Submitter : Mrs. Patricia Epple **Date:** 07/24/2007

Organization : Pennsylvania Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4124-P-32-Attach-1.DOC

CMS-4124-P-32-Attach-2.DOC

#32

508 North Third Street . Harrisburg, PA 17101-1199
phone: 717-234-6151 fax: 717-236-1618 website: www.PApharmacists.com

July 24, 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 Pennsylvania Pharmacists Association (PPA), 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.

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

PPA 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, PPA 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, PPA 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 our association at (717) 234-6151 or via email at pepple@papharmacists/.com.

Sincerely,

Patricia A. Epple, CAE
Executive Director

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

Organization : Indiana Pharmacists Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#33

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. Marc Steinberg **Date:** 07/24/2007

Organization : Families USA

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-34-Attach-1.DOC

#34

USA
The Voice for Health Care Consumers

July 24, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4124-P
P.O. Box 8014
Baltimore, Maryland 21244-8012

Via Electronic Submission

Re: File Code CMS-4124-P

To Whom It May Concern:

Families USA is pleased to submit these comments on the proposed regulations published in the Federal Register May 25, 2007, under the title Medicare Program: Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes. Families USA is the national, non-profit, non-partisan organization for health care consumers. Our mission is to ensure that all Americans have access to high-quality, affordable health care. Families USA strongly supports comprehensive, affordable health insurance for all residents of this nation.

Definitions (Secs. 422.2 and 423.4)

We believe that the new definitions of first tier entities and downstream entities are helpful clarifications. We hope CMS will take advantage of these new definitions to strengthen enforcement of beneficiary protections. "Downstream entities" have been responsible for serious abuse of beneficiaries, while the MA and Part D sponsors have been unwilling to accept responsibility.

Mandatory Self Reporting (Secs. 422.503 and 432.504)

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

We believe, however, that mandatory self-reporting should extend beyond instances of potential fraud and abuse and include reporting of non-fraudulent acts or omissions that

1201 New York Ave., NW, Suite 1100 ■ Washington, DC 20005 ■ 202-628-3030 ■ Fax 202-347-2417
E-Mail: info@familiesusa.org ■ Web site: www.familiesusa.org

have the potential to significantly affect beneficiaries. If, for example, a computer error results in thousands of enrollees being denied coverage at the pharmacy, the plan discovering the error should be required to report it to CMS so that the agency and advocates can field beneficiary calls and pharmacies can be notified. If plans do not self-report, the potential for misinformation is significant. More importantly, beneficiary access to necessary medications can be further jeopardized.

Contract Provisions (Secs. 422.504 and 423.505)

We appreciate that CMS is making it clear in Sections 422.504 and 423.505 that plan sponsors are ultimately responsible for contract violations of first tier entities, downstream entities and related entities, regardless of the nature of the relationship of the sponsor to those entities. We urge CMS to take aggressive action against irresponsible actors, regardless of their position in hierarchy of MA and Part D entities.

We also support the proposed subsection (2)(i) in this section that makes downstream entities subject to the same audit requirements as MA and Part D organizations.

Nonrenewal of a Contract (Secs. 422.506 and 423.507)

We support the proposal to limit a MA plan's or Part D sponsor's ("plans") ability to submit corrective action plans after a notice of nonrenewal or termination. Plans should not be able to extend their contracts by repeated submission of CAPs, especially when their performance has been inadequate and potentially harmful to beneficiaries.

Thank you for the opportunity to submit these comments. If you have questions, please do not hesitate to contact Marc Steinberg at (202) 628-3030 or msteinberg@familiesusa.org.

Very truly yours,
/s/
Marc Steinberg
Deputy Director, Health Policy

Submitter : Mrs. Patricia Epple **Date:** 07/24/2007

Organization : Pennsylvania Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached letter

CMS-4124-P-35-Attach-1.DOC

#35

508 North Third Street . Harrisburg, PA 17101-1199
phone: 717-234-6151 fax: 717-236-1618 website: www.PApharmacists.com

July 24, 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 Pennsylvania Pharmacists Association (PPA), 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.

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(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.

PPA 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, PPA 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, PPA 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 our association at (717) 234-6151 or via email at pepple@papharmacists/.com.

Sincerely,

Patricia A. Epple, CAE
Executive Director

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

Organization : NC Association of Pharmacists

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

#36

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 : Ms. Mary Ann Wagner **Date:** 07/24/2007

Organization : National Association of Chain Drug Stores

Category : Pharmacist

Issue Areas/Comments

Background

Background

The National Association of Chain Drug Stores (NACDS) has reviewed the above-referenced regulations and we are concerned that the rules and the preamble discussion preceding them appear to expand unduly the parameters for agency and Part D plan and MA-PD organization access to network provider records. This is apparently being done without the addition of formal regulatory language specifying CMS authority to do so and putting providers on notice of the expansion of authority. We must protest these expanded record-inspection requirements and the expanded access to the records seemingly being granted to Part D sponsors and MA-PD organizations.

We are also troubled by the new requirement 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. There's no evidence that mandatory training is needed for pharmacies or that the voluntary training recommendation of the Medicare Fraud Waste and Abuse Guidance has failed to work, and we believe that any new training mandate will raise pharmacies' costs of participating in Medicare Part D and thus ultimately raise drug costs.

Finally, the changes to the Part D sponsor contract renewal procedures will effectively truncate the period pharmacy providers have to consider joining a Part D sponsor s network. We ask that there be some contingent renewal notice authorized that Part D sponsors can send to network providers alerting the providers of the sponsors continued participation in Part D in the following year.

GENERAL

GENERAL

See Attachment

CMS-4124-P-37-Attach-1.PDF

CMS-4124-P-37-Attach-2.PDF

#37

July 24, 2007

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

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

The National Association of Chain Drug Stores (NACDS) has reviewed the above-referenced regulations and we are concerned that the rules and the preamble discussion preceding them appear to expand unduly the parameters for agency and Part D plan and MA-PD organization access to network provider records. This is apparently being done without the addition of formal regulatory language specifying CMS' authority to do so and putting providers on notice of the expansion of authority. We must protest these expanded record-inspection requirements and the expanded access to the records seemingly being granted to Part D sponsors and MA-PD organizations.

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Finally, the changes to the Part D sponsor contract renewal procedures will effectively truncate the period pharmacy providers have to consider joining a Part D sponsor's network. We ask that there be some contingent renewal notice authorized that Part D sponsors can send to network providers alerting the providers of the sponsors' continued participation in Part D in the following year.

NACDS represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 38,000 pharmacies, employ 114,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly $700 billion. They are the primary providers of Medicare prescriptions.

Expansion of Parameters for Agency Record Searches

As noted above, the preamble to the rules appears to expand, effective January 1, 2009, the parameters for agency record inspections and searches without CMS formally adding language that explicitly does so. This is troublesome, given that the rules also make the Part D sponsor or MA-PD organization legally liable for provider compliance with recordkeeping requirements and agency search compliance. While the revised rules do not require that providers offer their records for inspection by the Part D sponsor or MA-PD organization, the preamble states that the contracting parties are to assign responsibilities for submitting required information to CMS during contract negotiations. This appears to permit access by Part D plan sponsors and MA-PD organizations to all kinds of provider information, including proprietary information regarding price concessions by manufacturers or wholesalers to pharmacy providers and agreements with providers of on-site clinical and medical services.

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

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

While it is clearly justifiable and statutorily authorized under federal law for CMS to seek information on rebates granted PBMs by manufacturers, or even to seek information regarding pharmacy discounts and free goods offered to beneficiaries or Medicaid programs that might be construed as unlawful kickbacks, it is unclear by what authority CMS can seek information on discounts, chargebacks, or in-kind goods granted to pharmacy providers by manufacturers or wholesalers dispensed under Medicare. If the agency's recordkeeping and inspection authority is to be expanded to cover this type of information, it should be expressly stated in formal regulation adopted through the formal regulatory adoption process.

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

The Part D sponsor or MA-PD organization retains the ultimate responsibility for recordkeeping and inspection compliance by downstream entities such as pharmacy network providers. At the same time, while CMS emphasizes in the preamble that downstream entities are not required by this contract

provision to produce their books and records directly to the Part D sponsor, it states that the contracting parties may determine during their contract negotiations the process for submitting the requested information to CMS or its designees.

There is an inherent unequal bargaining power in the contractual relationship between network providers and Part D sponsors or MA-PD organizations. A potential network pharmacy would find it difficult to resist a Part D sponsor's or MA-PD organization's insistence on the right to inspect, for purposes of delivery to CMS or compliance with CMS-mandated contract provisions, all of a pharmacy provider's records. This is particularly troublesome given the unwritten expansion of the parameters for records inspection that CMS asserts in the preamble but omits from the regulation and leaves open to further informal and apparently unlimited expansion. In granting itself unlimited power to inspect a provider's records, CMS grants Part D plan sponsors and MA organizations the same unlimited authority by delegation. This poses a real threat to proprietary agreements between pharmacy providers and the other entities with which they do business, including wholesalers, manufacturers, and contract providers of clinical, medical, and medication therapy management services.

For these reasons, NACDS urges that the final version of these revised regulations strictly limit the authority of a Part D sponsor or MA-PD organization to a physical delivery of the records to CMS. Part D sponsors and MA-PD organizations should be expressly prohibited from physically inspecting any records submitted for delivery to CMS.

Unnecessary Mandatory Fraud and Abuse Training of All Employees of Downstream Entities by MA-PDs and Part D Sponsors Would Prove Administratively Burdensome and Costly

The new requirement proposed under 42 CFR 422.503 and 434.504 that Part D sponsors and MA-PD organizations train the employees of downstream entities such as pharmacy employees in detecting, correcting, and preventing fraud, waste, and abuse concerns us greatly..There's no evidence that mandatory training is needed for pharmacies or that the voluntary training recommendation of the Medicare Fraud Waste and Abuse Guidance has failed to work. A new training mandate is likely to raise pharmacies' costs of participating in Medicare Part D and thus could ultimately raise drug costs.

If CMS does insist on mandating training of downstream entities such as pharmacies, it should limit training only to pharmacists and at most those employees who submit claims. Pharmacy technicians, cashiers, and retail store clerks should not be forced to undergo training. Further, there must be some sort of uniformity in training, so that 100 different Part D plans and MA-PD organizations and not mandating 100 different training programs for the network pharmacies that serve each of their members. 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 would only serve to further exacerbate that labor shortage.

Changes to Contract Renewal Procedures Will Reduce Pharmacy Network Provider Notice

Finally, one other area of the proposed revised regulations that would 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 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.

NACDS fears that this later notification regarding plan contract non-renewal will require pharmacies to scramble even more than in the past 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.

Conclusions

Again, NACDS asks that revised Parts 422 and 423 be further revised in the published final versions to: (1) clearly delimit CMS' authority to inspect the records of pharmacy network providers and other downstream entities; (2) limit Part D sponsors' and MA-PD organizations' delegated authority with regard to records inspections of downstream entities to the delivery of those records to CMS; (3) require only employees of downstream entities / pharmacy providers who actually submit Medicare claims to undergo required training in the detection, prevention, and correction of fraud and abuse; and (4) standardize the mandated training so that a pharmacy's employees are not required to undergo multiple and possibly conflicting training programs given by each of the Part D plans and MA-PD organizations for which the pharmacy acts as a network provider.

We also ask that the final regulations provide for a contingent renewal notice that Part D sponsors and MA-PD organizations can send to network providers of their apparent continued participation in Medicare in the following year.

Thank you for the opportunity to comment on these regulations.

Sincerely,

Mary Ann Wagner
Senior Vice President
Policy and Pharmacy Regulatory Affairs

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

Organization : Texas Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-4124-P-38-Attach-1.DOC

#38

TEXAS PHARMACY ASSOCIATION

Serving Texas Pharmacy Since 1879

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 Texas Pharmacy Association and the approximately 20,000 pharmacists in Texas, we concur with the National Alliance of State Pharmacy Associations (NASPA), the national organization representing all fifty state pharmacy associations. We appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed regulations and revisions to Medicare Advantage (MA) and Part D prescription drug contract determinations and addressing appeals and intermediate sanctions processes dated May 25, 2007.

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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

1621 East Anderson Lane, Austin, Texas 78752-1806 • P.O. Box 14709, Austin, Texas 78761-4709
(512) 836-8350 • (800) 505-5463 • Fax (512) 836-0308 • www.texaspharmacy.org

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

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

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.

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

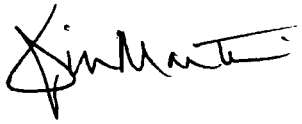
Conclusion

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

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

If you have any questions or need any additional information, please do not hesitate to contact me at (512) 836-8350 ext 131 or via email at jmartin@texaspharmacy.org.

Sincerely,



Jim Martin, R.P.h.
Executive Director/CEO

1624 East Anderson Lane, Austin, Texas 78752-1806 • P.O. Box 14709, Austin, Texas 78761-4709
(512) 836-8350 • (800) 505-5463 • Fax (512) 836-0308 • www.texaspharmacy.org

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-39-Attach-1.DOC

#39

Tennessee Pharmacists Association

500 Church Street, Suite 650 Nashville, Tennessee 37219
Phone: 615/256.3023 Fax: 615/255.3528
tpa@tnpharm.org www.tnpharm.org

July 31, 2007

Centers for Medicare and Medicaid 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 pharmacists in all practice settings in Tennessee and the patients they serve, the Tennessee Pharmacists Association (TPA) appreciates 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.

TPA 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 TPA 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. TPA 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, TPA is enthusiastically supportive of the CMS proposed regulations. TPA 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, TPA 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 TPA 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, TPA 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. TPA looks forward to receiving from CMS best practice guidance for training. Furthermore, TPA 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, TPA 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. TPA requests that CMS enforce that these plan-to-plan reconciliations are completed between the plans and not involve pharmacy point-of-sale transactions.

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

TPA 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, TPA 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, TPA 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 Baeteena M. Black, D.Ph., Executive Director, TPA, at (615)256-3023 or via email at bblack@tnpharm.org.

Sincerely,

Baeteena M Black

Baeteena M. Black, D.Ph.
Executive Director
Tennessee Pharmacists Association

Submitter : **Thaddeus Bereday** **Date: 07/24/2007**

Organization : **WellCare Health Plans**

Category : **Health Plan or Association**

Issue Areas/Comments

Background

Background

See Attachment.

GENERAL

GENERAL

See Attachment.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment.

CMS-4124-P-40-Attach-1.PDF

#40

Thaddeus Bereday
Senior Vice President and General Counsel

WellCare Health Plans, Inc.
The WellCare Group of Companies

WELLCARE OF FLORIDA, INC.

HEALTHEASE OF FLORIDA, INC.

WELLCARE OF NEW YORK, INC.

WELLCARE OF CONNECTICUT, INC.

HARMONY BEHAVIORAL HEALTH, INC.

WELLCARE OF [illegible], INC.

WELLCARE OF [illegible], INC.

WELLCARE OF OHIO, INC.

COMPREHENSIVE HEALTH MANAGEMENT, INC.

HARMONY HEALTH SYSTEMS, INC.

HARMONY HEALTH PLAN OF ILLINOIS, INC.

WELLCARE PRESCRIPTION INSURANCE, INC.

WELLCARE HEALTH INSURANCE OF ILLINOIS, INC.

WELLCARE HEALTH INSURANCE OF ARIZONA, INC.

WELLCARE HEALTH INSURANCE OF NEW YORK, INC.

8735 Henderson Road
Tampa, Florida 33634
Telephone: 813.290.6253

July 24, 2007

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

Attention: CMS-4124-P

Dear Sir or Madam:

As a leading health plan dedicated to ensuring quality, cost-effective health care for families, children, and individuals, including the Medicare population, WellCare appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule, "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes" (72 Fed. Reg. 29367, May 25, 2007). WellCare is headquartered in Tampa, Florida and operates Medicare Advantage (MA) programs in 40 states plus the District of Columbia and Part D Prescription Drug plans nationwide. Founded in 1985, our team of more than 3,000 associates, over 25,000 physician partners and 60,000+ pharmacies serve over 2.2 million members across the country. WellCare supports CMS in its efforts to ensure that adequate programmatic safeguards are in place to protect the Medicare program and its beneficiaries. Our comments are geared toward a pragmatic balancing of these program integrity efforts with beneficiary interest in maintaining a robust set of Part D plan choices, and Part D/MA sponsor interests in ensuring that internal and external functions, relationships, and communications can be structured to mitigate potential risk.

❖ **Proposed Changes to Sections 422.503 and 423.504 -- General Provisions.**

- CMS proposes to clarify that a MA organization or Part D sponsor compliance plan contain training, education, and effective lines of communication between the compliance officer and the organization's or sponsor's employees, as well as its first tier, downstream, and related entities. WellCare urges CMS to provide MA organizations and Part D sponsors with a more detailed explanation of this requirement. For example, it is not clear whether the organization or

sponsor may simply require the first tier and downstream entities to have a compliance plan, or if the organization or sponsor must require the first tier and downstream entities adopt the compliance program of the organization or sponsor. One consequence of requiring each organization and sponsor to impose its training and education programs on each first tier and downstream entity is that the first tier and downstream entities, particularly those that contract with multiple organizations and/or sponsors, may be overburdened with educational and training requirements from these multiple organizations and sponsors. Similarly, an MA organization or Part D sponsor should be able to rely upon a provision in its contracts with first tier and downstream entities to enforce the education and training compliance requirements. Organizations or sponsors should not be required to proactively monitor first tier and downstream entities compliance programs. Given CMS' stated intent that the Proposed Rule permit MA organizations and Part D sponsors to operate efficiently, WellCare urges CMS to provide clear guidance on efficient adherence to these compliance requirements in light of the likely burden on first tier and downstream entities contracting with multiple organizations and sponsors.

- In Preamble to this Proposed Rule, CMS acknowledged the difficulties associated with obtaining Part D related information from PBMs. WellCare supports CMS in its general efforts to ensure that any information needed to ensure appropriate Part D payment is available to the Agency for review. We do not, however, agree that simply imposing sanctions on the MA organization or Part D sponsor, or clarifying that the information can be submitted directly to CMS, would provide CMS with greater access to documents from first tier and downstream entities. Contracts between sponsors and these entities currently contain provisions requiring CMS access to requested information and, as indicated in the Preamble, CMS has not always been able to gain access to information below the sponsor level. We suggest that CMS permit sponsors to avoid imposition of penalties by terminating their contractual relationship with a non-complying first tier or downstream entity. This approach would place some of the burden of noncompliance on the entity that fails to provide information rather than solely on the plan sponsor, and would further Medicare beneficiary interests in drug coverage stability.

- WellCare agrees in principal with the proposed addition of a self-reporting requirement for MA organizations and Part D sponsors. We are concerned, however, that the requirement to report "potential" fraud and abuse or "misconduct" to the "appropriate" government authority is vague and does not lend itself to uniform interpretation or

implementation among these entities. Each actual instance of fraud, abuse, or misconduct has a point in time at which it could be characterized as "potential," even prior to management knowledge of the underlying circumstances. Similarly, the term "misconduct" is sufficiently broad to encompass everything from a single incident of personal use of a telephone or copy machine, or inappropriate language through clear violations of law related to administration of the Part D benefit. Finally, the phrase "appropriate government authority" should be clarified. The original Part C proposal discussed in the Preamble to this Proposed Rule required organizations to report to CMS and/or the OIG upon discovery of credible information of violation(s) of law. WellCare suggests that CMS develop regulatory language that clearly outlines the triggers for self-reporting as well as the government authority that must be apprised of information on particular violations of law.

- **Right to a Hearing and Burden of Proof.** WellCare does not share CMS' opinion that a Departmental Appeals Board determination placing the burden of proving program compliance on a rehabilitation center provides sufficient authority for establishing a regulatory shift of the burden of proving program compliance on an MA organization or Part D plan sponsor. Section 1857(h) of the Social Security Act provides MA organizations and Part D sponsors with a right to a hearing and does not authorize HHS or CMS to place the burden of compliance onto the appealing entity. The organizational structure, programmatic requirements, and contractual relationships inherent in the MA and Part D programs clearly differentiate an MA organization or Part D sponsor from the rehabilitation center that was the subject of the cited case authority for shifting the burden of proof. WellCare expects that implementing this regulatory text as proposed would simply move resolution of disputes into the courts and result in greater costs for both the Medicare program and the entity initiating the appeal. Moreover, it is not clear whether CMS intends that an organization or sponsor simply address the deficiencies or other issues triggering a nonrenewal or termination decision or that it produce evidence that it is in compliance with each MA or Part D requirement.

  - **Appeal Procedures for Civil Money Penalties.** CMS expressed its interest in achieving consistency between appeals processes for termination and/or nonrenewal and imposition of civil money penalties (CMPs). Specifically, CMS proposes to place the burden of persuasion in a CMP appeal by an MA organization or Part D sponsor onto that entity. In Preamble to the Proposed Rule, CMS asserts that this decision was "[b]ased on certain statutory requirements and policy considerations." WellCare urges CMS to reconsider this decision.

WellCare appreciates CMS' consideration of its comments, and welcomes the opportunity to answer any questions or provide additional information to assist the Agency in finalizing this rule. You may reach me by telephone at (813) 290-6353, or by email: [redacted].

Very truly yours,

Thaddeus Bereday
Senior Vice President and General Counsel

Submitter : Mr. Richard Stevens **Date:** 07/24/2007

Organization : West Virginia Pharmacists Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-41-Attach-1.DOC

#41

NASPA

NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

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

West Virginia Pharmacists Association
2016 ½ Kanawha Blvd, East
Charleston, WV 25311
Tel: 3043-344-5302

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 WEST VIRGINIA PHARMACISTS ASSOCIAITON (WVPA), a statewide organization representing pharmacists and pharmacies, 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.

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

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

If you have any questions or need any additional information, please do not hesitate to contact me.

Sincerely,

Richard D. Stevens

Richard D. Stevens
Executive Director
West Virginia Pharmacists Association

Submitter : Mr. Carmelo Cinqueonce **Date:** 07/24/2007

Organization : South Carolina Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4124-P-42-Attach-1.DOC

#42

South Carolina Pharmacy Association
1350 Browning Road Columbia, SC 29210-6903
phone: (803) 354-9977 fax: (803) 354-9207 www.scrx.org

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 South Carolina Pharmacy Association (SCPhA) 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.

SCPhA 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 SCPhA has expressed concern that PBM and mail order pharmacies (i) have contractual arrangements in many states that are not transparent in the healthcare system, and (ii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade. SCPhA continues to support CMS efforts to increase transparency in the health care system.

In large part, given the reasons above, SCPhA is supportive of the CMS proposed regulations. SCPhA 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 greater impact on the overall marketplace and thus, the practice of pharmacy. Furthermore, SCPhA believes that this clear delineation can lead to greater transparency with regard to drug pricing.

Below are more substantive comments 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 SCPhA concern. 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.

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Conclusion

In summary, SCPhA 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, SCPhA 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 at (803) 354-9977 or via email at ccinque@scrx.org.

Sincerely,

Carmelo Cinqueonce, MBA
Executive Vice President
South Carolina Pharmacy Association

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

Organization : Florida Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4124-P-43-Attach-1.DOC

#43

Florida Pharmacy Association

Supporting Florida Pharmacy Since 1887

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 Florida Pharmacy Association (FPA), the state organization representing Florida 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.

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

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

The Florida Pharmacy Association (FPA) 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. FPA was founded in 1887 in Florida.

If you have any questions or need any additional information, please do not hesitate to contact Michael Jackson, R.Ph., Executive Vice President and Chief Executive Officer FPA, at (850) 222-2400 or via email at mjackson@pharmview.com.

Sincerely,

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