Submitter : **Ms. Julie Johnson** **Date: 07/24/2007**

Organization : **Minnesota Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-4124-P-19-Attach-1.DOC

#19

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 t o Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

On behalf of the Minnesota Pharmacists Association (MPhA), 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.

MPhA 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 MPhA 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. MPhA 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, MPhA is enthusiastically supportive of the CMS proposed regulations. MPhA specifically a pplauds 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, MPhA 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.

MINNESOTA PHARMACISTS ASSOCIATION
1935 West County Road B-2, Suite 165 • Roseville, MN 55113-2795 • 800.451.8349 *mn* • 651-697-1771 *metro* • 651.697.1776 *fax*
www.mpha.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 MPhA 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, MPhA 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. MPhA looks forward to receiving from CMS best practice guidance for training. Furthermore, MPhA 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, MPhA 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. MPhA 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.

MPhA 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, MPhA 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, MPhA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

If you have any questions or need any additional information, please do not hesitate to contact Julie K. Johnson, Pharm.D., Executive Vice President and Chief Executive Officer MPhA, at (651) 789-3204 or via email at Julie@mpha.org.

Sincerely,

Julie K. Johnson, Pharm.D.
Executive Vice President and Chief Executive Officer
Minnesota Pharmacists Association

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

Organization : Group Health Cooperative

Category : Health Plan or Association

Issue Areas/Comments

Background

Background

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

Your Attachment Process does not seem to be working

GENERAL

GENERAL

Section 422.503(b)(4)(vi)(C) page 29384; Section 423.504 page 29393
Problems:How does organization make this kind of trainin-education available to all the required entities-how does organization track compliance for this requirement? Contracted entities can also contract with numerous organizations & must comply with each organization s compliance education and training.
Suggestion: 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
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 or its designees any pertinent contracts, books, documents, papers, and records relating to the Part D program to either the sponsor or directly to CMS or its designees.

This seems to imply that it is the first tier or downstream entities choice of how to supply this information to CMS.

Further, our current contracts do not contain this language and organizations will need some time in order to bring all contracts into compliance with this proposed rule

Suggestion for this requirement:
We d like to see the requirement language clarified that so that it is up to the Part D sponsor to specify in the contract with the first tier and downstream entities who will provide the requested information to CMS - whether it will be the Part D sponsor who will then give it to CMS, or whether the contracted entity will provide the information directly to CMS.

Implement no sooner than 2009 and continue to allow the organization to determine contractually with first tier-downstream contracted entities whether organization or the contracted entity will be the party submitting the requested information to CMS.
Section 422.506 Non-renewal of contract page 29385 _Problems:The time frame to respond to CMS notice of intent give only 45 days to respond- Suggestion: Keep the current provision in place. 45 days too short

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

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.

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 : Lynn Rolston **Date:** 07/24/2007

Organization : California Pharmacy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4124-P-21-Attach-1.DOC

#21

CALIFORNIA PHARMACY ASSOCIATION

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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

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CPhA 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 CPhA 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. CPhA 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, CPhA is enthusiastically supportive of the CMS proposed regulations. C PhA specifically a pplauds 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, CPhA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

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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, CPhA 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. CPhA looks forward to receiving from CMS best practice guidance for training. Furthermore, CPhA 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, CPhA 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. CPhA 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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Conclusion

In summary, CPhA 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.

If you have any questions or need any additional information, please do not hesitate to contact Lynn W. Rolston, Chief Executive Officer of the California Pharmacy Association, at (916) 779-1400 ext. 400 or via email at lrolston@cpha.com .

Sincerely,

Lynn W. Rolston
Chief Executive Officer
California Pharmacy Association

Submitter : Mrs. Tracy Baroni Allmon **Date:** 07/24/2007

Organization : SilverScript Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-22-Attach-1.DOC

#22

July 24, 2007

Submitted as an attachment via
www.cms.hhs.gov/eRulemaking

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

Dear Sir or Madam:

SilverScript[SM] Insurance Company (SSIC), a national Medicare Part D Sponsor, and SilverScript, Inc. (SSI), a Part D pharmacy benefit management company (PBM), both affiliates of Caremark Rx, Inc., a leading PBM company, appreciate the opportunity to provide comments on the draft 2008 Reporting Requirements.

SSIC is one of only 10 national PDPs servicing the Medicare Part D market. We have united with distribution partners, including health plans and Medicare Supplement providers, in the sales of our products nationwide. We bring substantial prescription drug benefit management experience through operating our own PDP (SSIC) as well as through our affiliate (SSI), a PBM offering prescription drug management services to Part D plans. SSI supports over 30 of our health plan clients, which have a combined membership of two million lives in Medicare Advantage and PDP programs.

I. Definitions of "First Tier" "Downstream" and "Related" Entities

CMS proposes to clarify the terms "first tier entity", "downstream entity" and "related entity" and remove the terms "contractor" and "subcontractor". We support CMS' decision to bring consistency to the use of these terms. However, we believe these terms should be better defined and distinguished to ensure that they are being consistently interpreted . Specifically, an entity is a "first tier entity" and "downstream entity" if it provides "administrative services or health care services for" an enrollee, but this phrase is nowhere defined and is very broad and vague.[1] For example, while we understand and agree that a marketing firm that accepts enrollment forms on behalf of the plan would qualify as a "first tier" or "downstream" entity, we do not believe that a stationery firm that provides blank stationery to be used to print the enrollment form so qualifies, or a printing firm that prints EOBs. To make this distinction clear, the definition should state that an entity is only a "first tier" or "downstream" entity if the administrative activity it performs falls within one of the activities listed in the "Subcontractor Function Chart" of the Part D application.[2] CMS has clearly and consistently stated that delegation of

[1] By contrast, CMS defines "related entity" as one that performs "management functions" or "furnishes services to" enrollees. It is not clear whether these terms encompass different activities from those encompassed by "administrative services or health care services for" and, if so, what these distinctions are. For example, it is not clear whether "management functions" refers to corporate management or program management, and precisely what functions are managerial vs. simply administrative.

[2] See Section 3.1.2.C of the 2008 PDP Application.

these functions requires the inclusion of designated flow down provisions in the subcontracts, which would bring the rule into alignment with this earlier guidance.

We also are puzzled as to the purpose of and need for the separate definition for "related entity", since the term is used in the Rule only in conjunction with, and in the same circumstances as, "first tier" and "downstream entity". While we recognize that a related entity is defined more broadly to include an entity that, for example, leases real estate to the Part D sponsor, it seems that this type of transaction would be relevant for reporting "significant business transactions" by a "party in interest" (which is defined more broadly and would include a related entity), but not for flowing down the various contractual obligations applicable to a Part D sponsor, since leasing real estate is not a "delegated" activity or required to be performed pursuant to any CMS instructions or guidance (other than the "party in interest" requirements, which do not require the "related entity" definition). Moreover, as pointed out above, the phrases "management functions" and "furnishes services to enrollees" are overly broad and vague and create undue confusion.

Recommendations: 1. Clarify the definitions of a "first tier" and "downstream" entity to include only those entities that perform the "subcontractor functions" listed in the Part D application; and 2. Delete the defined term "related entity" and remove reference to it in the rule, since it is confusing and unnecessary – the first tier and downstream requirements attach regardless of whether the entities are related, and do not attach in the absence of the entities also qualifying as first tier or downstream entities.

II. Access to Books and Records of First Tier, Downstream and Related Entities

A. Access to First Tier or Downstream Entity Rebate Contracts

CMS proposes to "clarify, without regulatory change", its right to access "records relating to Part D rebate and any other price concessions information from Part D sponsors or their first tier, downstream, or related entities. "[3] Specifically, CMS states that it is "taking this opportunity in this proposed rule to make explicit that "[it] has the authority to request for verification of payment purposes, any records relating to rebates and any other price concessions between PBMs and manufacturers that may impact payments made to sponsors in the Part D program." CMS states that the price concession information reported by sponsors "may provide some information, [but] it may not be enough for [CMS] to determine in all cases whether appropriate payments have been made to the sponsor. While we agree that a PBM is a first tier entity, we fail to see how a manufacturer with whom the PBM contracts for rebates and other discounts falls within the definition of downstream entity. "Downstream entity", as currently defined, includes only those entities that provide "administrative services or health care services for" an enrollee. PBMs' agreements with drug manufacturers, wholesalers and similar entities do not involve administrative services or health care services for an enrollee; they are simply rebate/purchase discount arrangements, and are no more downstream entity agreements than are pharmacy agreements with drug wholesalers or manufacturers.

CMS' reliance on section 1860D-15(d)(2)(A) and 1860D-15(f)(1) as authority to justify its access to this information as "necessary to carry out the payment provisions" is not supportable, since the Part D plan is required to report all rebates it is entitled to and receives, and this data is fully disclosed to CMS. These sections were intended to authorize CMS to verify that the Part D plan accurately reports what it

[3] Later in the discussion, CMS refers to its "proposal to obtain rebate and price-concession related records" making it unclear whether CMS believes that the current regulatory language provides it with such authority.

paid for the drugs, and there is nothing in either of those sections that would require CMS to verify on behalf of the Part D sponsor that what it paid was "appropriate.". CMS' apparent concern that Part D plans will not or are unable to ensure that they obtain the full rebates and price concessions from their PBM subcontractors in accordance with their contracts with the PBM is difficult to credit. It is in the Part D plan's interests to obtain the full rebates to which it is entitled, and plans are sophisticated purchasers of drugs and services and have years of experience in negotiating and obtaining rebates from PBMs. It is standard in PBM contracts for plans to have extensive audit rights to verify compliance, and there is no more need or reason for CMS to assume this audit or policing role on behalf of Part D plans than there is for it to do so with respect to other subcontractor purchase or service contracts, such as pharmacy agreements with wholesalers or marketing firm contracts' with product suppliers.

CMS also states that its rationale for focusing on the PBM rebate agreements is based on "the history of rebate reporting problems that government has encountered with PBMs in administering the Medicaid Drug Rebate Act" and to "fulfill our statutory duty of protecting beneficiaries from fraud and abuse." It is not clear to us exactly what rebate reporting problems CMS is referring to, or the applicability of those problems to the Part D context. If anything, in the Medicaid situation it would presumably be the government that is acting in a plan or payer capacity, which is precisely the role of the Part D sponsor in Part D. Further, any problems that may have been encountered under a separate government program should be resolved in the context of that program and not used as a basis for CMS to obtain information under the guise that it needs this information to perform its payment responsibilities under Part D.

We firmly believe that CMS' interest in ensuring that the plan receives all rebates to which it is entitled is more than adequately protected by the plan's even greater interest in ensuring the same outcome. However, if CMS still feels it necessary to obtain verification of this, it may do so by requiring the Part D plan to provide the necessary verification - including, if CMS deems it necessary - independent third party verification. As mentioned above, it is a standard term in the plans' contracts with PBMs for plans to have the right to audit rebates, either directly or through an independent third party auditor that is subject to the terms of a confidentiality agreement in order to protect the highly competitive and proprietary nature of rebate contracts. So if CMS believes that it needs verification that the plan is properly protecting its own interests in this one area, it could require the Part D plan to make the audit report provided by the independent auditor available to CMS. That way, CMS has not only the rebate reports from the plan which it can then compare against rebates reported by other plans to check for outliers, but it also has independent verification that the plan has indeed obtained all the rebates to which it is entitled, and all this done while respecting the highly confidential and proprietary nature of the rebate contracts.

Limited disclosure of the rebate contracts themselves is of the utmost importance, since it is only by drastically limiting distribution in this way that PBMs have been successful in keeping the rebate contract terms confidential, thereby maintaining the integrity and competitive nature of the rebate negotiation process. While CMS provides the assurance that rebate contracts will be treated as confidential by CMS, once the contracts are shared more broadly in this manner, the risk of leakage rises exponentially, despite the good faith attempts by all involved to prevent this. As CMS has stated on many occasions, the Part D program's foundation rests upon the principle of competitive market forces as they exist in the private sector. The broader dissemination of rebate contracts, and the inevitable leakage of proprietary and confidential information contained within them as a result, will erode these market forces by allowing competitors to learn about the rebate terms offered by others and limit their offers accordingly.

Indeed, the FTC staff has considered this issue on several occasions, and has consistently opined that the mandatory disclosure of PBM contracts with manufacturers, even to limited parties and subject to confidentiality protections, is likely to lead to tacit collusion among manufacturers, and will undermine competition and result in increased drug cost. Thus the FTC staff have stated with respect to disclosure requirements included in various state bills:

Public disclosure of proprietary information can foster tacit collusion or otherwise undercut vigorous competition on drug pricing. If, for example, pharmaceutical manufacturers learn the particulars of rebates and other payments and incentives offered by their competitors, then tacit collusion among them may be more feasible... Because particular products and their manufacturers can be excluded from formularies, manufacturers have powerful incentives to bid aggressively for inclusion. Knowledge of rivals' prices can dilute incentives to bid aggressively and facilitate tacit collusion, which increases prices.70 Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals.[4]

Recommendation: Delete the comment that CMS has the authority to request and review first tier and downstream entity rebate agreements with manufacturers, and confirm that such agreements do not fall within CMS' purview. Instead, provide that CMS may require Part D sponsors to provide verification that they have obtained the rebates to which they are contractually entitled. This may be done by requiring Part D sponsors to produce copies of the audit reports of independent third party auditors that confirm that the Part D sponsor has indeed received the rebates to which it is contractually entitled.

B. Preserving Confidentiality of First Tier and Downstream Entity Books and Records

CMS proposes to "leave it to the contracting parties to determine during their contract negotiations the process for submitting the requested information to CMS or its designees." Specifically, the contract "must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to CMS or directly to CMS or our designees." We understand and agree that CMS is entitled to request this information, and that it is not for CMS to determine how this should be done. Therefore, rather than stating in 42 CFR 423.505(i)(3)(iv) that the agreement must require the first tier, downstream or related party to produce the information "to either the Part D sponsor or directly to CMS or its designees", the requirement should be simply that the entity is required to produce the information "directly to CMS or its designees." This will not prohibit the parties from sharing the information with the Part D sponsor, but will simply state the regulatory requirement and goal, namely, that the information be provided to CMS or its designees. We are concerned that adding language concerning the option to go through the sponsor could create an expectation that the information should be shared with the Part D sponsor when this is not the case. Indeed, since downstream entities do not have a contractual relationship with the Part D sponsor, they would generally not expect to have to provide this information to the Part D sponsor itself and, given the breadth of information that can be requested, could raise concerns about disclosing proprietary or competitive information to parties with which the downstream entity has no contractual relationship and no assurances as to the protection of the proprietary or confidential nature of the information. For example, this requirement could be read to allow Part D sponsors to require pharmacies to provide to it copies of their contracts with wholesalers, which would contrary to the settled business expectations of confidentiality and undermine competition, and cannot be what CMS intended.

---

[4] FTC Staff Letter to Terry G. Kilgore, Member Virginia House of Delegates, October 2, 2006.

In any event, while we understand that Part D sponsors themselves may mark information as proprietary and confidential and explicitly seek exemption from disclosure under the Freedom of Information Act ("FOIA"), there is no requirement or mechanism to provide similar protection to material provided by entities below the level of the Part D sponsor. Therefore, we recommend that CMS add explicit language stating that entities below the level of the Part D sponsor will also be entitled to seek exemption from disclosure under FOIA for any documents and information that they provide to CMS or its designees.

Recommendations: **1. Revise 42 CFR 423.505(i)(3)(iv) to delete reference to the Part D sponsor and to require instead that first tier, downstream and related entities produce requested information "directly to CMS or its designees" only. 2. Add language stating that any information, books or records provided to CMS or its designees by first tier, downstream or related entities will automatically be treated as proprietary and confidential by CMS, and subject to exemption from disclosure under FOIA.**

III. Mandatory Self-Reporting of Potential Fraud and Misconduct

CMS proposes to add as a requirement in 42 CFR 423.504(b)(4)(vi)(G) that Part D sponsors have "procedures for mandatory self-reporting of 'potential fraud or misconduct" related to the Part D program to the appropriate government authority." CMS originally proposed mandatory self-reporting at the time the Part D Rule ("Rule") was being finalized, but ultimately decided against this approach, in part in response to the large number of comments objecting to this requirement as "vague and broad, with no basis in statute" and that the existing requirements were sufficient.[5] We believe these objections are still valid, and are concerned that the current proposed language does nothing to address them.

CMS explains that its reason for imposing this new mandatory reporting requirement is the occurrence of some highly publicized cases in which CMS first found out about a major MA organization "compliance issue" through the press, and 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." While we fully understand the concern about learning of instances of major noncompliance through the press, we do not believe that mandatory reporting of every "possible" or "potential" fraud or will avert major compliance issues at entities that are non-compliant. Indeed, in those serious cases of continuing non-compliance, it is unlikely that even with a mandatory reporting requirement, any report will be made.

In addition, the proposed language is overly broad and provides no parameters as to materiality of the suspected misconduct, the types of misconduct that warrant reporting, or the level of evidence or wrongdoing required to be found before a report is made. Plans receive numerous communications from a number of sources regarding potential fraud or misconduct. It is unreasonable to expect plans to act on and report each of these communications as potential fraud or misconduct without conducting a thorough investigation to confirm actual fraud or misconduct. In fact, we believe that it would be irresponsible and inappropriate to make a report that involves and implicates individuals until an informed determination has been made. Further, imposing on Part D sponsors the sweeping and open-ended obligation to report any information on "possible" or "potential" fraud or misconduct "as soon as possible" will hamper their own investigations and impede their ability to gather information effectively

[5] 70 Fed. Reg. at 4334.

and in accordance with their compliance and fraud, waste and abuse programs, as all the focus turns to what must be provided to the government and when. Indeed, in an effort to avoid triggering a perceived premature obligation to report (and any ensuing liability in the event there is no fraud or misconduct), Part D sponsors and their workforce members will likely seek to confirm and verify before reporting anything to anyone. Thus, perversely, the effect of this new mandatory reporting requirement will likely be precisely the opposite of what CMS intended, as it inhibits internal reporting and information sharing.

Finally, given the breadth of issues potentially includible in this reporting requirement, we are concerned that even in those instances where a report is made, the investigation and resolution of the issue will be delayed as MEDICs will now receive far more reports than they are able to handle and will have no means to prioritize them given that every "potential" fraud or misconduct has been reported. At the same time, as Part D sponsors cede control of the investigation to the government, their internal investigations will be cut short. The result is that investigation of the matter will be stalled at the most critical time, and as the party in the best position to do the investigation, namely the Part D sponsor, gives up control of it.

Recommendations: 1. Retain the requirement of voluntary self-reporting because requiring mandatory self-reporting is counterproductive and will serve only to further burden already compliant organizations and hamper them in their ability to investigate potential fraud or other misconduct.

IV. Compliance Plan Training and Communication Requirements

CMS proposes to clarify that Part D sponsors "need to apply [the compliance plan] training and communication requirements to all entities they are partnering with to provide benefits and services in the Part D program, and not just their direct employees within their organizations." However, CMS provides no elaboration or guidance on how it expects Part D sponsors to implement this requirement, particularly with downstream entities with which it has no direct contractual relationship. Even with first tier entities, it would be practically infeasible and contrary to the goal of ensuring that the Part D program "operate as efficiently as possible" to interpret this language to require that the Part D sponsor itself provide the training or communication channels with entities not even known to it. For example, a Part D sponsor may contract with a marketing company which may in turn contract with an advertising agency which may in turn contract with a graphics art firm. The Part D sponsor has no contractual relationship with the advertising agency or graphics art firm, and likely will have no knowledge even that they are in the contractual chain. It makes no sense in this situation for the Part D sponsor to itself have responsibility for training the employees of any of these entities, and advertising agency, and instead, each entity in the chain should be contractually bound to train its own employees.

This is especially the case if the training contemplated is that as described in Chapter 9 of the Prescription Drug Benefit Manual, which requires both "general compliance" and "specialized compliance training." While CMS uses the term specialized "compliance" training, we believe that any specialized training should be operational in nature, since the intent is for individuals working in these areas to be able to operate within the confines of the Rule. In Chapter 9, CMS states that the Part D sponsor may satisfy their training obligations for first tier, downstream and related entities by requiring that they conduct their own training, and we believe this approach is the most practical and effective to achieve CMS' objective, since it is only those supervising the employees or contractors in question that can effectively train them on the application of the Part D requirements to their specific job functions. Therefore, we recommend that CMS clarify in the proposed rule that the training requirement may be met by the Part D sponsor requiring that the first tier and downstream entities themselves engage in

appropriate training (based on the delegated activity they perform) and develop lines of communication with their employees and contractors. This will ensure that each entity in the chain is accountable for providing appropriate training while recognizing that it is neither efficient nor effective for any entity to provide job-related training to anyone other than those whose jobs it directly oversees, namely, its own workforce.

Recommendation: Clarify that Part D sponsors may comply with the training and communication requirements with respect to first tier and downstream entities by contractually requiring that these entities each train their own workforce on delegated activities, and establish lines of communication to the appropriate managers in those entities.

V. Corrective Action Plans ("CAPs")

The proposed rule states that before nonrenewing a contract, CMS will provide Part D sponsors with a reasonable opportunity to develop and submit a CAP. Specifically, Part D sponsors will be required to submit a CAP within 45 days after receiving a request for a CAP from CMS. However, CMS provides no information as to the process that would lead up to the request for a CAP, and the type of noncompliance that might give rise to a CAP request[6] . In particular, we believe it would be in the interests of both parties for CMS to first informally notify the Part D sponsor when it has concerns about the sponsor's compliance with Part D, and allow the Part D sponsor an opportunity to explain or respond to CMS' stated concerns. Based on this exchange, CMS may nevertheless decide to proceed with the request for a CAP, but at least the Part D sponsor will be aware of the issue and have had an opportunity to present information to CMS that might persuade CMS that a CAP is not necessary. With respect to the 45-day period in which to develop a CAP, this may well be sufficient where there is only one or a few deficiencies at the level of the Part D sponsor itself. However, if there are multiple issues or the issue involves first tier or downstream entities, 45 days may not be sufficient to coordinate and gather that information necessary to formulate a CAP. Thus, we recommend that CMS allow Part D sponsors to routinely ask for and be granted a one-time extension of the period for a further 45-days where the CAP may involve parties other than the Part D sponsor itself, or more than one issue.

CMS also states that it will provide Part D sponsors with a deadline by which the CAP must be implemented, but provides no minimum period for this purpose. Since CMS' intention here is to provide a more structured process, we recommend that CMS provide at least a 90 day period for Part D sponsors to implement the CAP and, since a CAP can apply to a single narrow issue or to a sponsor's entire program, a mechanism for Part D sponsors to request and be granted an extension of this implementation period where reasonable grounds for doing so are shown.

Recommendations: 1. Before requesting a CAP from a Part D sponsor, CMS should notify the sponsor of the reasons for the CAP and allow the sponsor a reasonable opportunity, to explain and defend its Part D activities. 2. CMS should allow a one-time automatic extension of the time frame for developing and submitting a CAP when the CAP may involve activities and/or functions by first tier, downstream or related entities, or more than one issue. 3. CMS should specify a minimum time period for implementation of the CAP, with a mechanism for seeking and granting an extension where reasonable grounds are shown for doing so.

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[6] CMS does state that it has the authority to use actions that occurred in any plan year and bases this conclusion on the fact that, since the CMS contracts are automatically renewable, they are multi-year contracts. We fail to see how automatic renewal of a one-year term contract converts it into a multi-year agreement.

VI. Changing Date of CMS Notification of Non-Renewal

CMS proposes to change the date it must provide notice of nonrenewal from May 1 to September 1. CMS states that its reason for doing so is that it has been its experience that the May 1 deadline does not provide it with enough time to obtain "accurate up-to-date information in order to make a decision about contract renewals," and that this change would provide more time to make an accurate determination concerning contract non-renewals. While we appreciate CMS' concern that it not issue a notice of non-renewal without accurate and up-to-date information, which suggests that the sponsor also be given a longer period to cure and/or provide information, we are concerned that delaying the deadline for issuing these notices will have unintended negative consequences for the Part D sponsor in question.

First, the sponsor would have invested significant time and resources in developing and submitting its bid, plan designs and formulary, as well as designed, obtained approval for and produced its marketing materials. The bulk of this effort and expenditure occurs between May and September, and it would be pointless for a Part D sponsor to pursue this if CMS has determined not to renew its contract. In this regard, it is not clear to us why the information available to CMS will be any less accurate or up-to-date as of the date of the notice if the notice is provided in May instead of September. Indeed, no matter when the notice is issued, it can only reflect information that has occurred to date, whatever date is chosen. Second, we note that if a notice of nonrenewal is issued, and the Part D sponsor requests a hearing, according to 423 CFR 423.650(c), notice of any decision favorable to the Part D sponsor must be issued by July 15 for the contract in question to be effective on January 1 of the following year. If CMS is only required to issue the notice by September 1, it effectively deprives the Part D sponsor of any opportunity to appeal that decision for the following year, since it is by definition too late for a favorable decision. Indeed, if the notice of nonrenewal is based on inaccurate information as CMS believes could occur, if it is provided by May 1, the Part D sponsor at least has the opportunity to appeal it for the upcoming year.

Recommendation: Retain the May 1 deadline for issuing a notice of non-renewal to Part D sponsors. This will protect Part D sponsors from investing significant resources into an enterprise which will not be going forward. In addition, it gives the Part D sponsor a meaningful opportunity to seek a hearing if it disagrees with the nonrenewal.

VII. Terminations of Contract by CMS

CMS proposes to revise the bases for contract termination to allow termination if the Part D sponsor "substantially failed to carry out the terms of its contract with [CMS] for the current term or its contract from a previous term." CMS justifies the expansion of the grounds for termination to breaches in the previous year on the basis that it has "adopted automatically renewable multi-year contracts" so that "failure to substantially carry out a contract term necessarily would apply to all years of the contract."

While it is appropriate for CMS to be able to terminate a contract based on performance failures during that contract period, we do not believe it is appropriate for CMS to be able to terminate a current contract based on performance failures in a contract which is no longer in effect. The fact that the contract has to renew each year, whether automatically or not, indicates quite clearly that the contract is not in fact a multi-year contract, but in fact a single year contract that is renewed or, in effect, re-entered into anew each year. Whether this occurs by affirmative action or by default in the absence of affirmative action affects only the manner in which the new contract is entered into, and does not change the fact that a new contract and a new contract period starts afresh each year.

As such, while CMS may certainly choose not to renew a contract based on deficient performance in a given contract year, once a new contract year begins, basic principles of contract as well as fairness require that only performance failures for that contract period may be grounds for termination of that contract.

Recommendation: Delete proposed section 423.510(a)(1)(ii) that would allow CMS to terminate a current contract based on a Part D sponsor's failure substantially to carry out the terms of a prior year's contract.

We appreciate the opportunity to provide these comments. If you have any questions or would like discuss our comments, please do not hesitate to contact me at 202-772-3501.

Sincerely,

Russell C. Ring
SVP, Government Relations

Submitter : Howard Schiff **Date:** 07/24/2007

Organization : Maryland Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

#23

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 : Georgia Burke **Date:** 07/24/2007

Organization : National Senior Citizens Law Center

Category : Attorney/Law Firm

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment

CMS-4124-P-24-Attach-1.DOC

#24

Justice
Independence
Dignity
Security

National Senior Citizens Law Center

1330 Broadway, Suite 525,
Oakland, CA 94612
510-663-1055 Fax: 510-663-1051
oakland@nsclc.org
www.nsclc.org

July 24, 2007

Comments Submitted on Behalf of the National Senior Citizens Law Center and the Center for Medicare Advocacy, Inc. on Draft Regulations Concerning Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

Re: File Code CMS-4124-P

The National Senior Citizens Law Center and the Center for Medicare Advocacy, Inc. are pleased to submit comments on the draft regulations concerning the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes published in the Federal Register on May 25, 2007.

Our comments are limited to a few issues:

Provisions of Proposed Regulations

Definitions.

We believe that the new definitions of first tier entities, downstream entities and related entities are helpful clarifications. We also appreciate that CMS is making it clear in Section 423.505 that plan sponsors are ultimately responsible for contract violations of first tier entities, downstream entities and related entities, regardless of the nature of the relationship of the sponsor to those entities.

Mandatory Self Reporting.

In our view, the decision to require mandatory self-reporting by plan sponsors of potential fraud or misconduct is necessary and important. Recent experience with marketing abuses has demonstrated the need for this provision.

We believe, however, that mandatory self-reporting should extend beyond instances of potential fraud and abuse and include reporting of non-fraudulent acts or omissions that have the potential significantly to affect beneficiaries. If, for example, a computer error results in thousands of enrollees being denied coverage at the pharmacy, the plan discovering the error should be required to report it to CMS so that the agency and

advocates can field beneficiary calls and pharmacies can be notified. If plans do not self-report, the potential for misinformation is significant. More importantly, beneficiary access to necessary medications can be further jeopardized.

We appreciate the opportunity to provide comments on the draft regulations. If any questions should arise about these comments, please contact Georgia Burke gburke@nsclc.org or Vicki Gottlich vgottlich@medicareadvocacy.org.

Sincerely,

Georgia Burke
Staff Attorney
National Senior Citizens Law Center

Vicki Gottlich
Senior Policy Attorney
Center for Medicare Advocacy, Inc.

Submitter : Ms. Debbie Garza **Date:** 07/24/2007

Organization : Walgreen Co.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-25-Attach-1.DOC

#25

Walgreens
The Pharmacy America Trusts

Government and Community Relations Department

July 24, 2007

Submitted Via eRulemaking

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: Revisions to Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

Dear Sir or Madam :

Walgreen Co. ("Walgreens") is writing to comment on the above-referenced matter, which concerns changes to the Part D Medicare pharmacy benefit and related programs.

Walgreens is the nation's leading community pharmacy, with more than 5,800 pharmacies in the 48 contiguous states and the Commonwealth of Puerto Rico. We employ more than 200,000 people, including more than 20,000 pharmacists, and we fill in excess of 529 million prescriptions each year. We participate in virtually all Medicare PDP and MA-PD plans.

Walgreens is a proud member of the National Association of Chain Drug Stores and we join their detailed comments submitted on this topic. We are writing separately to reiterate and amplify their comments.

Expansion of CMS Record Searches

As a general matter, we applaud CMS's efforts to ensure that the Medicare pharmacy benefit is fairly administered without fraud, waste or abuse that diminishes resources available for beneficiary services. However, we are greatly concerned that CMS has proposed in this rulemaking to expand the scope of its regulatory oversight

without following appropriate administrative processes. In particular, CMS states that it is:

> [P]roposing to clarify, without specific regulatory change in this rule that HHS, the Comptroller General, or their designees have the authority under the statute to request records relating to Part D rebate and price concessions information from Part D sponsors or their first tier, downstream or related entities (emphasis added).

This "clarification" is followed by a non-exclusive list of the types of records that CMS believes is subject to such a records request, including 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.

We question whether CMS has the statutory authority to request all of the information listed. For example, while federal law quite clearly authorizes CMS to seek information on rebates granted to PBMs by manufacturers, or even to seek information regarding pharmacy discounts and free goods offered to beneficiaries or Medicaid programs that might be construed as unlawful kickbacks, it is unclear by what authority CMS can seek information on discounts, chargebacks, or in-kind goods granted to pharmacy providers by manufacturers or wholesalers dispensed under Medicare. This language is also troubling because it leaves open the possibility of an infinite variety of records being subject to review and inspection.

Most importantly, however, is the fact that this expansion of inspection authority is occurring without a formal rulemaking, during which CMS's authority to request specific types of records would be set forth and reviewed and specific limits on the agency's authority would be formalized in a promulgated rule. To ensure that the regulatory and administrative system is fair to all parties, we respectfully request (1) that CMS withdraw this language concerning expansion of is recordkeeping and inspection authority and (2) if such authority is to be expanded at all, that CMS initiate a formal rulemaking concerning this topic.

Review by Part D Sponsors and MA Organizations of Network Provider Records

Apart from the issue of what pharmacy provider records may be subject to inspection by CMS, we respectfully request that CMS clarify that PDP sponsors and MA-PD organizations be prevented from directly accessing the proprietary records of the pharmacy providers in their networks. We appreciate that that CMS does specify that downstream entities -- such as network pharmacy providers -- are not required to produce their books and records directly to the Part D sponsor. Rather, CMS states that the contracting parties may determine during their contract negotiations the process for submitting the requested information to CMS or its designees.

However, there may be certain circumstances in which PDP sponsors and MA-PD organizations may have such disproportionate bargaining positions and power that they may be able effectively to demand that network pharmacy providers release all requested records directly to them. Such a situation would pose a real threat to proprietary agreements between pharmacy providers and the other entities with which they do business, including wholesalers; manufacturers; and contract providers of clinical, medical, and medication therapy management services.

To both ensure that CMS has the information it needs to protect the integrity of the Medicare pharmacy benefit and also to protect the proprietary information of network pharmacy providers, we respectfully request that CMS amend the proposed rule (in particular Sections 422.504 and 423.505) to require that the authority of Part D sponsors and MA-PD organizations concerning network pharmacy records be strictly limited to requiring the physical delivery of requested records either to (1) CMS or (2) a designee of CMS independent of any PDP sponsor or MA-PD organization.

Thank you for the opportunity to comment on these proposed changes.

Very truly yours,

Debbie Garza, R.Ph. /s/
Vice President, Government and Community Relations
202-624-3172
debbie.garza@walgreens.com

Submitter : fred eckel **Date:** 07/24/2007

Organization : NC Association of Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-4124-P-26-Attach-1.DOC

#26

North Carolina Association of Pharmacists
109 Church Street, Chapel Hill, NC 27516
phone: 919-967-2237 - fax: 919-968-9430
www.ncpharmacists.org

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 North Carolina Association of Pharmacists (NCAP), 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.

NCAP 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 NCAP 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. NCAP 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, NCAP 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, NCAP 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 NCAP 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, NCAP 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. NCAP looks forward to receiving from CMS best practice guidance for training. Furthermore, NCAP 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, NCAP 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. NCAP 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.

NCAP 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, NCAP 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, NCAP appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

The North Carolina Association of Pharmacists is the state organization representing the profession of pharmacy, organized to unite, serve and advance the profession of pharmacy for the benefit of society.

If you have any questions or need any additional information, please do not hesitate to contact Fred Eckel, Executive Director, 919-967-2237, fred@ncpharmacists.org

Sincerely,

Fred Eckel, RPh
Executive Director

Submitter : Joni Cover **Date:** 07/24/2007

Organization : Nebraska Pharmacists Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-27-Attach-1.DOC

#27

NPA
Nebraska Pharmacists 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 members of the Nebraska Pharmacists Association (NPA), I 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.

NPA 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 NPA 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. NPA 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, NPA is enthusiastically supportive of the CMS proposed regulations. NPA 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, NPA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

With this in mind, I 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

6221 South 58th Street, Suite A Lincoln, Nebraska 68516 | office: 402.420.1500 | fax: 402.420.1406
www.npharm.org

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 NPA 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, NPA 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. NPA looks forward to receiving from CMS best practice guidance for training. Furthermore, NPA 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, NPA 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. NPA 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, §

NPA
Nebraska Pharmacists Association

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Conclusion

In summary, NPA 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, NPA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

If you have any questions or need any additional information, please do not hesitate to contact me at 402-420-1500 or via email at joni@npharm.org.

Sincerely,

Joni Cover
Executive Vice President

6221 South 58th Street, Suite A Lincoln, Nebraska 68516 | office: 402.420.1500 | fax: 402.420.1406
www.npharm.org

Submitter : Mr. Jim Bracewell **Date:** 07/24/2007

Organization : Georgia Pharmacy Association Inc (GPhA)

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-4124-P-28-Attach-1.DOC

#28

GEORGIA PHARMACY ASSOCIATION, INC
50 Lenox Pointe NE • Atlanta, Georgia 30324
404-231-5074 phone

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 Georgia Pharmacy Association (GPhA), the state organization representing pharmacists in all practice sites in Georgia, 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.

The Georgia Pharmacy Association 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 GPhA 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. GPhA 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, GPhA is enthusiastically supportive of the CMS proposed regulations. GP hA 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 affect the overall marketplace and thus, the practice of pharmacy. Furthermore, GPhA 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

GPhA is concerned about 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. 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, GPhA 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. GPhA looks forward to receiving from CMS best practice guidance for training. Furthermore, GPhA 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, GPhA 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. GPhA 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.

GPhA 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, the Georgia Pharmacy Association 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, GPhA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

If you have any questions or need any additional information, please do not hesitate to contact Jim Bracewell, Executive Vice President and Chief Executive Officer of GPhA, at (404) 419-8119 or via email at jbracewell@gpha.org.

Sincerely,

James (Jim) R. Bracewell
Executive Vice President & CEO
Georgia Pharmacy Association

Submitter : Ms. Margherita Giuliano **Date:** 07/24/2007

Organization : Connecticut Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

i.e. See attachment

CMS-4124-P-29-Attach-1.DOC

#29

CONNECTICUT PHARMACISTS ASSOCIATION

35 Cold Spring Road, Suite 121
Rocky Hill, CT 06067 • (860) 563-4619
Fax: (860) 257-8241 • **Email:** members@ctpharmacists.org
Website: www.ctpharmacists.org

July 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS 4124-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 Connecticut Pharmacists Association (CPA), the state pharmacy organization representing close to 1000 pharmacists in the state of Connecticut, 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.

CPA 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 CPA 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. CPA 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, CPA is enthusiastically supportive of the CMS proposed regulations. CPA 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 impact on the overall marketplace and thus, the practice of pharmacy. Furthermore, CPA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

CONNECTICUT PHARMACISTS ASSOCIATION
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Website: www.ctpharmacists.org

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 concerns our organization. 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. To issue 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 additional 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, CPA 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. CPA looks forward to receiving from CMS best practice guidance for training. Furthermore, CPA 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, CPA 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. CPA 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.

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Conclusion

In summary, CPA 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, CPA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

If you have any questions or need any additional information, please do not hesitate to contact Margherita R. Giuliano, R.Ph., CAE, Executive Vice President and Chief Executive Officer CPA, at (860) 563-4619 or via email at mgiuliano@ctpharmacists.org.

Sincerely,

Margherita R. Giuliano

Margherita R. Giuliano, R.Ph., CAE
Executive Vice President and Chief Executive Officer
Connecticut Pharmacists Association

Submitter : Mr. Ron Fitzwater **Date:** 07/24/2007

Organization : Missouri Pharmacy Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4124-P-30-Attach-1.DOC

#30

MPA
MISSOURI PHARMACY ASSOCIATION

211 East Capitol Avenue • Jefferson City, MO 65101 • 573-636-7522 • Fax 573-636-7485
www.morx.com

July 31, 2007

Centers for Medicare and Medicaid Services
ATTN: CMS 2238-P, Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 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

I am writing on behalf of the Missouri Pharmacy Association (MPA), the professional association representing independent community pharmacists in Missouri. 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 (PD) prescription drug contract determinations, appeals and intermediate sanctions processes, dated May 25, 2007.

MPA 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 on CMS-proposed regulations, MPA 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 health care system and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade. MPA 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, MPA is enthusiastically supportive of the CMS proposed regulations. MPA 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) – proposed May 25, 2007 – to be codified at 42 C.F.R. § 422, § 423]. This clarification acknowledges the changes in the practice of pharmacy as "first-tier" entities continue to have a larger impact on the overall marketplace and thus, the practice of pharmacy. Furthermore, MPA 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 categories.

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In the event that CMS does require mandated training of downstream entities, such as pharmacies, MPA 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 already are 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. MPA looks forward to receiving best practice guidance for training from CMS. Furthermore, MPA 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, MPA 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. MPA 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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If you have any questions or need additional information, please contact me at (573) 353-0450 or ron@morx.com.

Sincerely,

Ron L. Fitzwater, CAE
Executive Vice President and Chief Executive Officer

Submitter : Joni Cover **Date:** 07/24/2007

Organization : Nebraska Pharmacists Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-31-Attach-1.DOC

#31

NPA

Nebraska Pharmacists Association

July 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4124-P, Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 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

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www.npharm.org

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NPA
Nebraska Pharmacists Association

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If you have any questions or need any additional information, please do not hesitate to contact me at 402-420-1500 or via email at joni@npharm.org.

Sincerely,

Joni Cover
Executive Vice President

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