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

Organization : Virginia Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Resubmitting comments with proper docket number included.

See attachment

CMS-4130-P-61-Attach-1.DOC

#61

VIRGINIA PHARMACISTS ASSOCIATION

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Pharmacists helping pharmacists to improve patient care.

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 Virginia Pharmacists Association (VPhA), 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, VPhA 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. VPhA 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

VPhA 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, VPhA 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.

VPhA 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. VPhA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and VPhA 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,' VPhA 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). VPHA 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 VPhA'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. VPhA views that the incentives created by spread pricing lead to

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

significantly higher costs to the payers and ultimately to the employer, pharmacy patient and the federal government.

Adequate Access to Home Infusion Pharmacies

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

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

Conclusion

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

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

Submitter : **Mr. John Siracusa** **Date: 07/24/2007**

Organization : **BIO**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-62-Attach-1.PDF

#62

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Department of Health and Human Services
Washington, D.C. 20201

RE: CMS-4130-P (Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit)

Dear Acting Deputy Administrator Kuhn:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed regulation, "Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit,"[1] (the Proposed Rule) released May 25, 2007 and issued pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,100 biotechnology centers, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering and ensuring patient access to new and innovative therapies. Many of the therapies developed by biotechnology companies target conditions that primarily affect seniors. BIO has been a strong supporter of the Medicare Part D prescription dug benefit, and we appreciate CMS' significant efforts to implement this program. We believe that the Part D benefit has helped increase patient access to critical therapies as well as ensure that patients will be able to receive and afford the treatment options that best meet their needs. We continue to encourage CMS to focus on patient access in its ongoing implementation of this important program.

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

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Specifically, with respect to the Proposed Rule, BIO urges CMS to finalize its proposed approach to ensuring coverage of inhalation drugs and supplies and requests that CMS broaden this language to cover other methods of administering insulin that may be developed in the future. Second, BIO urges CMS to issue in the final rule an interpretation that the Social Security Act permits Part D plans to cover FDA-approved therapies to treat obesity. Third, BIO supports CMS' efforts to strengthen the rules requiring adequate access to home infusion pharmacies and urges CMS to continue to seek ways to provide meaningful access to these therapies through coverage of the supplies and services necessary to administer these therapies. Fourth, BIO appreciates CMS' continued efforts to achieve greater transparency in the Part D program and seeks clarification of how CMS intends for administrative fees paid to pharmacy benefit managers (PBMs) by biotechnology companies and pharmaceutical manufacturers to be treated under the Part D reporting rules. We have discussed each of these comments in greater detail below.

I. Insulin Inhalation Drugs and Supplies

BIO appreciates CMS' recognition that Congress, in defining Part D drugs to include the "medical supplies associated with the injection of insulin", intended to ensure that beneficiaries with diabetes have access to both insulin and the supplies required to deliver insulin to the body, even where the insulin is delivered by a method other than injection. BIO agrees with CMS' understanding of the legislative history supporting this interpretation and strongly supports CMS' determination that the supplies necessary to administer inhaled insulin are included under the definition of a Part D drug. We urge CMS to clarify that medical supplies associated with the administration of insulin are covered under Part D regardless of the method of administration of the insulin.

We are concerned, however, about CMS' comment in the Proposed Rule that it expects Part D plan sponsors "to apply drug utilization management tools to ensure the appropriate use of these supplies."[2] We appreciate that CMS intends to include in the definition of a Part D drug only those supplies directly associated with the delivery of inhaled insulin to the body, yet this language appears to create a specific expectation that Part D plans must impose utilization management tools on these supplies. This may instead hinder access to inhaled

[2] *Id.* at 29406.

insulin when clinically appropriate. The supplies necessary to administer insulin into the lungs are fundamental to delivering the insulin to the body, and it is not necessary for plans to impose utilization management tools on the basic supplies necessary to accomplish this administration. BIO urges CMS to ensure that Part D plans not take actions that unnecessarily delay beneficiary access to inhaled insulin or any of its corresponding parts or actions that may be used to impede access to new and innovative methods of delivery.

The recent FDA approval of inhaled insulin represents a major development in diabetes therapy and offers millions of Medicare beneficiaries an alternative way of managing their diabetes. There are other promising developments in the delivery of insulin on the horizon, and we wish to clarify that CMS intends for the supplies associated with other insulin delivery methods approved in the future to be included in the definition of a Part D drug as well. We urge CMS to finalize proposed paragraph (vi) in the definition of "Part D drug" in 42 C.F.R. § 423.100 to read as follows: "Supplies that are directly associated with delivering insulin into the body through inhalation or other mechanisms, such as the inhaler or its individual components (chamber, base, release unit, or other component parts) used to deliver inhaled insulin, or similar supplies directly associated with other delivery methods." This would clarify that the supplies directly associated with alternative methods of delivery of insulin, including but not limited to inhalation of insulin, are included in the definition of Part D drug. This is consistent with the Congressional goal of providing Medicare beneficiaries with access to the full range of insulin therapies that are expected to be available in the near future.

II. Morbid Obesity

In the Proposed Rule, CMS interprets the Social Security Act and its implementing regulations at 42 C.F.R. § 423.100 as excluding coverage of drugs used to treat morbid obesity.[3] BIO believes that this interpretation is not a correct reading of the statutory language. Under the Social Security Act, Part D drugs are those drugs and biologicals approved for marketing by the Food and Drug Administration, as well as "medically accepted indications" of those drugs that are supported by citations in certain compendia.[4] Only specific classes of

[3] 72 Fed. Reg. at 29405.
[4] Social Security Act, (SSA) § 1860D-2(e)(1), referring to §1927(k)(6).

drugs and uses of certain drugs are statutorily excluded from coverage under Part D. This narrow list includes "agents when used for anorexia, weight loss, or weight gain,"[5] but it does not prohibit coverage of drugs indicated for "obesity" or "weight management" because these indications are different from simple weight loss or weight gain.

Because obesity is widely recognized as an illness distinct from weight loss or weight gain,[6] a drug that is used for a "medically accepted indication" of weight management or treatment of obesity would not be precluded from coverage under Part D. The Social Security Act defines "medically accepted indication" as any use for a covered outpatient drug approved under the Federal Food, Drug, and Cosmetic Act or a use of a covered

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[5] SSA § 1860D-2(e)(2)(A), referring to § 1927(d)(2).

[6] Obesity has been widely recognized as a disease distinct from weight loss or weight gain by the medical community. For example, The National Heart, Lung, and Blood Institute at the National Institutes of Health describes obesity as a "complex, multifactorial chronic disease that develops from an interaction of genotype and the environment." National Institutes of Health/National Heart, Lung, and Blood Institute, Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. NIH Pub. No. 98-4083. 1998, at xi. Also, the International Classification of Disease, 9th Edition, Clinical Modification (ICD-9-CM) coding system identifies obesity as a disease in the "other metabolic and immunity disorders" section of the system and assigns unique codes to this condition. International Classification of Diseases, Clinical Modification, Ninth Revision, codes 278.01 (morbid obesity), 278.00 (unspecified obesity). In contrast, the ICD-9-CM identifies weight loss and weight gain as mere symptoms of other conditions. The federal government also has recognized the distinction between weight loss and obesity. For example, FDA makes a distinction between obesity and weight loss or weight gain through the regulation of obesity agents under the part of the Federal Food, Drug, and Cosmetic Act that applies to drugs used to treat a disease, while regulating weight loss or weight gain agents under a different part of the law. Products making obesity claims "are covered by section 201(g)(1)(B) of the [Federal Food, Drug, and Cosmetic Act] because obesity is considered a disease," but products making claims for "conditions, like overweight, that are not considered diseases, but that affect the structure or function of the body" are covered by section 201(g)(1)(C) of the Act. 65 Fed.Reg.999, 1027 (Jan. 6, 2000). Indeed, CMS itself implicitly acknowledged that obesity is a disease when it revised its national coverage determinations manual to remove the following statement: "obesity itself cannot be considered an illness." https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=57 (announcing revision to Coverage Issues Manual § 35-26); subsequently reissued by Transmittal 23, October 1, 2004 (revising National Coverage Determinations Manual § 40.5). The revised policy now states: "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 disease as well as diabetes and hypertension. https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=57 (announcing revision to Coverage Issues Manual § 35-26); subsequently reissued by Transmittal 23, October 1, 2004 (revising National Coverage Determinations Manual § 40.5). Services in connection with treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these medical conditions...." In announcing this policy, the Secretary of the Department of Health and Human Services as well as the Administrator of CMS issued statements supporting expanded coverage for treatment of obesity-related conditions. *See* News Release: HHS Announces Revised Medicare Obesity Coverage Policy, July 15, 2004, quoting then-Secretary Tommy Thompson and then-Administrator of CMS Mark McClellan. Medicare also has recognized that obesity is a significant health risk by covering bariatric surgery for treatment of comorbidities associated with morbid obesity (Medicare National Coverage Determinations Manual, § 100.1) and by identifying obesity as a complication and comorbidity for other illnesses under the proposed inpatient hospital payment rule for 2008. 72 Fed.Reg. 24680, 24698 (May 3, 2007).

outpatient drug supported by one or more citations included or approved for inclusion in any of the following compendia: the American Hospital Formulary Service Drug Information; the United States Pharmacopeia-Drug Information or its successor publications; and the DRUGDEX Information System.[7] Therefore, if a use of a drug for obesity is a use that is included in the FDA-approved label or is supported by a citation in one of these compendia, this use is eligible for coverage under the definition of a Part D drug.

Coverage for drugs and biologicals used to treat obesity is consistent with CMS' treatment of other therapies that have a use excluded under § 1927(d)(2) of the Social Security Act. While the definition of a Part D drug expressly excludes the drugs or uses of drugs listed in § 1927(d)(2),[8] there are a number of circumstances in which CMS has clarified that certain therapies are not excluded under this statutory provision. For example:

- CMS has clarified that drugs used for AIDS wasting and cachexia are eligible for coverage under Part D,[9] even though those drugs are used to treat weight loss associated with AIDS and may cause weight gain. In fact, CMS states that these drugs are "not considered agents used for weight gain or agents used for cosmetic purposes", even though these drugs cause weight gain.[10]

- CMS permits Part D coverage of drugs used to treat acne, psoriasis, rosacea, or vitiligo because CMS has determined that these therapies are not considered cosmetic.[11]

- CMS has determined that Part D plans may cover cough and cold medications when used in "clinically relevant situations other than those of symptomatic relief of cough and colds."[12] While the statute excludes from Part D coverage "agents when used for symptomatic relief of cough and cold",[13] CMS does not consider these drugs to be excluded when they are used for a medically accepted indication that treats a cough produced by a medical condition unrelated to symptomatic cough and cold.

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[7] SSA § 1927(k)(6).
[8] Drugs used for smoking cessation are not excluded from the definition of a Part D drug.
[9] Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.
[10] Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.
[11] *Id.*
[12] *Id.*
[13] SSA § 1927(d)(2)(D).

- CMS has clarified that vitamin D analogs and prescription niacin products are not affected by the statutory exclusion of prescription vitamins. With respect to niacin, CMS has stated that prescription niacin products differ from vitamins used for nutritional supplementation (which are thus excluded under the statute) because they are used at higher doses and for different purposes than other vitamin products.[14]

In each case, these examples demonstrate that CMS can appropriately interpret the statutory exclusions of certain uses of drugs and categories of drugs to permit coverage of medically accepted indications of drugs even when other uses of those drugs might be excluded. We urge CMS to apply the same standards and cover drugs used for non-cosmetic, medically accepted indications for treatment of obesity rather than concluding that these drugs are excluded by the statute's prohibition on coverage for agents used for weight loss or weight gain.

In addition to the statutory language that we believe clearly permits the coverage of drugs used for treatment of obesity, there are clear public health reasons for the treatment of obesity to be covered under Part D. Obesity is a major public health problem in this country. The National Institutes of Health report that 97 million Americans are overweight or obese and that the costs attributable to obesity in this country alone approach $100 billion each year.[15] A chronic disease involving genetic, environmental, metabolic, and behavioral factors,[16] obesity is associated with multiple comorbid conditions, such as Type 2 diabetes, dyslipidemia, hyperinsulinemia, hypertension, cardiovascular disease, and impaired glucose tolerance.[17] Failure to provide payment for treatment for obesity simply does not make sense from a public health perspective.

BIO also wishes to clarify that CMS' most recent interpretation precluding coverage of drugs used for obesity is not intended to preclude coverage of drugs that have indications other than obesity but where use of the drug may result in weight loss. Specifically, some drugs have labeled or compendia-listed indications for conditions such as diabetes, yet use of the drug

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[14] Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.
[15] NATIONAL INSTITUTES OF HEALTH, THE CLINICAL GUIDELINES ON THE IDENTIFICATION, EVALUATION, AND TREATMENT OF OVERWEIGHT AND OBESITY IN ADULTS: THE EVIDENCE REPORT, available at http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf.
[16] *See, e.g.,* Rippe J, Crossley D, Ringer R. Obesity as a chronic disease: Modern medical and lifestyle management. J Am Diet Assoc. 1998 Oct;98(10 Suppl 2):S9-15.
[17] *Id.*

may result in weight loss. Type 2 diabetes is a serious problem in this country, resulting in millions of dollars in health care costs each year among Medicare beneficiaries alone. It is imperative that Medicare cover the drugs seniors need to treat this serious disease. BIO is extremely concerned that CMS' interpretation of the coverage of obesity drugs under Part D – an interpretation inconsistent with the statute itself – may be used to deny coverage of drugs that may result in weight loss, even if the drug's indication is not exclusively for weight loss. While clearly drugs treating medical conditions entirely separate from weight loss or weight gain are not excluded from the definition of Part D drugs, BIO urges CMS to state clearly that it does not intend any interpretation of Part D coverage of weight loss drugs to deny coverage of drugs currently covered under Part D that are used for treatment of diabetes or other indications but that may result in weight loss or weight gain. As an example, drugs used for the treatment of diabetes are eligible for coverage under Part D without regard for the statutory exclusion of coverage for agents when used for weight loss or weight gain. We urge CMS to state this clearly in its final rule.

Finally, CMS states in the Proposed Rule that it "erroneously" stated in the January 2005 final rule[18] that drugs for morbid obesity may be covered under Part D. However, CMS was legally correct in concluding that these drugs can be covered when used for a "medically accepted indication", as described above. Furthermore, this January 2005 final rule was issued in response to specific comments recommending that Part D cover the use of drugs for morbid obesity. CMS addressed these specific comments in the final rule, further suggesting that CMS' decision to cover drugs for morbid obesity was not a minor, technical error that can be corrected without notice and comment. If CMS wishes to change policy stated in a final rule, it must clearly state that it intends to do so in order to allow stakeholders meaningful opportunity to comment on any changes.

CMS describes its statements in the Proposed Rule as "clarifying existing policy" and "not expanding or changing current policy regarding the exclusion of agents used for weight loss from the definition of Part D drug."[19] In fact, CMS' current binding policy statements are found in the Part D final rule issued in January of 2005, and thus CMS is proposing a significant policy change in this Proposed Rule. Although CMS has issued subregulatory guidance that

[18] 70 Fed.Reg. 4193 (Jan. 28,. 2005).
[19] 72 Fed.Reg. 29405.

differs from the January 2005 final rule, these subregulatory statements are not binding and cannot be applied to limit Medicare coverage of drugs without further rulemaking. The proposed interpretation of coverage of obesity drugs set forth in the Proposed Rule is not simply a technical correction but instead a significant proposed policy change to which comments must be reviewed and considered.

III. Adequate Access to Home Infusion Pharmacies

BIO supports CMS' efforts to strengthen the rules requiring adequate access to home infusion pharmacies. Specifically, BIO supports CMS' clarification that home infusion pharmacies within a Part D plan's pharmacy network must be capable of delivering home infused drugs in a form that can be administered in a clinically appropriate fashion and providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

BIO also appreciates CMS' clarification that a single network pharmacy does not necessarily need to be capable of providing the full range of home infusion Part D drugs, as long as the home infusion network, in the aggregate, has a sufficient number of pharmacies capable of providing the full range of home infusion Part D drugs. It is equally important for the plans to provide access to the most appropriate form or presentation of drugs, as found in manufacturer prepared ready-to-use premixed medications or pharmacy filled single-use infusion devices, which promote enhanced patient safety through reduced risk of contamination and medication errors. CMS should clarify and instruct plans Part D plans and their pharmacy networks to ensure therapies are provided in such formats when available. In order to maintain a viable home infusion benefit for Medicare beneficiaries, it is essential that Part D plans provide access to the range of products that allow providers to deliver therapies to patients in the most appropriate and efficient manner.

This will help to ensure that Part D plans establish robust home infusion networks that afford patients adequate access to these pharmacies. BIO also supports the requirement that a Part D plan ensure that the professional services and ancillary supplies necessary for infusion therapy are in place before dispensing Part D home infusion drugs, yet we note that the lack of Medicare coverage for these services and supplies, as discussed below, makes this a difficult requirement for Part D plans to meet and ultimately falls short of

providing Medicare beneficiaries with meaningful access to home infusion therapies.

BIO also supports CMS' proposed requirement that Part D plan sponsors provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting. We agree with CMS' understanding that this timeframe is consistent with industry best practices, and we believe that this requirement will help to improve patient access to home infusion therapies. Home infusion therapy is a cost effective alternative to patients using outpatient clinics, physician offices, and hospital stays. Ensuring that patients will have prompt access to home infusion therapies is an important step in improving access to home infusion therapy.

BIO has long been concerned about the lack of adequate Medicare coverage for the home infusion services necessary for meaningful access to home infusion medication. Part D fills a critical part of this gap in Medicare coverage by providing payment for many drugs and biologicals administered in the home setting. Yet Part D plans are precluded from paying for the special costs associated with the administration of these drugs under the Part D benefit[20] and, at the same time, must ensure that the professional services and ancillary supplies (such as IV tubing, administration sets, and single-use infusion devices) necessary for the provision of home infusion are in place prior to dispensing of home infusion drugs. In many cases, there is no Medicare or other coverage available for these services. BIO continues to urge CMS to seek ways to provide appropriate coverage of the supplies and services necessary to make home infusion a meaningful benefit. Precluding payment under Part D for the supplies and services necessary to make home infusion a reality for many patients results in a Medicare policy that is not cost-effective and fails to ensure patient access to this important treatment alternative. BIO encourages CMS to conduct a study on the access of home infusion under part D and beneficiary out of pocket costs.

IV. Administrative Costs and Gross Prescription Drug Costs

BIO appreciates CMS' proposal to establish a definition of administrative costs as part of a continuing effort to achieve greater transparency in the Part D program. As CMS notes, there has been some uncertainty regarding

[20] Medicare Part D Manual, Ch. 5 § 20.6.

what costs are appropriately reported to CMS as gross prescription drug costs and which costs should be separately reported.[21] In finalizing its proposals on administrative costs and gross prescription drug costs, we urge CMS to provide greater clarity on how administrative fees paid to a PBM by a biotechnology company or pharmaceutical manufacturer should be reported to CMS by a Part D plan sponsor. Specifically, it is not clear whether CMS intends for such administrative fees to fall under the "other direct or indirect price concessions" language in the proposed definition of administrative costs. Providing greater clarity on this issue will be an important component of CMS' efforts to promote greater transparency in the Part D program

V. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact John Siracusa at 202-312-9281 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

John Siracusa
Manager, Medicare Reimbursement
& Economic Policy

[21] 72 Fed. Reg. at 29409.

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

Organization : Indiana Pharmacists Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Coamments Attached

CMS-4130-P-63-Attach-1.RTF

#63

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)

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Approval of Marketing Materials and Enrollment Forms

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Negotiated Prices

IPA 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, IPA 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.

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

IPA 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. IPA 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 IPA has historically been concerned with overly finite and potentially burdensome guidance or regulation

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

from the federal government because of unintended consequences, IPA 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. IPA 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

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

Conclusion

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

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

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

Sincerely,

Lawrence J. Sage
Executive Vice President
Indiana Pharmacists Alliance

CMS-4130-P-64 **Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit**

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

Organization : Kaiser Foundation Health Plan, Inc

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-4130-P-64-Attach-1.PDF

#64

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

Organization : Washington D.C. Pharmaceutical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4130-P-65-Attach-1.DOC

#65

WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION

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

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 Washington D.C. Pharmaceutical Association, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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

WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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.

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

WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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 WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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. WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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

WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION supports and appreciates CMS defining the term administrative costs. Of particular interest to WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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 WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION, again, supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

In summary, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION 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, WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION appreciates CMS' effort to clarify and codify the areas addressed in the proposed rule.

If you have any questions or need any additional information, please do not hesitate to contact Herb Kwash, R.Ph., President and Executive Director WASHINGTON D.C. PHARMACEUTICAL ASSOCIATION, at (202) 826-1515 or via email at midpharm@aol.com.

Sincerely,

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

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

Organization : **North Dakota Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Attached are comments regarding Policy and Technical Changes to the Medicare Prescription Drug Benefit 72 Fed. Reg. 29419

CMS-4130-P-66-Attach-1.DOC

#66

August 1, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human 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 North Dakota Pharmacists Association (NDPhA) and the North Dakota Pharmacy Service Corporation (NDPSC), an organization representing all ND state pharmacists, 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, NDPhA 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. NDPhA 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

NDPhA 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, NDPhA 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.

NDPhA 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. NDPhA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be - and NDPhA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers, and third party payers.

With regard to what is commonly referred to as 'spread pricing,' NDPhA 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). NDPhA 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 NDPhA'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. NDPhA 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

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

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

Conclusion

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

If you have any questions or need any additional information, please do not hesitate to contact Michael D. Schwab, Executive Vice President, NDPhA, at (701) 258-4922 or via email at mschwab@nodakpharmacy.net.

Sincerely,

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

CMS-4130-P-67 **Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit**

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

Organization : New Mexico Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-4130-P-67-Attach-1.DOC

#67

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

Organization : Iowa Pharmacy Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#68

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

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

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

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

Organization : **New Mexico Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

CMS-4130-P-69-Attach-1.DOC

#69

New Mexico Pharmacists Association

2716 San Pedro NE Suite C
Albuquerque, NM 87110

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

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 New Mexico Pharmacists Association (NMPhA), the association representing pharmacy and pharmacists in New Mexico, we appreciate the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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, NMPhA 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. NMPhA 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

NMPhA 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, NMPhA 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.

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

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

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

willingness of CMS to again assert that adequate access to home infusions pharmacies is an expectation of the Part D plans.

Administrative Costs

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

Conclusion

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

Sincerely,

R. Dale Tinker

R. Dale Tinker
Executive Director

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

Organization : Missouri Pharmacy Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4130-P-70-Attach-1.DOC

#70

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

August 1, 2007

Centers for Medicare and 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) (proposed May 25, 2007 – to be codified at 42 C.F.R. § 423)

I am writing on behalf of the Missouri Pharmacy Association (MPA), the professional association representing independent community pharmacists in Missouri. We appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services' (CMS) proposed 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 Enrollment," (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 categories.

Eligibility and Enrollment – Approval of Marketing Materials and Enrollment Forms

As a general matter of public policy, MPA 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 on Part D plan sponsors, so long as 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.

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The Guidelines, allowing pharmacists to provide their insight and expertise in helping their patients make informed decisions about their prescription drug plans.

Negotiated Prices

MPA 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, MPA 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) (proposed May 25, 2007 – to be codified at 42 C.F.R. § 423.100) regarding negotiated prices.

MPA 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 of 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. MPA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be – and MPA asserts they are not – shared with the community retail pharmacy networks, out-of-pocket customers and third party payers.

With regard to what is commonly referred to as 'spread pricing,' MPA again supports the clarifications offered in the proposed changes to 72 Fed. Reg. 29407 (2007) (proposed May 25, 2007 – to be codified at 42 C.F.R. § 423.100). MPA asserts that the equation in spread pricing is the amount the employer paid minus the amount the 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 a 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 MPA'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. MPA believes 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

MPA 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. We continually work with our members to inculcate best practices in the pharmacy community and agree that the 24-hour requirement is

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

consistent with accepted best practices. Furthermore, we support the new requirement, in particular because it is potentially a matter of patient safety. While MPA has historically been concerned with overly finite and potentially burdensome guidance or regulation from the federal government because of unintended consequences, we fully support the clarifications and additions to 72 Fed. Reg. 29419 (2007) [proposed May 25, 2007 – to be codified at 42 C.F.R. § 423.120(4)] and view such amendments as 72 Fed. Reg. 29419 (2007) [proposed May 25, 2007 – to be codified at 42 C.F.R. § 423.120(4)(iii)] as reasonable federal guidance. MPA appreciates the willingness of CMS to again assert that adequate access to home infusion pharmacies is an expectation of the Part D plans.

Administrative Costs

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

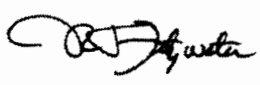
With regard to these sections, MPA supports and appreciates the additional clarification and codification of CMS guidance.

Conclusion

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

If you have any questions or need additional information, please contact me at (573) 353-0450 or ron@morx.com.

Sincerely,



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

Submitter : **Ms. Paula Yutzy** **Date: 07/29/2007**

Organization : **Ms. Paula Yutzy**

Category : **Other Practitioner**

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

Dear Administrator,

As a Certified Diabetes Educator, I provide care to hundreds of Medicare beneficiaries with diabetes in the Baltimore area. Medicare has taken great strides in recent years to provide access for beneficiaries to diabetes education, screening, and now - through the Part D program - insulin and other medications to treat diabetes as well as associated supplies.

It is my professional opinion that persons with diabetes can take control of their lives and make choices that are in their own best interest choices that will lead to the prevention of complications and a long and healthy life. The addition of inhaled insulin to the Part D benefit provides beneficiaries with one more choice and I applaud CMS for recognizing the importance of this choice for appropriate patients.

However, I strongly encourage CMS to broaden this proposal to include all non-durable mechanisms of insulin delivery so that beneficiaries have more choices as they are available there are many exciting novel delivery systems in development worldwide. When inhaled insulin was first available, there were many questions surrounding its coverage for Medicare patients. By broadening this proposal, Medicare can provide beneficiaries, especially those who struggle to keep their diabetes in control, with the assurance that new technologies in insulin delivery will be accessible through Part D. It will also make expensive and time-consuming CMS rule making unnecessary each time a novel insulin delivery system is approved by the FDA.

Although I fully recognize that Part D plans have leeway in developing formularies, CMS should encourage open access to as many therapies as possible. Instead, it appears CMS is urging plans to apply utilization management for inhaled insulin. Patients treatment teams - including physicians, certified diabetes educators, family members and of course the patients themselves are better suited than Part D plans or CMS to make decisions about the best course of treatment.

Again, I appreciate CMS recognizing the importance of choice in diabetes management by including inhaled insulin and related supplies in the Medicare Part D benefit. I simply encourage you to pave the way for ease of access to both inhaled insulin and to new technologies.

Thank you for your consideration. Please contact me at the number below should you have any questions regarding my comments.

Sincerely,
Paula S. Yutzy, RN, BSPA, CDE, D
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