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

Organization : Virginia Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Resubmitting comments with proper docket number included.

See attachment

CMS-4124-P-44-Attach-1.DOC

VIRGINIA PHARMACISTS ASSOCIATION

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#44

Pharmacists helping pharmacists to improve patient care.

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

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

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

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

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

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

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

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

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

Changes to Contract Renewal Procedures

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

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

Conclusion

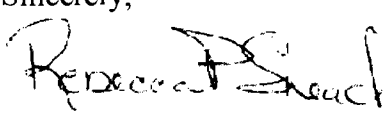
In summary, VPhA strongly supports CMS' proposed policy and regulatory changes to the Medicare Prescription Drug Benefit plan. Given the changing nature of the practice of pharmacy and the ever-increasing reliance on federal guidance, VPhA appreciates CMS' effort to clarify and codify the areas addressed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

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

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

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

Sincerely,



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

Submitter : Mr. Lawrence Sage **Date:** 07/24/2007

Organization : Indiana Pharmacists Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Comments Attached

CMS-4124-P-45-Attach-1.RTF

#45

July 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4124-P, Mail Stop C4-2605
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

On behalf of the Indiana Pharmacists Alliance, the state organization representing Indiana pharmacists, 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.

IPA 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 IPA 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. IPA 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, IPA is supportive of the CMS proposed regulations. IPA 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, IPA 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 IPA 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, IPA 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. IPA looks forward to receiving from CMS best practice guidance for training. Furthermore, IPA 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, IPA 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. IPA 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, IPA 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, IPA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

The Indiana Pharmacists Alliance (IPA) promotes leadership, sharing, learning, and policy exchange among pharmacy leaders in Indiana and other states and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. IPA was founded in 1882 as the Indiana Pharmaceutical Association (IPhA).

If you have any questions or need any additional information, please do not hesitate to contact Lawrence J. Sage, B.A., M.P.A., Executive Vice President of the IPA, at (317) 634-4968 or via email at ipalary@indianapharmacists.org

Sincerely,

/s/

Lawrence J. Sage
Executive Vice President
Indiana Pharmacists Alliance

Submitter : **Ms. Judith Mears** **Date: 07/24/2007**

Organization : **Kaiser Foundation Health Plan, Inc**

Category : **Health Care Industry**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachments

CMS-4124-P-46-Attach-1.PDF

#46

COMMENTS OF KAISER FOUNDATION HEALTH PLAN, INC.

On Proposed Rule CMS-4124-P

July 24, 2007

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

PROVISIONS OF THE PROPOSED REGULATIONS

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

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

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

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

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

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

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

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

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

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

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

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

p. 29385 Section 422.506 Nonrenewal of contract.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

p. 29393 Section 423.504 General provisions.

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

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

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

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

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

> "A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS or its designees any pertinent contracts, books, documents, papers and records relating to the Part D program to either the sponsor or directly to CMS or its designees."

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

> "A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS or its designees any pertinent contracts, books, documents, papers and records related to the Part D program, and a provision either requiring the entity to furnish such information to the Part D sponsor to transmit to CMS or its designees, or requiring the entity to furnish such information directly to CMS or its designees, in accord with the terms of the contract between the Part D sponsor and the entity."

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

p. 29394 Section 423.507 Nonrenewal of contract.

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

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

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

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

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

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

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

Submitter : Herbert Kwash **Date:** 07/24/2007

Organization : Washington D.C. Pharmaceutical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4124-P-47-Attach-1.DOC

#47

WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION

P.O. BOX 55264, WASHINGTON, D.C. 20040
PHONE: (202) 829-1515 EMAIL: MIDPHARM@AOL.COM

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

On behalf of the WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION, 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.

WASHINGTON D.C. PHARMACEUTICAL 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 WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION is enthusiastically supportive of the CMS proposed regulations. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION specifically applauds the CMS proposal " to c orrect a t echnical o versight in b oth r egulations b y inc luding t he de finitions o f '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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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 WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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 r ecent r eductions in r eimbursement c oupled w ith t he p otential a ddition b urden a nd c ost 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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 o f a vailable p lans, a de fined unif orm approach t o s uch t raining w ill no t o nly c reate 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. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION looks forward to receiving from CMS best practice guidance for training. Furthermore, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION requests t hat C MS e nforce t hat t hese p lan-to-plan r econciliations a re completed b etween t he 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.

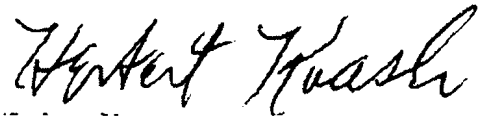
WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION has concern that this later notification regarding plan contract non-renewal will place an undue burden on pharmacies to join plan provider networks, as the period for provider contracting is effectively truncated. We ask that there be some contingent renewal 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, WASHINGTON D.C. PHARMACEUTICAL 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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 Herb Kwash, R.Ph., President and Executive Director WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION, at (202) 826-1515 or via email at midpharm@aol.com.

Sincerely,



Herbert Kwash, R.Ph
President and Executive Director
Washington D.C. Pharmaceutical Association

#18

CMS-4124-P

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

Submitter : Mr. Michael Schwab **Date:** 07/24/2007

Organization : North Dakota Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Comment are attached regarding proposed regulations 42 CFR Parts 422 and 423

CMS-4124-P-49-Attach-1.DOC

#49

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 North Dakota Pharmacists Association (NDPhA) and the ND Pharmacy Service Corporation (NDPSC), an organization representing all state pharmacists, 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.

NDPhA 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 NDPhA 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. NDPhA 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, NDPhA is enthusiastically supportive of the CMS proposed regulations. NDPhA 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, NDPhA 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 NDPhA 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, NDPhA 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. NDPhA looks forward to receiving from CMS best practice guidance for training. Furthermore, NDPhA 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, NDPhA 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. NDPhA requests that CMS enforce that these plan-to-plan reconciliation's 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.

NDPhA 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, NDPhA 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, NDPhA 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 Michael D. Schwab, Executive Vice President, NDPhA, at (701) 258-4922 or via email at mschwab@nodakpharmacy.net

Sincerely,

/s/

Michael D. Schwab
Executive Vice President
ND Pharmacists Association
ND Pharmacy Service Corporation
1641 Capitol Way
Bismarck, ND 58501-5600

Submitter : Mary Ninos **Date:** 07/24/2007

Organization : Coventry Health Care, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-50-Attach-1.DOC

#50

June 24, 2007

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

Attention: CMS 4124-P

Dear Sir or Madam:

I am writing on behalf of Coventry Health Care, Inc. (Coventry) to comment on the Centers for Medicare & Medicaid Services' (CMS) May 25, 2007 proposed rule: *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes* (CMS-4124-P).

Coventry is a diversified national managed healthcare company based in Bethesda, Maryland, operating health plans, insurance companies, network rental and workers' compensation services companies. Through its Commercial Business, Individual Consumer & Government Business, and Specialty Business Divisions, Coventry provides a full range of risk and fee-based managed care products and services to a broad cross section of individuals, employer and government-funded groups, government agencies, and other insurance carriers and administrators. Coventry participates in the Medicare program as a Medicare Part D Prescription Drug Benefit (Part D) program, Medicare Advantage (MA) plans, a stand-alone prescription drug plan (PDP), and a Medicare Advantage-Prescription Drug (MA-PD) plan.

We would like to thank you for the opportunity to provide comments on these proposed changes to the MA and Medicare Part D program. Coventry has identified several proposed changes that we believe either need further clarification or should be eliminated. These are discussed in detail in our comments below.

Specific Comments on *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes* (CMS-4124-P)

I. Requirement to apply Compliance Plan's training and communication requirements to first tier, downstream and related entities

We believe it is impracticable, unreasonable and cumbersome to both MA plans and providers to impose the requirement to apply the Compliance Plan's training and communication requirements at §422.503(b)(4)(vi) on health care providers. We fully agree that it is appropriate in the context of an MA Plan or any entity (related entity or not) providing management or administrative services on behalf of an MA Plan because the administrative and/or management services the subcontractor provides more than likely are unique to that MA Plan so there is a

need for training and education on that MA Plan's programs, requirements, etc. In addition, the subcontractor may or may not be familiar with the Medicare Advantage requirements, so the experience level of such subcontractors may vary as to their understanding of the Medicare Advantage program and applicable laws and regulations.

HOWEVER, with respect to health care providers, we don't believe this is true. It has been our experience that health care providers are quite familiar with the Medicare Advantage plan and the obligations applicable to contracting with such a plan. This is based on the providers' long standing experience with traditional Medicare and Medicare Advantage Plans.

Furthermore, health care providers contract with many Medicare Advantage Plans. As a result, health care providers will be inundated with training and education materials from all of the MA Plans if this rule is implemented as written. We believe this would result in quite the opposite of the intended effect. Providers will receive so much training and education materials that they will look at none of it rather than trying to read the tomes of information. We believe a more practical approach would be for CMS, working with the industry, to come up with a standard training and communication plan applicable to all providers and make it available on the web. That way the providers receive one comprehensive training and communication package that has been approved by CMS, and can focus on and review that one package. Thus, the providers and MA Plans can be assured that the provider has received and reviewed the necessary training and communication materials.

Ref Section: §422.504(b)(4)(vi)(B) It is also important to note that just as CMS allows a corporate entity to develop one Corporate Compliance Plan, the Compliance Structure should be determined based on the organizational structure for MCOs with multiple Health Plans.

II. Mandatory self-reporting of potential fraud or misconduct requirement for MA organizations and Part D Sponsors.

We are gravely concerned with CMS' proposal at §422.503(b)(4)(vi)(G)(3) and §423.504(b)(4)(vi)(G)(3) to reinstitute the prior requirement of mandatory self-reporting of possible fraud and/or misconduct for MA organizations and to make the self-reporting provision that applies to Part D Sponsors mandatory. We understand CMS' desire to have instances of fraud and misconduct reported to them in a timely manner. However, as it stands, CMS returns to a policy which unfairly subjects MA and Part D organizations to a self-reporting requirement that does not apply to other sectors of the health care industry. This would impose a self-reporting requirement on MA and Part D organizations which does not exist on other types of health care providers and suppliers participating in the Medicare program.

We understand CMS' concern that the government should have information on possible fraud or misconduct in order to determine appropriate action. However, CMS' process as reflected in the proposed rule inappropriately responds to these concerns. We believe that CMS should work with the industry to develop another manner in which MA organizations and Part D Sponsors could provide this information effectively. Through this partnership, CMS and the

industry could craft a viable, well thought out reporting mechanism which meets the needs of both government and business. We believe that by working together, a better process could be developed which both meets CMS' needs and prevents plans to a different standard than other Medicare providers.

Additionally, as currently crafted, the requirement is too vague to provide useful information and results. If this unfair provision requiring self-incrimination is maintained, CMS should clarify exactly what information must be reported as well as to which agency plans should report which of the various potential instances of fraud and/or misconduct. We are also concerned that CMS has provided no information as to what point a plan should report such an instance. For example, does CMS expect the plan to report immediately upon receipt of an unsubstantiated allegation of fraud without any time for the plan to investigate the allegation? Or, would CMS expect that the plan have time to perform an initial investigation to ascertain whether the allegation has any merit? Without allowing a plan the time to conduct an internal investigation to validate that there may in fact be a possible instance of fraud, plans may report to federal agencies a series of unsubstantiated fraud allegations with no accompanying investigative information to assist the federal agency in reviewing or responding to such allegations. This does not allow the plan to develop and maintain controls. The lack of clarity in the requirement leaves too much room for inconsistency in reporting and action across plans.

III. Requirement to obtain access to Part D sponsor's first tier, downstream and related entity's books and records through contractual arrangements

We understand and appreciate CMS' need to oversee Part D Sponsor's operations and therefore agree with most of the provisions/clarifications set forth in the proposed regulation. However, the requirement at proposed §423.505(i)(3)(iv) that a Part D Sponsor and first tier entity have to identify in their contract whether records will be provided directly to CMS or through the Part D Sponsor appears to be unnecessary and inefficient.

Depending on the nature of the records requested, volume of records requested, location of the records requested and time frame within which such records are needed, the decision as to how the records will be provided will significantly vary. Therefore, we believe it would be appropriate to let the parties determine how the records will be provided at the time of the request. As pointed out in the proposed regulation, it is already a contractual requirement between and Part D Sponsor and its subcontractors that the subcontractor make the records available. The how, where and when of that should be left to be determined between the Part D Sponsor and the subcontractor at the time of the request, to allow for flexibility with respect to the nature of the request.

- As pointed out in the proposed regulations, "any failure or omission by a first tier, downstream or related entity to provide information requested by [CMS], or to allow HHS access to its books and records relating to payment, would constitute a violation by the MA organization or Part D plan sponsor of its contract with [CMS] and a violation of the MA and Part D regulations." Such a threat provides more than sufficient motivation for MA Plans and their subcontractors to resolve any issues about access quickly.

Furthermore, if this section were implemented as drafted, for the reasons set forth above, we do not believe the contract would have the specificity CMS desires with respect to access to records. That is, Part D Sponsor and subcontractors would not want to lock themselves in to how and when the records will be produced, because it will depend on the nature of the records requested, volume and place to be produced. So the language will probably be vague at best.

IV. Change date of CMS' notification of non-renewal from May 1 to September 1

We are requesting clarification around CMS' proposed revisions of the process to notify an MA or Part D plan of CMS' intent to non-renew. At §422.506(b)(2)(i) and §423.507(b)(2)(i), CMS' proposed change includes delaying the time period the MA plans and Part D Sponsors are notified of the intent to non-renew for the upcoming year from the May 1 to September 1 of the current year. We are concerned that no notification would be made to the plan or sponsor prior to September 1 of CMS' intent to non-renew.

We understand the change of the this process would benefit CMS as outlined in the proposed rule. However, the benefit to the health plans and Part D Sponsors is less obvious. CMS has provided little detail to explain if the September 1st timeframe is the final date of the notice or is inclusive of timeframe for health plans or sponsors to cure any identified deficiencies in our submitted applications. The entity could presume themselves to be renewed for the upcoming year. If September 1 is the first opportunity for CMS to indicate to the plan that CMS will non-renew the contract, it may be almost impossible for a plan or sponsor to make the necessary changes within the short timeframe to be in a position for CMS to approve the contract for the coming year. We strongly believe that communication and notices of an intent to non-renew should occur prior to the September 1st date. In addition, this timeframe may place administrative burdens on MA plans and Part D Sponsors both renewing and non-renewing in completion of required activities for the upcoming contract year or notification to membership of the plan's non-renewal and the member's options. Moving the timeframe to July 1 would benefit both parties and reduce the potential burden on the health plans and Part D Sponsors. However if the plan is truly in jeopardy, providing notice prior the bid process is the better choice.

V. Provide for same administrative appeal rights (Including CAP) for all contract determination (non-renewal, expedited termination, termination) including a change regarding CAP process and the imposition of time limits on Corrective Action Plans

We are requesting that CMS clarify if the timeframes set forth in §422.506(b)(3) and §423.507(b)(3) of the proposed rules are calendar days or business days. The proposed timeframes would be more reasonable if the timeframes are business days.

We are supportive of CMS' efforts to provide more structure around the process for submission and review of CAPs. We agree that plans and sponsors should not have the ability to draw out the process indefinitely. However, we have some concerns around specific provisions of this.

We hope that CMS will continue to leave the lines of communication with plans and sponsors open with respect to working with these entities to develop appropriate and acceptable CAPs. CMS should work with the plans and sponsors in good faith as they develop and implement CAPs. We are dedicated to improving business practices when needed and rely upon a partnership with CMS in crafting plans to do so. We believe a cooperative relationship enhances the end result and benefits everyone. We are concerned about the requirement set forth in §422.506(b)(3) and §423.507(b)(3) that the plan or sponsor will only have one chance to remedy a CAP that CMS has found to be unacceptable. We believe that the organization should be allowed an additional 30 day period to remedy the CAP and resubmit to CMS. After this second opportunity, we agree that CMS is under no obligation to accept further revisions. In absence of this additional 30 day review period, we request that CMS provide some clarification regarding what CMS will define as an acceptable and an unacceptable CAP to ensure that a CAP submitted the first time meets all of CMS' requirements.

VI. Change immediate termination to expedited termination

With respect to adding §423.509(a)(5) as a basis for an expedited termination for MA organizations, we request that CMS provide guidance or examples of what it considers to be imminent and serious risk to enrollees. We believe this would assist both the MA plans and the Part D Sponsors in acting in an expedited and appropriate manner in conjunction with CMS.

VII. Burden of Proof for contract Determinations

We are very concerned about the creation of the requirement at §422.660(b) and §423.650(b) that once CMS determines that a MA organization or a Part D plan is out of compliance that these entities must demonstrate substantial compliance with relevant elements as of the earliest of the following: 1) date the organization or sponsor received written notice of the contract determination; 2) the date of the most recent on-site audit conducted as the basis of the termination; or 3) the date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS. While we understand CMS' desire to create a reference point as a "compliance date" to assist in developing more consistency, the development of this policy of the earliest of one of these three dates creates additional constraints for plans and sponsors in attempting to remedy the concerns. This new requirement effectively removes the plan or sponsor's ability to self-regulate and come into compliance once a potential issue is identified. We understand that having a reference date would allow consistency and provide the hearing officer appropriate, relevant information to arrive at a determination. However, this date must allow contracting entities the opportunity to fix identified concerns. If the date is fixed, for example on the date of the alleged breach, that provides the plan or sponsor practically no opportunity to cure the item and come back into compliance.

VIII. Request for Administrator review, submission of information and timeframe associated with Administrator review

We are encouraged that at §422.692 and §423.666 CMS clarifies that Administrator review is available for all appeals of CMS contract terminations, including decisions not to contract with

an applicant and nonrenewal. However, we do not find acceptable the provision at §422.692(c) and §423.666(c) in which CMS has given the Administrator the opportunity to decline to review. We do not find it acceptable that the Administrator has the option to fail to make a determination. We believe that to make this review carry any meaning or weight, CMS' Administrator must act in every instance to make a determination. Since the consequence of declining to review is that the hearing officer's decision becomes final and binding, CMS should change this provision to reflect that the Administrator either accepts or declines the request for review.

IX. Elimination informal reconsideration process used for review and decision by CMS to impose an intermediate sanction and to allow an MA organization or Part D sponsor to proceed directly to a hearing

We urge CMS to continue the practice of allowing to plans and sponsors the option of the informal reconsideration process in order to allow potential concerns to be worked through in a collaborative, expeditious manner. At §422.646 and §423.643, CMS proposes to eliminate the informal reconsideration process used for review and decision by CMS to impose an intermediate sanction. This appears to be another instance in which CMS is eliminating steps MA plans and Part D Sponsors use to remedy potential concerns prior to formal action. We would like to emphasize our desire to work with CMS to cure any instances of concern prior to a hearing. We find our close and cooperative relationship with CMS to be invaluable in providing the best care to Medicare beneficiaries and for quickly resolving and concerns. Removing a step for informal collaboration with CMS would create a process that may not be in the best interest of the beneficiaries plans serve.

Coventry appreciates the opportunity to comment on these proposed rules. If you have questions or would like additional information, please contact me at (301) 581-5519 or mninos@cvty.com.

Sincerely,

Mary Ninos
Vice President
Medicare Compliance Officer

Submitter : Ms. Mary Ninos **Date:** 07/24/2007

Organization : Coventry Health Care, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-51-Attach-1.DOC

#51

COVENTRY
Health Care

June 24, 2007

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

Attention: CMS 4124-P

Dear Sir or Madam:

I am writing on behalf of Coventry Health Care, Inc. (Coventry) to comment on the Centers for Medicare & Medicaid Services' (CMS) May 25, 2007 proposed rule: *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes* (CMS-4124-P).

Coventry is a diversified national managed healthcare company based in Bethesda, Maryland, operating health plans, insurance companies, network rental and workers' compensation services companies. Through its Commercial Business, Individual Consumer & Government Business, and Specialty Business Divisions, Coventry provides a full range of risk and fee-based managed care products and services to a broad cross section of individuals, employer and government-funded groups, government agencies, and other insurance carriers and administrators. Coventry participates in the Medicare program as a Medicare Part D Prescription Drug Benefit (Part D) program, Medicare Advantage (MA) plans, a stand-alone prescription drug plan (PDP), and a Medicare Advantage-Prescription Drug (MA-PD) plan.

We would like to thank you for the opportunity to provide comments on these proposed changes to the MA and Medicare Part D program. Coventry has identified several proposed changes that we believe either need further clarification or should be eliminated. These are discussed in detail in our comments below.

Specific Comments on *Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes* (CMS-4124-P)

I. Requirement to apply Compliance Plan's training and communication requirements to first tier, downstream and related entities

We believe it is impracticable, unreasonable and cumbersome to both MA plans and providers to impose the requirement to apply the Compliance Plan's training and communication requirements at §422.503(b)(4)(vi) on health care providers. We fully agree that it is appropriate

in the context of an MA Plan or any entity (related entity or not) providing management or administrative services on behalf of an MA Plan because the administrative and/or management services the subcontractor provides more than likely are unique to that MA Plan so there is a need for training and education on that MA Plan's programs, requirements, etc. In addition, the subcontractor may or may not be familiar with the Medicare Advantage requirements, so the experience level of such subcontractors may vary as to their understanding of the Medicare Advantage program and applicable laws and regulations.

HOWEVER, with respect to health care providers, we don't believe this is true. It has been our experience that health care providers are quite familiar with the Medicare Advantage plan and the obligations applicable to contracting with such a plan. This is based on the providers' long standing experience with traditional Medicare and Medicare Advantage Plans.

Furthermore, health care providers contract with many Medicare Advantage Plans. As a result, health care providers will be inundated with training and education materials from all of the MA Plans if this rule is implemented as written. We believe this would result in quite the opposite of the intended effect. Providers will receive so much training and education materials that they will look at none of it rather than trying to read the tomes of information. We believe a more practical approach would be for CMS, working with the industry, to come up with a standard training and communication plan applicable to all providers and make it available on the web. That way the providers receive one comprehensive training and communication package that has been approved by CMS, and can focus on and review that one package. Thus, the providers and MA Plans can be assured that the provider has received and reviewed the necessary training and communication materials.

Ref Section: §422.504(b)(4)(vi)(B) It is also important to note that just as CMS allows a corporate entity to develop one Corporate Compliance Plan, the Compliance Structure should be determined based on the organizational structure for MCOs with multiple Health Plans.

II. Mandatory self-reporting of potential fraud or misconduct requirement for MA organizations and Part D Sponsors.

We are gravely concerned with CMS' proposal at §422.503(b)(4)(vi)(G)(3) and §423.504(b)(4)(vi)(G)(3) to reinstitute the prior requirement of mandatory self-reporting of possible fraud and/or misconduct for MA organizations and to make the self-reporting provision that applies to Part D Sponsors mandatory. We understand CMS' desire to have instances of fraud and misconduct reported to them in a timely manner. However, as it stands, CMS returns to a policy which unfairly subjects MA and Part D organizations to a self-reporting requirement that does not apply to other sectors of the health care industry. This would impose a self-reporting requirement on MA and Part D organizations which does not exist on other types of health care providers and suppliers participating in the Medicare program.

We understand CMS' concern that the government should have information on possible fraud or misconduct in order to determine appropriate action. However, CMS' process as reflected in

the proposed rule inappropriately responds to these concerns. We believe that CMS should work with the industry to develop another manner in which MA organizations and Part D Sponsors could provide this information effectively. Through this partnership, CMS and the industry could craft a viable, well thought out reporting mechanism which meets the needs of both government and business. We believe that by working together, a better process could be developed which both meets CMS' needs and prevents plans to a different standard than other Medicare providers.

Additionally, as currently crafted, the requirement is too vague to provide useful information and results. If this unfair provision requiring self-incrimination is maintained, CMS should clarify exactly what information must be reported as well as to which agency plans should report which of the various potential instances of fraud and/or misconduct. We are also concerned that CMS has provided no information as to what point a plan should report such an instance. For example, does CMS expect the plan to report immediately upon receipt of an unsubstantiated allegation of fraud without any time for the plan to investigate the allegation? Or, would CMS expect that the plan have time to perform an initial investigation to ascertain whether the allegation has any merit? Without allowing a plan the time to conduct an internal investigation to validate that there may in fact be a possible instance of fraud, plans may report to federal agencies a series of unsubstantiated fraud allegations with no accompanying investigative information to assist the federal agency in reviewing or responding to such allegations. This does not allow the plan to develop and maintain controls. The lack of clarity in the requirement leaves too much room for inconsistency in reporting and action across plans.

III. Requirement to obtain access to Part D sponsor's first tier, downstream and related entity's books and records through contractual arrangements

We understand and appreciate CMS' need to oversee Part D Sponsor's operations and therefore agree with most of the provisions/clarifications set forth in the proposed regulation. However, the requirement at proposed §423.505(i)(3)(iv) that a Part D Sponsor and first tier entity have to identify in their contract whether records will be provided directly to CMS or through the Part D Sponsor appears to be unnecessary and inefficient.

Depending on the nature of the records requested, volume of records requested, location of the records requested and time frame within which such records are needed, the decision as to how the records will be provided will significantly vary. Therefore, we believe it would be appropriate to let the parties determine how the records will be provided at the time of the request. As pointed out in the proposed regulation, it is already a contractual requirement between and Part D Sponsor and its subcontractors that the subcontractor make the records available. The how, where and when of that should be left to be determined between the Part D Sponsor and the subcontractor at the time of the request, to allow for flexibility with respect to the nature of the request.

As pointed out in the proposed regulations, "any failure or omission by a first tier, downstream or related entity to provide information requested by [CMS], or to allow HHS access to its books and records relating to payment, would constitute a violation by the MA organization or Part D

plan sponsor of its contract with [CMS] and a violation of the MA and Part D regulations." Such a threat provides more than sufficient motivation for MA Plans and their subcontractors to resolve any issues about access quickly.

Furthermore, if this section were implemented as drafted, for the reasons set forth above, we do not believe the contract would have the specificity CMS desires with respect to access to records. That is, Part D Sponsor and subcontractors would not want to lock themselves in to how and when the records will be produced, because it will depend on the nature of the records requested, volume and place to be produced. So the language will probably be vague at best.

IV. Change date of CMS' notification of non-renewal from May 1 to September 1

We are requesting clarification around CMS' proposed revisions of the process to notify an MA or Part D plan of CMS' intent to non-renew. At §422.506(b)(2)(i) and §423.507(b)(2)(i), CMS' proposed change includes delaying the time period the MA plans and Part D Sponsors are notified of the intent to non-renew for the upcoming year from the May 1 to September 1 of the current year. We are concerned that no notification would be made to the plan or sponsor prior to September 1 of CMS' intent to non-renew.

We understand the change of the this process would benefit CMS as outlined in the proposed rule. However, the benefit to the health plans and Part D Sponsors is less obvious. CMS has provided little detail to explain if the September 1st timeframe is the final date of the notice or is inclusive of timeframe for health plans or sponsors to cure any identified deficiencies in our submitted applications. The entity could presume themselves to be renewed for the upcoming year. If September 1 is the first opportunity for CMS to indicate to the plan that CMS will non-renew the contract, it may be almost impossible for a plan or sponsor to make the necessary changes within the short timeframe to be in a position for CMS to approve the contract for the coming year. We strongly believe that communication and notices of an intent to non-renew should occur prior to the September 1st date. In addition, this timeframe may place administrative burdens on MA plans and Part D Sponsors both renewing and non-renewing in completion of required activities for the upcoming contract year or notification to membership of the plan's non-renewal and the member's options. Moving the timeframe to July 1 would benefit both parties and reduce the potential burden on the health plans and Part D Sponsors. However if the plan is truly in jeopardy, providing notice prior the bid process is the better choice.

V. Provide for same administrative appeal rights (Including CAP) for all contract determination (non-renewal, expedited termination, termination) including a change regarding CAP process and the imposition of time limits on Corrective Action Plans

We are requesting that CMS clarify if the timeframes set forth in §422.506(b)(3) and §423.507(b)(3) of the proposed rules are calendar days or business days. The proposed timeframes would be more reasonable if the timeframes are business days.

We are supportive of CMS' efforts to provide more structure around the process for submission and review of CAPs. We agree that plans and sponsors should not have the ability to draw out the process indefinitely. However, we have some concerns around specific provisions of this.

We hope that CMS will continue to leave the lines of communication with plans and sponsors open with respect to working with these entities to develop appropriate and acceptable CAPs. CMS should work with the plans and sponsors in good faith as they develop and implement CAPs. We are dedicated to improving business practices when needed and rely upon a partnership with CMS in crafting plans to do so. We believe a cooperative relationship enhances the end result and benefits everyone. We are concerned about the requirement set forth in §422.506(b)(3) and §423.507(b)(3) that the plan or sponsor will only have one chance to remedy a CAP that CMS has found to be unacceptable. We believe that the organization should be allowed an additional 30 day period to remedy the CAP and resubmit to CMS. After this second opportunity, we agree that CMS is under no obligation to accept further revisions. In absence of this additional 30 day review period, we request that CMS provide some clarification regarding what CMS will define as an acceptable and an unacceptable CAP to ensure that a CAP submitted the first time meets all of CMS' requirements.

VI. Change immediate termination to expedited termination

With respect to adding §423.509(a)(5) as a basis for an expedited termination for MA organizations, we request that CMS provide guidance or examples of what it considers to be imminent and serious risk to enrollees. We believe this would assist both the MA plans and the Part D Sponsors in acting in an expedited and appropriate manner in conjunction with CMS.

VII. Burden of Proof for contract Determinations

We are very concerned about the creation of the requirement at §422.660(b) and §423.650(b) that once CMS determines that a MA organization or a Part D plan is out of compliance that these entities must demonstrate substantial compliance with relevant elements as of the earliest of the following: 1) date the organization or sponsor received written notice of the contract determination; 2) the date of the most recent on-site audit conducted as the basis of the termination; or 3) the date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS. While we understand CMS' desire to create a reference point as a "compliance date" to assist in developing more consistency, the development of this policy of the earliest of one of these three dates creates additional constraints for plans and sponsors in attempting to remedy the concerns. This new requirement effectively removes the plan or sponsor's ability to self-regulate and come into compliance once a potential issue is identified. We understand that having a reference date would allow consistency and provide the hearing officer appropriate, relevant information to arrive at a determination. However, this date must allow contracting entities the opportunity to fix identified concerns. If the date is fixed, for example on the date of the alleged breach, that provides the plan or sponsor practically no opportunity to cure the item and come back into compliance.

VIII. Request for Administrator review, submission of information and timeframe associated with Administrator review

We are encouraged that at §422.692 and §423.666 CMS clarifies that Administrator review is available for all appeals of CMS contract terminations, including decisions not to contract with an applicant and nonrenewal. However, we do not find acceptable the provision at §422.692(c) and §423.666(c) in which CMS has given the Administrator the opportunity to decline to review. We do not find it acceptable that the Administrator has the option to fail to make a determination. We believe that to make this review carry any meaning or weight, CMS' Administrator must act in every instance to make a determination. Since the consequence of declining to review is that the hearing officer's decision becomes final and binding, CMS should change this provision to reflect that the Administrator either accepts or declines the request for review.

IX. Elimination informal reconsideration process used for review and decision by CMS to impose an intermediate sanction and to allow an MA organization or Part D sponsor to proceed directly to a hearing

We urge CMS to continue the practice of allowing to plans and sponsors the option of the informal reconsideration process in order to allow potential concerns to be worked through in a collaborative, expeditious manner. At §422.646 and §423.643, CMS proposes to eliminate the informal reconsideration process used for review and decision by CMS to impose an intermediate sanction. This appears to be another instance in which CMS is eliminating steps MA plans and Part D Sponsors use to remedy potential concerns prior to formal action. We would like to emphasize our desire to work with CMS to cure any instances of concern prior to a hearing. We find our close and cooperative relationship with CMS to be invaluable in providing the best care to Medicare beneficiaries and for quickly resolving and concerns. Removing a step for informal collaboration with CMS would create a process that may not be in the best interest of the beneficiaries plans serve.

Coventry appreciates the opportunity to comment on these proposed rules. If you have questions or would like additional information, please contact me at (301) 581-5519 or mninos@cvty.com.

Sincerely,

Mary Ninos
Vice President
Medicare Compliance Officer
Coventry Health Care Inc.

Submitter : **Mr. Dale Tinker** **Date: 07/24/2007**

Organization : **New Mexico Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-52-Attach-1.DOC

#52

New Mexico Pharmacists Association

2716 San Pedro NE Suite C
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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

On behalf of the New Mexico Pharmacists Association (NMPhA), the association representing pharmacy and pharmacists in New Mexico, we appreciate the opportunity to submit 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.

NMPHA 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 NMPHA 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. NMPHA 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, NMPHA is enthusiastically supportive of the CMS proposed regulations. NMPHA 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, NMPHA 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 NMPHA 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, NMPHA 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. NMPHA looks forward to receiving from CMS best practice guidance for training. Furthermore, NMPHA 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, NMPHA 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. NMPHA 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.

NMPHA 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, NMPHA 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

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reliance on federal guidance, NMPHA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

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

If you have any questions or need any additional information, please do not hesitate to contact Dale Tinker, Executive Director and Chief Executive Officer NMPhA, at (505) 265-8729 or via email at daletinker@cs.com.

Sincerely,

R. Dale Tinker
Executive Director

#53

CMS-4124-P

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

Submitter : Nicole Schultz **Date:** 07/24/2007

Organization : Iowa Pharmacy Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#54

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

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

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

Submitter : Mr. Dale Tinker **Date:** 07/24/2007

Organization : New Mexico Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Previous comments were submitted with incorrect CMS address.
See Attachment - corrected address.

CMS-4124-P-55-Attach-1.DOC

#55

New Mexico Pharmacists Association

2716 San Pedro NE Suite C
Albuquerque, NM 87110

(505) 265-8729 FAX (505) 255-8476 1-800-464-8729 (NM only)
Homepage: www.nm-pharmacy.com Email: nmpha-admin@qwest.com

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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Conclusion

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

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Sincerely,

R. Dale Tinker

R. Dale Tinker
Executive Director

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

Organization : Missouri Pharmacy Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4124-P-56-Attach-1.DOC

#56

MPA
MISSOURI PHARMACY ASSOCIATION

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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, 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.

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) (proposed May 25, 2007 – to be codified at 42 C.F.R. § 422, § 423) 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 MPA 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, 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.

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) (proposed May 25, 2007 – to be codified at 42 C.F.R. § 422, § 343) 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.

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

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