Submitter : **Ms. Lisa Goldman** **Date: 07/24/2007**

Organization : **Pfizer Inc**

Category : **Drug Industry**

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See attached document.

GENERAL

GENERAL

See attached comment letter.

CMS-4130-P-23-Attach-1.PDF

#23

Legal Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017

July 24, 2007

BY ELECTRONIC DELIVERY

Mr. Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4130-P; Medicare Program, Policies and Technical Changes to the Medicare Prescription Drug Benefit

Dear Mr. Kuhn:

I am writing on behalf of Pfizer Inc, a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. We appreciate the opportunity to comment on the proposed changes to the Medicare prescription drug benefit to be implemented in contract year 2009.[1] Pfizer strongly supports the Part D prescription drug benefit. In particular, we believe that the program is working well and achieving its objective of promoting high quality health care by providing Medicare beneficiaries with access to needed medications. Our comments below are limited to two discrete issues: 1) the expanded definition of covered Part D drugs to

[1] 72 Fed. Reg. 29,403 (May 25, 2006).

include supplies associated with delivering inhaled forms of insulin; and 2) the process by which CMS designates certain protected categories of medicines for which a Part D drug plan must cover "all or substantially all" of the available prescription medicines.

I. Insulin Inhalation Drugs and Supplies

Pfizer currently markets Exubera, the only FDA-approved inhaled form of insulin. We strongly support CMS's inclusion of "[s]upplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin" in the definition of a "Part D drug."[2] We agree with CMS that, in defining a Part D drug in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress intended to "ensure that a beneficiary with diabetes had access to both the insulin and the supplies required to deliver insulin into the body," whether through injection or inhalation.[3] Congress did not specifically reference inhalation supplies in the MMA simply because inhalation was not an approved method of insulin administration available to diabetics in 2003.

While we are very appreciative of CMS's consideration of this issue in the proposed rule, we urge the agency to further clarify the covered inhaled insulin supplies included in the definition of a Part D drug to ensure that beneficiaries are not denied access to this important new therapy and the supplies necessary for its delivery. Specifically, CMS should state that the covered supplies include not only the inhalation chamber, but also the base and release unit.

[2] *Id.* at 29,419

[3] *Id.* at 29,405.

Each of these items is an element of the fully assembled Exubera insulin inhaler and is directly associated with the delivery of insulin through inhalation.

We are also concerned about the language in the preamble stating that sponsors are expected "to apply drug utilization management tools to ensure the appropriate use of these supplies."[4] We urge CMS to clarify that, because these inhaled insulin supplies are essential to the delivery of insulin, they should not be subject to utilization management requirements. These supplies are in no way optional or auxiliary. We are unaware of any way in which they can be used in an abusive manner that would justify the imposition of utilization controls. Consequently, these supplies, whether packaged with the drugs or packaged separately, should not only be included in the definition of Part D drug, but they should also be exempt from utilization management requirements. We request that CMS address this issue in the final regulation.

II. Six Classes of Clinical Concern

On June 10, 2005, CMS issued guidance requiring all Medicare Part D plans to cover "all or substantially all" of the prescription drugs in six therapeutic categories: antineoplastics, HIV/AIDS, antidepressants, antipsychotics, anticonvulsants, and immunosupressants.[5] CMS has stated that "beneficiaries should be permitted to continue utilizing a drug in these categories that is providing clinically beneficial outcomes," recognizing that "interruption of therapy in these

[4] *Id.* at 29,406.

[5] CMS, FAQ No. 4923 (FAQ 4923) (June 10, 2005).

categories could cause significant negative outcomes to beneficiaries in a short timeframe."[6] This policy was also later included in the CMS Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures[7] and the CMS Medicare Part D Manual.[8]

Significantly, the requirement for coverage of "all or substantially all" drugs in these categories is not included in the statutory requirements for Part D formularies (Section 1860D-4(b)(3) of the MMA) or the Part D regulations. Instead, it is "sub-regulatory" guidance provided annually to Part D prescription drug plans and Medicare Advantage plans and must be renewed each year. As such, it us up to the Secretary to issue this guidance, and it may be revised or revoked without input or participation by affected stakeholders, including patients, health plans, and pharmaceutical manufacturers.

We strongly believe that the "all or substantially all" coverage requirement is an important patient protection to ensure access to necessary therapies. This is a crucial requirement that effectuates Congress' desire to prohibit discrimination against certain beneficiaries who are chronically or seriously ill. These beneficiaries often require numerous medications and frequently have specific individual reactions to the medicines prescribed. Therefore, drugs in these therapeutic classes are not interchangeable and switching medications

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[6] *Id.*

[7] CMS, Medicare Modernization Act 2007 Final Guidelines – Formularies; CMS Strategy for Affordable Access to Comprehensive Drug Coverage, *available at* http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07FormularyGuidance.pdf (last visited July 22, 2007).

[8] CMS, Medicare Part D Manual; Chapter 6 – Part D Drugs and Formulary Requirements, *available at* http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf (last visited July 22, 2007).

can have serious adverse effects on patients. Accordingly, we urge CMS to develop a more formal process to allow public comment and participation in the determination of the protected classes of drugs and any exceptions to this policy.

Specifically, we request that CMS provide for an annually recurring period of notice and comment, during which interested stakeholders can offer input regarding the determination of the protected categories of drugs, any exceptions to the "all or substantially all" coverage requirements, and other policy decisions related to these requirements. This need not be a formal rulemaking process. Rather, we are simply requesting a process that provides for public input and that enables CMS's decision-making process on these issues to be more transparent.

For example, CMS could institute a process similar to the National Coverage Determination (NCD) process, through which CMS would issue proposed decision memoranda on an annual basis, inviting public comment on CMS's proposed review of its policy requiring coverage of "all or substantially all" of the drugs in certain protected categories. Like the NCD decision memorandum process, CMS would then review the comments and promulgate a finalized decision memorandum setting forth a summary of the comments, the final policy, changes to the policy, the process followed, and the evidence considered. This process would allow CMS a certain level of flexibility while also making the determination process more predictable and transparent. Most importantly, those most affected by this policy—patient groups, Part D prescription drug plans, and drug manufacturers—will have the opportunity to

present to CMS valuable perspectives and information that the agency may not otherwise receive.

III. Conclusion

We thank you for the opportunity to comment on the important issues raised by the proposed rule. We appreciate the thoughtful consideration that is being given to the needs of patients who now avail themselves of inhaled insulin therapy. We urge you to continue to address the issues raised in the proposed rule in a manner that fully protects patient access to necessary medications and promotes high quality healthcare. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,

Lisa Goldman

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

Organization : National Alliance of State Pharmacy Associations

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4130-P-24-Attach-1.DOC

#24

CMS-

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

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

Organization : **Minnesota Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4130-P-25-Attach-1.DOC

#25

CMS-

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

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

Organization : **MAPRx Coalition**

Category : **Consumer Group**

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See Attachment

Administrative Costs

Administrative Costs

See Attachment

Application Timing

Application Timing

See Attachment

Coordination of Benefits with Part D Plans & Other Payers

Coordination of Benefits with Part D Plans & Other Payers

N/A

Data Match

Data Match

See Attachment

GENERAL

GENERAL

See Attachment. This is an UPDATE to comment number 191456.

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

See Attachment

Insulin Inhalation Drugs and Supplies

Insulin Inhalation Drugs and Supplies

N/A

Negotiated Prices

Negotiated Prices

N/A

Noncalendar Year Plans

Noncalendar Year Plans

N/A

CMS-4130-P-26-Attach-1.DOC

#26

July 24, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4130-P
7500 Security Blvd
Baltimore, MD 21244-1850

Re: Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Mr. Kuhn:

Medicare Access for Patients-Rx (MAPRx) is a coalition of patient, family caregiver and health professional organizations committed to safeguarding the well-being of patients with chronic diseases and disabilities under Medicare Prescription Drug Coverage. On behalf of the millions of beneficiaries represented by the MAPRx coalition, we thank you for the opportunity to submit comments on the Proposed Rule CMS-4130-P.

In the following comments, MAPRx members note our appreciation to CMS for multiple aspects of the proposed rule. In these comments, we also communicate to you our collective concerns regarding specific aspects of the proposed changes to the program as they may affect the ability of beneficiaries to access full Part D benefits.

Section II. A. Subpart B – Eligibility and Enrollment

1. Approval of Marketing Materials and Enrollment Forms. MAPRx supports CMS' action to codify that providers, provider groups and pharmacies may distribute materials from *all* Part D plans with which they contract and provide referral for beneficiaries for information on the full range of plan options available to them. For beneficiaries, this provides timely access to information/education about Part D from a knowledgeable source, emphasizes that annual review of options is important, and clarifies (and may facilitate access) by specifically identifying the plans in which their provider participates.

Section II. B. Subpart C – Benefits and Beneficiary Protections

1. Definitions, a. Part D Drug

(2) Morbid Obesity

MAPRx is deeply concerned at CMS' proposed action to reverse its position and now exclude weight loss agents deemed medically necessary for an individual from Part D coverage. This action seems to be taken against overwhelming evidence of the complications obesity presents for multiple chronic and acute diseases and disabilities (e.g. various cancers, diabetes, heart disease, etc.) experienced by Medicare beneficiaries, and inconsistent with the new CMS priority focus on prevention of illness. Treatment for (and prevention of) obesity is an intrinsic component of care for a majority of constituents represented by MAPRx organizations, and one around which patient and professional groups have united as a health community. In addition to the added, immediate burden this action will create or exacerbate for a vulnerable segment of

beneficiaries, this policy further inhibits any incentive for pharmaceutical development of new agents available in the future to treat this critical health problem in America. Instead, MAPRx encourages CMS to continue its exception of weight loss agents for medically accepted indication from statutory
exclusion under Part D, similar to its action on prescription niacin products Niaspan® and Niacor® for the treatment of dyslipidemia.

(3) Insulin Inhalation Drugs and Supplies.

MAPRx is pleased CMS is including insulin inhalation supplies directly associated with delivering insulin to the body, specifically, the inhalation chamber for coverage under Part D. We are concerned, however, that the "expectation" for sponsors to apply drug utilization management tools to this insulin delivery mechanism will restrict access for beneficiaries to inhaled insulin when clinically appropriate. Furthermore, MAPRx is concerned that access by beneficiaries to this novel delivery mechanism may be impeded by assignment to a higher tier on a plan's formulary, as is the case in many plans today. We encourage CMS to closely oversee individual plan policies regarding insulin inhalation supplies to ensure unimpeded beneficiary access to this therapy.

In a similar vein, MAPRx is hopeful that CMS will act immediately to ensure that the new drug patch for Exelon, approved by the FDA earlier this month for the treatment of Alzheimer's disease, is added to Part D plan formularies as quickly as possible, and without high tier or utilization management restrictions. We continue to be concerned about the significant lag time (up to 18-months) that generally confronts a new drug or drug delivery mechanism (of which these drugs are examples) from the time of FDA approval to inclusion in USP Model Guidelines or a plan's formulary.

(4) Vaccine Administration Fee

In previous comments to CMS over the past three years, MAPRx has urged CMS to extend coverage under Part D for the administration of vaccines. We are delighted that CMS is reflecting this statutory change, specified in the 2008 Call Letter, in the final rule. This action simplifies beneficiary access to vaccinations, and will ensure that more beneficiaries avail themselves of this important preventive health benefit under the Part D program.

1. Definitions, b. Long Term Care Facilities

MAPRx appreciates the clarification that institutions for mental disease meet the qualification of a LTC facility. Individual MAPRx member organizations have consistently advocated for this status before CMS and on Capitol Hill, and we recognize CMS' positive response to this issue.

In addition, MAPRx is pleased CMS has clarified that medical institutions and hospitals can meet the definition of a LTC facility as well as ensured Part D support for beneficiaries in these institutions whose Part A and B payment is no longer available for drugs that would otherwise meet the definition of the Part D program. We encourage CMS oversight to ensure enrollees in these settings have adequate access to convenient network LTC pharmacies as provided for in this final rule.

1. Definitions, d. Negotiated Prices

MAPRx is deeply concerned with the proposed change in definition of "negotiated " prices which requires a single approach for calculating beneficiary cost sharing based upon the price ultimately received by the pharmacy or other dispensing provider. This policy, while simplifying processes of plans' price calculation and reporting to CMS, undermines the transparency of this process to

Section II. D. Subpart G- Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

1. Definitions and Terminology, b. Gross Covered Prescription Drug Costs

MAPRx applauds CMS' action to amend the definition of gross covered prescription drug cost to allow attribution of beneficiary out-of-pocket costs, during the deductible and/or donut hole phases of Part D, to incurred costs (TrOOP) and total drug spending, for drugs purchased at a network pharmacy for a lower price than the plan's negotiated price. However, it is a burden to require that the individual beneficiary report each transaction to their plan when this can be more efficiently reported by the network pharmacy in its ongoing communications with the plan.

Additionally, MAPRx supports CMS' action to count any nominal co-payments made by beneficiaries for drugs accessed through a patient assistance program (PAP) toward TrOOP and total drug spending. MAPRx reiterates, however, our continuing grave concern regarding the inability of beneficiaries to apply costs paid for medications outside a plan's formulary to TrOOP and total drug spending. Because of the number and nature of the drugs (many of them brand only) that beneficiaries with chronic diseases and disabilities must use for symptom control, this policy represents a significant financial burden to these individuals and their families, often resulting in a beneficiary's inability to access drug treatment under Medicare Part D.

Section II. F. Subpart J- Coordination of Part D Plans With Other Prescription Drug Coverage

1. Application of Part D Rules to Certain Part D Plans On and After January 1, 2006, b. Coordination of Benefits with Part D Plans and Other Payers

MAPRx endorses CMS' action to codify guidance the agency has issued to reflect the need for plan-to-plan "timely reconciliation" of Part D beneficiary services. This is an important step to ensure seamless transition between plans for beneficiaries, particularly those with chronic diseases and disabilities, many of whom may transition as a result of annual plan formulary and price changes which impede their ability to access the medications they need. Historically, lags in information have resulted in beneficiaries delay in receiving Part D benefits, gaps in beneficiary Part D records, and/or mistakes in billing which have created significant, undue financial burden for this vulnerable segment of beneficiaries.

Section II. H. Subpart M – Grievances, Coverage Determinations, and Appeals

1. Definitions, a. Appointed Representative

MAPRx recognizes and supports CMS' action to amend previous regulation text and codify a policy which enables an appointed representative to act on behalf of an enrollee in filing a grievance, obtaining a coverage determination or in dealing with any level(s) of the appeals process. We encourage CMS to also state that this policy must operate consistent with state family and surrogate laws.

Section II. H. Subpart M – Grievances, Coverage Determinations, and Appeals

2. Expediting Certain Coverage Determinations

MAPRx supports CMS clarification that it is a plan's responsibility to inform an enrollee, *in writing* and within three calendar days of its denial of a request to expedite a coverage determination for that enrollee. It is MAPRx's position that this notice must also be sent to an enrollee's appointed representative, if such individual is on record.

Section II. I. Subpart P – Premiums and Cost-Sharing Subsidies for Low-income Individuals

1. Premium Subsidy Amount, b. Premiums Subsidy for Late Enrollment Penalty

We support CMS' action to codify its policy which details a calculated sliding scale late enrollment penalty subsidy for partial LIS-eligible individuals. We remind CMS that, even with this penalty subsidy, partial-subsidy individuals with chronic diseases and disabilities may face significant difficulties in paying plan premiums given the out-of-pocket expenses they must pay for the multiple medications they require.

We appreciate the opportunity to submit comments on the draft regulations. Should you have any questions or wish to discuss any aspect of these comments in more detail, please contact Mary Worstell, MAPRx Convener, at 202.439.1152 or via the internet at Worstell@lupus.org.

Sincerely,

AIDS Action
Alzheimer's Association
American Autoimmune Related Diseases Association
Epilepsy Foundation
Lupus Foundation of America
Men's Health Network
National Alliance on Mental Illness
National Family Caregivers Association
National Health Council
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
The Arc of the United States
United Cerebral Palsy
Visiting Nurse Associations of America

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

Organization : California Pharmacy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4130-P-27-Attach-1.DOC

#27

CALIFORNIA PHARMACY ASSOCIATION

4030 Lennane Dr.
Sacramento, CA 95834
Phone(916) 779-1400 ext. 400 Fax (916) 779-1401
lrolston@cpha.com
www.cpha.com

August 1, 2007

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

Subject: Policy and Technical Changes to the Medicare Prescription Drug Benefit
72 Fed. Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423) (proposed May 25, 2007)

On behalf of the California Pharmacy Association (CPhA), we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed policy and technical changes to the Medicare Prescription Drug Benefit plan dated May 25, 2007. We would like to comment, in particular, on the proposed changes and clarifications regarding (i) "Eligibility and Enrolment," (ii) "Negotiated Prices," (iii) "Adequate Access to Home Infusion Pharmacies," (iv) "Administrative Costs," and (v) "Gross Covered Prescription Drug Costs" "Coordination of Benefits With Part D Plans and Other Payers" and "Application Timing" – collectively. The following comments are meant to address the above-mentioned five (5) categories.

Subpart B – Eligibility and Enrollment
72 Fed. Reg. 29404 (2007) (to be codified at 42 C.F.R. § 423.50) (proposed May 25, 2007)
Approval of Marketing Materials and Enrollment Forms

As a general matter of public policy, CPhA supports federal measures attempting to better inform our member pharmacists and their patients. As such, we wholeheartedly support a clarification of the pharmacists' educational and informational abilities with regard to Part D plans. Clarifying that the providers, provider groups, or pharmacies may supply printed information of Part D plan sponsors, provided that they offer similar material for all contracted sponsors, will limit confusion of available Part D sponsors while offering a more clearly defined mechanism to better educate the patient.

Previous CMS guidance, regarding the educational and informational offerings of Part D plans, stated that it was "appropriate to allow providers and pharmacies to market to beneficiaries." (70 FR 4223) However, the broad, general nature of the guidance invited confusion and created the potential for interests other than patient education to enter into the Plan D plan descriptions. CPhA supports and appreciates the proposed clarification, which defines "marketing" in a more specific manner and expressly allows for the education and assisting in enrollment as defined in The Guidelines, allowing pharmacists to provide their insight and expertise in helping their patients make informed decisions about their prescription drug plans.

Negotiated Prices

CPhA strongly supports federal efforts that are designed to positively affect the affordability of and access to prescription drugs and the efforts of CMS to clarify the Medicare Prescription Drug Benefit plan. Furthermore, CPhA supports clarifying and providing further guidance on the definitions, means of determining, and identification of qualified entities affected under the Medicare Prescription Drug Benefit plans for negotiated prices. However, we are compelled to offer the following comments on the proposed changes to 72 Fed. Reg. 29407 (2007) (to be codified at 42 C.F.R. § 423.100) (proposed May 25, 2007) regarding negotiated prices.

CPhA continues to have concerns that the lack of price transparency present in entities such as pharmacy benefit managers (PBMs) and mail order facilities presents federal and state oversight challenges and that it remains possible that these entities are not providing best price solutions to their clients and patients. Previously, CMS has recognized the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships.[1] The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace requires CMS to continually address the methodologies used for basis pricing. CPhA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and CPhA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors.

With regard to what is commonly referred to as 'spread pricing,' CPhA again supports the clarifications offered in the proposed changes to 72 Fed. Reg. 29407 (2007) (to be codified at 42 C.F.R. § 423.100) (proposed May 25, 2007). CPhA asserts that the equation in spread pricing is the amount employer paid minus amount pharmacy is reimbursed. Given this, an increase in the amount an employer pays creates a larger spread. Therefore, it could be claimed that there is direct incentive, to the PBMs, to increase the employer price rather than lower it. This increase in price effectively increases the costs to the pharmacy patient because of the increased percentage of cost share. It is CPhA's contention that spread pricing is most often employed for generic prescriptions; this, in turn, leads to higher brand utilization, unnecessarily creating higher overall costs. CPhA views that the incentives created by spread pricing lead to significantly higher costs to the payers and ultimately to the employer, pharmacy patient and the federal government.

Adequate Access to Home Infusion Pharmacies

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[1] CMS 2238-P RIN 0938-AO20, Prescription Drugs, AMP Regulation; December 20, 2006.

CPhA supports the proposed rule regarding home infusion pharmacies that codifies existing operational policies and imposes a new requirement that access to home infusion be offered within 24 hours of release from an acute setting. CPhA continually works with its state association members to inculcate best practices in the pharmacy community. We agree that the 24-hour requirement is consistent with accepted best practices. Furthermore, we support the new requirement, in particular because it is potentially a matter of patient safety. While CPhA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, CPhA fully supports the clarifications and additions to 72 Fed. Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423.120(4)) (proposed May 25, 2007) and views such amendments as 72 Fed. Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423.120(4)(iii)) (proposed May 25, 2007) reasonable federal guidance. CPhA appreciates the willingness of CMS to again assert that adequate access to home infusions pharmacies is an expectation of the Part D plans.

Administrative Costs

CPhA supports and appreciates CMS defining the term administrative costs. Of particular interest to CPhA is what can be inferred by CMS' statement that PBMs' profit or loss is an administrative costs not a drug cost. As noted above in the comments regarding negotiated price, CPhA has continued interest in, and concerns, with the non-transparent business practices of PBMs.

Gross Covered Prescription Drug Costs; Coordination of Benefits with Part D Plans and Other Payers; and Application Timing

With regard to these sections CPhA, again, supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

In summary, CPhA strongly supports CMS' proposes policy and technical 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, CPhA appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

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

Sincerely,

Lynn W. Rolston
Chief Executive Officer
California Pharmacy Association

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

Organization : SilverScript Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-28-Attach-1.DOC

#28

July 24, 2007

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

Re: CMS - 4130-PComments on Part D Proposed Rule "Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit"

Dear Sir or Madam:

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

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

I. General Comments

The proposed rule makes major revisions in the Part D Rule ("Rule") to reflect CMS' stated intent to require Part D plans to utilize a "single approach" to drug pricing. Rather than merely "refining" certain definitions, the proposed rule signals a major policy shift in the Part D program -- little more than a year after its implementation and before the results of the first year performance are available -- from a market-based model in which competition between private parties drives pricing and purchasing decisions, to a quasi-government model under which CMS dictates these decisions.

The freedom to make pricing and purchasing decisions is the underpinning of a market-based competitive model. The proposed rule's restrictions on the Part D sponsor's ability to choose what it believes to be the most effective drug management and pricing model will result in an increase in both drug costs and premiums, to the ultimate detriment of beneficiaries and the Part D program. Most importantly, the proposed rule's departure from a market-based approach is directly contrary to the Medicare Modernization and Prescription Drug Improvement Act of 2003 (MMA), and Congress' clearly stated intent in enacting it. CMS fails to articulate any basis or rationale for this major policy change, or to explain how it is consistent with the statute. As such, the proposed change is beyond CMS' authority.

Below we discuss these general concerns in greater detail, and then provide comments to specific sections of the proposed rule.

1. The proposed rule violates the MMA by departing from a market-based model and exceeds CMS' authority by substituting CMS' view for that of Congress.

The proposed rule institutes a "single approach" to Part D pricing, namely, "pass-through" pricing. This designation by CMS of a single acceptable pricing structure is contrary to the MMA and Congressional intent. Congress made clear in enacting the MMA that it intended to establish a market-based model under which "the private sector negotiate their incentives for insurers to get lower costs," and the marketplace works to "squeeze costs and get efficiency out of the system" rather than have CMS "dictate prices for everybody." [1] CMS acknowledges this repeatedly in the preamble to the Part D Rule, stating that that Congress structured the Part D benefit to be a "market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs."[2] Section 1860D-11(i)(2) of the MMA also specifically states that CMS may not institute a "pricing structure for the reimbursement" of Part D drugs. By specifying a "single approach" to drug pricing that requires the plan to charge beneficiaries the amount paid to pharmacies, CMS is depriving Part D plans of the ability to make their own drug purchasing choices, directly interfering with the market mechanism that underpins the Part D benefit, and instituting a pricing structure. This is contrary not only to Congressional intent, but also to the express prohibition in the MMA against the institution of a pricing structure by CMS.

Absent any ambiguity or conflict, it is a cardinal rule of statutory construction that the plain meaning of a statute be followed. In addition, when a statute may be interpreted to abridge long-held rights, or make a large policy change, courts *will not* interpret the statute to make the change unless the legislature clearly states it. This rule of construction is based on the assumption that the legislature would not make major changes in a vague or unclear way. This is known as the "clear statement" rule. Congress was keenly aware of the role of pharmacy benefits managers (PBMs) in the prescription benefit market when it passed the MMA, and both Congress and CMS (in the current Rule's preamble) repeatedly state that it was Congress' intent that the Part D benefit mirror the operation of drug benefit programs in the commercial market.

The lock-in pricing approach was the dominant pricing model in the commercial drug benefit market at the time the MMA was passed and it still is today. Applying the "clear statement" rule of construction, if Congress had intended to disallow this model for Part D purposes, it would have done so clearly and explicitly. Indeed, the fact that Congress' own definitions of several key terms as stated in the MMA must be substantially amended, and a new defined term added which is contrary to its well-understood meaning[3], demonstrates that CMS is substituting its views for those of Congress in mandating the model under which Part D should operate. This fundamental principle, namely, whether Part D should be a market-based or government-directed program, was vigorously debated in Congress before it decided clearly and unequivocally to adopt a market-based model. We believe that only Congress can change this model, not CMS.

Congress decided that Part D sponsors should have the choice, as they do currently in the commercial market and under Part D, to decide which model works best for them and which delivers the best results. By dictating the purchasing and drug pricing methods that must be used by Part D sponsors, CMS is substituting the judgment of the government for that of the market, and assumes that the

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[1] Congressional Record, November 24, 2003, S15670.

[2] 70 Fed. Reg. at 4320.

[3] The new defined term "administrative costs" is contrary to the explanation of this term in preamble to the current Part D rule (see 70 Fed. Reg. at 4289-90), and contrary to the standard use of this terms for accounting and financial purpose.

government knows better than Part D sponsors how best to provide a high quality benefit with low drug costs. This assumption was explicitly rejected by Congress in enacting the MMA, when Congress noted that "private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator."[4]

It is notable that CMS provides no rationale for the proposed rule changes. It cites no harm to the program and no harm to beneficiaries. Indeed, it would be hard pressed to do so, not only because it has not even completed the first year payment reconciliation process and so does not know the full financial results for the year, but because it has pronounced the program a "resounding success" in testimony before Congress. Specifically, Acting Administrator Leslie V. Norwalk stated:[5]

> *Part D, enacted with passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implemented in January 2006, has been a resounding success. To date, more than 90 percent of Medicare beneficiaries have prescription drug coverage through Part D or another creditable source, including nearly 10 million low-income individuals receiving coverage with low or zero premiums and nominal cost-sharing. Beneficiary satisfaction with Part D is consistently at 75 percent or higher, exceeding 90 percent among low-income beneficiaries receiving extra help. Equally important, Part D premiums and estimated program costs have been declining steadily thanks in part to market forces encouraging strong competition among plans and smart choices by beneficiaries and in part because of lower-than-expected growth in prescription drug spending.*

Yet it is these very market forces that CMS proposes to override with the proposed rule, and without providing any explanation or rationale whatsoever. As courts have stated:[6]

> *[W]hen an agency reverses its course, a court must satisfy itself that the agency knows it is changing course, has given sound reasons for the change, and has shown that the rule is consistent with the law that gives the agency its authority to act. In addition, the agency must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection, sufficient to allow for meaningful judicial review. Although there is not a "heightened standard of scrutiny . . . the agency must explain why the original reasons for adopting the rule or policy are no longer dispositive." Even in the absence of cumulative experience, changed circumstances or judicial criticism, an agency is free to change course after reweighing the competing statutory policies. But such a flip-flop must be accompanied by a reasoned explanation of why the new rule effectuates the statute as well as or better than the old rule.*

In this case, CMS has provided no explanation for how its proposed change effectuates the MMA better than the prior rule. It has cited no harm or mischief either to beneficiaries or the program as a result of the current policy, nor has it attempted to justify the change as more consistent with either the

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[4] Conference Report to the MMA, p.302.

[5] Testimony before the House Energy and Commerce Subcommittee on Health, April 18, 2007.

[6] Fox Television Stations, Inc. et.al. vs. Federal Communications Commission, Docket Nos. 06-1760-ag (L), 06-2750-ag (CON), 06-5358-ag (CON), 2nd Circuit Court of Appeals, June 4, 2007, quoting from N.Y. Council, Ass'n of Civilian Technicians v. Fed. Labor Relations Auth., 757 F.2d 502, 508
(2d Cir. 1985).

language of the MMA or Congressional intent. CMS itself has repeatedly touted the success of the program, and has from the outset emphasized the Congressional requirement that it be market-based. By departing from Congressional intent and the language of the MMA without any explanation, CMS is acting beyond its authority.

2. The proposed rule will deprive Part D sponsors of the best drug management practices available in the private sector today, ultimately causing drug costs to rise for beneficiaries and the program. By effectively prohibiting[7] the price risk or "lock-in" pricing model, CMS will be departing from Congress' and its own goal of leveraging market- based best practices. Drug management techniques have evolved in the marketplace over the past 25 years from a claims processing pass-through model where PBMs do not participate in the drug purchasing and supply process to the lock-in model, where PBMs are an integral part of the drug supply chain. This model, developed in response to market demand, requires PBMs, like any other drug suppliers, to be at risk for their drug purchasing decisions, and to assure plans a drug price that is not conditioned on the costs at which the PBM obtains the drugs. Competition and aligned incentives drives PBMs to negotiate for the best pricing on drugs from pharmacies, resulting in lower drug prices for plan sponsors/clients and consumers and, under Part D, the government.

The proposed rule, by shifting drug costs to administrative costs and thus beneficiary premiums, will constrain Part D plans from utilizing the more innovative clinical drug management services and tools available in the market today. It will effectively reduce plans to using PBMs primarily for claims processing, where the pharmacy price is passed through as given, and the PBM is paid based simply on claims volume i.e. the number of claims processed. Plans will be less willing to implement more intensive, high-cost clinical interventions that have been developed by PBMs over time to improve medical outcomes and quality of care and, to the extent any drug management is implemented, the focus will become simply to ratchet down the use of drugs. Since drug costs cannot ultimately be lowered without improving health outcomes, the effect will be not only less drug cost trend management, but also inferior medical outcomes and lower beneficiary satisfaction.

While it is possible for Part D sponsors to institute performance guarantees in an attempt to better align incentives to retain better drug management tools, as Congress itself made clear by its choice of risk-based Part D model rather than a government-run plan, placing entities directly at risk for drug costs is far more effective than adjusting compensation through performance guarantees that attempt to mimic the incentives of true at-risk participants.

The lock-in model directly aligns the PBM's incentives with that of the plan and the Part D program to shift drug utilization to: (i) preferred brands from non-preferred brands; (ii) lower cost generic drugs; (iii)

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[7] While the proposed rule does not explicitly prohibit lock-in pricing, CMS does so implicitly by imposing a "single approach" to beneficiary cost sharing. Under Part D, beneficiaries and Part D sponsors share the cost of a drug in different proportions, depending on the phase of the benefit. Thus, if the beneficiary's cost sharing is based on a certain drug cost (e.g. 25% of $100) and the plan's cost sharing that may be included in gross covered prescription drug costs must be based only its drug costs up to that amount (i.e. $100 -$25), then it is not possible, by definition, for Part D sponsors to pay a drug supplier either more or less than $100 in total drug costs. In addition, while it would theoretically be possible to base subcontractor compensation on putative lock-in pricing, this would differ from lock-in pricing in the same crucial respect as purchasing on one's own account differs from purchasing as an agent of another – any differential would be fully disclosed and so simply become a range for determining administrative fees. As such, it would be a pointless exercise and the parties would move to simply setting administrative fees. Thus, lock-in pricing would be eliminated, both in calculating allowable drug costs and for purposes of setting administrative fees.

mail order pharmacy alternatives. This is because, under the lock-in model, PBMs typically take risk (and routinely lose money) on brand drug pricing, and make money on generic pricing. Therefore, PBMs are incented to promote cost effective preferred brand drugs, and encourage beneficiaries to move from higher cost brand drugs to generic drugs when clinically appropriate. Utilization of lower cost alternatives, such as preferred brands and generics, aligns with CMS' goals and beneficiary desires for lower drug costs. In contrast, pass-through pricing does not directly align a PBM's incentives with that of the plan or the Part D program. Pass through pricing provides no incentive to the PBM to lower overall drug costs through the use of preferred brands, generics and mail pharmacies. By basing PBM reimbursement directly on costs and number of drugs dispensed, the pass-through model would ironically reward PBMs for higher utilization.

3. Pass-through pricing is less equitable and more confusing to beneficiaries as they lose the benefit of consistent drug pricing across pharmacies and across different regions of the country.

Under a lock-in model, plans are able to provide uniform drug pricing for beneficiaries, irrespective of where they live or the pharmacy they choose to use. This is positive for beneficiaries in two respects. First, it protects beneficiaries who live in less competitive or underserved areas. This is because the price charged to the beneficiary is not directly tied to the price that the pharmacy is reimbursed, and so plans are able to negotiate a single fixed price with PBMs, irrespective of various prices at which PBMs are able to negotiate the purchase of drugs from different pharmacies. The highest negotiated pharmacy reimbursements are generally seen in rural and underserved areas where there is less competition and lower volume. In the lock-in model, the PBM absorbs these spikes and variations in pharmacy pricing, and provides all beneficiaries a standard, uniform price. Beneficiaries are thus not unfairly penalized for living in a less competitive market with fewer pharmacy choices.

Second, the lock-in model provides consistency and simplicity to beneficiaries, allowing them to better predict and budget for their out-of-pocket drug costs. This is particularly important for the elderly, many of whom are on fixed incomes with little flexibility or financial cushion to absorb price spikes or significant variations. It is particularly onerous for seniors to have to "pharmacy shop" to find the cheapest pharmacy, especially in the case of those who have long-established relationships with certain, sometimes smaller and less competitive, pharmacies. In addition, for many of the elderly who are "snowbirds" that spend significant parts of the year in different parts of the country, it is a major benefit and comfort to know that their medications will cost the same, regardless of which pharmacies they use.

In contrast, under a pass-through model, plans have no ability to shield beneficiaries from the variations in drug pricing as a result of different drug price reimbursement rates negotiated with different pharmacies. As a result, beneficiaries' drug prices will vary not only by geographical region, but even pharmacy to pharmacy. In competitive (usually urban) markets where there are many pharmacies in close proximity to one another, these variations will likely be small and of little consequence, but in rural and less populated areas, where beneficiaries have fewer pharmacy options, these variations are likely to be significant. As a matter of equity, beneficiaries outside urban areas should be able to benefit equally from the PBM's national reach and negotiating power, and should not face higher drug costs because of where they choose to live.

4. The proposed rule impermissibly disallows a portion of Part D sponsors' legitimate drug costs.
The proposed rule substantially amends three definitions and adds a fourth for the purpose of excluding a portion of Part D sponsors' legitimate drug costs from the definition of "allowable" drug costs under the Rule. CMS has created a definition of "administrative costs" that is based not on the nature of the

costs incurred, but on the entity from which the drugs are purchased. While there is no definition of the term "administrative costs" in the statute or the current Rule,[8] the generally recognized accounting and financial distinction, and that made elsewhere by CMS itself, is between the acquisition cost for the drugs or the "product purchased" as opposed to the costs or fees associated with administrative tasks, such as marketing, customer services, claims administration and other administrative services.[9] While it is within CMS' purview to examine whether certain costs are in fact for the purchase of drugs and not for the provision of services, as long as a Part D sponsor is paying for drugs, these costs should be recognized as drug costs to the plan and included in "allowable" drug costs under the Rule .

Throughout the MMA and the proposed rule, "administrative costs" are not defined to include the margin (positive or negative) a manufacturer charges over its production costs, or the margin a wholesaler charges over the wholesale acquisition cost, or the margin a pharmacy charges a PBM over the pharmacy acquisition cost. It is only the last transaction in this chain - the margin a PBM charges a Part D sponsor - that CMS disallows as part of the Part D sponsor's drug costs. In the preamble to the Rule, CMS explicitly acknowledges that a pharmacy may include a profit element in the amount it charges for drugs.[10] Similarly, if the plan purchases the drug directly from the wholesaler, manufacturer, or pharmacy, the price would include a mark-up by each of those entities and, in each case, the mark-up would not be identified as an "administrative" cost, even though in each case it would clearly include an increment to cover the cost of delivering the drug and related services as well as an element for profit. This is no different. Disallowing a portion of a Part D sponsor's drug costs by changing the definition of "administrative costs" is without any support in the MMA .

II. <u>Specific Comments</u>

Below are specific comments on certain of the proposed changes in the rule, including some of the changes discussed more broadly above.

A. Marketing Materials

CMS clarifies that contracted providers are not required to accept and display comparative materials of all Part D plans, but only those with which they contract, and that they may simply inform prospective enrollees where they can obtain information on the full range of plans available. CMS explains that its reason for this limitation is to avoid confusing prospective enrollees who might otherwise believe or expect that the provider is a network provider to all these plans. We appreciate this clarification, but believe that it does not go far enough in terms of addressing beneficiary confusion with the array of plans presented to them in the provider setting. When the Part D program was implemented, few expected there to be as many plans as there currently are. The result is that many providers have contracts with dozens of plans, from major national plans to smaller regional or local plans, and so are

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[8] The preamble does provide a list of costs that may generally be included as "administrative costs" in a plan sponsor's bid. See 70 Fed. Reg. at 4289-90. This list includes crossover fees paid to obtain information from other payers, MTMP expenses, marketing and sales, customer service, billing and claims administration, accounting operations, actuarial, legal and human resources, etc., none of which relate to the price paid to a PBM for drug costs. The bid instructions list the same types of administrative services.

[9] See 70 Fed. Reg. at 4289-90.See also 70 Fed. Reg. at 4398 (referring to the "actual costs" as the costs for "acquisition of drugs") and 4491 (describing the costs incurred by Part D plans in "administering the benefit").

[10] 70 Fed. Reg. at 4236 ("In addition, we clarify that we expect Part D plans and pharmacies to account for pharmacy profit as part of negotiated prices—either as part of overhead costs accounted for in dispensing fees or in the reimbursement rates for ingredient costs negotiated with pharmacies.")

often inundated with plan materials. Requiring providers to accept and display the materials from all these plans puts an undue burden on providers that have limited display space. Providers have no choice but to simply pile up the materials, with the result that the materials are often not easily accessible, not necessarily the most recent information available for all the plans involved, and frequently overwhelming to prospective enrollees by the sheer volume of material and number of plans presented.

Instead of requiring providers to display information of every plan with which they've contracted, we recommend that providers be permitted to display information of a reasonable cross-section of plans with which they have contracted, as long as they also post a notice clearly stating that the materials represent only a cross-section of the plans with which they have contracted, and informing prospective enrollees where they can obtain the full range of plans available to them.

Recommendation: Modify the requirement that providers accept and display materials from all contracted plans to state that providers may accept and display materials from reasonable cross-section of contracted plans, as long as the provider posts a notice informing beneficiaries that the material represents only a subset of contracted plans, and explaining where beneficiaries may obtain information on the full benefits available to them.

B. Vaccine Administration Fee

CMS proposes to amend the definition of Part D drug to include a reference to vaccine administration on or after January 1, 2008 in order to conform the definition to the statutory change made by the Tax Relief and Health Care Act of 2006. While we understand that coverage changes would require Congressional action, we would like to reiterate the concerns we have previously expressed to CMS regarding the operational aspects of implementing this change.

Specifically, there is currently no mechanism in place for physicians to bill PDPs directly, or for PDPs to pay physicians directly for this fee. Indeed, since physicians lack the information systems or contractual relationships to bill Part D plans directly, the coverage of vaccine administration fees under Part D is fundamentally at odds with the real time nature of the Part D program. This disconnect is exacerbated by CMS' stated expectation that when the vaccine and its administration fee are billed separately, Part D plans must ensure that " there is a reasonable correlation of prescription drug event (PDE) records for vaccines dispensed to PDE records for vaccine administration." Since any separate vaccine administration fee claim will be a paper claim, this takes the program further away from its real time nature, and will require that costly manual processes be instituted by Part D plans. This imposes yet more costs and administrative burdens on all the parties involved, including beneficiaries who must pay out-of-pocket for the administration and seek reimbursement afterwards. While various billing and payment methods are being considered, as MedPAC has stated,[11] these methods are largely untested and none is without operational challenges. In addition, given the relatively small number of vaccine claims from physicians that are processed under Part D, it is not efficient for either physicians or plans to build the technical or administrative infrastructure that would be required in order for physicians to be able to bill Part D plans directly for these few claims.

In light of these difficulties, we strongly endorse the recommendation of MedPAC to permit the coverage of certain vaccines under Part B instead of Part D. [12]In addition, given that the statutory

[11] MedPAC Report to the Congress, "Promoting Greater Efficiency in Medicare", June 2007, p.166.

[12] Although the MedPAC recommendation was limited to preventative vaccines, MEDPAC stated:

change takes effect only on January 1, 2008 and that the operational issues have not yet been fully teased out, let alone satisfactorily resolved, we urge CMS to consult closely with Part D sponsors before mandating any particular approach, and to allow Part D sponsors the maximum operational flexibility in handling these claims transactions so that they can provide the coverage with as little disruption to beneficiaries as possible. In particular, we urge CMS to allow Part D plans to treat the vaccine administration fee as if it were a drug, and to bill for it accordingly. In addition, CMS should allow Part D plans the maximum flexibility to process the vaccine itself and the administration fee as one transaction or two non-linked transaction at their discretion, and should not require that plans track and tie the two transactions together. Aside from the administrative burden involved to do this, it is monitoring a situation that is highly unlikely to occur, since few physician would administer a vaccine other than from their own stock, given the risks associated with administering a vaccine that has been outside the physician's control, including the risk of tampering, spoilage, and temperature damage, to name a few.

Recommendations: 1. Work with Congress and MedPAC to change the law to permit coverage of vaccines under Part B instead of Part D. 2. Work closely with Part D sponsors to develop the most efficient and cost-effective approach to billing and paying for vaccines and vaccine administration fees under Part D. This approach should, at a minimum, (i) treat the vaccine administration fee in all ways as if it were a separate Part D drug , and (ii) permit Part D sponsors as much operational flexibility as possible in handling these claims, and not require that the claim for the vaccine itself and the claim for the administrative fee be linked or otherwise correlated or tracked.

C. Long-Term Care Facilities

CMS clarifies that institutions for mental disease ("IMDs") fall within the definition of a "long term care facility" in 42 CFR 423.100. We appreciate this clarification, which is consistent with prior CMS guidance, but wish to point out that, as a practical matter, very few IMDs appear interested in contracting with Part D plans. We solicited state IMDs in all 50 states to participate in our Part D LTC network, but only about 10 have responded and are negotiating contracts. We are therefore concerned that the CMS standard does not take into account that entering contracts with IMDs requires the cooperation and interest of the IMDs too, and states simply that Part D plans must "ensure that they provide convenient access to network LTC pharmacies...for all their enrollees who are inpatients in a hospital" that qualifies as an IMD. The most that Part D plans can do is make a good faith effort to contract with the IMDs, and they cannot require or "ensure" that IMDs contract with them.

Recommendation: Clarify that Part D plans meet the "convenient access" requirement for LTC facilities that are IMDs if they make a good faith effort to contract with the IMDs, even if the contracts are ultimately not entered into with the IMDs.

D. Negotiated Prices

CMS states that it is requiring "a single approach for calculating beneficiary cost sharing, based upon the price ultimately received by the pharmacy" or other dispensing provider. CMS provides no rationale for requiring plans to determine their drug prices to beneficiaries exclusively on their reimbursement rates to pharmacies, and there is nothing in the statute to support this requirement. On the contrary, and as

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Although this section relates only to preventive vaccines, beneficiaries might have better access to some other drug products under Part B than under Part D. CMS is studying whether some drugs should be moved from one part of the program to the other. The Commission also will study potential cases in future work. Any significant shift of drugs from one part of the program to the other should consider the time needed for drug plans to take the changes into account before submitting their bids to CMS for the following year.

CMS later clarifies, section 1860D-2(d)(1)(B) of the MMA specifically states that "negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs." Since Part D sponsors may elect to pass through all or none of the price concessions negotiated with manufacturers, pharmacies or others, negotiated prices do not, nor are they required to, equal the price ultimately received by the pharmacy, and the MMA clearly contemplates that Part D sponsors will have the flexibility to determine and set their negotiated prices as they deem appropriate to be competitive.

As CMS itself states in the preamble to the Rule in discussing negotiated prices "How a Part D sponsor nets out negotiated price concessions in its negotiated prices is at the discretion of the Part D sponsor, but we expect that competition will create incentives for Part D sponsors to offer reasonable negotiated prices. "[13] Similarly, "[t]he Part D benefit was established by the MMA as a market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs. Given the market-based approach envisioned by the Congress, we are wary of regulating negotiations between private parties...."[14] Yet this is precisely what CMS seeks to do in changing the definition of "negotiated price" to limit how Part D sponsors set their prices. It is analogous to requiring a retailer to limit the amount it charges consumers for a product to the cost paid to the supplier by the retailer. Instead, a retailer may choose to mark up or lower the price as competition demands. Similarly, a Part D sponsor may choose to charge a lower price than the reimbursement rate to the pharmacy or a higher price that does not pass through any of the pharmacy or manufacturer discounts at POS, and instead take them into account in setting lower enrollee premiums or improving enrollee services.

The freedom to make these types of pricing decisions is at the heart of a market-based model, and the revised definition of "negotiated prices" seeks to limit that freedom by dictating how negotiated prices are to be set. This is in direct violation of the noninterference provision of the MMA, which states that CMS may not interfere with price negotiations or "institute a price structure for the reimbursement of covered Part D drugs."[15] As Congress made clear in the Conference Report to the MMA, this provision operates more broadly to prohibit CMS not only from "from interfering in any way with negotiations between prescription drug plan sponsors and ... and drug manufacturers, wholesalers, or other suppliers of covered drugs" but also from:

"...otherwise interfering with the competitive nature of providing prescription drug coverage through such entities and organizations. These negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator."[16]

Recommendation: Retain the current definition of "negotiated prices" in the Rule, which allows Part D sponsors to determine the drug price to charge enrollees, as required by the MMA, instead of seeking to limit drug prices to the reimbursement rate to pharmacies or other dispensing providers.

E. Administrative Costs

[13] 70 Fed. Reg. at 4245.
[14] 70 Fed. Reg. at 4244
[15] MMA §1860D-11(i).
[16] Conference Report to the MMA, p.302.

CMS proposes to define "administrative costs" as the Part D sponsor's costs "other than those incurred to purchase or reimburse the purchase of Part D drugs." However, CMS then adds that administrative costs include sponsor costs "that exceed the amount paid by or on behalf of the Part D sponsor to a pharmacy or other entity that is the final dispenser of the drug under the Part D plan." Lest there be any doubt as to its intent, CMS adds in the preamble "For example, the profit retained by a PBM that negotiates prices with pharmacies on behalf of a Part D sponsor is considered an administrative cost and not a drug cost."

We agree that administrative costs are costs other than those to purchase or reimburse the purchase of Part D drugs, since this is consistent with the traditional and well-understood meaning of the term. However, we strongly oppose CMS' attempt to broaden the term to include any amount paid to entities other than the dispenser as administrative costs, irrespective of the nature of the payment. CMS is in effect using the definition of "administrative costs" to dictate from whom a Part D sponsor is permitted to buy drugs by recognizing only those drug purchases from dispensers as legitimate drug costs. A cost is either a drug cost or an administrative cost based on whether the cost is to buy drugs or pay for services. If the cost is to purchase drugs, then it is a drug cost, irrespective of the party from whom the drug is purchased. In addition, CMS specifically requires that rebates negotiated with manufacturers reduce drug costs, even though these amounts are not received from the final dispenser of the product. Thus, CMS proposes to allow only drug costs paid to the pharmacy to count as drug costs under Part D, but at the same time to require that all drug discounts -- irrespective of whether these are received from the pharmacy or any other entity – to count as a reduction in drug costs. This asymmetrical treatment of drug costs and drug cost discounts, as well as the arbitrary exclusion from Part D drug costs of those drug costs incurred in the purchase of drugs from parties other than the final dispenser is arbitrary and capricious, and without any support in the MMA. Instead of the outright banning of the purchase of drugs from certain entities, which would be a clear violation of the noninterference language in the MMA, CMS has sought to do this indirectly by defining administrative costs to include these drug sales. Thus, by definition, the purchase of drugs from any party other than the final dispenser is an administrative cost.

Recommendation: Revise the definition of "administrative costs" to read: "Administrative costs" means costs incurred by a Part D sponsor in complying with the requirements of this Part for a coverage year and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs." Everything after this first sentence should be deleted.

F. Gross Covered Prescription Drug Costs ("Gross Drug Costs")

CMS proposes to rectify what it characterizes as conflicting definitions of the term Gross Drug Costs by requiring Part D sponsors to report as GCPDC "the amount ultimately received by the pharmacy, other dispensing provider, or agent (as opposed to the amount paid to an intermediary contracting organization that does not serve as an agent, such as a PBM)." CMS then proceeds to add back into Gross drug Costs various costs in addition to those ultimately received by the pharmacy,", such as amounts paid to physicians and other dispensers, amounts paid to other plans, amounts paid by an enrollee outside the benefit in certain circumstances, including nominal cost sharing paid to patient assistance programs ("PAPs") and when the enrollee obtains a lower price than the negotiated price when responsible for 100% cost sharing. Gross Drug Costs therefore include amounts paid by the Part D sponsor for drug costs to:

- pharmacies
- physicians

- other dispensers
- other Part D plans
- SPAPs
- other payers
- enrollees

Excluded from Gross Drug Costs are amounts paid by the Part D sponsor for drug costs to:

- PBMs

As with the definition of "administrative costs", we believe that this definition is arbitrary and capricious in that it is based not on the nature of the costs, but on the party to whom they are paid. Without any justification or rationale, CMS seeks, by definition, to preclude the purchase of drugs by Part D sponsors from certain entities. There is no support for this in the MMA, where Congress defined Gross Drug Costs as:

...the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.[17]

This is mirrored in the Conference Report, which defines Gross Drug Costs as follows:
Gross covered drug costs would be defined as costs (not including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded basic coverage and regardless of when the payment for the drugs was made.[18]

Thus, all that the MMA requires is that the costs be (i) for drugs, and (ii) incurred under the plan. There is no support in the MMA for imposing limitations on a Part D sponsor's ability to purchase drugs from whom it chooses, and to do so is directly contrary to the noninterference clause in the MMA which prohibits CMS from interfering in negotiations between Part D sponsors and others and from seeking to impose a pricing structure. Limiting from whom Part D sponsors may purchase Part D drugs and mandating a single pricing approach flies in the face not only of Congressional intent, but the express language of the MMA, and it is no less a violation because it is achieved indirectly through definitions than directly through an outright prohibition.

Recommendation: Revise the definition of "gross drug costs" to reflect the definition in the MMA, namely, the amount incurred by the Part D sponsor for Part D drugs.

[17] MMA §1860D-15(b)(3).
[18] MMA Conference Report , p.47.

G. Waiver or Reduction of Part D Cost-Sharing by Pharmacies

CMS states that although it will "generally allow waivers or reductions of Part D cost-sharing by pharmacies to count toward incurred costs, this will not be the case for pharmacies affiliated with entities whose wraparound coverage does not count as incurred cost." While we understand that CMS is focused here particularly on safety-net providers that are considered government-funded health programs under 42 CFR 423.100, we are concerned that the broad and undefined terms "affiliated" and "wraparound coverage" that "does not count as incurred costs" could be misconstrued to disallow waivers by pharmacies that are affiliated with Part D sponsors that provide enhanced coverage. We recommend that CMS clarify that this prohibition on counting cost-sharing reductions by pharmacies applies only if the reduction is in fact part of the coverage provided by a health plan or other third party payment arrangement, and not a waiver funded by the affiliated pharmacy itself.

Recommendation: **Clarify that only cost-sharing reductions that are in fact paid for by group health plans, government-funded health programs or other third party payer arrangements will not count toward "incurred costs" and that cost sharing waivers by a pharmacy, even if the pharmacy is affiliated with a payer, will count toward "incurred costs".**

H. Adequate Access to Home Infusion Pharmacies

The proposed rule states that plans must "ensure" that HI network pharmacies, "at a minimum" are capable of meeting the four requirements specified by CMS regarding HI drug delivery, including the requirement to ensure that the professional services and ancillary supplies are in place before dispensing and that drugs are delivered within at least 24 hours of discharge from an acute setting. We are concerned that, as written, this suggests that Part D plans have greater control and involvement in these activities than they in fact do. All that a Part D plan can do is to contractually require that HI network pharmacies meet these requirements to the extent that they are in control of these issues and then, as appropriate, audit the pharmacies for compliance with all their contractual obligations. While Part D plans can contractually require that HI pharmacies be capable of delivering home infusion drugs within 24 hours of discharge from an acute setting, the pharmacy must in turn rely on the hospital's discharge staff notifying it beforehand of the discharge to coordinate this, and Part D plans cannot themselves effectively assume the role of the hospital's discharge staff or require that HI network pharmacies do so.

Recommendations: **CMS should clarify that Part D sponsors meet their obligations with respect to the requirements in proposed section 423.120(a)(4) (i)-(iv) by including these requirements in their contracts with HI pharmacies, and that the requirement to deliver HI drugs within 24 hours of discharge from an acute setting is contingent on the HI pharmacy being informed of the discharge by the enrollee or hospital staff before it occurs.**

I. Coordination of Benefits ("COB") with Part D Plans and Other Payers

CMS explains that it developed the payer-to-payer reconciliation procedures in large part to alleviate the "significant administrative and financial burden" that would otherwise be placed on pharmacies to reverse and re-adjudicate claims based on incorrect information accepted by pharmacies "in good faith." CMS also states "unforeseeable future events" may create the need for further reconciliation processes when a payer other than the correct Part D plan pays as primary, and that Part D plans will be required to coordinate benefits with these payers "on a timely basis."

While we support CMS' efforts to mitigate the burden placed on pharmacies, and also understand and support the requirement that Part D plans coordinate benefits with other payers, we are concerned that CMS does not address or even allude to the significant burdens – financial as well as operational -- placed on Part D plans by these processes, even though the Part D plans too, have relied in good faith on information provided to them by CMS. We are also concerned that CMS requires Part D plans to coordinate benefits with other payers "on a timely basis", but makes no provision on behalf of Part D plans to require pharmacies or other payers to submit COB claims to it on a timely basis, particularly in situations where these entities may have obtained or been in possession of the correct payer information for some period.

Based on our experience this year, we are particularly concerned that in adding new COB obligations on Part D plans, CMS does not address the payment reconciliation process and deadlines for submitting PDE claims and adjustments, or provide any indication of how it plans to adjust this process to allow Part D plans to receive reinsurance and risk corridor payments for claims received after the end of the coverage year. In the preamble to the current Rule, CMS noted that its definition of the term "coverage year" was intended to "provide timely closure for payment determination processes such as reinsurance, risk corridor and employer subsidies" and that a 3-month close-out window was warranted due to "highly automated and point of sale nature of prescription drug claims processing." CMS added that it believed that "the number and value of claims that will potentially be missed will be immaterial, consisting primarily of paper claims."[19] CMS then went on to quote industry statistics that at least 98% of drug claims are paid within 3 months of submission, pointing out that, in addition to this 3 month claims run-out period, plans would have 6 months to submit data, thus giving plans "the extra time necessary to compile the data necessary for retroactive reconciliation."[20]

Clearly, and as CMS indicates in the proposed rule, it did not anticipate the various post-point-of-sale ("POS") reconciliation processes between Part D plans and other payers, including other Part D plans, SPAPs, states and even long-term care facilities. Thus, it is no longer the case that non-POS claims are immaterial. Indeed, it appears likely that these will be a significant and ongoing aspect of the Part D program for the foreseeable future. In any event, whatever the period for which Part D plans must continue to accept claims for processing, CMS clearly recognized in the preamble that plans should be provided at least three months from date of submission to pay those claims, and at least six months from the date of final claims submission to compile the data necessary for retroactive reconciliation. In order that Part D plans be able to receive the reinsurance and risk corridor payments to which they are entitled under the MMA, CMS must extend the deadlines for claims and data submission by three and six months respectively after the last date on which such claims may be submitted to the Part D plan for payment by other parties.

Recommendations: Add a provision in the Rule extending the time period for Part D sponsors to (i) submit claims for payment reconciliation to three months after the last date on which Part D plans are required to accept such claims from other parties, and (ii) submit other data for reconciliation to six months from the last date on which Part D plans are required to accept claims for payment from other parties. This will ensure that Part D sponsors are provided the three and six month time periods that CMS intended for them to be able to submit claims and other data for payment reconciliation so that

[19] 70 Fed. Re. at 4309.
[20] Id.

they are able to obtain the reinsurance and risk corridor subsidy payments that on these claims as Congress directed.

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

Sincerely,

Russell C. Ring
SVP, Government Relations

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

Organization : Maryland Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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. Roger Schwartz **Date:** 07/24/2007

Organization : National Association of Community Health Centers

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Thank you.

CMS-4130-P-30-Attach-1.PDF

#30

National Association of
Community Health Centers, Inc.

July 24, 2007

[If by electronic means]
http://www.cms.hhs.gov/eRulemaking

Herb Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

Attention: **CMS-4130-P**

Re: Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Administrator Kuhn:

The National Association of Community Health Centers, Inc. ("NACHC") is pleased to respond to the above-cited solicitation from the Department of Health and Human Services ("DHHS") Centers for Medicare & Medicaid Services ("CMS") for comments on the proposed rules related to the Medicare Prescription Drug Benefit ("Part D") technical changes published at 72 Fed. Reg. 29403 (May 25, 2007).

NACHC is the national membership organization for federally supported and federally recognized health centers (hereinafter interchangeably referred to as "health centers" or "FQHCs") throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization.

I. Background

There are, at present, approximately 1100 FQHCs nationwide serving close to 16 million patients. More than one million of these FQHC patients are Medicare recipients. Most of these FQHCs receive Federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b) from the Bureau of Primary Health Care ("BPHC"), within the Health Resources and Services Administration ("HRSA") of DHHS. Under this authority, health centers fall into four general categories:

MAIN OFFICE
7200 Wisconsin Ave, Suite 210
Bethesda, MD 20814
301-347-0400
301-347-0459 fax

FEDERAL AND STATE AFFAIRS OFFICE
1400 Eye Street NW, Suite 330
Washington, DC 20005
202-296-3800
202-296-3526 fax

(1) those centers serving medically underserved areas (invariably poor communities), (2) those serving homeless populations within a particular community or geographic area, (3) those serving migrant or seasonal farm worker populations within similar community or geographic areas, and (4) those serving residents of public housing.

§ 423.120 ACCESS TO COVERED PART D DRUGS

NACHC is pleased to see health center pharmacies listed as a non-retail pharmacy that Part D plans may count toward the standards for convenient access to network pharmacies. Health centers serve approximately 1.2 million Medicare beneficiaries, many of whom experience multiple chronic diseases. Because the vast majority of them are low-income, health centers serve a disproportionate share of dual-eligibles. Medicare Part D has been a tremendous help for many health center patients. The low-income subsidy (LIS or "extra help"), has expanded the number of health center patients with close to fully-subsidized drug coverage. This benefit helps many health center patients purchase their drugs ultimately improving their overall health. Listing health center pharmacies as non-retail pharmacies that Part D plans may count toward their convenient access standards encourages Part D plans to coordinate with health centers to better serve Medicare patients; particularly those with fewer resources and often greater health care needs.

§ 423.100 DEFINITION OF GOVERNMENT-FUNDED HEALTH PROGRAM

NACHC appreciates the opportunity to raise the issue of CMS' designation of FQHCs as a "government-funded health program" for the purpose of excluding health center cost-sharing from counting towards Part D beneficiaries' true-out-of-pocket expenditures. We strongly urge CMS to reconsider its interpretation of the law and allow health centers' cost-sharing to count towards a Part D enrollee's TrOOP requirement. The current regulation defines a government-funded health program as "any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, *which uses public funds*, in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs. 42 C.F.R § 423.100 [Emphasis added]. FQHCs are not listed in the rule as a "government-funded health program" along with the Medicaid program, the Indian Health Service program and the veterans' health care program however the preamble identifies FQHCs as a "government funded health program."

> Thus, insurance or otherwise encompasses not just traditional health insurance coverage that is not considered a group health plan, but also government programs and entities (including the Department of Veterans Affairs (VA), IHS, Federally Qualified Health Centers (FQHC), Department of Labor (DOL) Federal Workers' Compensation Program), government insurers (including Medicaid, Medicaid 1115 demonstrations, and the State Children's Health Insurance Program (SCHIP)), and government-sponsored funds (including black lung benefits, Ryan White CARE Act funds, and State special funds that assist certain

individuals with their medical costs such as a special fund for AIDS patients). 70 Fed. Reg. 4241, Jan. 28, 2005.

Unlike the other programs listed in the preamble, FQHCs do not necessarily use government funds to pay the cost of Part D drugs. Rather, FQHCs are non-profit charitable corporations that rely on a variety of sources to provide health care services, including revenue from private payers, public charitable donations, and State Pharmaceutical Assistance Programs. Moreover, so-called FQHC "look-a-likes" do not receive any federal grant funds under Section 330 of the Public Health Service Act despite meeting the qualifications for eligibility for such grant funds. The other "entities" on the excluded list are distinctly federally-funded health care programs. In contrast to such federal programs, FQHCs are a type of provider entity that must meet rigorous federal requirements to qualify for certain benefits and to become eligible for grant funding.

Moreover, CMS' recent decision to allow Disproportionate Share Hospitals (DSH) funds to count towards a beneficiaries TrOOP requirements further supports allowing beneficiaries to count health centers' cost-sharing towards their TrOOP requirement. Section 30.4 of the Chapter 5 Medicare Part D Prescription Drug Manual (Pharmacy Waiver/ Reduction of Cost-Sharing and Applicability toward TrOOP) provides:

> Receipt of Medicaid or Medicare Disproportionate Share Hospital (DSH) payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a "government-funded health program." We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services, and not akin to government grants and funding that are used, in whole or in part, to provide to (or pay on behalf of) an individual the costs of Part D drugs.

As a result Medicaid and Medicare DSH payments do not automatically designate a hospital as a TrOOP-excluded entity. Applying this same logic to FQHC provider types, the receipt of any source of federal funding should not automatically result in excluding health center cost-sharing from TrOOP expenditures.

§423.464 COORDINATION OF BENEFITS WITH PART D PLANS AND OTHER PAYERS

As CMS establishes methods for more effective coordination of drug benefits, we ask that CMS revise its current statutory interpretation disallowing health center expenditures for a Part D beneficiary to count towards his or her TrOOP requirement. The Medicare Part D final rule reads, "A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold." 42 C.F.R. § 423.464(f)(2). CMS lists FQHCs among other health plans and payers as entities "that provide other prescription drug coverage." 42. C.F.R. § 423.464(f)(1). We strongly disagree with CMS' decision to include health centers in that definition.

As you know, Congress provided for a new exception in the anti-kickback statute that permits pharmacies to waive or reduce the co-pay for Part D drugs under certain conditions and allowed the result of such expenditures to count toward the beneficiary's TrOOP calculation in limited circumstances. However CMS' treatment of health center expenditures for the purposes of TrOOP requirements significantly harms health centers financial viability and serves as an obstacle to low-income Medicare beneficiaries. Specifically, some patients who have had their cost sharing waived by the health center pharmacy may never move out of the coverage gap because of the CMS rule. As a result, health centers will perpetually be required to use their resources to help their low-income seniors access their much needed drugs, further taxing the health center's finances. NACHC urges CMS to change its interpretation of health center expenditures as it applies to Part D TrOOP requirements.

We appreciate the opportunity to comment on the proposed regulations, and we would welcome the opportunity to further discuss these concerns. If you have questions, please contact, Roger Schwartz, Legislative Counsel and Senior Director of State Affairs, at 202.298.3800.

Respectfully submitted,

Roger Schwartz, Esq.
Legislative Counsel and
Senior Director of State Affairs

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

Organization : National Senior Citizens Law Center

Category : Attorney/Law Firm

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See Attachment

Administrative Costs

Administrative Costs

See Attachment

Application Timing

Application Timing

See Attachment

Data Match

Data Match

See Attachment

GENERAL

GENERAL

See attached re late enrollment penalty.

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

See Attachment

CMS-4130-P-31-Attach-1.DOC

#31

Justice
Independence
Dignity
Security

NSCLC

National Senior Citizens Law Center

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

July 24, 2007

Comments Submitted on Behalf of the National Senior Citizens Law Center and the Center For Medicare Advocacy, Inc. on Draft Regulations Concerning The Medicare Prescription Drug Benefit

Re: File Code CMS-4130-P

The National Senior Citizens Law Center and the Center for Medicare Advocacy, Inc. are pleased to submit comments on the draft regulations concerning policy and technical changes to the Medicare prescription drug benefit published in the Federal Register on May 25, 2007.

BENEFICIARIES AND BENEFICIARY PROTECTION

Drugs for Morbid Obesity (Sec. 423.100)

We urge CMS to reverse its current interpretation that the exclusion of drugs for "weight loss" extends to drugs prescribed for morbid obesity. Such a blanket exclusion is inconsistent with Medicare policy on provision of medical services in relation to obesity. That policy covers treatment of obesity when connected to treatment of other serious conditions:

"Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Non-surgical services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these medical conditions. Certain designated surgical services for the treatment of obesity are covered for Medicare beneficiaries who have a BMI > 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with the medical treatment of obesity."
NCDM at 40.5.

Medicare also provides coverage of certain treatments when weight loss is necessary before surgery. Id.

Nothing in the statutory exclusion set forth in Part D suggests Congressional intent to further narrow this policy with respect to Part D prescription drugs. CMS should articulate a policy that provides coverage of weight loss drugs that is consistent with current Medicare policy for non-drug treatments for similar conditions.

Insulin Inhalation Drugs and Supplies (Sec. 423.100)

We appreciate CMS's proposal to extend coverage to insulin inhalation supplies and agree that such an extension is consistent with Congressional intent. We believe, however, that CMS's proposed scope of coverage for such supplies is overly restrictive. The MMA, at 42 U.S.C. 1395w-102(e)(1)(B), calls for Part D coverage of "associated" supplies. The statutory use of the term "associated" evidences a Congressional intent to cover insulin supplies broadly. CMS, however, has added the requirement that supplies be "*directly* associated" with delivering insulin. CMS's stated concern is that providing coverage of important supplies would "inappropriately broaden" the Part D benefit. This concern is not supported by the statute or its legislative history. (See Conference Report at 1823 directing coverage of insulin supplies that are "reasonable and necessary.") CMS is attempting to create artificial distinctions among necessary supplies. A device to hold an insulin inhaler may not meet CMS's definition of "directly associated" with insulin delivery, but for an individual who, because of other medical conditions, cannot otherwise manipulate the inhaler, it is very necessary.

Long Term Care Facilities (Sec. 423.100)

We appreciate the clarification with respect to Part D coverage of beneficiaries in institutions for mental disease and those in hospitals who have exhausted their Part A inpatient days benefit and for whom payment is no longer available under Part A or Part B.

NEGOTIATED PRICES (Sec. 423.100 and 423.104(d)(2)(i))

We have serious concerns that current pharmacy pricing practices for Part D drugs and the regulations proposed by CMS do not reflect Congressional intent that consumers share the benefit of all rebates and discounts negotiated by plans.

Specifically, we believe the current and proposed definition of "negotiated prices" is too narrow. The definition limits the "negotiated prices" to prices negotiated between the plan (or PBM) and the pharmacy and does not include price concessions negotiated between plan and the drug manufacturer. This narrow definition has no statutory basis.

Our understanding is that Part D prescription drug pricing operates similar to pricing in the private, non-Part D sector.[1] Rebates and discounts negotiated between the plan and the drug manufacturer are not generally reflected in the amount paid to the pharmacy but,

[1] For a discussion of private plan pricing, see Congressional Budget Office, "Prescription Drug Pricing in the Private Sector" (Jan., 2007).

instead, should have some impact on competitively-set premium charges. This pattern does not comport with the statutory language, which expects that all discounts and rebates should be reflected primarily in pricing, rather than in premiums. See 42 USC 1395w-102(d)(1)(B). Despite this disconnect, the presumed impact of rebates and discounts on premiums may create a rough equivalence in consumer benefit, but only until the beneficiary reaches the doughnut hole.

Under the proposed regulations, in the doughnut hole, the consumer would not get the benefit of the rebates and discounts negotiated between the plan and the manufacturer, but the plan would. This amounts to a hardship for the beneficiary and a windfall for the plan that is not contemplated, or permitted, by the statute.

As we understand the proposed regulations, in a case where the pharmacy price, including dispensing fee, is $100 and after-sale rebates and discounts paid to the plan by the drug manufacturer amount to $10, the pricing would work as follows:

- Before reaching the doughnut hole, the plan pays $75 (75%), the beneficiary pays $25 (25%), and the pharmacy receives $100. The plan then receives $10 from the manufacturer in discounts and rebates. At the end of the day, the cost to the plan is $65 and the cost to the beneficiary is $25, so the total cost to the plan and beneficiary is $90.

- After reaching the doughnut hole, under the proposed regulations, the plan pays nothing, the beneficiary pays $100, and the pharmacy receives $100. The plan then receives $10 from the manufacturer in discounts and rebates. The total cost to the beneficiary is $100 and the plan, which has paid nothing, receives a $10 windfall.

- In both cases, the plan negotiates with the manufacturer to obtain a $10 rebate on the medication. Before the beneficiary reaches the doughnut hole, that $10 helps the plan pay its 75% to the pharmacy. After the beneficiary reaches the doughnut hole, the plan keeps the entire $10 and pays nothing. The beneficiary does not receive the benefit of the plan's negotiation with the manufacturer. In fact, the beneficiary is hurt by the negotiation, since the plan is willing to pay the pharmacy more for a drug when it knows it will receive a rebate from the manufacturer.

Thus, before reaching the doughnut hole, all beneficiaries lose out on 25% of the benefit of manufacturer rebates and discounts, a loss that might be offset by competitive pricing of premiums. But those beneficiaries unfortunate enough to reach the doughnut hole lose out on 100% of the benefit of manufacturer rebates and discounts. They are disproportionately and unfairly affected because rebates and discounts negotiated between the plan and manufacturer are not reflected in the pharmacy price. Beneficiaries are disproportionately and unfairly harmed and plans are disproportionately and unfairly remunerated.

This is not what Congress intended. The plain language of the statute, as well as the statute's legislative history, clearly demand that all beneficiaries, and especially beneficiaries in the doughnut hole, receive the full benefits of all rebates, discounts, subsidies and remunerations, not just those that are reflected at the pharmacy counter. Under Part D, plans are able and expected to negotiate significant savings with manufacturers. The statute requires that these savings be passed on to beneficiaries.

CMS should not finalize regulations supporting a scheme that is contrary to both the letter and intent of the MMA. The proposed definition of "negotiated prices" must be revised to include all discounts, rebates, subsidies, remunerations and other price concessions negotiated by plans.

ADEQUATE ACCESS TO HOME INFUSION PHARMACIES (Sec. 423.120(a)(4))

We do not believe that the proposed 24 hour timeframe for home infusion pharmacies to deliver medication to beneficiaries is adequate. In its commentary to the proposed new regulation, CMS itself states that "we have learned that best practices involve the availability of infusion services upon discharge from a hospital either by the next required dose or within twenty-four hours of the discharge." This best practices standard should apply and Section 423.120 (a)(4)(iv) should be changed to: "(iv) Provide delivery of home infusion drugs either by the next required dose or within 24 hours of discharge from an acute setting, whichever is sooner."

GROSS COVERED PRESCRIPTION DRUG COSTS (Sec. 423.308)

We appreciate the clarification that beneficiary payments to PAPs can count toward their TrOOP.

COORDINATION OF BENEFITS WITH PART D PLANS AND OTHER PAYERS (Sec. 423.464(f))

Although we do not have specific comments on the details of plan-to-plan reconciliation, we do want to emphasize the importance of using such procedures rather than pharmacy reversals and readjudication of claims. We continue to see beneficiaries denied necessary medications at the pharmacy because of enrollment lags and data errors. The problem is exacerbated by low income beneficiaries' inability to obtain correct cost-sharing in a timely manner (despite the reissued best available evidence policy) and CMS' limitations on scope and usage of the Point of Sale (POS) mechanism. Having a workable and mandatory plan-to-plan reconciliation process is one element in addressing this continuing serious problem.

PREMIUM SUBSIDY FOR LATE ENROLLMENT PENALTY (Sec. 423.780(e))

We appreciate the change in the regulation that applies partial premium subsidies to beneficiaries who qualify for the partial low-income subsidy. The change correctly reflects statutory requirements.

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

Sincerely,

Georgia Burke
Staff Attorney
National Senior Citizens Law Center

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

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

Organization : **NC Association of Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-32-Attach-1.DOC

#32

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

August 1, 2007

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

Subject: Policy and Technical Changes to the Medicare Prescription Drug Benefit
72 Fed. Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423) (proposed May 25, 2007)

On behalf of the North Carolina Association of Pharmacists (NCAP), we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed policy and technical changes to the Medicare Prescription Drug Benefit plan dated May 25, 2007. We would like to comment, in particular, on the proposed changes and clarifications regarding (i) "Eligibility and Enrolment," (ii) "Negotiated Prices," (iii) "Adequate Access to Home Infusion Pharmacies," (iv) "Administrative Costs," and (v) "Gross Covered Prescription Drug Costs" "Coordination of Benefits With Part D Plans and Other Payers" and "Application Timing" – collectively. The following comments are meant to address the above-mentioned five (5) categories.

Subpart B – Eligibility and Enrollment
72 Fed. Reg. 29404 (2007) (to be codified at 42 C.F.R. § 423.50) (proposed May 25, 2007) Approval of Marketing Materials and Enrollment Forms

As a general matter of public policy, NCAP supports federal measures attempting to better inform our member pharmacists and their patients. As such, we wholeheartedly support a clarification of the pharmacists' educational and informational abilities with regard to Part D plans. Clarifying that the providers, provider groups, or pharmacies may supply printed information of Part D plan sponsors, provided that they offer similar material for all contracted sponsors, will limit confusion of available Part D sponsors while offering a more clearly defined mechanism to better educate the patient.

Previous CMS guidance, regarding the educational and informational offerings of Part D plans, stated that it was "appropriate to allow providers and pharmacies to market to beneficiaries." (70 FR 4223) However, the broad, general nature of the guidance invited confusion and created the potential for interests other than patient education to enter into the Plan D plan descriptions. NCAP supports and appreciates the proposed clarification, which defines "marketing" in a more specific manner and expressly allows for the education and assisting in enrollment as defined in The Guidelines, allowing pharmacists to provide their insight and expertise in helping their patients make informed decisions about their prescription drug plans.

Negotiated Prices

NCAP strongly supports federal efforts that are designed to positively affect the affordability of and access to prescription drugs and the efforts of CMS to clarify the Medicare Prescription Drug Benefit plan. Furthermore, NCAP supports clarifying and providing further guidance on the definitions, means of determining, and identification of qualified entities affected under the Medicare Prescription Drug Benefit plans for negotiated prices. However, we are compelled to offer the following comments on the proposed changes to 72 Fed. Reg. 29407 (2007) (to be codified at 42 C.F.R. § 423.100) (proposed May 25, 2007) regarding negotiated prices.

NCAP continues to have concerns that the lack of price transparency present in entities such as pharmacy benefit managers (PBMs) and mail order facilities presents federal and state oversight challenges and that it remains possible that these entities are not providing best price solutions to their clients and patients. Previously, CMS has recognized the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships.[1] The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace requires CMS to continually address the methodologies used for basis pricing. NCAP is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and NCAP asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors.

With regard to what is commonly referred to as 'spread pricing,' NCAP again supports the clarifications offered in the proposed changes to 72 Fed. Reg. 29407 (2007) (to be codified at 42 C.F.R. § 423.100) (proposed May 25, 2007). NCAP asserts that the equation in spread pricing is the amount employer paid minus amount pharmacy is reimbursed. Given this, an increase in the amount an employer pays creates a larger spread. Therefore, it could be claimed that there is direct incentive, to the PBMs, to increase the employer price rather than lower it. This increase in price effectively increases the costs to the pharmacy patient because of the increased percentage of cost share. It is NCAP's contention that spread pricing is most often employed for generic prescriptions; this, in turn, leads to higher brand utilization, unnecessarily creating higher overall costs. NASPA views that the incentives created by spread pricing lead to significantly higher costs to the payers and ultimately to the employer, pharmacy patient and the federal government.

Adequate Access to Home Infusion Pharmacies

NCAP supports the proposed rule regarding home infusion pharmacies that codifies existing operational policies and imposes a new requirement that access to home infusion be offered within 24 hours of release from an acute setting. NCAP continually works with its state association members to inculcate best practices in the pharmacy community. We agree that the 24-hour requirement is consistent with accepted best practices. Furthermore, we support the new requirement, in particular because it is potentially a matter of patient safety. While NCAP has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, NCAP fully supports the clarifications and additions to 72 Fed. Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423.120(4)) (proposed May 25, 2007) and views such amendments as 72 Fed. Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423.120(4)(iii)) (proposed May 25, 2007) reasonable federal guidance. NASPA appreciates the willingness of CMS to again assert that adequate access to home infusions pharmacies is an expectation of the Part D plans.

Administrative Costs

NCAP supports and appreciates CMS defining the term administrative costs. Of particular interest to NCAP is what can be inferred by CMS' statement that PBMs' profit or loss is an administrative costs not a drug cost. As noted above in the comments regarding negotiated price, NCAP has continued interest in, and concerns, with the non-transparent business practices of PBMs.

Gross Covered Prescription Drug Costs; Coordination of Benefits with Part D Plans and Other Payers; and Application Timing

With regard to these sections NCAP, again, supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

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

---

[1] CMS 2238-P RIN 0938-AO20, Prescription Drugs, AMP Regulation; December 20, 2006.

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

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

Sincerely,

Fred Eckel, RPh
Executive Director

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

Organization : Astellas Pharma US

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-4130-P-33-Attach-1.PDF

BY HAND DELIVERY AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

July 24, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4130-P; Comments Regarding the Proposed Rule on Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Ms. Norwalk:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the proposed rule concerning Policy and Technical Changes to the Medicare Prescription Drug Benefit published by the Centers for Medicare and Medicaid Services (CMS).[1] Astellas is among the top 20 global research-based pharmaceutical companies, with global sales of approximately $8 billion, and the number two Japan-based pharmaceutical company. Our fundamental goal is to improve the health of Americans by developing and marketing cures for unmet medical needs in key therapeutic areas. Our North American product lines, which focus on the therapeutic areas of infectious disease, immunology, cardiology, dermatology, and urology, are used by Medicare Part D beneficiaries in a variety of settings.

Astellas is pleased that CMS has proposed to clarify and incorporate in regulation some of its Part D policies that enhance beneficiaries' access to needed medicines and improve quality of care. Incorporating key patient protections in the Part D regulations will strengthen the Part D benefit and sustain continued growth in enrollment, and we would welcome additional steps in this

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

direction. Our comments focus on two important areas where the proposed rule would promote better access and higher-quality care: increased participation in Part D plan networks by hospital pharmacies, and adoption of best practice standards for assuring adequate access to home infusion drugs.

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A. Benefits and Beneficiary Protections; Definitions; LTC Facilities

The definition of a long-term care (LTC) facility in the Part D regulations includes a "medical institution . . . for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the [Social Security] Act."[2] The proposed rule clarifies that "as medical institutions, hospitals . . . that receive payments under section 1902(q)(1)(B) of the Act can meet the definition of an LTC facility."[3] Part D plans must therefore "ensure that they provide convenient access to network LTC pharmacies (which, in the case of a hospital, is typically the hospital's in-house pharmacy) for all of their enrollees who are inpatients in a hospital [that is] a 'medical institution' under 1902(q)(1)(B) and therefore would meet the definition of an LTC facility and whose Part A benefits have been exhausted."[4]

Astellas strongly supports this clarification requiring that Part D plans provide convenient access to certain in-house hospital pharmacies; given the role that Part D plans play as hospital patients are discharged to the LTC or home setting, including more hospital pharmacies in Part D networks can help to ensure continuity of care for hospitalized Part D beneficiaries who are transitioning to other settings. Accordingly, we would encourage CMS both to emphasize this point in its final rule on Part D policy and technical changes, and to adopt additional measures to

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2 42 C.F.R. § 423.100.

3 72 Fed. Reg. at 29406. In circumstances where inpatients in these hospitals exhaust their Part A inpatient days benefit, and Part A or B payment is no longer available for drugs that otherwise qualify as "Part D drugs," such drugs are Part D drugs. Id.

4 Id. at 29407.

encourage Part D plans to provide their enrollees with better in-network access to hospital pharmacies.

B. Access to Covered Part D Drugs; Adequate Access to Home Infusion Pharmacies

Home infusion drugs, which include Part D infusible drugs for both short-term acute care (e.g., IV antibiotics) and long-term chronic care (e.g., alpha protease inhibitors), are essential to the health of many Part D beneficiaries. Under the existing regulations, Part D plans must provide their enrollees with "adequate access" to home infusion pharmacies, consistent with CMS guidelines and instructions.[5] In the proposed rule, CMS proposes: (1) to codify in regulation subregulatory guidance it has previously issued on access to home infusion pharmacies; and (2) to add a new requirement that Part D plans, through their pharmacy networks, provide covered home infusion drugs within at least 24 hours of a patient's discharge from an acute care setting such as a hospital.[6] CMS notes that "home infusion therapy may serve as a vehicle to promote early hospital discharge" and that, in its ongoing discussions with home infusion providers "we have learned that best practices involve the availability of infusion services upon discharge from a hospital either by the next required dose or within 24 hours of the discharge."[7]

Astellas urges CMS to finalize this proposal, which can help both to improve care for many Part D beneficiaries and to reduce overall Medicare costs. We agree with CMS that requiring delivery of home infusion services within at least 24 hours of a patient's hospital discharge represents a best practice in the home infusion industry that should be incorporated in the Part D regulations. In addition, we agree that home infusion therapy can promote earlier hospital discharges and thus significantly reduce Medicare Part A costs.

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5 42 C.F.R. § 423.120.

6 72 Fed. Reg. at 29408-09; proposed 42 C.F.R. § 423.120(a)(4).

7 72 Fed. Reg. at 29408.

Astellas appreciates the opportunity to provide these comments, which we hope will be useful to CMS in developing its final rule. If you have any questions or would like additional information, please contact me at 202-812-6162 or via e-mail (michael.ruggiero@us.astellas.com).

Sincerely,

s/ Michael Ruggiero

Michael J. Ruggiero
Senior Director, Government Policy and
External Affairs