Submitter : Mrs. Ann Kaplan **Date:** 07/24/2007

Organization : Pharmaceutical Research and Manufacturers of Ameri

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please see our comments attached.

CMS-4130-P-41-Attach-1.PDF

#41

PhRMA

July 24, 2007

VIA E-MAIL AND U.S. MAIL
Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-4130-P; Comments Regarding Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit**

Dear Mr. Kuhn:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the proposed rule published by the Centers of Medicare and Medicaid Services (CMS) concerning policy and technical changes to the Medicare Prescription Drug Benefit.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PHRMA companies are leading the way in the search for cures.

PhRMA strongly supports the Part D program and the increased access to prescription drugs that it has provided to Medicare beneficiaries, and we applaud CMS for its continued success in implementing the program. We firmly believe that the competitive, market-based structure of the program has provided broad access to medicines while driving down costs for beneficiaries and taxpayers. The consistently high satisfaction rates reported by Part D beneficiaries is clear evidence that this program is providing significant value. We look forward to working with CMS in the future to ensure the program continues to provide access to a broad range of prescription drugs to meet the needs of Medicare beneficiaries. In that regard, we provide the following comments on the proposed rule.

* * * *

[1] 72 Fed. Reg. 29403 (May 25, 2007).

I. Subpart D – Benefits and Beneficiary Protections

Part D Drug- Morbid Obesity

In the proposed rule, CMS states that it is "clarifying existing policy regarding the definition of a Part D drug that excludes agents used for weight loss, including in connection with morbid obesity."[2] The preamble states that CMS is confirming its position first stated in a Q&A that reverses the position that CMS originally took in the final Part D rule. This is the first opportunity to comment on CMS' new position. CMS has not in the proposed rule clearly stated the basis for its reversal which does not appear to be supported by the statute. CMS should treat agents prescribed for obesity differently than those for "weight loss," similar to the way it covers treatments for certain diagnoses differently when those treatments are used for excluded purposes.

Obesity is recognized as a serious medical condition that threatens patients' health and differs from simply being overweight or otherwise desiring weight loss. Since the mid-seventies, the prevalence of overweight and obesity has increased sharply for both adults and children. Data from two NHANES surveys show that among adults aged 20–74 years the prevalence of obesity increased from 15.0% (in the 1976–1980 survey) to 32.9% (in the 2003–2004 survey).[3] These increasing rates raise concern because of their implications for Americans' health. Obesity increases the risk of many diseases and health conditions, including the following:

- Hypertension
- Dyslipidemia (for example, high total cholesterol or high levels of triglycerides)
- Type 2 diabetes
- Coronary heart disease
- Stroke
- Gallbladder disease
- Osteoarthritis
- Sleep apnea and respiratory problems
- Some cancers (endometrial, breast, and colon)

---

[2] 72 Fed. Reg. at 29405.
[3] http://www.cdc.gov/nccdphp/dnpa/obesity/

One of the national health objectives set forth by the Department of Health and Human Services for the year 2010 is to reduce the prevalence of obesity among adults to less than 15%. Thus, CMS' policy should be supportive of this objective. CMS already covers bariatric surgery procedures for Medicare beneficiaries. As noted at the time of this coverage expansion, "[b]ariatric surgery is not the first option for obesity treatment".[4] Coverage of drug treatments for obesity may be an alternative to surgery for some patients.

Both as a legal and clinical matter, people who suffer from obesity are distinct from those who want or need to lose weight. Thus, a plain reading of the Medicare statute supports the conclusion that CMS reached in the Part D final rule: that agents when used to treat obesity are covered Part D drugs. Accordingly, CMS should withdraw its current guidance prohibiting Part D reimbursement of "obesity" drugs and clarify that agents used to treat obesity (as opposed to merely promoting "weight loss") qualify as "covered Part D drugs."

MMA excludes from Part D coverage a very limited subset of drugs.[5] Of particular relevance, Section 1860D-2(e)(2)(A) of the Social Security Act (SSA) excludes from Part D coverage those "drugs, classes of drugs, or their medical uses" that may be excluded from Medicaid coverage under Section 1927(d)(2) of the SSA.[6] The list of drugs in SSA Section 1927(d)(2) includes agents when used for "anorexia, weight loss or weight gain". MMA does not exclude drugs prescribed for the treatment of obesity,[7] and the statutory reference to drugs used for "weight loss" should not be interpreted so expansively as to encompass drugs used to treat the disease of obesity. Both the scientific literature[8] and government definitions demonstrate that obesity is a disease state distinguishable from the term "weight loss."[9] Treating obesity as the same as being overweight is inconsistent with CMS policy in a number of areas. For example, in October 2004, CMS liberalized its policies with respect to obesity by

---

[4] http://www.cms.hhs.gov/pf/printpage.asp?ref=http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1786

[5] SSA § 1860D-2(e)(2).

[6] SSA § 1860D-2(e)(2)(A).

[7] As previously indicated, CMS agreed with this conclusion in the final Part D rule. 70 Fed. Reg. 4194, 4230 (January 28, 2005).

[8] Recent scientific literature recognizes obesity as a chronic disease with an etiology that involves genetic, environmental, metabolic, and behavioral factors. Rippe J, Crossley S, Ringer R. Obesity as a chronic disease: Modern medical and lifestyle management. J Am Diet Assoc. 1998 Oct;98(10 Suppl 2):S9-15

[9] CMS uses the International Classification of Diseases ("ICD-9-CM") system. Under this system, diseases and disorders are classified under different groups of codes than symptoms. Under the ICD-9 system, "weight loss" is defined as a mere symptom and is not identified as a condition, disorder, or disease. On the other hand, the system provides a distinct code with unique descriptors for both "morbid obesity" and unspecified obesity. These codes are grouped in the "other metabolic and immunity disorders" section of the system. In addition, CDC, NIH and the Surgeon General all have a specific definition of obesity.

eliminating language in the National Coverage Determinations Manual stating that "obesity itself cannot be considered an illness."[10]

There are a number of areas where CMS has provided coverage for drugs with multiple uses when the drugs are used for covered conditions. There is no reason provided by CMS for treating the class of drugs that may be prescribed to treat obesity differently. The medical community distinguishes between medical uses that are therapeutic in nature and those that relate merely to cosmetic use or to non-specific symptoms that do not sufficiently indicate the presence or likely presence of a condition, disorder, or disease. Accordingly, the same analysis applies to drugs used to treat obesity. So long as a drug that treats obesity is being used for a purpose other than weight loss, it must be considered a covered Part D drug. Some examples of CMS' coverage of drugs with dual uses are as follows:

(1) Agents When Used for Weight Gain

Despite the exclusion under Section 1927(d)(2) for agents when used for weight gain, CMS specifically provides coverage for prescription drugs used to treat cachexia[11] or AIDS wasting: "Prescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain or agents used for cosmetic purposes, and therefore such products are NOT excluded . . . ."[12] Although weight gain is the desired outcome of using prescription drugs to treat AIDS wasting and cachexia, CMS does not interpret this result as a statutory bar to coverage of these drugs simply because they result in weight gain. CMS should apply this same logic to affirm the conclusion that it reached in the Part D final rule: that the mere fact that the desired end result of using a prescription drug is to achieve weight loss does not mean that such a drug should be denied Part D coverage when it is used to treat the disease of obesity.

(2) Agents Used For Cosmetic Purposes or Hair Growth

Agents used for cosmetic purposes are statutorily excluded from Part D coverage, except when they are used to treat psoriasis, acne, rosacea, or vitiligo.[13] Using a prescription drug to treat a skin condition such as acne certainly has cosmetic benefits, but such a use is not statutorily excluded simply because of this result.

---

[10] MLN Matters Number MM3502, October 1, 2004.
[11] Cachexia is defined as "general physical wasting and malnutrition usually associated with chronic disease." MERRIAM-WEBSTER ONLINE DICTIONARY, U.S. NATIONAL LIBRARY OF MEDICINE AND THE NATIONAL INSTITUTES OF HEALTH (2005), *at* http://www2.merriam-webster.com/cgi-bin/mwmednlm?book=Medical&va=cachexia.
[12] CMS, PART D DRUGS/PART D EXCLUDED DRUGS (updated Apr. 19, 2006).
[13] Id.

(3) Antihistamines/Decongestant Combinations (RX)

Prescription antihistamines/decongestant combinations are covered under Part D except when used for symptomatic cough and cold relief.[14]

(4) Botox®

Botox® injections are covered by Medicare Part B when used for therapeutic purposes, such as strabismus (an eye disorder) or blepharospasm (a disorder causing involuntary facial movement). Medicare does not cover Botox® for mere cosmetic uses as it is excluded under the cosmetic surgery exclusion in the Medicare statute.

As these examples demonstrate, Medicare coverage is frequently available for one use of an agent and rejected for another. Accordingly, providing coverage for drugs used in the treatment of obesity, but denying coverage for the same drugs when used for weight loss, is consistent with CMS' historical coverage policy on dual-use drugs.

Part D Drug- Vaccine Administration Fee

In the preamble, CMS proposes to amend the definition of Part D drug to include a reference to vaccine administration on or after January 1, 2008 to conform to the statutory change made in the Tax Relief and Health Care Act of 2006. However, CMS did not include proposed language in the regulatory text of the proposed rule. We suggest that CMS amend Section 423.100 to add the following language to the definition of Part D drug under (1) (v): "(and for vaccine administration on or after January 1, 2008, its administration) after "Public Health Service Act" to conform to the statutory change.

II. Gross Prescription Drug Costs (§ 423.308)

In the preamble, CMS confirms earlier guidance that nominal beneficiary copays to patient assistance programs (PAPs) in connection with assistance that is provided outside the benefit will count toward TrOOP. [15] CMS states that the definition of " 'gross prescription drug costs' has been revised to include these drug costs and to reflect this sub-regulatory guidance." It is unclear from the new definition of "gross prescription drug costs" that CMS has achieved this objective. Moreover, it is unclear that this

---

[14] Id.
[15] 72 Fed. Reg. at 29410.

definition is the right place to codify this policy. It is more important to clarify the definition of "incurred costs" in Section 423.100 to ensure that it reflects this policy.

The term "incurred costs" means "costs incurred by a Part D enrollee for *covered Part D drugs* – (1) That are not paid for under the Part D plan as a result of application of *any annual deductible or other cost sharing rules* for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold..." [16] Nominal copays for PAP assistance may not meet this definition. PAP assistance that is provided "outside the benefit" might be provided without regard to the application of the deductible or other cost sharing rules. In addition, the definition of covered Part D drugs requires that the drugs be obtained at a network pharmacy or at an out of network pharmacy in accordance with Section 423.124. PAP drugs may not always be distributed through network pharmacies or in accordance with the out of network pharmacy rule's requirements. Thus, CMS should revise the definition of "incurred costs" to reflect the policy permitting nominal copays to PAPs to be counted toward TrOOP. We propose the following language for CMS' consideration (additional language in underline):

Incurred costs means cost incurred by a Part D enrollee for

(1) (a) covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under §423.124(b); or

(b) nominal copays in connection with patient assistance program assistance for drugs which would be covered part D drugs, except that the drugs might not be obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

(2) That are paid for...

Subpart M – Grievances, Coverage Determinations and Appeals

Projected Value (§ 423.560)

CMS proposes to amend the definition of "projected value" at 42 CFR § 423.560 to conform to the text at 42 CFR § 423.610(b). Specifically, CMS proposes to delete the existing language which includes in projected value "future charges that will be incurred within 12 months from the date the request for coverage determination or

[16] 42 C.F.R. 423.100 (emphasis added).

exception is received by the plan" with language which would limit the definition to "any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year."

Although CMS notes that Sections 423.560 and 423.610(b) conflict, CMS does not point to any basis for conforming Section 423.560 to the language of Section 423.610(b) rather than the other way around. In fact, Section 423.560 provides the specific definitions for the Subpart M-Grievance, Coverage, Determinations and Appeals section. There should not be the need to define the term "projected value" once again in Section 423.610. The definition of "projected value" is used to determine whether a Part D enrollee meets CMS' amount in controversy threshold for appealing a claims denial to an administrative law judge ("ALJ"). By limiting the "projected value" of the beneficiary's costs from a claims denial to only those costs which will be incurred through the remainder of the plan year, CMS would effectively deny appeal rights to beneficiaries who are prescribed a drug late in the plan year. We believe this would be arbitrary, particularly given the fact that the great majority of Part D beneficiaries stay in the same Part D plan through annual renewals. [17] In order to be fair to all enrollees regardless of when the prescription which is the subject of the appeal is prescribed during the plan year, CMS should retain the 12-month timeframe currently included in the definition of "projected value," and amend Section 423.610(b) to conform to that section.

A beneficiary (or group of beneficiaries, as contemplated by 42 CFR §423.610(c)(2)) should not be deprived of their appeal rights based solely on the time of the year when their physician believes a particular drug is medically necessary for them. If a beneficiary goes through all of the steps to reach an ALJ appeal and the ALJ approves the drug as medically necessary, the beneficiary should receive the benefit of a successful appeal and should be able to obtain coverage from the plan for at least 12 months (so long as the beneficiary remains in the plan and the physician continues to prescribe the drug). Thus, CMS should retain the current language in Section 423.560 and should revise Section 423.610(b) to remove the last sentence.

---

[17] As a related issue, CMS should mandate in the Chapter 18 of the Prescription Drug Benefit Manual (Part D Enrollee Grievances, Coverage Determinations and Appeals) that when a Part D beneficiary wins an appeal to an ALJ, the Part D plan must grant coverage of the drug in accordance with the ALJ decision for at least twelve months (so long as the beneficiary remains in that plan and the physician continues to prescribe the drug). Currently, the Manual is silent on this issue, although Section 30.2 of the Manual indicates that when a plan itself grants a formulary exception request, the plan may continue providing coverage in the following year or, if it satisfies certain notice requirements, discontinue coverage at the end of the plan year.

* * * * *

PhRMA appreciates the opportunity to comment on this proposed rule. We hope that these comments will be useful to CMS in developing its final rule. We look forward to further dialogue on these issues, and please feel free to contact us with any questions or requests for additional information.

Sincerely,

Daniel T. Durham
Deputy Vice President

Ann Leopold Kaplan
Assistant General Counsel

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

Organization : Nebraska Pharmacists Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-42-Attach-1.DOC

#42

NPA
Nebraska Pharmacists Association

August 1, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P, Mail Stop C4-2605
7500 Security Blvd
Baltimore, MD 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 members of the Nebraska Pharmacists Association (NPA), I appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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, NPA 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. NPA 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.

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

NPA
Nebraska Pharmacists Association

Negotiated Prices

NPA 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, NPA 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.

NPA 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. NPA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and NPA 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,' NPA 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). NPA 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 NPA'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. NPA 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

NPA 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. NPA continually works with its members to promote best practices in the pharmacy community. We agree that the

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

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

NPA
Nebraska Pharmacists Association

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 NPA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, NPA 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. NPA 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

NPA supports and appreciates CMS defining the term administrative costs. Of particular interest to NPA 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, NPA 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 NPA, again, supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

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

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

Sincerely,

Joni Cover
Executive Vice President

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

Submitter : **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 attachment.

GENERAL

GENERAL

See attachment.

CMS-4130-P-43-Attach-1.PDF

#43

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

---

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

Organization : **Pennsylvania Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4130-P-44-Attach-1.DOC

#44

PENNSYLVANIA PHARMACISTS ASSOCIATION

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

July 24, 2007

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

Subject: 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 Pennsylvania Pharmacists Association (PPA), an association representing the pharmacists of our state, 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, PPA 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. PPA 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

PPA 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, NASPA 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.

PPA 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. PPA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and PPA 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,' PPA 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). PPA 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 PPA'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. PPA 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

PPA 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. PPA 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

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

requirement, in particular because it is potentially a matter of patient safety. While PPA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, PPA 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. PPA 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
PPA supports and appreciates CMS defining the term administrative costs. Of particular interest to PPA 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, PPA 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 PPA, again, supports and appreciates the additional clarification and codification of CMS guidance.

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

If you have any questions or need any additional information, please do not hesitate to contact our association at (717) 234-6151 or via email at pepple@papharmacists.com.

Sincerely,

Patricia A. Epple, CAE
Executive Director

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

Organization : **Indiana Pharmacists Alliance**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

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

Organization : Families USA

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-46-Attach-1.DOC

FamiliesUSA
The Voice for Health Care Consumers

July 24, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Via Electronic Submission

Re: File Code CMS-4130-P

To Whom It May Concern:

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

DRUGS FOR MORBID OBESITY (Sec. 423.100).

We urge CMS to reverse its proposed 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." National Coverage Determiniation for Treatment of Obesity (40.5).

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

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

Nothing in the statutory exclusion 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 support the proposal to extend coverage to insulin inhalation supplies. However, we believe that CMS's proposed scope of coverage for such supplies is overly restrictive. The MMA, at Section 1860D-2(e)(1)(B), includes Part D coverage of "associated" supplies. The statutory use of the term "associated" evidences a Congressional intent to cover insulin supplies broadly. However, CMS, however, has added the requirement that supplies be "*directly* associated" with delivering insulin. This addition is not based on statutory language and creates artificial distinctions among necessary supplies.

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. Implementation of the provision may be difficult, as Part D sponsors have had difficulties working smoothly with long-term care pharmacies. We urge CMS to oversee this requirement with vigilance.

NEGOTIATED PRICES (Sec 432.100)

We agree that CMS should require Part D sponsors to base cost sharing on the actual prices paid by beneficiaries at the point of sale, rather than the price the sponsor paid to an intermediary. The prices that beneficiaries pay out-of-pocket determine when the beneficiaries enter the coverage gap, and should be used to determine cost-sharing.

This change, however, does not address a fundamental problem with the operation of negotiated prices under Part D. Part D sponsors continue to be permitted to retain most of their discounts, rebates, and other price concessions. As we noted in our initial comments dated October 4, 2004, the regulations should require plans to pass along all of their negotiated savings to beneficiaries, in order to maximize the assistance provided to beneficiaries.

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

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

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

Organization : Pennsylvania Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached letter

CMS-4130-P-47-Attach-1.DOC

#47

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

July 24, 2007

Centers for Medicare and Medicaid Services
Attention CMS 4130-P Mail Stop C4-2605
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 Pennsylvania Pharmacists Association (PPA), an association representing the pharmacists of our state, 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, PPA 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. PPA supports and appreciates the proposed clarification, which defines "marketing" in a more specific

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 PPA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, PPA 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. PPA 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
PPA supports and appreciates CMS defining the term administrative costs. Of particular interest to PPA 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, PPA 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 PPA, again, supports and appreciates the additional clarification and codification of CMS guidance.

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

If you have any questions or need any additional information, please do not hesitate to contact our association at (717) 234-6151 or via email at pepple@papharmacists.com.

Sincerely,

Patricia A. Epple, CAE
Executive Director

#48

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

Organization : **NC Association of Pharmacists**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-4130-P-49-Attach-1.DOC

#749

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 & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P, Mail Stop C4-2605
7500 Security Blvd
Baltimore, MD 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 : **Ms. Mary Ann Wagner** **Date: 07/24/2007**

Organization : **National Association of Chain Drug Stores**

Category : **Pharmacist**

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

Coverage of Insulin Inhalation Drugs and Supplies (42 CFR 423.100)

CMS looks to Medicare Modernization Act legislative history in concluding that Congress would have intended coverage of the insulin drugs developed since passage of that act that are designed to be delivered by inhalation, as well as the supplies used to directly deliver the insulin inhalation powder to the patient, such as an inhalation chamber. NACDS agrees with this assessment, and supports coverage of this and any other new technology designed to provide crucial pharmaceutical products in a safer and more efficient manner to Medicare beneficiaries.

Administrative Costs

Administrative Costs

Calculating Cost-Sharing (42 CFR 423.100)

Under this proposed revision, CMS changes the definition of negotiated price for purposes of calculating the beneficiary s 25 percent initial co-insurance to provide that cost sharing should be based on the price the network dispensing pharmacy (or other provider, in the case of a physician-administered drug) receives in total for a particular drug. This new definition would be implemented for the 2009 contract year. Until now, plans could base cost-sharing not on the price ultimately charged by the pharmacy, but rather on the negotiated price the plan paid a pharmacy benefit manager (PBM) or other intermediary for the drug. NACDS and its member pharmacies are supportive of this change. Cost-sharing should be reflective of the dispensing pharmacy s actual costs.

Application Timing

Application Timing

Immediate Access to Home Infusion Pharmacies (42 CFR 423.120(a)(4))

Under this proposed revision, CMS adds a requirement that Part D enrollees be provided with adequate access to Part D-covered home infusion therapies within 24 hours of discharge from an acute setting. This requires that Part D plans demonstrate to CMS that their network is capable of providing, in the aggregate, the full array of home infusion Part D drugs (no single pharmacy must provide the full range of drugs, as long as the drugs are available across the network). The network must be capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care, and the drugs must be made available in a form that can be administered in a clinically appropriate fashion. The plan s in-network contracted pharmacies that do not provide ancillary services must receive plan assurances that another entity, such as a home health entity, can arrange for the necessary professional services and ancillary supplies. NACDS is supportive of this proposed revision, which would allow a wider array of pharmacies to provide home infusion products, thereby ensuring greater beneficiary access to these crucial treatments.

GENERAL

GENERAL

See attachment

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

Part D Plans Must Coordinate With Other Part D Plans (42 CFR 423.464(f))

Under this revised provision, CMS adds other Part D plans to the list of entities with which plans must coordinate benefits through the sharing of enrollment files, the processing of claims payments, claims reconciliation reports, application of incurred costs, and other administrative processes developed by CMS. This is intended to make
permanent the process mandated in the start-up of Part D under which plans are to make reconciling payments between themselves when coverage by the wrong plan is incorrectly communicated to the pharmacy at point of sale. We agree with CMS that this should avoid pharmacy reversals and the need to re-adjudicate claims, and we are grateful to the agency for recognizing this as a significant concern that could, if unaddressed, affect pharmacy access for Medicare Part D beneficiaries. We also support CMS decision to mandate that a new Part D plan of record make reconciling payments based on amounts reported to it by CMS, and without regard to the new plan s own formulary or utilization review audits.

In addition, NACDS supports CMS extension of the mandate for cross-plan reconciliation to other third-party payors that are not Part D plans, such as the state Medicaid programs. We also appreciate and strongly support the agency s direction here that when the wrong payor is required to pay for benefits, the Part D

sponsor should achieve timely reconciliation using established processes or new processes established by CMS, rather than by requesting pharmacies to reverse claims and re-adjudicate. Again, access concerns and issues of fairness demand this approach.

CMS-4130-P-50-Attach-1.PDF

#50

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Memorandum

July 24, 2007

Alissa deBoy
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-4130-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Proposed Revisions to 42 CFR 423, Medicare Prescription Drug Program (CMS-4130-P), 72 *Federal Register* 29403 through 29423, May 25, 2007

Dear Ms. deBoy:

The National Association of Chain Drug Stores (NACDS) has reviewed the above referenced proposed revised regulations and supports revisions relating to (1) the distribution of Part D plan marketing information by pharmacies, (2) the extension of benefit coordination requirements to coordination with other Part D plans and state Medicaid programs, (3) the revised calculation of cost-sharing, (4) the requirement that a network pharmacy be licensed, (5) coverage of insulation inhalation drugs and supplies, and (6) access to home infusion pharmacies.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

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

Approval of Marketing Materials and Enrollment Forms (42 CFR 423.50(f))

This change clarifies that that while a Part D plan may require a provider, provider group, or pharmacy to distribute printed information comparing the benefits of Part D plans, those providers, provider groups, or pharmacies are not required to accept and display printed comparative materials from Part D plans with whom they do not contract. We agree with CMS that this revision would eliminate an important area of beneficiary confusion. With this change, beneficiaries could no longer be misled into using a plan with which the pharmacy has not contracted. NACDS supports this provision.

Part D Plans Must Coordinate With Other Part D Plans (42 CFR 423.464(f))

Under this revised provision, CMS adds other Part D plans to the list of entities with which plans must coordinate benefits through the sharing of enrollment files, the processing of claims payments, claims reconciliation reports, application of incurred costs, and other administrative processes developed by CMS. This is intended to make

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

permanent the process mandated in the start-up of Part D under which plans are to make reconciling payments between themselves when coverage by the wrong plan is incorrectly communicated to the pharmacy at point of sale. We agree with CMS that this should avoid pharmacy reversals and the need to re-adjudicate claims, and we are grateful to the agency for recognizing this as a significant concern that could, if unaddressed, affect pharmacy access for Medicare Part D beneficiaries. We also support CMS' decision to mandate that a new Part D plan of record make reconciling payments based on amounts reported to it by CMS, and without regard to the new plan's own formulary or utilization review audits.

In addition, NACDS supports CMS' extension of the mandate for cross-plan reconciliation to other third-party payors that are not Part D plans, such as the state Medicaid programs. We also appreciate and strongly support the agency's direction here that when the wrong payor is required to pay for benefits, the Part D sponsor should achieve timely reconciliation using established processes or new processes established by CMS, rather than by requesting pharmacies to reverse claims and re-adjudicate. Again, access concerns and issues of fairness demand this approach.

Calculating Cost-Sharing (42 CFR 423.100)

Under this proposed revision, CMS changes the definition of "negotiated price" for purposes of calculating the beneficiary's 25 percent initial co-insurance to provide that cost sharing should be based on the price the network dispensing pharmacy (or other provider, in the case of a physician-administered drug) receives in total for a particular drug. This new definition would be implemented for the 2009 contract year. Until now, plans could base cost-sharing not on the price ultimately charged by the pharmacy, but rather on the "negotiated price" the plan paid a pharmacy benefit manager (PBM) or other intermediary for the drug. NACDS and its member pharmacies are supportive of this change. Cost-sharing should be reflective of the dispensing pharmacy's actual costs.

Pharmacy in Network Must be Licensed (42 CFR 423.100)

Under this proposed revision, CMS clarifies that a "contracted pharmacy" must be licensed. This brings the definition into line with the requirement that retail pharmacies be licensed. NACDS believes this change will serve to further safeguard beneficiaries' safety, and we strongly support the change.

Coverage of Insulin Inhalation Drugs and Supplies (42 CFR 423.100)

CMS looks to Medicare Modernization Act legislative history in concluding that Congress would have intended coverage of the insulin drugs developed since passage of that act that are designed to be delivered by inhalation, as well as the supplies used to directly deliver the insulin inhalation powder to the patient, such as an inhalation chamber. NACDS agrees with this assessment, and supports coverage of this and any other new technology designed to provide crucial pharmaceutical products in a safer and more efficient manner to Medicare beneficiaries.

Immediate Access to Home Infusion Pharmacies (42 CFR 423.120(a)(4))

Under this proposed revision, CMS adds a requirement that Part D enrollees be provided with adequate access to Part D-covered home infusion therapies within 24 hours of discharge from an acute setting. This requires that Part D plans demonstrate to CMS that their network is capable of providing, in the aggregate, the full array of home infusion Part D drugs (no single pharmacy must provide the full range of drugs, as long as the drugs are available across the network). The network must be capable of

providing infusible Part D drugs for both short-term acute care and long-term chronic care, and the drugs must be made available in a form that can be administered in a clinically appropriate fashion. The plan's in-network contracted pharmacies that do not provide ancillary services must receive plan assurances that another entity, such as a home health entity, can arrange for the necessary professional services and ancillary supplies. NACDS is supportive of this proposed revision, which would allow a wider array of pharmacies to provide home infusion products, thereby ensuring greater beneficiary access to these crucial treatments.

Conclusion

For each of the reasons listed above, NACDS supports the revisions proposed by CMS to Part D rule provisions governing (1) the distribution of Part D plan marketing information by pharmacies, (2) the extension of benefit coordination requirements to coordination with other Part D plans and state Medicaid programs, (3) the revised calculation of cost-sharing, (4) the requirement that a network pharmacy be licensed, (5) coverage of insulation inhalation drugs and supplies, and (6) access to home infusion pharmacies.

Thank you for the opportunity to share our perspectives on these issues.

Sincerely,

Mary Ann Wagner

Mary Ann Wagner
Senior Vice President
Policy and Pharmacy Regulatory Affairs

Submitter : Mr. Derek Asay **Date:** 07/24/2007

Organization : Eli Lilly and Company

Category : Drug Industry

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.

CMS-4130-P-52 **Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit**

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-52-Attach-1.DOC

#52

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

Organization : **WellCare Health Plans**

Category : **Health Plan or Association**

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

See Attachment.

Data Match

Data Match

See Attachment.

GENERAL

GENERAL

See Attachment.

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

See Attachment.

Insulin Inhalation Drugs and Supplies

Insulin Inhalation Drugs and Supplies

See Attachment.

Negotiated Prices

Negotiated Prices

See Attachment.

Noncalendar Year Plans

Noncalendar Year Plans

See Attachment.

CMS-4130-P-53-Attach-1.PDF

#23

Thaddeus Bereday
Senior Vice President and General Counsel

WellCare Health Plans, Inc.
The WellCare Group of Companies

WELLCARE OF FLORIDA, INC.
HEALTHEASE OF FLORIDA, INC.
WELLCARE OF NEW YORK, INC.
WELLCARE OF CONNECTICUT, INC.
HARMONY BEHAVIORAL HEALTH, INC.
WELLCARE OF LOUISIANA, INC.
WELLCARE OF GEORGIA, INC.
WELLCARE OF OHIO, INC.
COMPREHENSIVE HEALTH MANAGEMENT, INC.
HARMONY HEALTH SYSTEMS, INC.
HARMONY HEALTH PLAN OF ILLINOIS, INC.
WELLCARE PRESCRIPTION INSURANCE, INC.
WELLCARE HEALTH INSURANCE OF ILLINOIS, INC.
WELLCARE HEALTH INSURANCE OF ARIZONA, INC.
WELLCARE HEALTH INSURANCE OF NEW YORK, INC.

8735 Henderson Road
Tampa, Florida 33634
Telephone: 813.290.6353

July 24, 2007

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

Attention: CMS-4130-P
Insulin Inhalation Drugs and Supplies
Long-Term Care Facilities
Negotiated Prices
Adequate Access to Home-Infusion Pharmacies

Dear Sir or Madam:

WellCare appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Proposed Rule, "Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit" (72 FR 29403, May 25, 2007). WellCare is a leading health plan dedicated to ensuring quality, cost-effective health care for Medicare, Medicaid, and State Children's Health Insurance Program beneficiaries. Founded in 1985, our team of more than 3,000 associates, over 25,000 physician partners, and 60,000+ pharmacies serve over 2.2 million members across the country. WellCare sponsors Medicare Part D Prescription Drug Benefit (Part D) stand-alone prescription drug plans (PDPs), as well as Medicare Advantage and Medicare Advantage-Prescription Drug (MA-PD) plans.

As discussed in further detail below, WellCare generally supports CMS in its efforts to provide clarification and ensure technical consistency through the Proposed Rule.

- **Insulin Inhalation Drugs and Supplies.** WellCare supports CMS in availing Medicare beneficiaries with insulin-dependent diabetes of an alternative to injected insulin. As CMS noted in the Preamble to the Proposed Rule, Part D coverage is available for insulin and supplies associated with delivery methods that are not covered under Part A or Part B, including the Durable Medical Equipment (DME) benefit. Just as Congress did not anticipate the introduction of inhaled insulin as a diabetes management tool, neither CMS nor the stakeholders submitting comments to this Proposed Rule can accurately predict future advances in the delivery of inhaled insulin. Similarly, there is a lack of clarity on

the supplies that are covered under this expansion of Part D coverage. WellCare suggests that:

- Consistent with CMS' stated intent to avoid an inappropriate expansion of the Part D benefit, the regulatory language related to inhaled insulin at 423.100 be revised to state "(vi) Supplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin, *provided that the inhalation device is not covered under Part A or Part B, including the durable medical equipment benefit.*" Although this section of the Part D regulations clearly excludes Part D coverage for **drugs** that would be covered under Part A or Part B, coverage confusion may result for inhalation devices that are most accurately characterized as durable medical equipment if the regulations do not contain a similar limitation for inhalation devices.
- The distinction between Part D covered items that are directly associated with the delivery of inhaled insulin and non-covered auxiliary supplies is not sufficiently clear to guide Part D plans on coverage of items such as the "release units" that must be replaced every two weeks for the inhalation chamber that is the subject of this regulatory clarification. Additional clarification through the more informal guidance process or within the Preamble to the Final Rule would help ensure uniformity in Part D plan coverage, and permit sponsors to avoid unintentional noncompliance with contractual obligations.

❖ **Long-Term Care Facilities.** WellCare is concerned that the Preamble language concerning Part D coverage of drugs for beneficiaries who have exhausted their Part A inpatient days benefit is confusing and may create an unintended expansion of the Part D benefit. WellCare agrees that Part D coverage is available for drugs that are not covered under Part A or Part B. It is our understanding, however, that the particular circumstances of the prescribing, distribution, and administration of the product to the specific patient drive the determination of whether the drug is a Part D covered drug. Beneficiaries determining to forego Part B enrollment, however, do not qualify for expanded Part D benefits simply by virtue of that decision. WellCare urges CMS to provide more specific guidance, consistent with the Part D statutory and regulatory framework, regarding the circumstances under which Part D coverage would be available to patients who have exhausted their Part A inpatient days and for whom Part B coverage is not available.

❖ **Negotiated Prices.** WellCare appreciates CMS' recognition that Part D sponsors cannot readily apply discounts and rebates to further reduce the price for drugs negotiated at the pharmacy level and its clarification to sponsors that any discounts or rebates that are not actually passed down to the point of sale do not reduce "negotiated prices." WellCare enrollees recognize significant savings,

both during the "deductible" phase of coverage and through the "donut hole", by access to WellCare's negotiated prices for covered products. CMS' clarification related to this important benefit of Part D participation will ensure that Medicare beneficiaries continue to receive quality, cost-effective access to medically necessary drugs.

- **Adequate Access to Home Infusion Pharmacies (§423.120(a)(4)).** CMS proposes to codify certain policies related to home infusion pharmacy access. Of particular concern to WellCare is the potential ramifications of regulatory requirements that (a) Part D plans duplicate the efforts of discharging entities and physicians in ensuring that the supplies and services are in place for administration of covered drugs, and (b) that the sponsor ensure delivery of home infusion drugs to the patient within 24 hours of discharge from an acute setting. WellCare agrees in principal with CMS' preamble statement that "best practices involve availability of infusion services upon discharge from a hospital either by the next required dose or within twenty-four hours of the discharge." We support a carefully crafted and clearly articulated process that ensures Part D enrollee access to home infusion therapy drugs. WellCare urges CMS to incorporate efficient use of resources as a substantial component of the "best practices" employed to realize this goal.

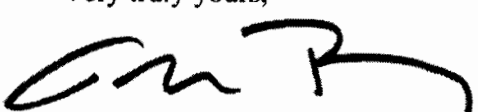
  - WellCare requests that CMS clarify its policy that the Part D in-network pharmacy provider responsible for delivering home infusion drugs "receive assurances that another entity" (e.g., home health entity) can provide necessary ancillary services to ensure that drugs are safely administered. Services such as arranging for home infusion drugs and services, and other necessary post-discharge care, are included within the Medicare-reimbursed services provided by acute care facilities through hospital discharge planning staff, and/or the discharging physician. Any Part D policy that creates an apparent shift in responsibility for post-discharge care will likely result in confusion and duplication of efforts among and between discharging facilities and the Part D contracted pharmacy. WellCare suggests that the discharging entity is in the best position to evaluate the patient and determine the ancillary services necessary to ensure safe home infusion drug administration and to provide the Part D contracted pharmacy with the assurances required under Section 423.153(c). We request that the Final Rule clarify that Part D contracted pharmacies providing drugs for home infusion need not make arrangements for home health care services ancillary to the supplied drugs and that the pharmacies may seek and rely upon assurances that the discharging entity has arranged for the supplies and services necessary for safe drug administration.

  - WellCare supports CMS in ensuring that patients receive necessary home infusion products on a timely basis. We are concerned, however, that the 24 hour delivery requirement may be arbitrary and create situations in which the

pharmacy is required by regulation to deliver products well in advance of the next scheduled dose, potentially compromising product integrity. Moreover, the proposed regulatory language requiring drug delivery "within at least 24 hours of discharge from an acute setting" lends itself to two conflicting interpretations that set the 24 hour requirement as (a) a minimum number of hours that must elapse between discharge and drug delivery, or, alternatively, as (b) a maximum number of elapsed hours from discharge. WellCare suggests that, if CMS codifies a time requirement for post-discharge home infusion product delivery, that it incorporate language consistent with the following: "provided that the discharging entity informs the appropriate Part D entity of the patient's impending discharge, and the appropriate Part D entity receives from the discharging entity assurances that supplies, and ancillary and professional services necessary for safe drug administration have been arranged; the Part D entity shall ensure that prescribed infusion drugs are delivered at the later of 24 hours after discharge or the time the product(s) are required for the first post-discharge dose." Alternatively, WellCare supports regulatory language that reflects the industry practice of differentiating between initiation of **home infusion therapy services** (e.g., services in preparation for delivery of drug therapy), which generally occur prior to or within 24 hours of notification of discharge, and initiation of **drug therapy.** Initiation of drug therapy is dependant upon the next scheduled dose of the medication, and may not occur within 24 hours of discharge.

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

Very truly yours,



Thaddeus Bereday
Senior Vice President and General

CMS-4130-P-54 **Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit**

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

Organization : **West Virginia Pharmacists Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4130-P-54-Attach-1.DOC

#54

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 : Mr. Bruce Roberts **Date:** 07/24/2007

Organization : National Community Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached Word document

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

Organization :

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-56-Attach-1.DOC

#56

Tennessee Pharmacists Association

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

August 1, 2007

Centers for Medicare and Medicaid Services
Attention CMS-4130-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 pharmacists in all practice settings in Tennessee and the patients they serve, the Tennessee Pharmacists Association (TPA) appreciates the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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, TPA 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. TPA 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

TPA 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, TPA 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.

TPA 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. TPA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and TPA 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,' TPA 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). TPA 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 TPA'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. TPA 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

TPA 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. TPA 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 TPA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, TPA fully supports the

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

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. TPA 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

TPA supports and appreciates CMS defining the term administrative costs. Of particular interest to TPA is what can be inferred by CMS' statement that PBMs' profit or loss is an administrative cost not a drug cost. As noted above in the comments regarding negotiated price, TPA 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 TPA, again, supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

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

If you have any questions or need any additional information, please do not hesitate to contact Baeteena M. Black, D.Ph., Executive Director, at (615)256-3023 or via email at bblack@tnpharm.org.

Sincerely,

Baeteena M. Black

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

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

Organization : **South Carolina Pharmacy Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-57-Attach-1.DOC

#57

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

August 1, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P, Mail Stop C4-2605
7500 Security Blvd
Baltimore, MD 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 South Carolina Pharmacy Association (SCPhA) we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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, SCPhA 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. SCPhA 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. This effectively allows pharmacists to provide their insight and expertise in helping their patients make informed decisions about their prescription drug plans.

Negotiated Prices

SCPhA 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, SCPhA supports clarifying and providing further guidance on the definitions, means of

determining, and identifying 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.

SCPhA 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. Previously, CMS has recognized the inherent lack of transparency 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. SCPhA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be 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,' SCPhA 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).

Adequate Access to Home Infusion Pharmacies

SCPhA 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. SCPhA 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 SCPhA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, SCPhA 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. SCPhA 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

SCPhA supports and appreciates CMS defining the term administrative costs. Of particular interest to SCPhA is what can be inferred by CMS' statement that PBMs' profit or loss is an administrative cost not a drug cost. As noted above in the comments regarding negotiated price, SCPhA 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, SCPhA supports and appreciates the additional clarification and codification of CMS guidance.

---

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

Conclusion

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

If you have any questions or need any additional information, please do not hesitate to contact at (803) 354-9977 or via email at ccinque@scrx.org.

Sincerely,

Carmelo Cinqueonce, MBA
Executive Vice President
South Carolina Pharmacy Association

Submitter : Ms. Suzanne Pattee **Date:** 07/24/2007

Organization : Cystic Fibrosis Foundation

Category : Consumer Group

Issue Areas/Comments

Application Timing

Application Timing

The Cystic Fibrosis Foundation commends CMS for codifying into regulation that Part D enrollees receive adequate access to Part D-covered home infusion therapy, which is an important component of care for people with CF. We are pleased that CMS is taking these steps to require coordination of coverage between Medicare Parts B and D to ensure access to professional services and supplies in conjunction with home infusion therapies.

People with cystic fibrosis (CF) rely on antibiotics to fight chronic lung infections. As the severity of lung disease increases, individuals often must use a number of antibiotics, requiring stronger doses and administration routes, including intravenous (IV) administration. Based on the 2005 Cystic Fibrosis Foundation National Patient Registry, more than 20 percent of people with CF needed home infusion therapy for IV antibiotics that year. In fact, nearly 45 percent of adults with CF age 18 and over had one or more acute exacerbations requiring hospitalization and/or a course of home IV antibiotics in 2005.

While IV antibiotics are often covered by Medicare Part D, this is not true of the professional services and medical equipment, such as IV pumps and supplies, to administer these treatments. Many people with CF report problems obtaining Medicare coverage for the IV drugs and supplies for home care therapies they require. Clarifying these regulations will be very helpful in ensuring timely coverage under Medicare Part D for people with CF.

We agree with the rule s expectation that Part D plans must deliver home infused drugs in a form that can be administered in a clinically appropriate fashion. Additionally, we agree that the Part D plans must require their contracted network pharmacies that deliver home infusion drugs to ensure that the necessary professional services and ancillary supplies are in place before dispensing the drugs. It would be best if CMS could clarify further how Part D plans will ensure this as each component is essential for drug delivery. Without providing the services and supplies, patients cannot use home infusion therapies. Thus, delays will ensue and patients will needlessly suffer.

We support the rule s provision that Part D plans must have in place contracts with pharmacies that can provide either short term acute care or long term chronic care, as long as both types of care are provided within their pharmacy network. As CF becomes more severe, individuals who once relied on intermittent short term home infusion therapy may need long term provision of these therapies.

Finally, we are very concerned about the change to the regulations regarding the timeliness of delivery of home infusion drugs under Part D. We believe that requiring Part D sponsors to only provide such coverage within 24 hours of discharge from an acute setting is insufficient. For people with CF receiving IV antibiotics, it is critical to maintain the pharmacokinetics (i.e., a constant level of drug in the blood) needed in order to fight infection. Therefore, CMS must reasonably require that Part D sponsors provide such coverage upon discharge from the hospital by the next required dose as the standard for a reasonable timeframe for delivery, rather than merely within 24 hours of discharge.

GENERAL

GENERAL

Submitter : **Mr. Val Kalnins** **Date: 07/24/2007**

Organization : **Colorado Pharmacists Society**

Category : **Pharmacist**

Issue Areas/Comments

Administrative Costs

Administrative Costs

CPS 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, CPS 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.

CPS 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. 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. CPS is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and CPS 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, CPS 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). CPS 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 CPS 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. CPS 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.

Application Timing

Application Timing

CPS 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. CPS 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 CPS has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, CPS 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. CPS appreciates the willingness of CMS to again assert that adequate access to home infusions pharmacies is an expectation of the Part D plans.

Coordination of Benefits with Part D Plans & Other Payers

Coordination of Benefits with Part D Plans & Other Payers

CPS supports and appreciates CMS defining the term administrative costs. Of particular interest to CPS 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, CPS has continued interest in, and concerns, with the non-transparent business practices of PBMs.

Data Match

Data Match

With regard to these sections CPS, again, supports and appreciates the additional clarification and codification of CMS guidan

GENERAL

GENERAL

See attachment

CMS-4130-P-59-Attach-1.WPD

#59

Colorado Pharmacists Society

6825 E. Tennessee Ave., Suite 440

Denver, CO 80224
303-756-3069 phone
303-756-3649 fax
val@copharm.org
www.copharm.org

August 1, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P, Mail Stop C4-2605
7500 Security Blvd
Baltimore, MD 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 Colorado Pharmacists Society (CPS), the state pharmacy organization representing over 750 pharmacists in all practice settings, 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, CPS 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. CPS 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

CPS 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, CPS 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.

CPS 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. CPS is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and CPS 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,' CPS 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). CPS 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 CPS'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. CPS 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.

---

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

Adequate Access to Home Infusion Pharmacies

CPS 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. CPS 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 CPS has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, CPS 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. CPS 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

CPS supports and appreciates CMS defining the term administrative costs. Of particular interest to CPS 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, CPS 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 CPS, again, supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

In summary, CPS 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, CPS 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 Val Kalnins, R.Ph., Executive Director of the Colorado Pharmacists Society, at (303) 756-3069 or via email at val@copharm.org.

Sincerely,

Val Kalnins
CPS Executive Director

CMS-4130-P-60 **Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit**

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

Organization : Florida Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4130-P-60-Attach-1.DOC

#60

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.