes
42 CFR Parts 422 and 423

Federal Register, Vol. 72, No. 101, Friday, May 25, 2007

Comment:

Page 29372, column1
Page 29381, column 1

Use of the term "directors"

When you use the term *directors*, should you clarify that you are referring to a health plans *board of directors*?

Your language on page 29372 states: ...effective lines of communication between the compliance officer, and the organization's employees, contractors, agents, directors, and managers. ...

The management structure of many organizations contain departmental "directors", for example a director of sales, director of finance or director of corporate integrity. Should you clarify your intent by using the words "board of directors"?

The term *directors* is also used in many other CMS publications associated with the MA-PD program and it is not always clear at times what is meant.

Thank you.

Submitter : Mr. Michael Yount **Date:** 07/23/2007

Organization : Rite Aid

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-4124-P-7-Attach-1.PDF

#1

RITE AID

RITE AID Corporation

LEGAL DEPARTMENT

MICHAEL C. YOUNT, R.Ph., J.D.
Vice President, Regulatory Law
Compliance Officer
Privacy Officer

• **MAILING ADDRESS**
P.O. Box 3165
Harrisburg, PA 17105

• **GENERAL OFFICE**
30 Hunter Lane
Camp Hill, PA 17011

• **Telephone (717) 761-2633**

July 23, 2007

Alissa deBoy
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4124-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Proposed Regulations: 42 CFR Parts 422 and 423: Medicare Program (CMS-4130-P), 72 *Federal Register* 29403 through 29423, May 25, 2007

Dear Ms. deBoy,

Rite Aid Corporation has reviewed the above-referenced regulations and we have several concerns relating to the potential imposition of new fraud and abuse training requirements on retail pharmacies, as well as potential new expanded abilities of Part D plans and the Medicare program to have access to proprietary retail pharmacy cost and pricing data.

Rite Aid Corporation is one of the nation's leading drug store chains, operating approximately 5,100 pharmacies in 31 states and the District of Columbia. We are major providers of pharmacy services to Medicare Part D beneficiaries.

Expansion of Parameters for Agency Record Searches

While the revised rules do not require that providers offer their records for inspection by the Part D sponsor or MA-PD organization, the preamble states that the contracting parties are to assign responsibilities for submitting required information to CMS during contract negotiations. This appears to permit access by Part D plan sponsors and MA-PD organizations to all kinds of provider information, including proprietary information regarding price concessions by manufacturers or wholesalers to pharmacy providers and agreements with providers of on-site clinical and medical services.

Specifically, regulations governing contract provisions (42 CFR 422.504 and 423.505) are revised to clarify that contracts with providers must specify their obligations to make records available to inspection. The revised regulations specify that HHS and the Comptroller General *or their designees* may audit, evaluate, or inspect *any* books, contracts, medical records, patient care documentation, and other records of the sponsor or organization, or its first tier, downstream, or related entities that pertain to *any* aspect of services performed, reconciliation of benefit liabilities, and determination of reimbursement payable that the Secretary of HHS deems necessary to enforce the contract.

CMS states in the preamble that it is taking the opportunity "*to clarify, without specific regulatory change in* [the] *rule* that HHS, the Comptroller General, or their designees have the authority 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. CMS lists the following examples of records that could be sought: rebate agreements between PBMs and manufacturers; records reflecting discounts; price concessions; chargebacks; rebates; cash discounts; free goods contingent on a purchase agreement; up-front payments; coupons; goods in kind; free or reduced price services; grants; or price concessions or similar benefits offered to some or all purchasers. It also leaves the list open to further informal and apparently unlimited expansion by stating it will not commit the list to formal, specific, regulatory language (72 Fed Reg 29374, column 3).

We do not believe that CMS can seek information on discounts, chargebacks, or in-kind goods granted to pharmacy providers by manufacturers or wholesalers for drugs dispensed under Medicare without a more formal regulatory notice and comment period. If the agency's recordkeeping and inspection authority is to be expanded to cover this type of information, this expansion should be expressly stated in formal regulation adopted through the formal regulatory adoption process.

Moreover, Rite Aid urges that the final version of these regulations strictly limit the ability of a Part D sponsor or MA-PD organization expressly prohibit Part D plans from physically inspecting any records submitted for delivery to CMS. With respect to the "records" that CMS should have the authority to obtain, pharmacy providers should be required to provide the same information that would be provided upon submission of a claim to the Part D Sponsor or MA Organization.

Any further information required by HHS to complete an investigation should be provided directly by the pharmacy to CMS. It is critical, in light of direct pharmacy competitor ownership of PBMs or plan sponsors, that confidential and proprietary information not be made available to pharmacy competitors. Therefore, downstream entities such as pharmacies must be protected from sharing information with PBMs or plan sponsors to which they would not otherwise have access. A clarification that "HHS or the Comptroller General" only would have access to such records beyond the claims data is a necessary protection.

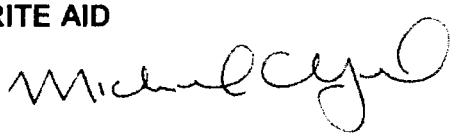
Fraud Waste and Abuse Programs

The proposed regulations that require Part D sponsors and MA organizations to apply their training and education and effective lines of communication requirements to their first tier, downstream, and related entities lacks clarity. Would this amendment require that pharmacy providers, such as Rite Aid, accept the training and/or education courses of each Part D sponsor or MA organization and be required to implement it as its own? If so, this is an unreasonable requirement. In addition to the operational burden that would be created if each plan were to require pharmacies to complete the plan's individual training course, this training would also lack the specificity of the pharmacy provider's own training and educational courses.

A training course imposed by a plan could not adequately address a pharmacy provider's policies and procedures for detecting and preventing fraud and the specific training requirements that the pharmacy provider might find necessary to implement. Pharmacies must be provided the ability to certify to the Part D sponsor/MA organization that the pharmacy has a FWA training/educational program and should not be required to implement a third party's training program.

Thank you for the opportunity to comment on these regulations.

Sincerely,
RITE AID



Michael C. Yount, R.Ph., J.D.
Vice President, Regulatory Law
Compliance Officer/Privacy Officer

Submitter : Mr. Steve Tucker

Date: 07/23/2007

Organization : UnitedHealth Group

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Steven Tucker **Date:** 07/23/2007

Organization : UnitedHealth Group

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-4124-P-9-Attach-1.DOC

#9

OVATIONS

A UnitedHealth Group Company

July 23, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-4124-P, *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes*

Dear Mr. Kuhn,

Thank you for the opportunity to present comments on the *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes* proposed rules. We have been honored to serve Medicare beneficiaries for over 25 years and look forward to continued participation in Medicare as it changes.

Ovations is the UnitedHealth Group company committed to meeting the health and well-being needs of adults of all ages, with a particular focus on those age 50 and above. We serve one out of every five Medicare beneficiaries through our array of Medicare products, including: Medigap plans that supplement traditional fee-for-service, Medicare Prescription Drug plans, and Medicare Advantage plans, including special needs plans for the chronically ill, dual eligible and beneficiaries living in an institutional setting. Our Medicare offerings are designed to meet the individual needs of our customers, their families, physicians and communities.

We participate in the Medicare program in the following ways:

- Traditional fee-for-service -- Our Medigap offerings provide supplemental insurance on behalf of AARP to nearly three million of its members.

- Medicare Advantage -- We provide health care coverage to more than 1.3 million people through health plans, Preferred Provider Organizations (PPOs), private fee-for-service, and group health plans operating in diverse geographic areas ranging from Omaha to New York.

- Medicare Part D -- The nation's leading source of prescription drug coverage for over 5.8 million Medicare beneficiaries and the only provider of Medicare Part D plans endorsed by AARP.

- Evercare -- Serves more than 150,000 people nationwide through Medicaid, Medicare, and private-pay health plans, programs and services, Evercare is a leading provider of Special Needs Plans designed to help people who are chronically ill, dual eligible or living in an institutional setting stay as healthy and independent as possible.

The attached document contains the key considerations that we believe are needed to ensure the continued success of the Medicare Advantage and/or Prescription Drug Programs. We greatly appreciate this opportunity to share our comments about the proposed rules, and look forward to working with you. Please do not hesitate to contact me (or my colleagues) if you have any questions or need further information. Thank you.

Sincerely,

Steven M. Tucker, Vice President of Regulatory Affairs, Ovations
Ovations
Mail Route CA112-0536
5995 Plaza Drive
Cypress, CA 90630

CMS-4124-P, Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determination, Appeals, and Intermediate Sanctions Processes

Comments Submitted by
UnitedHealth Group/Ovations
July 23, 2007

PROVISIONS OF THE PROPOSED REGULATIONS

1. **Definition of "Downstream" and "First Tier" Entity**
   Section 422.2 and 423.4-Definitions, p 29371

   Issue: The term "administrative services" within the definitions of "downstream entity" and "first tier entity" is too broad.

   Recommendation: CMS should define "entities providing administrative services" as those entities that either (1) perform some of the Part D sponsor or MA organization's management functions under contract or delegation; (2) furnish services to Medicare enrollees; or (3) lease real property or sell materials to the Part D sponsor or MA organization at a cost of more than $2500 during a contract period.

   Rationale: There are many entities that provide "administrative services" to Plan sponsors that do not have a substantive regulatory impact on the Part D program. Plan sponsors need flexibility to ensure that resources are being used in the most effective manner. CMS should not include entities that provide non-compliance related or non-regulated functions such as clerical or copying services within the definition of entities that provide "administrative services." By restricting the definition of "entities providing administrative services" to those entities whose services actually impact the Part D program, Plan sponsors will be able to better implement more effective compliance programs.

2. **Mandatory self-reporting requirement for fraud, waste, and abuse**
   Section 422.503 and 423.504-General Provisions, p 29372

   a. **I ssue:** The mandatory requirement that Plan sponsors report instances of "potential fraud" does not provide sufficient guidance regarding what will be considered a reportable event.

      Recommendation: CMS should adopt language similar to that used by the OIG regarding the reportable events for providers operating under Corporate Integrity Agreements and require that Plan sponsors "promptly report the existence of a probable violation of any civil, criminal, or administrative law related to any Federal healthcare program for which penalties or exclusions may apply within a reasonable period, but not more than 60 days, after determining that there is credible evidence of a violation."

Rationale: Plan sponsors must have sufficient time to conduct appropriate investigations into allegations of potential fraud to determine whether the allegations have merit before reporting such allegations to the appropriate authorities. By providing Plan sponsors with the opportunity to investigate these allegations, Plan sponsors will be able to eliminate meritless allegations, better utilizing plan and government resources.

b. Issue: While CMS has designated the MEDIC as the entity to whom Plan sponsors report potential fraud related to prescription drugs, CMS has not designated a similar entity for MA Plan sponsors to report potential fraud related to medical services.

Recommendation: CMS issue additional guidance following the implementation of this rule, which will specify to whom MA Plan sponsors must report potential fraud related to medical services.

Rationale: At present MA Plan sponsors are not required to report instances of potential fraud to a centralized entity. Based on the current experience within Medicare Part D, reports to the MEDIC have resulted in efficient identification of cross-country fraud schemes.

3. Access to facilities and records
Section 422.504 and 423.505-General Provisions, p 29374

a. Scope of Requests for Rebate Information
Comments on page 29375

Issue: The right to request rebate and price concession information directly from first tier entities is written too broadly and will likely dampen the ability of a first tier entity to obtain price concessions from pharmaceutical manufacturers.

Recommendation: CMS should clarify that any requests to first tier entities for rebate and price concession information will be narrow in scope and directly related to the Plan sponsor being audited.

Rationale: We agree that CMS must have the ability to conduct oversight activities and to determine whether actual paid costs have been submitted appropriately. However, requests for any and all rebate information from first tier entities without limiting the request to information that is reasonably related to CMS' audit of a particular Plan sponsor will affect the first tier entity's ability to contract with pharmaceutical manufacturers. Pharmaceutical manufacturers consider all rebate information to be highly confidential in nature and will be less

likely to negotiate for deep discounts if such information becomes accessible to a broader audience.

b. Penalties for failure or omission to disclose requested information
Comments on page 29375

(i) **Issue**: Penalizing the Plan sponsor by imposition of intermediate sanctions, CMPs or contract termination for the failure or omission of a first tier, downstream, or related entity to provide information is inappropriate and would create unnecessary instability within the Part D and MA programs.

Recommendation: The appropriate remedy for noncompliance by a first tier, downstream, or related entity is to require us to implement a corrective action plan with the noncompliant entity or to terminate the noncompliant entity. The imposition of intermediate sanctions, civil monetary penalties or contract termination against the Plan sponsor should be reserved for extreme cases where the Plan sponsor is responsible for the failure or omission to provide information.

Rationale: While Plan sponsors should be held accountable for compliance of the first tier, downstream, and related entities with whom they contract, the appropriate recourse should be either the implementation of a corrective action plan or termination of a noncompliant entity. Despite a Plan sponsor's best efforts, it may not be able to obtain the information requested from the first tier, downstream, or related entity for CMS. It is only when the Plan sponsor is responsible for, promoting, or encouraging the first tier, downstream, or related entities' noncompliance that the more aggressive adverse actions are appropriate.

(ii) **Issue**: Utilizing "any failure or omission" to disclose requested information by first tier, downstream, or related entities as the standard for penalizing a Plan sponsor is overly broad and unduly burdensome.

Recommendation: These penalties should only apply if the first tier, downstream, or related entity is acting intentionally, recklessly, or is willfully blind to the information that is requested by CMS.

Rationale: "Any failure or omission" does not allow for human error or unintentional oversight. Plan sponsors need to know that they will not face the significant penalties of intermediate

sanctions, CMPs, or contract termination based on a minor infraction by a first tier, downstream, or related entity.

c. **Scope of audits**
Section 422.504(e)(2) and 423.505(e)(2), pp29385 & 29394

Issue: Auditors should be limited to requesting only those records directly related to an audit, as outlined in the scope of the audit.

Recommendation: CMS should add a statement to Sections 422.504(e)(2) and 423.505(e)(2), which clarifies that only those records related to the subject matter of the audit, as outlined in the scope of the audit, may be requested.

Rationale: Auditors may inappropriately request items not within the scope of an audit that may contain proprietary and confidential information of the Plan sponsor or affiliated entities or for records from affiliated entities that are not providing services related to an audit. By clarifying that the requests must be reasonably related to the scope of the audit, inappropriate release of proprietary and confidential information may be prevented.

4. **Nonrenewal of a Contract**
Sections 422.506(b)(2) and 423.507(b)(2), p 29376

Issue: While the proposed changes provide a significantly improved process for notification of nonrenewal of a contract, the proposed September 1st deadline is too late.

Recommendation: CMS should provide notification of its decision not to renew in June or July.

Rationale: By September 1st, Plan sponsors would have invested significant time and monies into planning and implementation actions for the following contract year. In addition, the late notification may negatively impact Medicare beneficiaries who will need to be transitioned from their current plan to a new plan in a very short time frame.

5. **Expedited termination of contract for imminent threat or serious risk to health of beneficiaries**
Sections 422.510 and 423.509, p 29376

Issue: Immediate termination of a plan in situations where CMS believes that an imminent threat or serious risk to the health of beneficiaries creates too much instability for Medicare beneficiaries.

Recommendation: An expedited hearing process should be implemented to allow for the determination of any imminent or serious threat to the health of beneficiaries. Should a determination of imminent threat or serious risk to health be made, the effective date for the termination should be determined in consultation with the Plan sponsor to better meet the needs of plan beneficiaries.

Rationale: While CMS may believe that an imminent threat or serious risk to beneficiary health exists, Plan sponsors may have access to additional information that would affect CMS' determination. The provision of an expedited hearing process would provide Plan sponsors with an opportunity to provide such information to CMS creating additional stability for Medicare beneficiaries. If the CMS' determination is correct, an arbitrary date set by CMS may not take into account beneficiary needs and/or the ability of a Plan sponsor to immediately transition beneficiaries to alternative plans. Instead, CMS should work with the Plan sponsor to develop a transition plan that would minimize potential disruptions for the Medicare beneficiary.

6. **Review by Administrator**
   Sections 422.692 and 423.666, pp 29387 & 29396

   Issue: Limiting the Administrator's review to the record and any written arguments submitted by the parties does not provide an opportunity for the Plan sponsor to contest the hearing officer's determination of the facts.

   Recommendation: An Administrator should be able to review the record below in its entirety and accept additional evidence and/or documentation to make his or her determination.

   Rationale: If there is an error in the record with respect to the facts, then the Plan sponsor should be able to correct the record before the Administrator makes his or her determination. To permit this level of review, the Administrator should not be bound by the factual findings of the hearing officer, but instead should be permitted to review the entire record as well as any written agreements provided to the Administrator.

7. **Appeals Procedures for Civil Monetary Penalties – Burden of Proof**
   Subpart T, p 29380

   Issue: Imposing the burden of proof on the MA or Part D organization as opposed to the entity imposing the CMP is contrary to traditional principles of jurisprudence and imposes an undue burden on the MA or Part D organization.

   Recommendation: While the MA or Part D sponsor should be required to come forward with evidence to rebut a claim of non-compliance, i.e., carry the burden of *production*, CMS, as the entity imposing the CMP, should carry the ultimate burden of *proof* to justify the imposition of a CMP.

Rationale: While an MA or Part D organization is typically in possession of the most complete evidence of the state of its compliance, CMS, as the entity imposing the CMP, should carry the ultimate burden of persuading the ALJ that the CMP is warranted. The MA or Part D sponsor should not be placed in a position of having to prove that CMS is not justified in imposing a CMP.

8. **Intermediate Sanctions – Suspension of All Marketing Activities**
Subpart O, Sections 422.750(a)(3) and 423.750(a)(3), pp 29387 & 29396

Issue: The suspension of all marketing activities to Medicare beneficiaries by an MA or Part D plan sponsor for all of its plans is too severe a penalty for most noncompliant behavior.

Recommendations: Retain the current intermediate sanction which allows CMS to suspend all plan marketing activities to Medicare beneficiaries *only for the specific MA or Part D plan that is subject to the noncompliant behavior/intermediate sanction.*

Rationale: The suspension of all marketing activities of a Plan sponsor will severely limit a Plan sponsor's ability to continue to provide any MA or Part D plans to Medicare beneficiaries. In cases where the Plan sponsor's noncompliant activity only affects one MA or Part D plan, CMS should only penalize the plan that is engaging in the improper activities. The suspension of all marketing activities should be used vary sparingly for Plan sponsors that are engaging in activity that places Medicare beneficiaries in serious harm or where there are pervasive instances of fraud, waste or abuse.

Submitter : **Mr. Steven Tucker** **Date: 07/23/2007**

Organization : **UnitedHealth Group**

Category : **Health Plan or Association**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment.

CMS-4124-P-10-Attach-1.DOC

#10

July 23, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-4124-P, *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes*

Dear Mr. Kuhn,

Thank you for the opportunity to present comments on the *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes* proposed rules. We have been honored to serve Medicare beneficiaries for over 25 years and look forward to continued participation in Medicare as it changes.

Ovations is the UnitedHealth Group company committed to meeting the health and well-being needs of adults of all ages, with a particular focus on those age 50 and above. We serve one out of every five Medicare beneficiaries through our array of Medicare products, including: Medigap plans that supplement traditional fee-for-service, Medicare Prescription Drug plans, and Medicare Advantage plans, including special needs plans for the chronically ill, dual eligible and beneficiaries living in an institutional setting. Our Medicare offerings are designed to meet the individual needs of our customers, their families, physicians and communities.

We participate in the Medicare program in the following ways:

- Traditional fee-for-service -- Our Medigap offerings provide supplemental insurance on behalf of AARP to nearly three million of its members.

- Medicare Advantage -- We provide health care coverage to more than 1.3 million people through health plans, Preferred Provider Organizations (PPOs), private fee-for-service, and group health plans operating in diverse geographic areas ranging from Omaha to New York.

- Medicare Part D -- The nation's leading source of prescription drug coverage for over 5.8 million Medicare beneficiaries and the only provider of Medicare Part D plans endorsed by AARP.

- Evercare -- Serves more than 150,000 people nationwide through Medicaid, Medicare, and private-pay health plans, programs and services, Evercare is a leading provider of Special Needs Plans designed to help people who are chronically ill, dual eligible or living in an institutional setting stay as healthy and independent as possible.

The attached document contains the key considerations that we believe are needed to ensure the continued success of the Medicare Advantage and/or Prescription Drug Programs. We greatly appreciate this opportunity to share our comments about the proposed rules, and look forward to working with you. Please do not hesitate to contact me (or my colleagues) if you have any questions or need further information. Thank you.

Sincerely,

Steven M. Tucker, Vice President of Regulatory Affairs, Ovations
Ovations
Mail Route CA112-0536
5995 Plaza Drive
Cypress, CA 90630

CMS-4124-P, Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determination, Appeals, and Intermediate Sanctions Processes

Comments Submitted by
UnitedHealth Group/Ovations
July 23, 2007

PROVISIONS OF THE PROPOSED REGULATIONS

1. **Definition of "Downstream" and "First Tier" Entity**
   Section 422.2 and 423.4-Definitions, p 29371

   Issue: The term "administrative services" within the definitions of "downstream entity" and "first tier entity" is too broad.

   Recommendation: CMS should define "entities providing administrative services" as those entities that either (1) perform some of the Part D sponsor or MA organization's management functions under contract or delegation; (2) furnish services to Medicare enrollees; or (3) lease real property or sell materials to the Part D sponsor or MA organization at a cost of more than $2500 during a contract period.

   Rationale: There are many entities that provide "administrative services" to Plan sponsors that do not have a substantive regulatory impact on the Part D program. Plan sponsors need flexibility to ensure that resources are being used in the most effective manner. CMS should not include entities that provide non-compliance related or non-regulated functions such as clerical or copying services within the definition of entities that provide "administrative services." By restricting the definition of "entities providing administrative services" to those entities whose services actually impact the Part D program, Plan sponsors will be able to better implement more effective compliance programs.

2. **Mandatory self-reporting requirement for fraud, waste, and abuse**
   Section 422.503 and 423.504-General Provisions, p 29372

   a. **I ssue:** The mandatory requirement that Plan sponsors report instances of "potential fraud" does not provide sufficient guidance regarding what will be considered a reportable event.

      Recommendation: CMS should adopt language similar to that used by the OIG regarding the reportable events for providers operating under Corporate Integrity Agreements and require that Plan sponsors "promptly report the existence of a probable violation of any civil, criminal, or administrative law related to any Federal healthcare program for which penalties or exclusions may apply within a reasonable period, but not more than 60 days, after determining that there is credible evidence of a violation."

Rationale: Plan sponsors must have sufficient time to conduct appropriate investigations into allegations of potential fraud to determine whether the allegations have merit before reporting such allegations to the appropriate authorities. By providing Plan sponsors with the opportunity to investigate these allegations, Plan sponsors will be able to eliminate meritless allegations, better utilizing plan and government resources.

b. Issue: While CMS has designated the MEDIC as the entity to whom Plan sponsors report potential fraud related to prescription drugs, CMS has not designated a similar entity for MA Plan sponsors to report potential fraud related to medical services.

Recommendation: CMS issue additional guidance following the implementation of this rule, which will specify to whom MA Plan sponsors must report potential fraud related to medical services.

Rationale: At present MA Plan sponsors are not required to report instances of potential fraud to a centralized entity. Based on the current experience within Medicare Part D, reports to the MEDIC have resulted in efficient identification of cross-country fraud schemes.

3. Access to facilities and records
Section 422.504 and 423.505-General Provisions, p 29374

a. Scope of Requests for Rebate Information
Comments on page 29375

Issue: The right to request rebate and price concession information directly from first tier entities is written too broadly and will likely dampen the ability of a first tier entity to obtain price concessions from pharmaceutical manufacturers.

Recommendation: CMS should clarify that any requests to first tier entities for rebate and price concession information will be narrow in scope and directly related to the Plan sponsor being audited.

Rationale: We agree that CMS must have the ability to conduct oversight activities and to determine whether actual paid costs have been submitted appropriately. However, requests for any and all rebate information from first tier entities without limiting the request to information that is reasonably related to CMS' audit of a particular Plan sponsor will affect the first tier entity's ability to contract with pharmaceutical manufacturers. Pharmaceutical manufacturers consider all rebate information to be highly confidential in nature and will be less

likely to negotiate for deep discounts if such information becomes accessible to a broader audience.

b. Penalties for failure or omission to disclose requested information
Comments on page 29375

(i) **Issue**: Penalizing the Plan sponsor by imposition of intermediate sanctions, CMPs or contract termination for the failure or omission of a first tier, downstream, or related entity to provide information is inappropriate and would create unnecessary instability within the Part D and MA programs.

Recommendation: The appropriate remedy for noncompliance by a first tier, downstream, or related entity is to require us to implement a corrective action plan with the noncompliant entity or to terminate the noncompliant entity. The imposition of intermediate sanctions, civil monetary penalties or contract termination against the Plan sponsor should be reserved for extreme cases where the Plan sponsor is responsible for the failure or omission to provide information.

Rationale: While Plan sponsors should be held accountable for compliance of the first tier, downstream, and related entities with whom they contract, the appropriate recourse should be either the implementation of a corrective action plan or termination of a noncompliant entity. Despite a Plan sponsor's best efforts, it may not be able to obtain the information requested from the first tier, downstream, or related entity for CMS. It is only when the Plan sponsor is responsible for, promoting, or encouraging the first tier, downstream, or related entities' noncompliance that the more aggressive adverse actions are appropriate.

(ii) **Issue**: Utilizing "any failure or omission" to disclose requested information by first tier, downstream, or related entities as the standard for penalizing a Plan sponsor is overly broad and unduly burdensome.

Recommendation: These penalties should only apply if the first tier, downstream, or related entity is acting intentionally, recklessly, or is willfully blind to the information that is requested by CMS.

Rationale: "Any failure or omission" does not allow for human error or unintentional oversight. Plan sponsors need to know that they will not face the significant penalties of intermediate

sanctions, CMPs, or contract termination based on a minor infraction by a first tier, downstream, or related entity.

c. **Scope of audits**
Section 422.504(e)(2) and 423.505(e)(2), pp29385 & 29394

Issue: Auditors should be limited to requesting only those records directly related to an audit, as outlined in the scope of the audit.

Recommendation: CMS should add a statement to Sections 422.504(e)(2) and 423.505(e)(2), which clarifies that only those records related to the subject matter of the audit, as outlined in the scope of the audit, may be requested.

Rationale: Auditors may inappropriately request items not within the scope of an audit that may contain proprietary and confidential information of the Plan sponsor or affiliated entities or for records from affiliated entities that are not providing services related to an audit. By clarifying that the requests must be reasonably related to the scope of the audit, inappropriate release of proprietary and confidential information may be prevented.

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Sections 422.506(b)(2) and 423.507(b)(2), p 29376

Issue: While the proposed changes provide a significantly improved process for notification of nonrenewal of a contract, the proposed September 1st deadline is too late.

Recommendation: CMS should provide notification of its decision not to renew in June or July.

Rationale: By September 1st, Plan sponsors would have invested significant time and monies into planning and implementation actions for the following contract year. In addition, the late notification may negatively impact Medicare beneficiaries who will need to be transitioned from their current plan to a new plan in a very short time frame.

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Issue: Immediate termination of a plan in situations where CMS believes that an imminent threat or serious risk to the health of beneficiaries creates too much instability for Medicare beneficiaries.

Recommendation: An expedited hearing process should be implemented to allow for the determination of any imminent or serious threat to the health of beneficiaries. Should a determination of imminent threat or serious risk to health be made, the effective date for the termination should be determined in consultation with the Plan sponsor to better meet the needs of plan beneficiaries.

Rationale: While CMS may believe that an imminent threat or serious risk to beneficiary health exists, Plan sponsors may have access to additional information that would affect CMS' determination. The provision of an expedited hearing process would provide Plan sponsors with an opportunity to provide such information to CMS creating additional stability for Medicare beneficiaries. If the CMS' determination is correct, an arbitrary date set by CMS may not take into account beneficiary needs and/or the ability of a Plan sponsor to immediately transition beneficiaries to alternative plans. Instead, CMS should work with the Plan sponsor to develop a transition plan that would minimize potential disruptions for the Medicare beneficiary.

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   Issue: Limiting the Administrator's review to the record and any written arguments submitted by the parties does not provide an opportunity for the Plan sponsor to contest the hearing officer's determination of the facts.

   Recommendation: An Administrator should be able to review the record below in its entirety and accept additional evidence and/or documentation to make his or her determination.

   Rationale: If there is an error in the record with respect to the facts, then the Plan sponsor should be able to correct the record before the Administrator makes his or her determination. To permit this level of review, the Administrator should not be bound by the factual findings of the hearing officer, but instead should be permitted to review the entire record as well as any written agreements provided to the Administrator.

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Issue: The suspension of all marketing activities to Medicare beneficiaries by an MA or Part D plan sponsor for all of its plans is too severe a penalty for most noncompliant behavior.

Recommendations: Retain the current intermediate sanction which allows CMS to suspend all plan marketing activities to Medicare beneficiaries *only for the specific MA or Part D plan that is subject to the noncompliant behavior/intermediate sanction.*

Rationale: The suspension of all marketing activities of a Plan sponsor will severely limit a Plan sponsor's ability to continue to provide any MA or Part D plans to Medicare beneficiaries. In cases where the Plan sponsor's noncompliant activity only affects one MA or Part D plan, CMS should only penalize the plan that is engaging in the improper activities. The suspension of all marketing activities should be used vary sparingly for Plan sponsors that are engaging in activity that places Medicare beneficiaries in serious harm or where there are pervasive instances of fraud, waste or abuse.

Submitter : Dr. Timothy Musselman **Date:** 07/24/2007

Organization : Virginia Pharmacists Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4124-P-11-Attach-1.DOC

VIRGINIA PHARMACISTS ASSOCIATION

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(37)

Pharmacists helping pharmacists to improve patient care.

July 31, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Proposed Regulations: 42 CFR Parts 422 and 423: Medicare Program: Revisions to Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

On behalf of the Virginia Pharmacists Association (VPhA), we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed regulations and revisions to Medicare Advantage (MA) and Part D prescription drug contract determinations and addressing appeals and intermediate sanctions processes dated May 25, 2007.

VPhA appreciates and supports federal efforts that, in the end, work to protect or improve pharmacy patients' health care access and affordability. In previous public comments to CMS-proposed regulations VPhA has expressed concern that PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade. VPhA continues to support CMS efforts to increase transparency in the health care system and broaden patient accountability by health care providers.

In large part, given the reasons above, VPhA is enthusiastically supportive of the CMS proposed regulations. VPhA specifically applauds the CMS proposal "to correct a technical oversight in both regulations by including the definitions of 'downstream entity,' 'first tier entity,' and 'related entity,' in the overall definitions of both the MA and part D regulations." Fed. Reg. 29371 (2007) (to be codified at 42 C.F.R. § 422, § 423) (proposed May 25, 2007). This clarification acknowledges the changes in the practice of pharmacy as "first tier" entities continue to have a larger and impact on the overall marketplace and thus, the practice of

pharmacy. Furthermore, VPhA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

With this in mind, we would only like to comment on the proposed regulations regarding the (i) mandatory fraud and abuse training of all employees of downstream entities by MA-PDs and Part D Sponsors and (ii) changes to contract renewal procedures. The following comments are meant to address the above-mentioned two (2) categories.

Mandatory Fraud and Abuse Training of All Employees of Downstream Entities by MA-PDs and Part D Sponsors

The new requirement proposed under 42 CFR 422.503 and 423.504 72 Fed. Reg. 29384 (2007) (to be codified at 42 C.F.R. § 422, § 423) (proposed May 25, 2007) that Part D sponsors and MA-PD organizations train the employees of downstream entities such as pharmacy employees in detecting, correcting, and preventing fraud, waste, and abuse gives VPhA pause. The voluntary training recommendation of the Medicare Fraud Waste and Abuse Guidance is not mature enough to determine if the program was a success or failure. A new training mandate could raise pharmacies' costs of participating in Medicare Part D and thus could ultimately raise drug costs. The recent reductions in reimbursement coupled with the potential addition burden and cost associated with mandated training may lead to creating an undue burden on pharmacists and pharmacies.

In the event that CMS does require mandated training of downstream entities, such as pharmacies, VPhA requests that the training be limited only to pharmacists or at most pharmacists and those employees who submit claims. Pharmacy technicians, cashiers, and retail store clerks should not be required to undergo training. Furthermore, there is a strong need for some sort of uniformity in training. Given the breadth of available plans, a defined uniform approach to such training will not only create efficiencies in the program but is an absolute necessity. For example, there will need to be a methodology established to clarify and guide "downstream entities" when conflicting training, by separate entities, occurs. Pharmacies are already hard-pressed to meet the labor demands of their industry; requiring that each of their employees take the time to undergo multiple and - possibly conflicting training - programs on the same topic could serve to further exacerbate the increasing costs, problems and difficulties of the existing labor shortage and demands on staff time. VPhA looks forward to receiving from CMS best practice guidance for training. Furthermore, VPhA suggests that CMS create a national panel of pharmacy experts to establish Best Practice Guidelines for training. To reinforce the need for best practice guidance, VPhA suggests clarification by CMS of the coordination of benefit process between health plans. Currently pharmacies are bearing the administrative burden to reconcile plan-to-plan differences; however, initial CMS guidelines indicated that this should be resolved between the differing plans - not by participating pharmacists. VPhA requests that CMS enforce that these plan-to-plan reconciliations are completed between the plans and not involve pharmacy point-of-sale transactions.

Changes to Contract Renewal Procedures

Another area of the proposed regulations that could indirectly affect pharmacy is the change in the method by which Part D and MA-PD contracts are renewed. Under provisions of 42 CFR 422.506 and 423.507, 72 Fed. Reg. 29385 (2007) (to be codified at 42 C.F.R. § 422, § 343) (proposed May 25, 2007) that would take effect on January 1, 2008, contracts would automatically renew unless notice of non-renewal is provided to the Part D sponsor or MA organization by September 1. Currently, notice of renewal must be affirmatively provided by CMS by May 1.

VPhA has concern that this later notification regarding plan contract non-renewal will place an undue burden on pharmacies to join plan provider networks, as the period for provider contracting is effectively truncated. We ask that there be some contingent renewal notice authorized that Part D sponsors and MA-PD organizations can send to network pharmacy providers alerting those providers of the sponsors' and organizations' continued participation in Medicare in the following year.

Conclusion

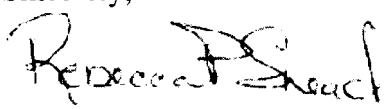
In summary, VPhA strongly supports CMS' proposed policy and regulatory changes to the Medicare Prescription Drug Benefit plan. Given the changing nature of the practice of pharmacy and the ever-increasing reliance on federal guidance, VPhA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

The Virginia Pharmacists Association founded in 1881, is the professional association representing the pharmacists of Virginia. Its 2000 members represent pharmacists, student pharmacists and technicians throughout the Commonwealth practicing in all aspects of pharmacy including community, hospital, industry, government, and education.

The purpose of the Association is to assure the viability and vitality of the profession of pharmacy by advocating for pharmacists in legislative, regulatory and public affairs. The focus of advocacy shall be to maximize contributions of the profession to public health, and patient care and to increase public awareness of the value of pharmacists' services.

If you have any questions or need any additional information, please do not hesitate to contact Rebecca P. Snead, R.Ph., Executive Director VPhA, at (804) 285-4431 or via email at becky@vapharmacy.org.

Sincerely,



Rebecca P. Snead, R.Ph
Executive Director
Virginia Pharmacists Association

Submitter : **Ms. Caroline Blankenship** **Date: 07/24/2007**

Organization : **New Mexico Medical Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

"See Attachment"

GENERAL

GENERAL

"See Attachment"

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

"See Attachment"

CMS-4124-P-12-Attach-1.DOC

CMS-4124-P-12-Attach-2.DOC

#12

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July 24, 2007

Submitted Electronically to
Centers for Medicare and Medicaid Services to
http://www.cms.hhs.gov/eRulemaking/

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 4124-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: CMS-4124-P. Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

To Whom It May Concern:

Thank you for providing the New Mexico Medical Society the opportunity to comment on this proposed rule. An original and two copies of our comment are enclosed.

Please do not hesitate to contact me if you have any further questions. I am the contact person relevant to these comments for the New Mexico Medical Society. I can be contacted at 505-842-1950, via email at cblankenship@mstlaw.com, or at the above address. Thank you.

Very truly yours,

Caroline Blankenship

Caroline Blankenship

CB:rrw
Enclosures

July 24, 2007
Submitted Electronically to http://www.cms.hhs.gov/eRulemaking/

To Whom It May Concern:

Re: CMS-4124-P.

On behalf of the New Mexico Medical Society, we submit these comments to the

> Revisions to the Medicare Advantage and Part D
> Prescription Drug Contract Determinations, Appeals, and
> Intermediate Sanctions Processes ("Proposed Rules").

We are objecting to any requirements, in the Proposed Rules or related rules, which provide that the Department of Health and Human Services ("DHHS") can inspect records of Medicare Advantage ("MA") organizations, specifically health care providers, for ten (10) years ("retention requirement") after the termination of a MA contract or completion of an audit. If DHHS elects to keep this ten-year retention requirement, then we ask that medical records are exempted. Our comments and rationale are below.

At present, the regulations pertaining to Part D and MA plans provides that a MA organization must allow DHHS, or its designee, access to records for ten years. Section 422.504(d) requires that "[t]he MA organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices...." Similarly, Section 422.504(e)(4) requires that:

> (4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extend through 10 years from the end of the final contract period or completion of audit, whichever is later unless—
>
> (i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA organization at least 30 days before the normal disposition date.
>
> (ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or
>
> (iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

(emphasis added).

The Proposed Rules note that there is 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. 72 Fed. Reg. 29368, 29373 (May 25, 2007) "Records" apparently includes the medical records. 72 Fed. Reg. 29368, 29381 (May 25, 2007) (noting that Part D sponsors must make available records pertaining to Medicare enrollees including medical records).

We do not object to the DHHS, or its designees, having the authority to inspect books and records of MA organizations for ten years if medical records developed by health care providers are exempt. These medical records should be exempt from the ten-year retention requirement for two reasons:

1. The triggering event for record retention should not be the termination of a MA contract but rather the termination of the patient/physician relationship.

Under the Proposed Rules and related rules pertaining to MA organizations, the triggering event that "starts the clock" on the record retention requirement is an event wholly outside of the patient and the patient's relationship with the MA organization. Typically, the triggering event for medical records retention relates to the patient whose medical records are at issue and begins when the patient's relationship is terminated with a particular health care provider. However, in this case, the triggering event for retention of a patient's medical records – and for the records of all the patients seen by a health care provider – is dependent on the termination or audit of a MA contract. The ten (10) year retention requirement proposed in Sections 422.504(d) and 423.503(e) does not begin after the final date of service to a Medicare beneficiary but rather starts "ten years from the end date of a MA contract or the completion of an audit, whichever is later" with few exceptions. Medicare Managed Care Manual § 110.4.3; 42 C.F.R. § 422.504(e)(4).

In contrast, health care providers generally retain medical records for a certain time following the last date of service to a patient. To require health care providers to retain records for ten (10) years after the end or the audit of a MA contract is not practicable. It is unduly burdensome on health care providers to impose a medical record retention requirement that does not somehow relate to the patient/health care provider relationship and the termination of that relationship. The implementation issues are endless – for example, if a MA contract is terminated with a health care provider who maintains a panel of 3,000 patients who are largely Medicare beneficiaries, how does the health care provider differentiate and track the medical records acquired before or after the termination of the MA contract? Moreover, a record retention requirement that is triggered by termination of a MA contract, rather than termination of a patient's relationship with a health care provider, conflicts with existing federal and state law.

2. Record retention triggered by the termination of a MA contract conflicts with existing federal and state law.

Federal and state law already establishes the requirements for medical record retention. For example, federal regulations require that providers maintain medical and billing records for Medicare (Title XVIII), Medicaid (Title XIX) and Maternal and Child Health (Title V) for at least six years. Federal law also requires that mammogram radiology films are kept for a period of not less than five years, or not less than 10 years if no additional mammograms of the patient are available, or longer if mandated by state or local law. 42 U.S.C.A. § 263b(f)(1)(G)(i)(I). New Mexico state law requires that medical records are kept for six years for Medicaid providers and ten years for hospitals. NMSA 1978 § 27-11-4 A. (1999); NMSA 1978 § 14-6-2 A. The New Mexico Medical Board recently adopted regulations requiring that physicians retain medical records for at least two years beyond what is required by state insurance laws and Medicare and Medicaid regulations. NMAC § 16.10.17.10 C. (2006) (emphasis added). This means that physicians in New Mexico currently must retain medical records for adult patients for at least eight years.

Importantly, the triggering event for record retention in all of the above cases is either the start or the finish of the patient's relationship with the health care provider. The triggering event is not, as in the Proposed Rules, based on an external contract with a MA organization. It is at minimum, problematic to implement and track a record retention policy that is first, triggered by the termination of an external contract between a health care provider and another entity, and second, wholly unrelated to a patient's relationship with a health care provider.

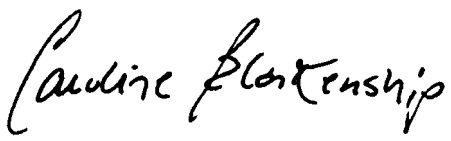
The Proposed Rules, coupled with the New Mexico Medical Board's regulations requiring retaining medical records for "at least two years beyond that which is required by state insurance laws and [M]edicare and [M]edicaid regulations," means that, in New Mexico, MA organizations must retain medical records for a minimum of twelve years. This twelve-year time frame could conceivably be even longer than twelve years because the Proposed Rules require record retention "ten years from the end date of a MA contract or the completion of an audit, whichever is later" with few exceptions. See Medicare Managed Care Manual § 110.4.3; 42 C.F.R. § 422.504(e)(4). The triggering event in the proposed and related MA regulations is open-ended, unrelated to the physician/patient relationship, and wholly dependent on the termination or audit of a MA contract. This requirement is not only problematic in its implementation but also burdensome for New Mexico health care providers.

The Proposed Rules unnecessarily extends the minimum amount of time that the DHHS, the Comptroller General or their designees can inspect the medical records maintained by health care providers.

In conclusion, the New Mexico Medical Society objects to the Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes and asks that DHHS consider exempting medical records of health care providers from the record retention requirement.

We appreciate this opportunity to comment on the Proposed Rules. Please do not hesitate to contact us if you have any questions. Thank you.

Very truly yours,



Caroline Blankenship

Submitter : **Ms. jane galvin** **Date: 07/24/2007**

Organization : **BlueCross and BlueShield Association**

Category : **Health Plan or Association**

Issue Areas/Comments

Background

Background

see attachment

GENERAL

GENERAL

see attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

see attachment

CMS-4124-P-13-Attach-1.WPD

#13

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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July 24, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
The Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Attention: CMS-4124-P

Re: Comments on Proposed Rule CMS-4124-P: Medicare Program: Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes

Dear Mr. Kuhn:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on this proposed rule to modify the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes (Proposed Rule). BCBSA represents the 39 independent Blue Cross and Blue Shield Plans (Plans), many of which sponsor Medicare Advantage and Medicare Prescription Drug Benefit Plans. Plans serve several million Medicare beneficiaries enrolled in Medicare Advantage and Medicare Prescription Drug Plans.

While many of the provisions of this rule codify selected existing policies issued by the Centers for Medicare and Medicaid Services (CMS) as memorandums to sponsors of Medicare Advantage and Medicare Prescription Drug Benefit Plans (Plan sponsors) since implementation of the Medicare Advantage and Part D Programs in January 2006, BCBSA has significant concerns with certain aspects of this Proposed Rule as they impose undue burdens on Plan sponsors.

One of our most significant concerns is with the proposed mandatory self-reporting requirement for Plan sponsors. While Plans are required to have compliance programs independent of federal rules, BCBSA strongly oppose the proposed requirement related to compliance for mandatory self-reporting of violations. CMS has proposed mandatory self-reporting on several previous occasions, and in each instance, CMS has eliminated the requirement. As we discuss in our comments, CMS should again withdraw its proposed inclusion of mandatory self-reporting in Part D and Medicare Advantage compliance programs. Mandatory self-reporting is not required for providers in the traditional Mediare program and also places unreasonable business risks on Plans who are partnering with CMS in these important programs. It is not required under any provision as established in law and should be withdrawn at this time.

BCBSA is also very concerned with CMS's approach to imposing significant compliance requirements on a Plan sponsor's first tier and downstream entities, as CMS has defined those terms. The proposal to require Plan sponsors to provide training to all such entities, including all providers, is unworkable and too broad in scope. The proposals leave the incorrect impression that Plan sponsors can guarantee the appropriateness of all activities, not only of entities to which they delegate core administrative functions, but also the conduct of all contracted providers and downstream entities.

These problems are particularly acute because CMS proposes to import concepts already articulated for the Part D Program into the Medicare Advantage Program. Because Medicare Advantage covers a far broader range of services and providers, the proposed requirements would be particularly burdensome to implement if adopted in a final rule.

We appreciate the opportunity to offer our comments, which we believe provide critical and practical insight into CMS's proposed modifications and will strengthen the Medicare Advantage and Part D Programs.

We believe that these revisions could result in significant unintended consequences and difficulties, particularly for Medicare Advantage Organizations in contracting with providers. We would be pleased to meet with you to discuss any of our concerns and to develop potential modifications to these policies that may simultaneously achieve CMS's policy goals without unduly burdening Plans. Please contact me if you have any questions about these comments. I can be reached at 202.626.8651.

We look forward to continuing to work with you and your staff as partners with Plans in the Medicare Advantage and Part D Programs.

Sincerely,

Jane Galvin
Director, Regulatory Affairs
Blue Cross and Blue Shield Association

Attachment

Blue Cross and Blue Shield Association

Comments on
"Medicare Program: Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes"
(CMS-4124-P, May 25, 2007)

I. Definitions - First Tier Entity and Downstream Entity - 422.2 and 423.4 and Application of Compliance Program Requirements to First Tier Entities and Downstream Entities (422.503 and 423.504)

CMS Proposed Rule: CMS proposes to define the terms "first tier entity" and "downstream entity." These terms are then utilized throughout the regulations, including in sections defining compliance responsibilities for Medicare Advantage (MA) Organizations and Part D sponsors (collectively referred to as Plan sponsors), contract requirements, and CMS inspection authorities.

Issues: The definitions, and the requirements associated with them, are too broad. BCBSA recognizes that these terms are presently utilized and defined in one portion of the current Part D regulations and also are in the Medicare Managed Care Manual. However, CMS is now proposing broader responsibilities for Plan sponsors – and in particular, is proposing to expand the use of these definitions to the very different context of the MA Program. BCBSA submits that CMS should review and revise these definitions and carefully calibrate the requirements that are imposed on Plan sponsors with respect to these third parties.

A. Inclusion of both providers and administrative service contractors in the same definition

The definitions of "first tier entity" and "downstream entity" are so broad that they reach health care providers (such as physicians, hospitals, skilled nursing facilities, durable medical equipment companies, pharmacies, etc.) as well as providers of administrative services. However the nature of the contractual relationship is different in these two situations and the requirements to be imposed should be carefully calibrated to reflect these differences. In order to do so, CMS should utilize separate terms for administrative contractors and providers.

A Plan sponsor's relationship with health care providers is fundamentally different from the Plan sponsor's relationship with their administrative contractors. Part D sponsors in general contract with thousands of pharmacies to meet access requirements and a pharmacy also can join a network under the "any willing pharmacy" rule. MA Organizations also are subject to a number of requirements that apply only to their contracts with healthcare providers, and that are designed to protect the rights of providers. For example, MA Organizations must establish mechanisms to consult with physicians about medical policy and other matters.[1] They may not interfere with providers' advice to enrollees, and there are constraints on MA Organizations' ability to terminate provider contracts.[2] In fact, Part 422 contains an entire Subpart E governing MA Organizations' relationships with providers.

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[1] Centers for Medicare and Medicaid Services, Medicare Managed Care Manual, Chapter 6 §. 21.
[2] Id. §§ 40, 60.4.

Plan sponsors do not "delegate" the provision of medical care to physicians, hospitals, and other providers, and a MA Organization does not directly serve as a provider and provide medical care. As a result, providers do not exercise authority delegated to them by MA Organization, as do core administrative contractors.

Plan sponsors' obligations towards providers are different and therefore should be recognized in this Proposed Rule. CMS has recognized in the Medicare Managed Care Manual that MA Organizations are not responsible for all misconduct, including malpractice, committed by their contracted providers. Similarly, if health care providers falsify data submitted to an MA Organization, the MA Organization is the victim of the provider's fraud, and should not be responsible for the provider's action (although the MA Organization should, and Plans do, have a program to detect fraud and abuse by providers).

B. Compliance requirements for providers

One example of the problems that result from including providers in these definitions is the proposed requirements for Plan sponsors to provide training and education and to have "effective lines of communications" with their first tier and downstream entities. We discuss these difficulties further in Section III of these comments.

Including providers in the definitions of first-tier and downstream entities may make it more difficult to grow and maintain MA Organizations' provider networks, since there would be greater administrative burdens and risks for providers, including the compliance requirements.

C. Core administrative services

The Proposed Rule's definition of first tier and downstream entities may also be read to include a Plan sponsor's janitorial services, law firms, secretarial temporary services, information technology vendors, real estate brokers, and other vendors, because the term "first tier entity" is defined as any party that enters into a written arrangement "to provide administrative services."

CMS should limit the definitions and clarify what types of administrative contractors are within the definitions. In Chapter 11 of the Medicare Managed Care Manual, for example, CMS articulated a concept of "core administrative services," such as claim processing. These types of entities, including PBMs, outsourced customer service providers, vendors assisting in enrollment, or vendors administering wellness programs would be the types of entities serving core administrative services that would probably be in the definitions of first tier and downstream entities. CMS should incorporate this concept into the regulations and the definitions in order to assure that all of the regulatory requirements are not construed to apply to each and every service provider that contracts with a MA Organization or Part D sponsor.

D. Downstream entity

CMS proposes to define the term downstream entity very broadly. The proposed definition 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.

The definition extends to any party that enters into a written arrangement "below the level of the arrangement between an MA Organization and a first tier entity." However, there is no limit on which written arrangements are at issue or how far this definition reaches. If the term extends broadly to all administrative service contractors, as discussed above, all of a PBM's (a first tier entity's) contractors and service providers might be considered within the definition of a downstream entity. For example, the PBM may contract with real estate firms, information technology vendors, and other entities whose services are not core administrative services and are unrelated to the provision of the prescription drug benefits under the Part D Program.

Similarly, are all of a hospital's contractors within the definition of a downstream entity? Hospitals contract with numerous entities in the course of their business, including nursing agencies, third party billing companies, information technology vendors, legal counsel, medical device companies, and pharmaceutical companies. Are each of these entities considered "downstream entities?" If so, the potential reach of the compliance and other contracting requirements is enormous as well as unworkable.

The Proposed Rule also suggests that individual pharmacists employed by a pharmacy are "downstream entities." By analogy, then, the question arises whether individual nurses contracted by a home health agency are considered "downstream entities?" Is each and every employee of an administrative service entity or a contracted provider also considered a "downstream entity?"

Additionally, the phrase "acceptable to CMS" in this definition is unclear. Must CMS pre-approve the written arrangement? How is it determined whether an arrangement is acceptable to CMS, and what is the consequence if the written arrangement is not acceptable to CMS? Is the contracted entity not considered a downstream entity in those circumstances? Again, this section requires clarification.

BCBSA Recommendations:

1. CMS should define separate terms for "contracted providers" and "administrative service contractors." For example, the term "contracted providers" could be used to define those providers or pharmacies with which a Plan sponsor contracts to provide covered health care items or services. As is already the case, the regulations could expressly reference the term contracted providers only in those circumstances when the regulatory requirement is appropriate.

2. CMS should limit the definition of administrative service contractors and focus on those entities that provide "core" administrative services to a MA Organization or Part D sponsor.

3. CMS should carefully consider as well as limit the reach of the concepts of "downstream entities" for both providers and administrative services. CMS should consider and resolve difficulties relating to part-time employees, contractors providing temporary staffing services, locum tenens practitioners, providers of peripheral administrative services, and other such issues.

4. CMS should eliminate or clarify the meaning of the phrase "acceptable to CMS" in the definitions.

5. CMS should clarify that the definitions do not cover any non-contracted providers or providers that are "deemed contracted."

II. Compliance Program Provisions (§422.503(b)(4)(vi)(G)(3) and 423.504(b)(4)(vi)(H)): Mandatory Reporting of Misconduct

Proposed Rule: CMS proposes in the above-designated sections to require Plan sponsors to "have procedures for mandatory self-reporting of potential fraud or misconduct related to the [MA Program][Part D Program] to the appropriate government authority. The [MA Organization][Part D sponsor] is required to report potential fraud or misconduct related to the [MA Program][Part D Program] to the appropriate government authority."

CMS has previously proposed mandatory self-reporting for the MA Program on several occasions. Those proposals have never been implemented in final regulations. CMS proposed a mandatory self-reporting requirement in the Medicare+Choice program in 2000. After considerable discussion, CMS eliminated the requirement. CMS again proposed mandatory self-reporting in 2004 for the MA and Part D Programs, but removed the requirement from the final rule after considerable comment in opposition. In 2005, CMS included mandatory self-reporting in the draft Chapter 9 of the Medicare Prescription Drug Benefit Manual, and again deleted it from the final version of the chapter.

Issues: BCBSA supports requiring all MA Organizations and Part D sponsors to have compliance plans. However, CMS should not implement a mandatory self-reporting requirement. This proposal should be withdrawn.

A. CMS' proposal exceeds its authority under the statute

Congress has not mandated self-reporting in either the MA or Part D Programs, and CMS lacks the statutory authority to impose this provision. Congress required a fraud waste and abuse program for the Part D Program but has never authorized or required mandatory self-reporting. CMS's general regulatory authority does not support requiring mandatory self-reporting.

B. No similar reporting requirements

The Proposed Rule singles out Plan sponsors and subjects them to a broad, burdensome, and potentially costly regulatory requirement. No other entites are subject to such a reporting requirement, including Medicare providers or Department of Defense or other government contractors. CMS previously recognized this discrepancy, concluding in 2000 that "it is arguably unfair to impose a self-reporting requirement on M+C Organizations but not on other types of healthcare providers and suppliers participating in the Medicare program, and we have eliminated any requirement of self-reporting."[3] CMS then withdrew its proposal to

[3] "Medicare Program; Establishment of the Medicare+Choice Program," 65 Fed. Reg. 40170, 40264 (June 29, 2000).

require mandatory self-reporting. CMS has not provided any reason for reversing course at this time other than a vague reference to reading about items associated with Plan sponsors in the media and that such reports were CMS's source of data of a potential problem in many cases.

C. Mandatory self-reporting is contrary to established principles of compliance

Mandatory self-reporting also subjects Plan sponsors to an inability to be assessed reduced penalties under the False Claims Act. Mandatory self-reporting increases dramatically the business risk of a health plan contracting with CMS under the MA and Part D Programs. Such an increase in the business risk for Plan sponsors contracting with CMS for either MA or Part D Programs is not within the best interest of the agency that should be, and currently is, viewed as a partner with Plan sponsors.

A mandatory reporting requirement is at odds with the compliance structure set up by Congress and the U.S. Sentencing Commission that provides incentive for voluntary self disclosures. The U.S. Sentencing Commission provides for dramatically reduced penalties under the federal sentencing guidelines for organizations convicted of crimes that self-report. Indeed, an article by a former vice-chair of the U.S. Sentencing Commission has expressed, not only that mandatory self-reporting is problematic, but suggests that materials generated during compliance activities should be protected from disclosure.[4] The federal False Claims Act similarly provides reduced financial penalties for those who self-report violations.[5] The HHS Office of Inspector General (OIG) has also implemented a Voluntary Self-Disclosure protocol to "encourage providers to make voluntary self-disclosures."[6]

CMS asserts that the mandatory self-reporting requirement is necessary because:

> we believe the decision to eliminate a mandatory self-reporting requirement has contributed to some highly publicized cases in which we have first found out about a major MA Organization compliance issue when it appeared in the press. We believe that it is important for the government to have information on possible fraud or misconduct as soon as possible in order to determine whether any actions would be appropriate. We therefore are proposing to restore a mandatory self-reporting requirement for MA Organizations, and to make the self-reporting provision that applies to Part D sponsors mandatory.[7]

But CMS often learns of compliance issues involving providers in the traditional Medicare Program that the providers did not themselves report. This information may come through press reports, through audits conducted by CMS or the OIG, or through reports from whistleblowers. Nonetheless, CMS is not proposing to, and does not require, mandatory self-reporting for Medicare participating providers and therefore it would be unfair to impose this on Plan sponsors.

If Plan sponsors are required to make reports, they would become ineligible for the benefits offered to those who make voluntary self-reports under the OIG's self-disclosure protocol, the

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[4] Michael Goldsmith and Chad W. King, Policing Corporate Crime: The Dilemma of Internal Compliance Programs, 50 V and. L. Rev. 1, 39-40 (1997).
[5] 31 U.S.C. § 3729 (2000).
[6] 63 Fed. Reg. 58399, 58400 (October 30, 1998).
[7] 72 Fed. Reg. at 29373.

Sentencing Guidelines, and the federal False Claims Act.[8] BCBSA sees no basis for the government to treat Plan sponsors differently from Medicare providers and other government contractors.

A mandatory reporting requirement also could discourage employees from coming forward to seek correction of errors. For example, an employee who wishes to see an incorrect practice cease may be unwilling to place themselves or their office workmates at risk of investigation by the government. Thus, if the person knows there is a broad federal mandatory requirement to report conduct that "may" constitute a violation, the employee may choose not to act on the concerns. This result would inhibit compliance, not promote it.

Plan sponsors have worked hard to publicize fraud and compliance hotlines and to foster a culture of openness to any reports of suspected misconduct. It would be counterproductive to require reporting of all instances of potential fraud or misconduct, which could result in CMS being involved in routine investigations of concerns raised in the normal course of business.

Moreover, the provision as drafted is overly broad and ambiguous. Failure to comply could subject Plan sponsors to separate penalties, including under the False Claims Act, since the compliance program provisions are required by the contract and the regulations. At a minimum, Plan sponsors will incur significant costs trying to comply.

Specific problems with the proposal as it is drafted are as follows:

- Read literally, the requirement that Plan sponsors report "potential" fraud or "misconduct" to "the appropriate government authority" is too broad and vague.

- What is "misconduct related to" the MA or Part D Programs? The term "misconduct" lacks definition, and appears as if it is not limited to violations of law. Does it extend to a breach of contract? A common law tort? Does it extend to a physician's violations of professional rules of conduct? Does it extend to an individual's violation of an internal compliance standard that exceeds legal requirements? Does it extend to state laws and regulations? Municipal rules? What does the term "related to" the MA or Part D Programs mean? Does it encompass all activity that relates to services under the Medicare contract? Is an allegation of sexual harassment "misconduct related to" the MA or Part D Programs?

- When does an allegation rise to the level of being "potential" fraud or misconduct? Must a Plan Sponsor make a report when there is *any* potential for "misconduct," even if there is only an allegation and no supporting evidence? Health care regulation is technical and complex and there may often be "potential" that a violation exists.

  Indeed, virtually every legal opinion, including those from the U.S. Department of Justice's Office of Legal Counsel, and OIG's advisory opinions speaks in terms of "possibilities." Must every one of these situations be reported? What if there is a factual allegation that does not appear credible but has not been disproved? Under

[8] HHS Office of the Inspector General, Voluntary Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998); U.S. Sentencing Commission Federal Sentencing Guideline Manual (2005), available at www.ussc.gov; 31 U.S.C. § 3729.

these circumstances, will a Plan sponsor be forced to conclude that there is "potential misconduct" and therefore report it to the government? If so, the government will be inundated with immaterial instances of "potential misconduct."

- As drafted, the Proposed Rule would require Plan sponsors to police providers' delivery of care, including, for example, allegations that a provider committed malpractice or illegal discrimination against a patient. And if a MA Organization contracts with a hospital that then gets into a dispute with its employed physicians about payment for the services they provided to a member, the MA Organization could be forced to make a report to the government. This would constitute a fundamental and controversial shift in the nature of health plans' relationships with providers.

  These examples may seem extreme and it may not be CMS's intent to require investigation and reporting in these ways. However, the regulations define the scope of an organization's legal obligations and *qui tam* relators and other enforcement officials can and do interpret them literally. MA Organizations should not be required to guess whether the regulations in fact mean what they say or to risk enforcement actions based on an overly broad regulation.

- The Proposed Rule lacks any statute of limitations. Thus, a Plan sponsor could be required to investigate and report even minor "misconduct" that occurred twenty years ago.

- Whose potential misconduct must be reported? The first sentence refers to "procedures for mandatory self-reporting," which suggests that the regulation is directed at reporting to the government the Plan sponsor's own misconduct, or that committed by its employees or agents. But the second sentence simply states that the organization must report "potential fraud or misconduct" related to the MA and Part D Programs. Is this intended to require reporting of any misconduct by anyone relating to the MA and Part D Programs? Reporting of potential fraud or misconduct by beneficiaries is different from potential fraud or misconduct by hospitals, physicians or other providers, or from potential fraud or misconduct by administrative subcontractors.

BCBAS Recommendation: CMS should delete this new proposed requirement, as it has done in the past. It is not based in statutory authority, is inconsistent with principles of compliance and voluntary self-reporting, and is vague and unworkable.

III. Compliance Program Requirements (Application to First Tier, Downstream, and Related Entities and Revisions to Fraud Waste and Abuse program) (422.503(b)(4)(iv)(C), (D), 423.504(b)(4)(vi)(C), (D))

CMS Proposed Rule: CMS proposes to expand compliance program requirements to extend beyond the Plan sponsor itself, to first tier, downstream, and related entities. Specifically, CMS proposes to require "Effective training and education between the compliance officer and the [MA Organization's][Part D sponsor's] employees, managers and directors, and the [MA Organization's] [Part D sponsor's] first tier, downstream, and related entities," and to require "effective lines of communication between "the compliance officer,

members of the compliance committee, the [MA Organization's][Part D sponsor's] employees, managers and directors, and the [MA Organization's][Part D sponsor's] first tier, downstream, and related entities."

CMS also proposes to incorporate the current separate requirement for a fraud waste and abuse program for Part D sponsors into the compliance program requirements. CMS proposes to do so for both Part D and MA Programs.

Issues: BCBSA and Plans recognize the importance and value of compliance programs. We believe our long-standing support for compliance efforts as well as Plans' experience in establishing and maintaining such programs provide us with valuable insight and practical knowledge relating to compliance programs that can assist CMS.

1. The Proposed Rule treats third parties as extensions of the Plan sponsor and therefore within the scope of a compliance program. By definition, a compliance program is designed to monitor and control a Plan Sponsor's own conduct. Indeed, the Sentencing Guidelines' compliance principles apply only to an entity's employees and agents. The seven elements of compliance set forth by the U.S. Sentencing Commission – which were written and designed to allow an organization to monitor its own conduct – should not be extended to apply to third parties without careful thought and consideration.

2. As discussed in Section I, including providers within the definitions of first tier and downstream entities is particularly problematic, including in the compliance requirements. It does not make sense for Plan sponsors to establish "training and education between" their own compliance officer and each and every contracted provider and downstream provider. Plan sponsors can seek to impose contractual compliance requirements on providers, with the providers themselves performing the steps. CMS also could require providers to undertake desired compliance steps through Medicare provider contracts, or through regulations specifying requirements for these entities.

It is not practical for Plan sponsors to provide training and education or have "effective lines of communication" with each and every provider. MA Organizations would have to train all of their providers, all of their contracted hospitals, all of their contracted pharmacies, home health agencies – each and every provider. That could be thousands of entities for a single Plan sponsor. In addition, the Proposed Rule suggests that an individual physician who contracts with a physician group is a "downstream entity." Thus, each individual physician would have to be trained. Similarly, the definition of downstream entity would seem to require the MA Organization to train each temporary agency nurses, locum tenets physicians, hospital medical directors and medical staff physicians.

Even if Plan sponsors could provide this training, health care providers would be overrun by training and compliance requirements from each entity with which they contract. It is not uncommon in many parts of the health care system for physicians and hospitals to contract with multiple MA Organizations or for pharmacies to contract with multiple Part D sponsors. The proposed requirement is logistically impossible to meet, and would make it more difficult to maintain and grow MA provider networks due to the associated administrative burdens on providers. It also incorrectly places the burden on Plan sponsors to provide training to health care providers, who should instead be responsible for their own compliance activities.

3. BCBSA recognizes that Plan sponsors may delegate core administrative functions to third parties. However, the steps that are appropriate to monitor third parties providing core administrative services may be different from the seven elements of compliance. The Proposed Rule, as drafted, may impose unnecessary requirements with respect to those entities that are delegated core administrative functions. For example, Plan sponsors could require core administrative contractors to have their own compliance programs, and provide certifications of those steps, subject to oversight and monitoring by the Plan sponsor. This would be a preferred mechanism for oversight and is different from requiring that these contractors be incorporated into each element of the Plan sponsors' compliance program. Plan sponsors also could perform periodic audits of these delegated entities on a select and targeted basis.

4. The use of the term "fraud, waste, and abuse program" is confusing. As discussed above, BCBSA believes that there is a distinction between a compliance program, which is designed to ensure that an entity and its agents are operating in a compliant fashion, and an external investigations component that is directed at misconduct by third parties. CMS's proposed approach combining the "fraud, waste and abuse program" and the compliance program into one inappropriately imposes identical structures on both, blurs this distinction, and is confusing. CMS should recognize the distinctions, and clarify when it is talking about an external monitoring component as opposed to an internal compliance program component.

BCBSA Recommendations:

1. CMS should not make the proposed revisions to subparagraphs (C) and (D), adding references to first tier, downstream, and related entities. In addition, CMS should not combine the fraud, waste and abuse requirement into the compliance program requirements. Rather, Plan sponsors should:

   (a) be responsible for having compliance programs focused on their own conduct, consistent with the approach of the sentencing guidelines;

   (b) be required to exercise oversight of their core administrative contractors; and

   (c) have fraud waste and abuse programs, and other monitoring programs such as those specified in the Medicare Managed Care Manual, designed to monitor the conduct of providers.

   CMS should also clarify its discussions of, and distinguish between, internal compliance and external monitoring components. CMS's present use of the term "fraud, waste and abuse," is confusing and imprecise.

2. Rather than requiring Plan sponsors to provide training and have effective lines of communication with providers as part of its compliance program, CMS should consider developing approaches that carefully target compliance steps that would be desirable for providers and others to take. For example, providers who contract with Plan sponsors arguably should provide training to their own employees. CMS should consider imposing this as a separate requirement directly on providers and others or imposing this as a required provision in Plan sponsors' contracts with providers. However, CMS should not impose the training and communication requirement on Plan sponsors as it is unworkable.

3. CMS should clarify that Plan sponsors are not expected to guarantee or be responsible for the conduct of providers. However, as part of their fraud, waste, and abuse programs, Plan sponsors should exercise appropriate oversight steps, as set forth in Chapter 6 of the Medicare Managed Care Manual and relevant sections of the regulations. They should also have a targeted program to identify providers who are violating their contracts or program requirements, or committing fraud.

IV. Inspection Authority

CMS Proposal: CMS proposes to expand its inspection authority to allow it to seek information from all downstream entities, first tier entities, and related entities as defined in the Proposed Rule. This information could include price and rebate data, rebate agreements and PDE records. CMS also proposes that it could make such requests directly to the contracted entities, rather than first asking the Plan sponsor.

CMS also proposes that if a first tier, downstream, or related entity fails to provide requested information or allow HHS requested access, the Plan sponsor would be in violation the rule and would be subject to adverse action including potentially, the imposition of intermediate sanctions, Civil Monetary Penalties (CMPs), or contract termination.[9]

Issues: This provision appears to allow CMS to extend its inspection authority to entities other than those organizations that are actually under contract with CMS for the MA or Part D Programs – including pharmacy benefit managers, pharmaceutical manufacturers, suppliers to hospitals, temporary staffing agencies, and others. (See discussion above regarding definition of first tier entities and downstream entities).

BCBSA is highly concerned with CMS's statement that any "downstream entity's" failure to provide requested information could subject the Plan sponsor to sanctions, CMPs, or even contract termination. Although Plan sponsors are responsible for complying with their contracts, and can include contractual and oversight provisions for their contracting entities, they cannot guarantee compliance by those third parties. Moreover, CMS proposes to define the entities broadly. As written, it appears that a pharmaceutical manufacturer could be considered a downstream entity (since it contracts with a PBM), and if the PBM or the manufacturer failed to provide data, the preamble to the Proposed Rule suggests that the Part D sponsor's contract could be terminated.

BCBSA is concerned about the broad scope of inspection authority CMS is claiming as well as CMS's suggestion that Plan sponsors be responsible for assuring compliance with the inspection authorities – and other requirements – by all downstream entities. CMS has previously stated in the Medicare Managed Care Manual that MA Organizations are responsible for compliance with the contract, even if they delegate some functions. However, such responsibility does not automatically make the MA Organization liable for penalties and contract termination for violations by third parties.

In addition, given the broad scope of the terms first tier and downstream entities, the regulation would require a very significant recontracting effort.

CMS also suggests that it could ask for data directly from administrative contractors. Where the entities are directly contracted with the Plan sponsor, and are exercising delegated

[9] 72 Fed. Reg. at 29375.

authority, CMS should always direct any and all requests for data directly to the Plan sponsor.

BCBSA has also expressed, in its comments to Proposed Rule 4130-P, that it is concerned that Part D sponsors will have difficulty accurately reporting the third party data necessitated by CMS's interpretations regarding pass-through reporting of drug costs, the proposed definition of administrative costs, and CMS's proposed approach to reporting of remuneration and rebates received by PBMs and not passed along to Part D sponsors.[10] CMS proposes extensive inspection authorities with respect to these third party financial transactions. BCBSA is concerned that Part D sponsors not be subject to penalties if they take reasonable steps to obtain accurate data. CMS should recognize that Plan sponsors are dependent on third parties and cannot necessarily assure that all data will be fully accurate. The extensive inspection authorities CMS is proposing illustrate the difficulty of implementing CMS's proposed definition of administrative costs.

BCBSA Recommendations:

1. CMS should revise the definitions of first tier entities and downstream contractors.

2. CMS should clarify that it will direct all of its information requests that may impact the Plan sponsor to the Plan sponsor directly.

3. CMS should clarify that a Plan sponsor is not automatically liable for penalties, intermediate sanctions, or termination of the contract or other forms of liability based on violations by third parties. Plan sponsors can be and are responsible for the provisions of their contract, even if they delegate some of its functions, as provided for in the regulations. However, Plan sponsors cannot serve as guarantors of the conduct of a broad range of third parties – subject to potential penalties, contract termination, and potential liability under the False Claims Act or other provisions for all violations by such third parties. CMS should clarify that this is not CMS's intent.

4. To the extent the government may seek records from pharmaceutical manufacturers or other suppliers or entities far down the contracting chain in connection with investigations, CMS should rely upon subpoena authority, or upon requirements placed on such entities directly through regulation, provider contracts, etc. Plan sponsors cannot be responsible for obtaining and supplying such data, subject to the penalty of possible termination for non-compliance by such "downstream entities."

V. Nonrenewal of a Contract

CMS Proposal: CMS proposes to notify Plan sponsors of contract nonrenewals on September 1 for the following year, rather than May 1.

Issue: A September 1 notice of contract non-renewal would cause difficulties for the Plan sponsor, beneficiaries, and other Plan sponsors. BCBSA believes that September 1 is too late for orderly planning and implementation of any non-renewal. As of September I, a Plan sponsor already would have submitted a bid to sponsor a MA or Part D Plan, submitted marketing materials for review, entered into contractual arrangements for the benefit year and undertaken other related activities, thereby incurring significant costs. Non-renewal at

[10] "Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit;" 72 Fed. Reg. 29403 (May 25, 2007).

such a late date would create significant logistical hurdles and would need to make business decisions as to how to respond to loss of an entire line of business. It is unfair to delay this notice until months after the bid is due.

In addition, a September 1 notice would not give beneficiaries enough time to transition to other MA or Part D plans, and would interfere with proper auto-assignment of dual eligible beneficiaries.

BCBSA Recommendation: BCBSA recommends that CMS notify all organizations of non-renewals by June 1. We also would find keeping the current May 1st date acceptable.

VI. Hearing Procedures

CMS Proposal: CMS proposes that Plan sponsors would have the burden of establishing compliance in response to enforcement, termination, or contract non-renewals by CMS.

Issue: BCBSA believes that CMS should bear the burden of establishing non-compliance of Plan sponsors against which CMS intends to impose significant enforcement actions. Such a rule is consistent with the general rule articulated by the Supreme Court that the party seeking to take action ordinarily bears the burden of persuasion. See, e.g., Schaffer v. Weast.

BCBSA Recommendation: CMS should not impose the burden of proof on Plan sponsors.

VII. Appeals to Administrator

CMS Proposal: CMS proposes to allow CMS to appeal adverse decisions to the Administrator, and to allow the Administrator to decline to hear appeals of adverse decisions.

Issue: The proper focus of appeal rights should be to preserve due process for the Plan sponsor.

BCBSA Recommendation: The Administrator should not have discretion to decline review of appeals by Plan sponsors and CMS should not be able to appeal an adverse decision to its own Administrator.

VIII. Expedited Termination

CMS Proposal: CMS proposes to expand the grounds for expedited termination (for which CMS need not offer an opportunity for a CAP) for MA Organizations. The Proposed Rule would add terminations under §422.510(a)(4), involving instances in which there is "credible evidence that the MA Organization committed or participated in false, fraudulent, or abusive activities affecting the Medicare Program, including submission of false or fraudulent data."[11]

[11] 72 Fed. Reg. at 29376-77. The Preamble to the Proposed Rule incorrectly states that this ground is already the basis for immediate termination in the rule, and that §422.510(a)(5) is being added as a ground for immediate termination. (§422.510(a)(5) states that "the MA Organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to

Issue: Expedited termination is a dramatic step with a potentially severe impact for Plan sponsors as well as beneficiaries, and should be reserved for those instances in which immediate action is needed to protect beneficiaries or the Medicare Program from serious harm.

The Proposed Rule would allow expedited termination for submission of any inaccurate ("false") data, without any requirement of fraudulent intent or knowledge, even if the impact is not significant, and even if there are alternative remedies. BCBSA recognizes that this is already a ground for immediate termination under the Part D regulations. However, expedited termination in both instances should be available only if the violation was intentional, the consequences to the program are material, and other remedies are not sufficient.

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make services available to the extent that such a risk to health exists"). In fact, the situation is reverse: presently, (a)(5) is a ground for termination but (a)(4) is not.

Submitter : Mr. Rod Shafer **Date:** 07/24/2007

Organization : Washington State Pharmacy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-14-Attach-1.DOC

#14

wspa

WASHINGTON STATE PHARMACY ASSOCIATION

July 31, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Proposed Regulations: 42 CFR Parts 422 and 423: Medicare Program: Revisions to Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

On behalf of the Washington State Pharmacy Association (WSPA), the organization representing pharmacists in Washington, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed regulations and revisions to Medicare Advantage (MA) and Part D prescription drug contract determinations and addressing appeals and intermediate sanctions processes dated May 25, 2007.

WSPA appreciates and supports federal efforts that, in the end, work to protect or improve pharmacy patients' health care access and affordability. In previous public comments to CMS-proposed regulations WSPA has expressed concern that PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade. WSPA continues to support CMS efforts to increase transparency in the health care system and broaden patient accountability by health care providers.

In large part, given the reasons above, WSPA is enthusiastically supportive of the CMS proposed regulations. WSPA specifically applauds the CMS proposal "to correct a technical oversight in both regulations by including the definitions of 'downstream entity,' 'first tier entity,' and 'related entity,' in the overall definitions of both the MA and part D regulations." Fed. Reg. 29371 (2007) (to be codified at 42 C.F.R. § 422, § 423) (proposed May 25, 2007). This clarification acknowledges the changes in the practice of pharmacy as "first tier" entities continue to have a larger and impact on the overall marketplace and thus, the practice of pharmacy. Furthermore, WSPA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

With this in mind, we would only like to comment on the proposed regulations regarding the (i) mandatory fraud and abuse training of all employees of downstream entities by MA-PDs and Part D Sponsors and (ii) changes to contract renewal procedures. The following comments are meant to address the above-mentioned two (2) categories.

1501 Taylor Ave SW, Renton, WA 98055 425-228-7171 Fax 425-277-3897 wsparx.org

Mandatory Fraud and Abuse Training of All Employees of Downstream Entities by MA-PDs and Part D Sponsors

The new requirement proposed under 42 CFR 422.503 and 423.504 72 Fed. Reg. 29384 (2007) (to be codified at 42 C.F.R. § 422, § 423) (proposed May 25, 2007) that Part D sponsors and MA-PD organizations train the employees of downstream entities such as pharmacy employees in detecting, correcting, and preventing fraud, waste, and abuse gives WSPA pause. The voluntary training recommendation of the Medicare Fraud Waste and Abuse Guidance is not mature enough to determine if the program was a success or failure. A new training mandate could raise pharmacies' costs of participating in Medicare Part D and thus could ultimately raise drug costs. The recent reductions in reimbursement coupled with the potential addition burden and cost associated with mandated training may lead to creating an undue burden on pharmacists and pharmacies.

In the event that CMS does require mandated training of downstream entities, such as pharmacies, WSPA requests that the training be limited only to pharmacists or at most pharmacists and those employees who submit claims. Pharmacy technicians, cashiers, and retail store clerks should not be required to undergo training. Furthermore, there is a strong need for some sort of uniformity in training. Given the breadth of available plans, a defined uniform approach to such training will not only create efficiencies in the program but is an absolute necessity. For example, there will need to be a methodology established to clarify and guide "downstream entities" when conflicting training, by separate entities, occurs. Pharmacies are already hard-pressed to meet the labor demands of their industry; requiring that each of their employees take the time to undergo multiple and - possibly conflicting training - programs on the same topic could serve to further exacerbate the increasing costs, problems and difficulties of the existing labor shortage and demands on staff time. WSPA looks forward to receiving from CMS best practice guidance for training. Furthermore, WSPA suggests that CMS create a national panel of pharmacy experts to establish Best Practice Guidelines for training. To reinforce the need for best practice guidance, WSPA suggests clarification by CMS of the coordination of benefit process between health plans. Currently pharmacies are bearing the administrative burden to reconcile plan-to-plan differences; however, initial CMS guidelines indicated that this should be resolved between the differing plans - not by participating pharmacists. WSPA requests that CMS enforce that these plan-to-plan reconciliations are completed between the plans and not involve pharmacy point-of-sale transactions.

Changes to Contract Renewal Procedures

Another area of the proposed regulations that could indirectly affect pharmacy is the change in the method by which Part D and MA-PD contracts are renewed. Under provisions of 42 CFR 422.506 and 423.507, 72 Fed. Reg. 29385 (2007) (to be codified at 42 C.F.R. § 422, § 343) (proposed May 25, 2007) that would take effect on January 1, 2008, contracts would automatically renew unless notice of non-renewal is provided to the Part D sponsor or MA organization by September 1. Currently, notice of renewal must be affirmatively provided by CMS by May 1.

WSPA has concern that this later notification regarding plan contract non-renewal will place an undue burden on pharmacies to join plan provider networks, as the period for provider contracting is effectively truncated. We ask that there be some contingent renewal notice authorized that Part D sponsors and MA-PD organizations can send to network pharmacy providers alerting those providers of the sponsors' and organizations' continued participation in Medicare in the following year.

Conclusion

In summary, WSPA strongly supports CMS' proposed policy and regulatory changes to the Medicare Prescription Drug Benefit plan. Given the changing nature of the practice of pharmacy and the ever-increasing reliance on federal guidance, WSPA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

The Washington State Pharmacy Association (WSPA) exists to support and advance the practice of pharmacy to ensure that the public receives optimal medication therapy management and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health.

If you have any questions or need any additional information, please do not hesitate to contact Rod Shafer, RPh, Chief Executive Officer WSPA, at (425) 228-7171 or via email at rshafer@wsparx.org.

Sincerely,

Rod Shafer, RPh.
CEO
Washington State Pharmacy Association

Submitter : Samantha DeLoache **Date:** 07/24/2007

Organization : National Alliance of State Pharmacy Associations

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-15-Attach-1.DOC

#15

NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS
5501 PATTERSON AVE., SUITE. 202, RICHMOND, VA 23226
PHONE: (804) 285-4431 FAX: (804) 285-4227 EMAIL: BECKY@NASPA.US
WWW.NASPA.US

July 31, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Proposed Regulations: 42 CFR Parts 422 and 423: Medicare Program: Revisions to Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

On behalf of the National Alliance of State Pharmacy Associations (NASPA), the national organization representing all fifty state pharmacy associations, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed regulations and revisions to Medicare Advantage (MA) and Part D prescription drug contract determinations and addressing appeals and intermediate sanctions processes dated May 25, 2007.

NASPA appreciates and supports federal efforts that, in the end, work to protect or improve pharmacy patients' health care access and affordability. In previous public comments to CMS-proposed regulations NASPA has expressed concern that PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade. NASPA continues to support CMS efforts to increase transparency in the health care system and broaden patient accountability by health care providers.

In large part, given the reasons above, NASPA is enthusiastically supportive of the CMS proposed regulations. NASPA specifically applauds the CMS proposal "to correct a technical oversight in both regulations by including the definitions of 'downstream entity,' 'first tier entity,' and 'related entity,' in the overall definitions of both the MA and part D regulations." Fed. Reg. 29371 (2007) (to be codified at 42 C.F.R. § 422, § 423) (proposed May 25, 2007). This clarification acknowledges the changes in the practice of pharmacy as "first tier" entities continue to have a larger and impact on the overall marketplace and thus, the practice of

pharmacy. Furthermore, NASPA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

With this in mind, we would only like to comment on the proposed regulations regarding the (i) mandatory fraud and abuse training of all employees of downstream entities by MA-PDs and Part D Sponsors and (ii) changes to contract renewal procedures. The following comments are meant to address the above-mentioned two (2) categories.

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In the event that CMS does require mandated training of downstream entities, such as pharmacies, NASPA requests that the training be limited only to pharmacists or at most pharmacists and those employees who submit claims. Pharmacy technicians, cashiers, and retail store clerks should not be required to undergo training. Furthermore, there is a strong need for some sort of uniformity in training. Given the breadth of available plans, a defined uniform approach to such training will not only create efficiencies in the program but is an absolute necessity. For example, there will need to be a methodology established to clarify and guide "downstream entities" when conflicting training, by separate entities, occurs. Pharmacies are already hard-pressed to meet the labor demands of their industry; requiring that each of their employees take the time to undergo multiple and - possibly conflicting training - programs on the same topic could serve to further exacerbate the increasing costs, problems and difficulties of the existing labor shortage and demands on staff time. NASPA looks forward to receiving from CMS best practice guidance for training. Furthermore, NASPA suggests that CMS create a national panel of pharmacy experts to establish Best Practice Guidelines for training. To reinforce the need for best practice guidance, NASPA suggests clarification by CMS of the coordination of benefit process between health plans. Currently pharmacies are bearing the administrative burden to reconcile plan-to-plan differences; however, initial CMS guidelines indicated that this should be resolved between the differing plans - not by participating pharmacists. NASPA requests that CMS enforce that these plan-to-plan reconciliations are completed between the plans and not involve pharmacy point-of-sale transactions.

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Another area of the proposed regulations that could indirectly affect pharmacy is the change in the method by which Part D and MA-PD contracts are renewed. Under provisions of 42 CFR 422.506 and 423.507, 72 Fed. Reg. 29385 (2007) (to be codified at 42 C.F.R. § 422, § 343) (proposed May 25, 2007) that would take effect on January 1, 2008, contracts would automatically renew unless notice of non-renewal is provided to the Part D sponsor or MA organization by September 1. Currently, notice of renewal must be affirmatively provided by CMS by May 1.

NASPA has concern that this later notification regarding plan contract non-renewal will place an undue burden on pharmacies to join plan provider networks, as the period for provider contracting is effectively truncated. We ask that there be some contingent renewal notice authorized that Part D sponsors and MA-PD organizations can send to network pharmacy providers alerting those providers of the sponsors' and organizations' continued participation in Medicare in the following year.

Conclusion

In summary, NASPA strongly supports CMS' proposed policy and regulatory changes to the Medicare Prescription Drug Benefit plan. Given the changing nature of the practice of pharmacy and the ever-increasing reliance on federal guidance, NASPA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among pharmacy leaders in all 50 states and Washington, DC, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives (NCSPAE).

If you have any questions or need any additional information, please do not hesitate to contact Rebecca P. Snead, R.Ph., Executive Vice President and Chief Executive Officer NASPA, at (804) 285-4431 or via email at becky@naspa.us.

Sincerely,

/s/

Rebecca P. Snead, R.Ph
Executive Vice President and Chief Executive Officer
National Alliance of State Pharmacy Associations

Submitter : **Ms. Kim Piper** **Date: 07/24/2007**

Organization : **Group Health Cooperative**

Category : **Health Plan or Association**

Issue Areas/Comments

Background

Background

CMS Proposed Rule on Revisions to the MA and Part D Contract Determinations, Appeals, and Intermediate Sanctions Processes

Comments due to CMS by 5pm EDT

GENERAL

GENERAL

Section 422.503(b)(4)(vi)(C) page 29384; Section 423.504 page 29393

CMS proposes (for Part C and Part D) that the compliance plan include effective training and education for MAO employees, managers and directors, and first tier, downstream and related entities.

Under these proposed regulations all MAO training and education programs for Part C and Part D must expand to include a vast expansion of current requirements around MAO training and education requirements as the MAO s responsibility would be training, education and monitoring of that training and education for any and all MAO contracted entities and their staff that provide any service to our Medicare Advantage members.

Problems with this requirement for organizations: How does the organization make this kind of training and education available to all the required entities, and how does the organization track compliance for this requirement? First Tier and downstream entities can contract with numerous organizations and must comply with each organization s compliance education and training.

Suggestion for this requirement: Based on this CMS understanding of the complexity needed to provide Part D Fraud, Waste and Abuse training for contracted entities, it would be helpful for CMS to apply consistency across the requirement for all training and education and allow plans the same flexibility for Part C that it allows for Part D.
CMS Chapter 9 of the Prescription Drug Benefit Manual, Fraud, Waste and Abuse, gives other options for MAOs to provide this training and education such that contracted entities can access the Part D sponsor s training "to the extent that it is feasible and reasonable", or they can develop and implement Part D compliance training themselves, or they can provide some combination of both to their staff.

Prescription Drug Benefit Manual Chapter 9 Part D Program to Control Fraud, Waste and Abuse
50.2.3 Training and Education (Rev.2, 04-25-2006) The Part D Sponsor must provide effective training and education between the Part D Compliance Officer and organization employees, subcontractors, agents, and directors who are involved in the Part D benefit.
All persons involved with the Sponsor s administration or delivery of the Part D benefit should receive general compliance training. To the extent that it is feasible and reasonable, first tier entity, downstream entity, and related entity staff should be permitted to attend the Sponsor s training or agree to conduct their own Part D compliance training in accordance with the guidance provided below.

This allows the first tier and downstream entity the choice of accessing the organization s training and education, or providing proof to the organization of their own compliant education and training.

Section 422.505(i)(3)(iv) - page 29394

CMS has the authority to conduct investigations and audits of Part D sponsors and their first tier, downstream or related entities

The proposed regulation clarifies that upon CMS request, the first tier, downstream or related entity can provide the requested information to either 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 provide the requested information directly to CMS or to the Part D sponsor to give to CMS, but contracts must be clear on this point.

Problems with this requirement for organizations: We find the language seems vague on whether it is up to the plan to write the format for delivery of information to CMS into their contracts with first tier and downstream entities as to how information is to be provided to CMS it seems to give the first tier and downstream entities the option of providing the information either to the Part D sponsor or directly to CMS:

A provision requiring the Part D sponsor s first tier, downstream, and related entities to produce upon request by CMS

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Section 422.503(b)(4)(vi)(C) page 29384; Section 423.504 page 29393

CMS proposes (for Part C and Part D) that the compliance plan include effective training and education for MAO employees, managers and directors, and first tier, downstream and related entities.

Under these proposed regulations all MAO training and education programs for Part C and Part D must expand to include a vast expansion of current requirements around MAO training and education requirements as the MAO s responsibility would be training, education and monitoring of that training and education for any and all MAO contracted entities and their staff that provide any service to our Medicare Advantage members.

Section 422.505(i)(3)(iv) - page 29394

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The proposed regulation clarifies that upon CMS request, the first tier, downstream or related entity can provide the requested information to either 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 provide the requested information directly to CMS or to the Part D sponsor to give to CMS, but contracts must be clear on this point.

Section 422.506 Non-renewal of contract page 29385.

The existing provisions require CMS to provide plans with notice of both renewal and non-renewal decisions by May 1. CMS proposed provisions would make contract renewal automatic, without notice, unless CMS notifies the MAO or Medicare Part D plan sponsor of cms intent to non-renew the contract by September 1 of the current contract year.
CMS proposes that they provide notice of CMS intent Not to Renew by September 1 of the contract year, rather than May 1. For purposes of this proposed rule, a non-renewal would take effect on January 1 of the following contract year.

Changing the notification deadline to September 1 gives CMS additional time to make a determination as to whether an MAO or Part D plan sponsor is in compliance with CMS requirements / should have its contract renewed for the following contract year. CMS state that the May 1 deadline does not provide CMS with enough time to obtain accurate up-to-date information in order to make a decision about contract renewals.

CMS states that they will provide an opportunity to organizations and sponsors prior to issuing a notice of intent to non-renew or a notice of intent to terminate that will give the MAOs and Part D plan sponsors 45 days to put in place and respond to CMS with the Corrective Action Plan (CAP).

Once CMS issues a notice of non-renewal or a notice of termination, the MAO or Part D plan sponsor would not have an opportunity to submit a CAP.

Submitter : Ms. CATHERINE KAJUBI **Date:** 07/24/2007

Organization : Aetna Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Oppose the suggested September 1, non-renewal notification date change, unless CMS specifically outlines the timeframe in which it will notify an MAO that it s determined to be in jeopardy of receiving a non-renewal notice. This clarification to the proposal is necessary to ensure the MAO has adequate time to prepare and submit a CAP prior to receipt of the September 1, non-renewal notification being issued. As noted above CMS needs to outline the timeline in which it will notify a non-compliant MAO prior to issuing the non-renewal notice based on their suggested change from May 1 to Sept 1. Applying the proposed CAP submission timelines of 45 & 30 days, it appears CMS would have to notify non-compliant plans by June in order to allow for the 45 & 30 day CAP submission timeframes. If CMS failed to notify by June and instead notified an MAO in July/Aug, it would limit the MAOs time to correct, develop and submit a CAP before the Sept 1, non-renewal notice is issued. Not entirely opposed to this suggested change; however, it s important for CMS to recognize the inconsistencies in the Regional Offices for the review of new contract filings & SAE applications, which in some regions is mainly based on reviewer opinion and interpretation rather than the application requirements/guidelines. This inconsistent regional office review process has resulted in unnecessary reconsideration requests being initiated, which end up being resolved by the RO and MAO without having to initiate the appeals process. Based on this information, if the reconsideration process is eliminated, CMS needs to recognize and prepare for the potentially high volume of requested appeal hearings if this issue is not addressed with the ROs.
Comment: suggest changing to 15 calendar days, 30 days is to long given the other suggested timelines involved in the contract determination and appeals process.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

42 C.F.R. ?? 422.503(b)(4)(vi)(G) & 423.504(b)(4)(vi)(G)
42 C.F.R. ? 422.503(b)(4)(vi)(C)

Submitter : **Ms. Kim Piper** **Date: 07/24/2007**

Organization : **Group Health Cooperative**

Category : **Health Plan or Association**

Issue Areas/Comments

Background

Background

CMS Proposed Rule on Policy and Technical Changes to Medicare Part D

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Section 422.503(b)(4)(vi)(C) page 29384; Section 423.504 page 29393

Section 422.505(i)(3)(iv) - page 29394

Section 422.506 Non-renewal of contract page 29385.