**Submitter :** **Ms. Marissa Schlaifer** **Date: 07/23/2007**

**Organization :** **Academy of Managed Care Pharmacy**

**Category :** **Pharmacist**

**Issue Areas/Comments**

**Adequate Access to Home Infusion Pharmacies**

Adequate Access to Home Infusion Pharmacies

With the passage of the Medicare Modernization Act, Congress included medical supplies associated with the injection of insulin (as defined in regulations of the Secretary) within the definition of Part D drug found in section 1860D-2(e) of the Act. CMS has proposed revising the definition of Part D drug to include supplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin.

Inhaled insulin is a dry powder inhaler that requires a patient to place a small amount of powdered insulin into a hand-held chamber that permits inhalation of the insulin into the lungs. With the approval of the first inhaled insulin in 2006, the Academy recognizes the needed for supplies associated with the inhalation of insulin to be included in the definition of a Part D drug.

The Academy strongly supports the comments made by CMS in the proposed rule change indicating that, while this new definition would make these inhalation supplies eligible for reimbursement as a Part D drug, it would be the Part D sponsor s decision whether to place these items on formulary. It is the responsibility of a Part D sponsor to use the experience and knowledge of the health care professionals on its Pharmacy and Therapeutics (P&T) Committee and the information gathered through drug utilization evaluations to make those determinations. The Academy also strongly supports the indication that CMS would expect sponsors to apply drug utilization management tools to ensure the appropriate use of such supplies.

**Administrative Costs**

Administrative Costs

In the proposed rule changes, CMS has proposed revising the definition of negotiated prices. At various levels in the benefit structure (for example, in the initial deductible, during the 25% coverage period and in the coverage gap), beneficiaries are to pay a percentage of or 100% of actual cost. During these periods, beneficiaries are provided with access to a Part D plan s negotiated price. Currently the negotiated price for a covered Part D drug is defined as being: available to beneficiaries at the point of sale at network pharmacies; inclusive of dispensing fee; and reduced by those discounts, subsidies, rebates and other price concessions or remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale.

To reduce confusion, CMS is proposing to amend the definition for 2009 to require that beneficiary cost sharing must be based on the price ultimately received by the pharmacy or other dispensing provider. In other words, the negotiated prices would be the prices that the Part D sponsor or intermediary and the network dispensing pharmacy or other dispensing provider have negotiated as the amount the pharmacy or provider will receive in total for a particular drug.

The Academy agrees that this change is reasonable. It is a financial burden for plan sponsors who must apply expected, but unrealized, discounts to real time transactions. Many rebate contracts are based on market share performance metrics which fluctuate from quarter to quarter. In addition, claims transactions systems are not equipped to handle application of secondary discounts that are not related to those in the pharmacy network contract. As CMS has indicated in comments related to this change, in practice Part D sponsors are unable to actually apply discounts, rebates and other price concessions at the point of sale in order to reduce the price negotiated with the dispensing pharmacy or other dispensing provider. The Academy supports a change that makes negotiated price calculations more uniform and feasible.

**Application Timing**

Application Timing

In the draft rules, CMS proposes to codify into regulation guidance already issued with regard to access to home infusion pharmacies. The codification is to ensure that the regulations provide specificity to the requirement that Part D enrollees receive adequate access to Part D-covered home infusion therapy. In addition, CMS is proposing one change to the regulations. This modification would require that Part D sponsors provide covered home infusion drugs within 24 hours of discharge from an acute setting.

The Academy conceptually supports this change. Continuity of care is an essential aspect of patient care. The Academy would like CMS to provide an exception for situations where the Part D plan sponsor has not been notified that the beneficiary has been discharged from an acute setting. Without that vital information, the plan sponsor cannot be expected to comply with this proposed regulation. In addition, CMS must acknowledge that challenges in the delivery process may occur which are out of the plan sponsor s control. The Academy recommends that the regulatory language be amended to reflect that the Part D plan sponsor be required to provide covered home infusion drugs within 24 hours of the time the Part D plan is notified of the discharge from an acute setting and that initiation of delivery of services be the measure that the plan has complied with this rule.

**GENERAL**

GENERAL

See attachment

CMS-4130-P-9-Attach-1.PDF

#9

AMCP Academy of Managed Care Pharmacy

CELEBRATING AMCP'S 20th ANNUAL MEETING
APRIL 16-19, 2008 • MOSCONE WEST CONVENTION CENTER • SAN FRANCISCO, CA •

July 23, 2007

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

Re: Policy and Technical Changes to the Medicare Prescription Drug Benefit; file code CMS-4130-P

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments on the Centers for Medicare & Medicaid Services' (CMS') proposed rule to both codify prior clarifications of CMS policies associated with the Medicare Prescription Drug Benefit (Medicare Part D) and propose certain clarification of these policies.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 5,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Academy is offering comment on three areas of the proposed rule:

- Insulin inhalation drugs and supplies
- Negotiated prices
- Adequate access to home infusion pharmacies

The Academy has not commented on some areas that codify prior clarifications or those that focus on reconciliation and subsidies.



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www.amcp.org

Insulin Inhalation Drugs and Supplies

With the passage of the Medicare Modernization Act, Congress included "medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)" within the definition of "Part D drug" found in section 1860D-2(e) of the Act. CMS has proposed revising the definition of Part D drug to include "supplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin."

Inhaled insulin is a dry powder inhaler that requires a patient to place a small amount of powdered insulin into a hand-held chamber that permits inhalation of the insulin into the lungs. With the approval of the first inhaled insulin in 2006, the Academy recognizes the needed for supplies associated with the inhalation of insulin to be included in the definition of a Part D drug.

The Academy strongly supports the comments made by CMS in the proposed rule change indicating that, while this new definition would make these inhalation supplies eligible for reimbursement as a Part D drug, it would be the Part D sponsor's decision whether to place these items on formulary. It is the responsibility of a Part D sponsor to use the experience and knowledge of the health care professionals on its Pharmacy and Therapeutics (P&T) Committee and the information gathered through drug utilization evaluations to make those determinations. The Academy also strongly supports the indication that CMS would expect sponsors to apply drug utilization management tools to ensure the appropriate use of such supplies.

Negotiated Prices

In the proposed rule changes, CMS has proposed revising the definition of "negotiated prices." At various levels in the benefit structure (for example, in the initial deductible, during the 25% coverage period and in the coverage gap), beneficiaries are to pay a percentage of or 100% of actual cost. During these periods, beneficiaries are provided with access to a Part D plan's "negotiated price." Currently the "negotiated price" for a covered Part D drug is defined as being: available to beneficiaries at the point of sale at network pharmacies; inclusive of dispensing fee; and reduced by those discounts, subsidies, rebates and other price concessions or remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale.

To reduce confusion, CMS is proposing to amend the definition for 2009 to require that beneficiary cost sharing must be based on the price ultimately received by the pharmacy or other dispensing provider. In other words, the "negotiated prices" would be the prices that the Part D sponsor or intermediary and the network dispensing pharmacy or other dispensing provider have negotiated as the amount the pharmacy or provider will receive in total for a particular drug.

The Academy agrees that this change is reasonable. It is a financial burden for plan sponsors who must apply expected, but unrealized, discounts to real time transactions. Many rebate contracts are based on market share performance metrics which fluctuate from quarter to quarter. In addition, claims transactions systems are not equipped to handle application of secondary discounts that are not related to those in the pharmacy network contract. As CMS has indicated in comments related to this change, in practice Part D sponsors are unable to actually apply discounts, rebates and other price concessions at the point of sale in order to reduce the price negotiated with the dispensing pharmacy or other dispensing provider. The Academy supports a change that makes "negotiated price" calculations more uniform and feasible.

Adequate Access to Home Infusion Pharmacies

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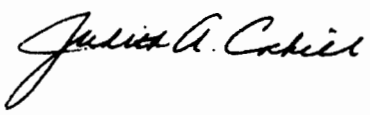
The Academy conceptually supports this change. Continuity of care is an essential aspect of patient care. The Academy would like CMS to provide an exception for situations where the Part D plan sponsor has not been notified that the beneficiary has been discharged from an acute setting. Without that vital information, the plan sponsor cannot be expected to comply with this proposed regulation. In addition, CMS must acknowledge that challenges in the delivery process may occur which are out of the plan sponsor's control. The Academy recommends that the regulatory language be amended to reflect that the Part D plan sponsor be required to provide covered home infusion drugs within 24 hours of the time the Part D plan is notified of the discharge from an acute setting and that initiation of delivery of services be the measure that the plan has complied with this rule.

If you have any questions regarding our comments or require any additional information, please do not hesitate to contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,



Judith A. Cahill, CEBS
Executive Director

**Submitter :** **Dr. Mary Hager** **Date: 07/23/2007**

**Organization :** **American Dietetic Association**

**Category :** **Dietitian/Nutritionist**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment.

CMS-4130-P-10-Attach-1.PDF

#10

**American Dietetic Association**
www.eatright.org | *Your link to nutrition and health™*

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Connie B. Diekman, MEd, RD, LD, FADA
*President*

Ronald S. Moen
*Chief Executive Officer*

July 23, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4120-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Comments on Docket No. CMS-4130-P, Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit**

The American Dietetic Association (ADA) appreciates this opportunity to submit comments to the Centers for Medicare & Medicaid Services on its proposed rules and clarification of the Medicare Part D drug benefit. ADA is the largest association of Registered Dietitians (RDs) and other food and nutrition professionals in the United States, with a membership exceeding 67,000. ADA serves the public by promoting optimal nutrition, health and well-being using information based on sound science.

Thousands of ADA members work with obese individuals as they try to make behavioral modifications that will result in better dietary intake and physical activity patterns to achieve healthful weight loss that can be maintained. In addition, ADA's Weight Management Dietetic Practice Group members specialize in the treatment of obesity and they work with medical teams that use state-of-the-science interventions that include pharmacological interventions, as well as bariatric surgery. In some cases, ADA members work with patients who must take prescription medications to control their chronic conditions; examples of such medications include hypoglycemic and psychotropic agents, which promote weight gain.

Hundreds of ADA members -- including those who are members of Dietitians in Nutrition Support, HIV/AIDS, Gerontological Nutrition, Consultant Dietitians in Health Care Facilities and Oncology Dietetic Practice Groups -- are the experts frequently called on to address problems related to the nutritional adequacy of diets. They would describe among their concerns Medicare's continued unwillingness to cover medications that would enhance an individual's appetite under Part D. Combined with the meager coverage of nutritional supplemental feeding support (plus no coverage for the medical devices that deliver enteral and parenteral feedings),

Medicare's policies undermine the stated CMS commitment to keep beneficiaries, both disabled and aging, healthy and living independently.

ADA has previously commented on CMS' unwillingness to cover orexigenic drug interventions under Part D.

**General Comments**

ADA members are committed to providing patients care that is timely, effective, efficient and patient-centered consistent with the six aims of quality care.[1] To disallow access to pharmacologic interventions that assist patients in achieving medical treatment goals is ill-conceived, particularly for the Medicare beneficiary 65 years and older for whom CMS has also excluded from bariatric surgery and behavioral options for weight management.

While it is the position of the American Dietetic Association that "*successful weight management to improve overall health for adults requires a lifelong commitment to healthful lifestyle behaviors emphasizing sustainable and enjoyable eating practices and daily physical activity,*"[2] ADA members acknowledge that effective healthcare is multimodal and tailored to patient's individual needs and responsiveness to various individual treatments. Lifestyle modifications in food intake and exercise remain the hallmarks of effective treatment, but are difficult to initiate and sustain over the long term. As a consequence, pharmacotherapy becomes a viable option to use, particularly when an obese patient develops or sustains several high risk co-morbidities. When weight loss drugs are prescribed they should be part of a comprehensive treatment plan including behavior therapy, diet, and physical exercise.[3]

**Conclusion**

ADA has carefully reviewed the proposed rule published May 25, 2007 (72 FR 29403) and believes that the rule and proposed clarification regarding medications used for anorexia, weight loss, and weight gain is flawed. There are many medically accepted indications for which approved drugs should be covered and accessible to Medicare beneficiaries, both disabled and aging.

Medicare patients suffer from a variety of chronic conditions, including diabetes, hypertension, hyperlipidemia and pre-diabetes, in which even a modest weight loss can improve and even reverse the course of the disease. Furthermore, these studies have shown their effectiveness specifically in the Medicare age population.

ADA asks, how can U.S. health policies rationalize being generous in some of the more expensive treatment options for morbid obesity among disabled individuals, but not cover the medically conservative treatments which are preventive and recognized as cost-effective in the broader Medicare population?

---

[1] Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* National Academy Press:Washington, DC. 2001.

[2] Cummins S, Parham ES, Strain GW. Position of the American Dietetic Association: Weight Management. *J Am Diet Assoc.* 2002;102:1145-1155.

[3] NIH and NAASO. The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. NIH Publication Number 00-4084, 2000: 35-38.

We urge that CMS reconsider this interpretation of the MMA and cover drug agents that have been specifically approved for anorexia, weight loss and weight gain. Please feel free to contact our senior manager of regulatory affairs Mary Hager at mhager@eatright.org or 202-775-8277, ext 6007, for additional information or clarification of these comments.

Sincerely,

Connie Diekman

Monica Krygowski MH

Connie B. Diekman, MEd, RD, LD, FADA
President, American Dietetic Association

Monica Krygowski, MS, RD, LD
Chair, Weight Management Dietetic Practice Group

**Submitter :** **Mr. Steven Wojcik** **Date: 07/23/2007**

**Organization :** **National Business Group on Health**

**Category :** **Consumer Group**

**Issue Areas/Comments**

**GENERAL**

GENERAL

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-11-Attach-1.DOC

#11

NATIONAL BUSINESS GROUP ON HEALTH
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*Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow*

July 23, 2007

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

Re: File Code CMS-4130-P
Request for Comments on Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Sir or Madam:

The National Business Group on Health (the "Business Group") appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule on Policy and Technical Changes to the Medicare Prescription Drug Benefit published in the May 25, 2007 Federal Register.

The Business Group recognizes the significant complexity involved in administering the Medicare prescription drug benefit and commends CMS for its ongoing efforts to facilitate the Retiree Drug Subsidy (RDS) process for employers. In providing health coverage to more than 55 million U.S. workers, retirees and their families, our member organizations face a multitude of associated administrative tasks each day. For the RDS program to remain a viable option for large employers, CMS must continue its focus on ease of administration for employers.

The Business Group, representing 277 large employers, is the nation's only non-profit organization devoted exclusively to finding innovative and forward-thinking solutions to large employers' most important health care and related benefits issues. Business Group members are primarily Fortune 500 and large public sector employers, with 62 members in the Fortune 100.

The Business Group offers the following comments and recommendations:

**Retiree Drug Subsidy Application Timing**

While an end-of-month application deadline would be easier for plan sponsors to administer than the current deadline, the proposal to publish the deadline annually would present greater administrative challenges for plan sponsors. Even with sufficient advance

notice, a deadline that is not clearly specified in the regulations requires plan sponsors to continually monitor CMS communications for the announcement of the deadline each year. Set deadlines allow plan sponsors to better plan their work activities and resource needs.

The preamble to the proposed rule implies that CMS will make one application deadline announcement each year, presumably for plan sponsors with calendar-year plan years. If this is the case, it is unclear how plan sponsors with non-calendar-year plan years will be advised of their application deadlines each year. If CMS makes one announcement each year that announces deadlines for all plans, this could result in some non-calendar-year plan sponsors not having adequate notice of the application deadline. If CMS makes multiple announcements each year to address the needs of non-calendar-year plan sponsors, this would appear to be a greater administrative burden to CMS.

CMS should include a defined end-of-month deadline for filing the retiree drug subsidy application in the regulations. For example, the deadline could be the last day of the ninth month of the plan year preceding the plan year for which the plan sponsor is filing the application. This proposal would address both the need for an end-of-month deadline and the flexibility needed for non-calendar-year plans. It would also eliminate the need for plan sponsors to continually monitor CMS communications for the application deadline announcement.

**Data Match**

We support the proposed change, provided:

- The change does not negatively impact employers by , for example, using multiple systems of record that may not reflect consistent data or changing systems of record being utilized mid-year or with little advance notice to employers;
- CMS is diligent in maintaining the data across all systems of record to ensure consistency; and
- The change results in more accurate data matches more quickly and in less administrative work for plan sponsors in the ongoing reporting and annual reconciliation processes related to the retiree drug subsidy.

**Medicare Supplemental Adjustment**

The Business Group recommends that the applicable section of the regulation read as follows to clarify that employers will qualify for the Medicare Supplemental Adjustment in the net test if they make the supplemental coverage available to qualifying covered retirees who enroll in Part D, regardless of whether any such retirees actually elect to participate (or opt not to participate) in the supplemental coverage:

> "(*2*) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage ***actually made available to qualified covered retirees*** by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(*2*)."

**Non-Calendar Year Plans and Medicare Defined Standard Prescription Drug Coverage**

We agree with the proposed changes as they provide additional flexibility for plan sponsors of non-calendar-year plans to use either the current or subsequent year's Part D limits in their actuarial attestations.

**Benefit Options Not Included in Net Value Calculation/Claiming Retiree Drug Subsidy**

No comment.

**Submission of Actuarial Attestation Upon Material Change**

We agree with CMS' guidance and re-iteration of their previous interpretation since it does not require employers to make another submission of the actuarial attestation as long as the plan remains actuarially equivalent and no benefit options are added.

Again, the Business Group appreciates the opportunity to provide comments to the CMS on the proposed rules related to the Medicare prescription drug benefit. The Business Group would welcome the opportunity to provide additional information that would be of assistance to CMS or to meet with CMS to discuss in more detail any of the comments or recommendations raised in this letter.

Sincerely,

Steven Wojcik

Steven Wojcik
Vice President, Public Policy

**Submitter :** **Mr. Steven Tucker** **Date: 07/23/2007**

**Organization :** **UnitedHealth Group**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**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.

CMS-4130-P-12-Attach-1.DOC


July 23, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Mr. Kuhn

Thank you for the opportunity to present comments on the *Policy and Technical Changes to the Medicare Prescription Drug Benefit* proposed rules. We have been honored to serve Medicare beneficiaries for over 25 years and look forward to continued participation in Medicare as it changes.

Ovations is the UnitedHealth Group Company committed to meeting the health and well-being needs of adults of all ages, with a particular focus on those age 50 and above. We serve one out of every five Medicare beneficiaries through our array of Medicare products, including: Medigap plans that supplement traditional fee-for-service, Medicare Prescription Drug plans, and Medicare Advantage plans, including special needs plans for the chronically ill, dual eligible and beneficiaries living in an institutional setting. Our Medicare offerings are designed to meet the individual needs of our customers, their families, physicians and communities.

We participate in the Medicare program in the following ways:

- Traditional fee-for-service -- Our Medigap offerings provide supplemental insurance on behalf of AARP to nearly three million of its members.

- Medicare Advantage -- We provide health care coverage to more than 1.3 million people through health plans, Preferred Provider Organizations (PPOs), private fee-for-service, and group health plans operating in diverse geographic areas ranging from Omaha to New York.

- Medicare Part D -- The nation's leading source of prescription drug coverage for over 5.8 million Medicare beneficiaries and the only provider of Medicare Part D plans endorsed by AARP.

- Evercare – Evercare serves more than 150,000 people nationwide through Medicaid, Medicare, and private-pay health plans, programs and services. Evercare is also a leading provider of Special Needs Plans designed to help people who are chronically ill, dual eligible or living in an institutional setting stay as healthy and independent as possible.

While the attached document contains our detailed comments, we want to first highlight one additional issue that may impact the current success of the Medicare Advantage and Prescription Drug Program for dual-eligible and low-income individuals.

## ADMINISTRATIVE COSTS, NEGOTIATED PRICE, GROSS PRESCRIPTION DRUG COSTS

Under the proposed rules, Plan sponsors would be required to include costs that exceed the amount paid by or on behalf of the Part D sponsor to a pharmacy or other entity ("lock-in pricing") as part of administrative costs. Currently, Plan sponsors can include this cost differential as part of medical costs. As a result, while this change does not eliminate the ability of Plan sponsors to utilize a "lock-in pricing" model, we are concerned that this change may have unintended negative consequences for Medicare beneficiaries, especially low-income individuals. In particular, we are concerned that this change will increase beneficiaries' premiums, decrease beneficiary choice and impact the overall stability of the Part D program.

The inclusion of the price differential between the lock-in price and the price paid to the pharmacy increases a Plan sponsor's administrative costs. Additional administrative expenses will also be incurred as Plan sponsors create the necessary systems to track the difference between the lock-in price and the price paid by the pharmacy. Increased administrative costs means increased premiums for Medicare beneficiaries.

Our market research has shown that low premiums are the most significant factor in determining which plan is chosen by potential members. Lower premiums benefit all enrollees in a particular Part D plan. While moving the cost of lock-in pricing to an administrative expense reduces the cost of individual prescriptions, it primarily benefits those members that are in the coverage gap -- a much smaller subset of the population. On the other hand, higher premiums may (i) limit the number of plans low-income individuals are able to afford and/or increase the cost to the government for the premium subsidy, (ii) decrease the number of plans that are able to serve the dual-eligible population, and (iii) disincent individuals with low drug utilization needs from participating in the Medicare Part D program.

We realize that this is a complex issue and that lock-in pricing has many implications for the federal government. We appreciate that lock-in pricing does cause beneficiaries to reach the coverage gap sooner and that beneficiaries' costs are higher if their drug costs are based on the negotiated price of the drug. We also understand that one of the goals of the Prescription Drug Program is to provide access to low cost drugs. We therefore urge CMS to carefully consider how this change will impact the Part D program and in particular those individuals with limited means.

We greatly appreciate this opportunity to share our comments about the proposed rules and look forward to working with you. Please do not hesitate to contact me (or my colleagues) if you have any questions or need further information. Thank you.

Sincerely,

Steven M. Tucker, Vice President of Regulatory Affairs, Ovations
Ovations
Mail Route CA112-0536
5995 Plaza Drive
Cypress, CA 90630

## NEGOTIATED PRICES

***Section 423.100, p 29407***

**(1)** **Issue**: The current guidance does not specify what price Part D sponsors can base beneficiary cost sharing on for 2008.

**Recommendation**: CMS should clarify that until 2009, plan sponsors will be able to choose whether to base beneficiary cost-sharing on the price charged to the pharmacy or the price the sponsor pays a pharmacy benefit manager (PBM) or other intermediary.

**Rationale**: In 2006 and 2007, CMS has provided that Plan sponsors could base beneficiary cost sharing not on the price ultimately charged by the pharmacies for the drug, but on the price the Plan sponsor paid a PBM. The proposed rule requires a change to this process for 2009, but does not specify what Plan sponsors will be required to do for 2008. This will cause the least amount of disruption for plan participants and will minimize the costs incurred by Plan sponsors.

**(2)** **Issue**: The definition of "negotiated price" is not limited to the reimbursement received by the network entity at the point of sale.

**Recommendation**: The definition of "negotiated price" should be clarified to state that it includes the amount that the network entity receives, in total, for a particular drug at the point of sale.

**Rationale:** The current rules exclude payments made to pharmacies after the point-of-sale, such as generic incentive payments,[1] from the definition of "negotiated price." The new proposed language, however, does not contain a similar restriction. Instead, the new proposed language appears to include any and all payments made to pharmacies for drugs dispensed as part of the "negotiated price" definition. Such an obligation on the Plan sponsors would be administratively infeasible and would unnecessarily increase the administrative costs for the plan. It is believed that CMS intended to limit this to the total amount a network entity received at the point-of-sale for a particular drug.

[1] A generic incentive program provides payments or penalties to pharmacies based on whether the pharmacy has successfully met a target for generic dispensing.

## ADMINISTRATIVE COSTS

*Section 423.308, p 29420*

**Issue:** The definition of "administrative costs" is confusing.

**Recommendation:** Either (i) clarify the definition of "administrative costs" to address only lock-in pricing or (ii) expand the definition to address other forms of administrative costs in a manner that is consistent with CMS' previous guidance.

**Rationale:** Currently the definition of "administrative costs" states:

> When an intermediary acts on behalf of a Part D sponsor to negotiate prices with dispensing entities such as pharmacies, any profit retained by the intermediary contracting organization as a result of such negotiation (through discounts, manufacturer rebates, or other direct or indirect price concessions) is considered an administrative cost to the Part D sponsors and not a drug cost.

By including "manufacturer rebates" within this definition, it appears that "administrative costs" is being defined to address more than just lock-in pricing. The preamble discussion (page 29409), however, is more limited and focuses solely on how Plan sponsors should account for lock-in pricing.

If CMS intends to expand the definition of "administrative costs" to include manufacturer rebates, direct and indirect price concessions, and discounts (Direct and Indirect Remuneration), CMS should make sure that the definition is consistent with other guidance issued by CMS, such as the recent Direct and Indirect Remuneration Reporting Requirements. We are supportive of creating a definition of "administrative costs" that would address these issues so long as the definition is consistent with other guidance previously issued by CMS.

## ADEQUATE ACCESS TO HOME INFUSION PHARMACIES

*Section 423.120(a)(4), p 29408*

**Issue**: Stand-alone PDPs do not have access to information regarding when a beneficiary is discharged from an acute setting and therefore will not be in a position to determine whether its network pharmacies are able to meet this new requirement.

**Recommendation**: CMS should either (i) eliminate the requirement that Part D Sponsors ensure that home infusion pharmacies provide the delivery of home infusion drugs within at least 24 hours of discharge from an acute setting or (ii) require that home infusion pharmacies provide delivery of home infusion drugs as soon as is reasonably appropriate. The requirement that home infusion drugs should be delivered within 24

hours should instead be cited as a best practice within Chapter 5 of the Medicare Prescription Drug Benefit Manual.

**Rationale**: While it may be best practice to deliver home infusion drugs within 24 hours of discharge from an acute setting, stand-alone PDPs do not have access to the medical information required to determine when an individual was discharged from an acute setting. Therefore, while Plan sponsors can require that their network pharmacies comply with the 24 hour best practice, sponsors of PDP plans will be unable to determine whether their pharmacies have complied with this requirement.

## PREMIUM SUBSIDY FOR LATE ENROLLMENT PENALTY

***Section 423.780(e), p 29414***

**Issue:** The proposed addition to the regulation addressing other LIS eligible (partial subsidy) individuals appears to require Plan sponsors to calculate the Late Enrollment Penalty (LEP) subsidy based on income information currently unavailable to Plan sponsors.

**Recommendation:** CMS should either (i) take a similar approach to the current LEP guidance and calculate the subsidy and report it to the Plan sponsors or (ii) provide a flat rate that Plan sponsors can apply to each low-income subsidy level. In addition, given that the final LEP guidance recently published is to be implemented by August 1, 2007, CMS should delay the application of this subsidy or address retroactivity issues in any guidance provided on this subsidy.

**Rationale:** The proposed regulation appears to require Plan sponsors to calculate the appropriate LEP subsidy for members based on their current income levels. Plan sponsors cannot calculate the subsidy as proposed because they do not have member income levels. Further the sliding scale will require new administrative systems and will be difficult to administer. In addition, since the current LEP guidance must be implemented by August 1, 2007, application of this LEP subsidy this fall will result in retroactive adjustments and cause confusion among Medicare beneficiaries.

**Submitter :** **Mr. Matthew Insley** **Date: 07/23/2007**

**Organization :** **Ohio Northern University**

**Category :** **Academic**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4130-P-13-Attach-1.RTF

#13

**DATE:** July 22, 2007

**TO:** CMS

**FROM:** Matthew Insley
PharmD Candidate
Ohio Northern University

**SUBJECT:** Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit [CMS-4130-P]

Thank you for the opportunity to review and comment on the proposed Medicare rule. This rule adequately clarified the policies associated with the Medicare Prescription Drug Benefit. My comments are not directed towards a particular section of this rule, instead they are concerning potential problems facing Medicare beneficiaries.

According to the Office of Inspector General's report in June 2007, 97% of participating retail pharmacies participate in at least half of the available PDPs in their region. It is encouraging to see participation in these private PDPs at such a high rate in both independent and chain pharmacies. Pharmacy participation in these plans is not the concern, it is independent pharmacies that are closing due to slow and low reimbursement for their services. According to the National Community Pharmacist's Association, three independent pharmacies are forced to halt operations every day due to Medicare plans. The OIG's report does not examine the likelihood of an independent pharmacy closing down because of cash flow shortages. This is a public health concern in rural areas.

U.S. Senator Charles Schumer released a report showing that in 2006, 221 independent pharmacies closed their doors in New York State. The New York State Board of pharmacy reveals that there are only 477 community pharmacies left in Upstate New York. Independent pharmacies serve a higher proportion of Medicare beneficiaries than chain pharmacies in this region, and they typically serve multi-county areas, often up to a 45 mile radius.

HR 1474 was introduced to 110$^{th}$ Congress in March 2007. This bill is designed to require prompt payment (14 days) from the sponsor to the provider. HR 971 is a similar bill that will allow independent pharmacies the same leverage that much larger chains enjoy when negotiating third-party contracts. Although these bills are a step in the right direction, there is no guarantee that they will be passed and nothing is currently being done to prevent independents from closing due to these issues. Something needs to be accomplished federally to assure that not only Medicare beneficiaries, but all patients in a particular rural area are not stranded without a pharmacy.

Independents are forced to take out bulky loans in order to deal with cash flow problems. Federal funds should be allocated towards a specific loan program with low interest and

flexible terms. This may help alleviated some of the interest cost and the timelines associated with normal private loans. A policy regarding prompt payment to providers should be added into the current Medicare policy changes if possible. Most importantly, specific rural areas and their patient's pharmaceutical access should be frequently monitored and dealt with on an individual basis.

The current situation involving independent pharmacies in rural areas is quite alarming. Current Medicare policy needs to be revised to require fast payment to these pharmacies. This is a public health concern not only for Medicare Beneficiaries, but for the entire patient population in certain rural areas.

**Submitter :** Dr. John A. Gans **Date:** 07/24/2007

**Organization :** American Pharmacists Association (APhA)

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4130-P-14-Attach-1.PDF

#14

# American Pharmacists Association®

Improving medication use. Advancing patient care.

APhA

July 23, 2007

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

[Submitted electronically to: http://www.cms.hhs.gov/eRulemaking]

RE: Proposed Rule, 42 CFR Part 442 and 443 – Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the proposed rule, 42 CFR Part 422 - Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes; and 42 CFR Part 443: Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit, published in the *Federal Register* on May 25, 2007 (72 FR 29368). The proposed rule would clarify provisions within the Medicare Prescription Drug Benefit (Medicare Part D), and codify prior clarifications and propose new clarifications for certain policies related to the drug benefit. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

As stated in the background section of the notice, the proposed regulations are based on experience that the Agency has gained while working with the Medicare Advantage (MA) organizations and Part D sponsors through the implementation of Medicare Part D. APhA supports the Agency's effort to provide clarification and codify guidance on several sections within the current Part D regulations based on its experiences with implementation. Our comments will focus on clarifications to: contract requirements and downstream terminology, marketing and enrollment activities, insulin inhalation drugs and supplies, negotiated drug prices, waiver and reduction of Part D cost-sharing, adequate access to home infusion pharmacies, administrative costs, prescription drug price reporting, and coordination of benefits for Part D beneficiaries.

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www.aphanet.org • www.pharmacist.com

## 42 CFR Part 422
**Provisions of the Proposed Regulations**

***Section 442.2 – Definitions***
APhA supports the Agency's technical correction to remove the term "subcontractor" due to the confusion this term created in managing contacts with MA organization and Part D sponsors. APhA supports the proposal to include the terms "first tier entity", "downstream entity" and "related entity" to better clarify the relationships between entities that have arrangements or contracts with MA organizations or Part D sponsors. In addition, the revised "Example of Stakeholder Relationship Flow Chart" is a helpful diagram outlining pharmacies and pharmacists as downstream entities.

***Section 422.503 and 423.504 – General Provisions***
APhA supports the clarification, based on the revised downstream terminology, requiring that all MA organizations and Part D sponsors institute uniform compliance plans requiring training and education and effective lines of communication. Such plans apply to direct employees and to all downstream entities (including pharmacies and pharmacists) that provide services for those MA organizations or Part D sponsors that deliver the Part D benefit.

## 42 CFR Part 423
**Provisions of the Proposed Regulation**

**Subpart B – Eligibility and Enrollment**
***Section 423.50 – Approval of Marketing Materials and Enrollment Forms***
APhA strongly supports the Agency's clarification with regards to the approved marketing materials and enrollment forms that can be displayed in pharmacies and the acceptable educational and enrollment activities that can take place in a pharmacy. The *Medicare Marketing Guidelines* (updated July 25, 2006) states that Part D plan sponsors must ensure that those contracting with the plan to provide services to part D beneficiaries, such as pharmacies and pharmacists, do not engage in marketing activities that would steer or attempt to steer a beneficiary to a particular plan or group of plans for which they would expect compensation for such marketing activities. The proposed rule seeks to clarify that the definition of marketing does not preclude entities, such as pharmacies or pharmacists, from educating beneficiaries about Part D plans or assisting beneficiaries with enrollment. It also clarifies that pharmacies or other provider groups can display or distribute Part D plan printed information comparing benefits from different Part D plans that they contract with; however, if the pharmacy or other provider group is not contracted with a Part D sponsor then they are not required to provide information regarding that plan. APhA appreciates the Agency's efforts to better clarify the non-marketing educational activities that are acceptable in a pharmacy as many Part D beneficiaries look to their local pharmacist or pharmacy first to navigate the vast array of Part D plans.

**Subpart C - Benefits and Beneficiary Protections**
**Definitions**
***Section 423.100(a)(3) - Insulin Inhalation Drugs and Supplies***
In January of 2006 the Food and Drug Administration (FDA) approved the first inhaled insulin product which requires patients to use a hand-held device and place a small amount of insulin in a chamber to inhale into their lungs. Given that this new product was not specifically defined as a Medicare Part D drug, sponsors questioned the reimbursement of this product and its supplies. APhA supports the

Agency's proposed rule to clarify Congress' intent that beneficiaries receiving treatment for diabetes have access to appropriate diabetes medications and the supplies required to use those medications, such as syringes, needles, alcohol swabs, gauze, and insulin delivery devices not covered by Part B (insulin pens, pen supplies, and needle-free syringes) and should not be limited to medications approved at the time of Medicare Part D implementation. We agree that Part D beneficiaries should also have access to novel new therapies that are introduced into the market. Understanding that medicines used to treat diabetes are subject to placement on a plan formulary, APhA appreciates the Agency's clarification that insulin inhalation medication and supplies are eligible for Part D reimbursement.

***Section 423.100 (d) Negotiated Prices***

APhA strongly supports the Agency's effort to clarify the beneficiary cost-sharing structure associated with negotiated Part D drug prices. We appreciate the proposed rule amendment of "negotiated prices" to reflect prices that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy (or other network dispensing provider have negotiated) will receive, in total, for a particular drug – meaning, the actual acquisition cost. Understanding that in order to minimize the disruption to plan operations, the Agency previously allowed beneficiary cost-sharing to be based on the price charged by the pharmacy, or on the price the sponsor paid to a PBM or other intermediary for the drug, we appreciate that the Agency took this opportunity to re-determine a single approach to calculating beneficiary cost-sharing. Not only does this revised approach simplify administration of the benefit, it clearly is a more accurate policy to calculate cost-sharing and allows pharmacists and Medicare beneficiaries accurate information to help track beneficiaries costs towards TrOOP. Additionally, this provision supports the Agency's efforts to improve drug pricing transparency for the Part D benefit.

***Section 423.104 - Requirements Related to Qualified Prescription Drug Coverage – Waiver of Reduction of Part D Cost-Sharing by Pharmacies***

The proposed rule will generally allow waiver or reductions of Part D cost-sharing by pharmacies to count toward TrOOP as incurred costs, however, such action will not be allowed for pharmacies affiliated with entities whose wraparound coverage does not count as an incurred cost. This includes pharmacies with an obligation to pay for covered Part D drugs. Consequently, many safety net providers, who are fully or partially funded by government grants, are unable to have any waiver or reduction of costs apply to Part D cost sharing and count as an incurred costs.

Although APhA appreciates the clarification of costs that are acceptable to count towards a beneficiaries TrOOP costs, it may be counter-productive to have policy that does not allow safety-net providers, those who care for our nation's most vulnerable patient population, to be unable to have their contributions (waiver or reduction of cost sharing) count toward a Medicare Part D beneficiary's incurred costs. Although it is true that many of these facilities receive partial or full funding from the Government and have an obligation to offer care to the uninsured or under-insured, as a matter of public policy, the proposed clarification places another barrier to the full integration of safety net providers into Medicare Part D.

APhA encourages the Agency to revisit this determination, and permit expenditures made by safety net providers, including those who receive government funds, to count toward their patients' TrOOP. Policy decisions such as this have created disincentives for many of the uninsured, who may be dual-eligibles, or eligible for low-income subsidies, to sign up for Medicare Part D. Many of these patients have established their healthcare homes with safety net providers, and should not be forced to changed

providers in order to maximize the benefit of the Part D program, especially when their chosen provider specializes in caring for the underserved.

***Section 423.120(a)(4) – Adequate Access to Home Infusion Pharmacies***

APhA supports the Agency's proposed action to codify existing guidance regarding adequate access to Part D covered home infusion drugs and home infusion pharmacies. The guidance states that Part D sponsors are required to have adequate access to home infusion pharmacies based on the number of enrollees covered in their services area and the capacity of home infusion pharmacies given the geographic area. APhA appreciates that as the Agency has gained more experience with Part D programs, they have identified additional areas that need clarification with regards to timeliness of home infusion therapy deliver. APhA supports the Agency's proposed rule clarifying that home infusion pharmacies, that are part of the Part D plan's network and deliver home infusion drugs, ensure that the necessary ancillary supplies and professional services required for home infusion therapy are in place before dispensing the Part D covered home infusion therapy. Additionally, we support the language that home infusion drugs be delivered in a timely manner, specifically within 24 hours of acute setting discharge, as long as the Part D plan has been assured that appropriate professional and ancillary services have been arranged.

**Subpart G – Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage Definitions and Terminology**

***Section 423.308(a) – Administrative Costs***

APhA supports the defining of 'administrative costs' in the proposed rule as the term is not defined in statue or in the January 28, 2005 final rule for Medicare Part D. As stated on the proposed rule discussion, the definition of administrative costs is the Part D sponsors' costs other than those incurred to purchase or reimburse the purchase of Part D drugs under the plan. Included in the administrative costs are amounts incurred by Part D plans that exceed the price charged by a dispensing entity for covered Part D drugs. (i.e. the profit of a PBM that negotiated drug prices between a Part D plan sponsor and pharmacies). CMS is required by statue to exclude administrative costs of a Part D sponsor from the calculation of gross covered prescription drug costs. Clarification of the Agency's meaning of this term will help with continued efforts to improve price transparencies within the Part D benefit and base calculations for Part D drugs on the actual pharmacy acquisition cost.

***Section 423.308(b) – Gross Covered Prescription Drug Costs***

As stated in the discussion of this section, the Agency has received questions regarding the appropriate drug costs to report and specifically when a PBM is contracted with a Part D sponsor. Unfortunately, many plans reported prices negotiated with PBMs and not the price that was actually received by the pharmacy. APhA appreciates the Agency's effort to address this confusion and inaccurate reporting by referring back to the January 28, 2005 final rule and clarifying that a drug price is not the negotiated price between a PBM and the Part D sponsor, but the ultimate price received at the pharmacy. In addition, the Agency clarifies that any profit or loss retained at the PBM level is part of 'lock-in pricing' and part of the administrative costs of the Part D plan sponsor. Again, APhA is in support of these clarifications as accurate price reporting will lead to overall better understanding of the costs associated with Part D drugs. Accurate price reporting based on the price received at the pharmacy will allow patients to better understand the costs of their medications and the cost sharing that they incur for their Part D drugs.

***Section 423.464(f) – Coordination of Benefits with Part D Plans and Other Payers***
APhA supports the Agency's intent to codify existing guidance issued to Part D sponsors regarding plan-to-plan reconciliation procedures for Part D drug claims. Coordination of benefits is challenging for patients that have the opportunity to switch plans given the lag time needed to update data systems for pharmacy claims adjudications. APhA appreciates the Agency's efforts to direct payment reconciliation to the plan or payer level and not put additional financial or administrative burdens on pharmacies for re-adjudication of those claims.

Thank you for the opportunity to comment on this important issue. We look forward to continued work with the Agency. If you have any questions or require additional information please contact Marcie Bough, Director of Federal Regulatory Affairs at (202)429-7538 or MBough@aphanet.org.

Sincerely,

John A. Gans, PharmD
Executive Vice President

cc: Catherine M. Polley, RPh, Chief Policy Officer, Senior Vice President, Government and Professional Affairs
Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs

**Submitter :** **Mr. Howard Bedlin** **Date: 07/24/2007**

**Organization :** **National Council on Aging**

**Category :** **Other**

**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. Howard Bedlin** **Date: 07/24/2007**

**Organization :** **National Council on Aging**

**Category :** **Other**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4130-P-16-Attach-1.DOC

#16

NCOA
NATIONAL COUNCIL ON AGING

July 24, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
PO Box 8014
Baltimore, MD 21244-8014

**RE: File Code CMS-4130-P**

To Whom It May Concern:

Attached please find comments to the proposed rule on 42 CFR Part 423 from the National Council on Aging (NCOA). The mission of NCOA is to help Medicare beneficiaries with limited incomes enroll in available needs-based benefits, and our comments are written from that perspective. Thank you for the opportunity to comment.

If you have any questions or need further information please contact Sara Clary, NCOA's Director for Benefits Access Policy at sara.clary@ncoa.org or (202) 479-6678.

Sincerely,

Howard Bedlin
Vice-President
Public Policy & Advocacy
NCOA

**Comments to 42 CFR Part 423**
**File Code CMS-4130-P**
**From the National Council on Aging (NCOA)**

1. Sec. A. Subpart B—Eligibility and Enrollment
   1. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

      **Comment**: The distinction between marketing and education may be very difficult for providers to maintain in their everyday encounters with their patients. We urge CMS to recommend that health care providers, especially pharmacists, refer beneficiaries to trusted resources for enrollment counseling.

2. Sec. B. Subpart C—Benefits and Beneficiary Protections
   1. Definitions
   a. Part D Drug
   (2) Morbid Obesity

      **Comment**: We urge CMS to adopt a more generous construction of agents used for the chemotherapeutic treatment of morbid obesity. In light of the peer-reviewed evidence of the obesity epidemic this nation currently confronts and the many serious chronic and life-threatening co-morbidities for which morbidly obese individuals are at high risk, we recommend that CMS interpret the statute to permit Part D coverage of agents approved for use in treating morbid obesity, while precluding coverage of such drugs for cosmetic purposes of inducing anorexia. Such a construction of the statute would be far more consistent with CMS's focus on managing and preventing complications of chronic diseases, as it is well-known that obesity heightens risk for so many co-morbidities in Medicare populations.

3. Sec. B. Subpart C—Benefits and Beneficiary Protections
   1. Definitions
   a. Part D Drug
   4. Vaccine Administration Fee

      **Comment**: NCOA is concerned about the regulatory provision implementing §202 of the *Tax Relief and Health Care Act of 2006* that allows for the administration fees of Part D covered vaccines to be paid for under Part D beginning January 1, 2008.

      Our concern is that the majority of Part D vaccines will be administered by a physician, during an office visit, rather than by a pharmacist, yet most physicians do not have the ability to bill under Part D (unlike pharmacies). We are concerned that the billing system established by this regulation creates disincentives to physicians which may pose significant vaccine access issues, especially for Medicare beneficiaries with limited incomes. Moreover, we urge CMS not to place physician's offices in the position of having to require Part D beneficiaries to pay for the vaccine administration up front, and thereafter have to seek reimbursement from their Plan.

We recommend establishing a procedure to ensure that people who need Part D covered vaccines are able to access them at their physician's office, if they choose, without having to pay out of pocket, except, of course, for applicable cost sharing.

4. Sec. B. Subpart C—Benefits and Beneficiary Protections
2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)—Waiver of Reduction of Part D Cost-Sharing by Pharmacies

**Comment**: We commend CMS for highlighting the option for commercial, non-safety net pharmacies to waive Part D copays in selected cases of financial hardship.

5. Sec. B. Subpart C—Benefits and Beneficiary Protections
3. Access to Covered Part D Drugs (§ 423.120)
b. Adequate Access to Home Infusion Pharmacies (§ 423.120(a)(4))

**Comment**: The 24-hour standard proposed in this rule is inadequate. For patients discharged from an acute setting on home infusion therapy, some of whom may require more than one dose per 24-hour period, the only reasonable standard CMS can establish is one that allows for a beneficiary to receive therapy as prescribed in a timely, therapeutic manner upon discharge from in-patient treatment settings.

We are concerned about the need imposed by the proposed regulation for rapid coordination among many essential players, including hospital discharge departments, certified home health agencies and home infusion pharmacies to facilitate discharge of patients in need of short or long-term home infusion therapy before the 24 hour timeline begins to run. As long as the 24 hour timeline on delivery of the drugs is tolled until arrangements have been made for administration of the infused medication, there is a high risk that hospital discharges could be delayed, resulting in higher costs to patients and Medicare, as well as less than optimal service delivery to Medicare patients. We urge CMS to build into the regulation more mandated and timely coordination in order to meet the needs of Medicare patients who must have home infused therapies in place to be discharged from the hospital.

6. Sec. D. Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage
1. Definitions and Terminology
b. Gross Covered Prescription Drug Costs (§ 423.308)

**Comment**: We commend CMS for codifying previous guidance confirming that PAP copays or deductibles count towards TrOOP. Codifying this policy will help low-income beneficiaries who are just above the Extra Help eligibility levels to obtain needed drugs at an affordable price, particularly while they are in the coverage gap.

7. Sec. H. Subpart M—Grievances, Coverage Determinations, and Appeals
1. Definitions (§ 423.560)
a. Appointed Representative

**Comment:** NCOA supports codifying the definition of "Appointed Representative" to permit a Part D plan enrollee's appointed representative to request a grievance, obtain a coverage determination, or deal with any of the levels of the appeals process on the enrollee's behalf. Many Medicare beneficiaries want or need the assistance of their Appointed Representative to deal with complex appellate procedures. Appointed Representatives should be allowed to act on behalf of the beneficiary with respect to all aspects of the appeal process and to give and receive personal information (including decisions) on behalf of the beneficiary.

8. Sec. G. Subpart K—Application Procedures and Contracts With Part D Plan Sponsors
   2. Expediting Certain Coverage Determinations (§ 423.570)

**Comment**: §423.570 (d) (3) should be amended to clearly state that plan sponsors must provide written notice to the enrollee within three calendar days when they deny a request to expedite a coverage determination. We believe this regulation should mandate that the written notice must be "received by" the enrollee within the three calendar day time frame, and not merely placed in the mail within that time frame. Expedited coverage determinations are requested by beneficiaries or their physicians only when there is an immediate need for a prescription drug, therefore, a decision not to grant review under the expedited timeframe should be communicated to the beneficiary as soon as possible, but not more than three days after the request is made.

9. Sec. I. Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals
   1. Premium Subsidy Amount (§ 423.780)
   b. Premiums Subsidy for Late Enrollment Penalty

**Comment**: We commend CMS for amending § 423.780 (e) in order to provide partial subsidy-eligible individuals with assistance with any late-enrollment premium penalty based on a sliding scale. Although CMS has waived any late-enrollment premium penalty for LIS eligible beneficiaries so far—and we urge CMS to continue to do so—if the late-enrollment premium penalties were to be imposed upon low income subsidy recipients in the future, partial low-income subsidy eligible individuals will need assistance in paying the premium penalty.

**Submitter :** **Mr. Russell Bodoff** **Date: 07/24/2007**

**Organization :** **National Home Infusion Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4130-P-17-Attach-1.DOC

NHIA
National Home Infusion Association
*Providing solutions for the infusion therapy community*

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: Comments on Proposed Rule— Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit, CMS-4130-P; 72 Federal Register 29403 (May 25, 2007). ADEQUATE ACCESS TO HOME INFUSION PHARMACIES**

Dear Ms. Norwalk:

The National Home Infusion Association (NHIA) submits these comments on the proposed rule clarifying and codifying the Center for Medicare and Medicaid Services' (CMS') policies associated with the Medicare Prescription Drug Benefit, as issued in the Federal Register on May 25, 2007.[1] We specifically focus our comments on Section 3.b. of the preamble, Adequate Access to Home Infusion Pharmacies, and the relevant proposed regulation § 423.120(a)(4).

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with acute or chronic conditions. Currently, NHIA has 2,000 members.

NHIA appreciates the opportunity to address two issues related to access to home infusion therapy raised by proposed 42 C.F.R. § 423.120(a)(4):

(1) the requirement that Part D network pharmacies ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs; and, the requirement that Part D network pharmacies provide delivery of home infusion drugs within at least 24 hours of discharge from an acute setting.

[1] 72 Federal Register 29403 (May 25, 2007).

100 Daingerfield Road • Alexandria, VA 22314 • Phone: 703-549-3740
• Fax: 703-683-1484 • www.nhianet.org

To summarize, we believe CMS' proposals on these issues are important steps in the right direction. While we generally support CMS' proposals on these points, we do have several recommendations that we believe will improve beneficiary access to home infusion therapy under Part D.

## I. Requirement to Ensure that Professional Services and Ancillary Supplies are in Place § *423.120(a)(4)(iii)*

In this proposed rule, CMS seeks to codify its previous, sub-regulatory policy[2] that Part D plans must require their contract network pharmacies to ensure that the necessary professional services and ancillary supplies required for home infusion therapy are in place before dispensing home infusion drugs. NHIA applauds CMS for recognizing that the provision of such supplies, equipment and professional services is critical to the safe and efficient administration of home infused drugs to Medicare beneficiaries. Without the availability of these services and supplies, there cannot be true access to clinically-intensive infusion therapy in the home.

CMS' acknowledgement of the vital nature of these services, however, only underscores the necessity to provide Medicare *coverage* for them as well. CMS cannot fulfill its stated purpose of ensuring adequate access to home infusion therapy unless it ensures coverage reimbursement for all necessary components of this therapy. The majority of expenses associated with administering infusion drugs in the home are related to the non-drug components of the therapy. Yet, in the very same rule in which CMS intends to clarify its requirement that Medicare enrollees receive adequate access to home infusion therapy, the agency states that it "do[es] not expect Part D plans to . . . pay for supplies, equipment, or the professional services needed." CMS cannot reasonably expect assurances that such services will be provided to Medicare beneficiaries in the absence of assured coverage.

CMS explicitly acknowledges in the preamble to this regulation that "home infusion therapy may serve as a vehicle to promote early hospital discharge" and that plans may benefit from the "reduced medical costs associated with home infusion."[3] Indeed, private health insurance plans have long recognized this potential for reduced costs and provided complete coverage of home infusion therapy. Likewise, Medicare Advantage plans cover home infusion therapy as a medical benefit. They do so not only because of patients' preference for home care and the desire to avoid hospital-acquired infections, but also because such coverage has demonstrated significant reductions in medical spending.[4] It is only reasonable, then, that the Medicare fee-for-service program should also provide coverage of professional services and ancillary supplies. Even if Part D plans do not have the incentive to provide these services, the Medicare program pays the higher cost of infusion therapy for beneficiaries in an inpatient hospital or nursing home setting when home infusion therapy is not accessible. Medicare coverage of these services will not only reduce the costs of the program overall, but is necessary for CMS to provide the meaningful access to home infusion therapy intended by this regulation.

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[2] *See* CMS Policy Memorandum (Mar. 10, 2006) *at* http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/HomeInfusionReminder_03.10.06.pdf.

[3] 72 Fed. Reg. at 29408.

[4] *See Financial Impact of a Home Intravenous Antibiotic Program on a Medicare Managed Care Program*, Joseph R. Dalovisio, Jan Jeneaus, Katherine Baumgarten, and Hon Kateiva; Clinical Infectious Diseases 2000; 30:639-642.

For these reasons, we urge CMS to either reconsider its position that it does not have the authority to cover infusion services, supplies and equipment under Part D, or work with the infusion community to secure passage of legislation providing CMS with that authority. It is clear that the current situation is not resulting in meaningful access to home infusion therapy.

**2. Requirement to provide delivery of home infusion drugs within 24 hours of discharge § *423.120(a)(4)(iv)***

CMS specifically invites comments on the specification of a reasonable timeframe for delivery of home infusion drugs under Part D. Proposed regulation § 423.120(a)(4)(iv) requires that contracted network pharmacies "provide delivery of drugs within at least 24 hours of discharge from an acute setting." NHIA very much appreciates CMS' recognition of the importance of timely delivery of infusion drugs to patients' who are to receive infusion therapy in the home setting. However, we urge CMS to conform its requirement to the advice it specifically acknowledges having received from home infusion providers. CMS states in the preamble that:

> [i]n our ongoing discussions with home infusion providers we have learned that best practices involve the availability of infusion services upon discharge from a hospital either by the next required dose or within twenty-four hours of the discharge.[5]

CMS proposes to require delivery "within at least 24 hours of discharge." There may well be instances, however, in which a patient's next required dose will be in less than 24 hours from discharge. Under the proposed regulation, such a patient could not be assured that he/she would timely receive the infusion drugs in the home setting. As a result, the patient may have to remain in a hospital or nursing facility, delaying his/her return to the more comfortable and appropriate home setting and incurring additional costs to the Medicare program. We recommend that CMS modify the proposed regulation to be consistent with the feedback CMS has received on this issue and require that Part D plans ensure that such network pharmacies "provide delivery of home infusion drugs upon discharge from an acute care setting within the earlier of 24 hours or before the patient's next required dose."[6]

We believe further that there needs to be an understanding among CMS, the PDPs, discharge planners, and infusion therapy providers as to what is necessary to ensure that beneficiaries have meaningful and timely access to home infusion therapy as described above. The PDPs must ensure that they are communicating effectively with physicians, infusion providers and discharge planners as to infusion beneficiaries' needs. Likewise, the PDPs must ensure that their formulary practices, drug utilization controls and other policies do not thwart compliance with this regulation. This is eminently achievable. Private health plans routinely take the appropriate steps so that their subscribers in need of home infusion therapy can in fact

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[5] 72 Fed. Reg. at 29408.

[6] We note that CMS may have tried to capture this point by requiring delivery "within *at least* 24 hours of discharge;" however, it is not clear that "at least" conveys no more than 24 hours later, and the more specific language will ensure that patients receive the medication before the needed dose.

obtain these therapies in a timely manner. The PDPs are the outliers in this regard, and the proposed regulation, as modified by our recommendation, could bring the PDPs into compliance with established standards of care with respect to timely qualification of patients for homecare.

This issue is having a measurable impact on patients' choice and the cost of their care. A November 2006 survey of hospital discharge planners found that more than two-thirds of respondents reported delays in hospital discharges for Part D-covered patients due to complications in arranging access for home infusion therapy under Part D.[7] Of those reporting delays, 86 percent said the delays were significant, lasting one or more days.[8] Given the expensive nature of inpatient care, NHIA estimates the annual cost of such delays for all Part D-covered patients may exceed $4.5 billion.[9]

In addition, access problems for dual eligibles have increased since these patients were transitioned to Part D drug coverage from Medicaid coverage of infusion drugs, which in many states includes at least some home infusion services and supplies. "Sixty-three percent of hospital discharge planners said they are placing more dual eligibles in nursing homes or hospital outpatient settings for infusion treatment than before Part D, due to problems in accessing home infusion under Part D."[10]

We can do better than this. We reiterate our recommendation that CMS either reconsider its position with respect to its authority to cover home infusion therapy, or seek Congressional authorization for such coverage. The current dilemma should not be acceptable to beneficiaries, providers, prescription drug plans, or to CMS.

* * * *

NHIA welcomes the opportunity for further communication regarding these issues and would be pleased to provide any additional information you might need. Please feel free to contact me at 703-838-2678 if you have any questions or requests.

Sincerely,

Russell T. Bodoff
Executive Director

---

[7] NHIA Survey Report, *Discharging Dual Eligibles Needing Home Infusion Therapy Under Medicare Part D: National Survey of Hospital Discharge Planners* (Nov. 15, 2006) 1-2, *at* http://www.nhianet.org/documents/DchgPlnrSurvyReportFinal111506.pdf.

[8] *Id.* at 2.

[9] *Id.* This estimate uses survey data and information from the "American Hospital Association/Lewin Group Trendwatch 2006."

[10] *Id.*

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

**Organization :** **MAPRx Coalition**

**Category :** **Consumer Group**

**Issue Areas/Comments**

**Adequate Access to Home Infusion Pharmacies**

Adequate Access to Home Infusion Pharmacies

See Attachment

**Administrative Costs**

Administrative Costs

See Attachment

**Application Timing**

Application Timing

See Attachment

**Coordination of Benefits with Part D Plans & Other Payers**

Coordination of Benefits with Part D Plans & Other Payers

N/A

**Data Match**

Data Match

See Attachment

**GENERAL**

GENERAL

See Attachment

**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

N/A

**Noncalendar Year Plans**

Noncalendar Year Plans

N/A

CMS-4130-P-18-Attach-1.DOC

#18


July 24, 2007

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

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

Dear Mr. Kuhn:

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

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

Section II. A. Subpart B – Eligibility and Enrollment

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

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

1. Definitions, a. Part D Drug

(2) Morbid Obesity

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

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

(3) Insulin Inhalation Drugs and Supplies.

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

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

(4) Vaccine Administration Fee

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

1. Definitions, b. Long Term Care Facilities

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

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

1. Definitions, d. Negotiated Prices

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

the public. Prior to and since the launch of Part D, MAPRx has repeatedly expressed its concern about the lack of transparency of price-setting for the drugs offered on plan formularies. It is recognized that under MMA, manufacturers may offer price discounts and rebates to individual plans. However, there is no requirement that these savings be passed on to the beneficiaries enrolled in the plan, and no means for the public to discern if a plan has, indeed, taken this action.

Part D beneficiaries served by MAPRx member organizations represent some of America's most vulnerable seniors and individuals with disabilities, suffering multiple disease state co-morbidities, and frequently using 10-to-20 medications, many of them branded drugs which do not have a generic alternative. It is imperative that these beneficiaries have broad access to their medications on Part D plan formularies and at the very best price possible. The policy, as proposed, further obfuscates CMS' and the public's ability to determine if price concessions to plans and network pharmacies are transferring to the beneficiaries. Higher drug costs move a beneficiary into the coverage gap period sooner and ensure higher total drug spending for a majority of these individuals who will not achieve catastrophic drug coverage. Equally important, these beneficiaries must carefully choose which formulary covers all or nearly all of their medications, frequently only available on the plan's highest tier. Plans with an expanded formulary demand higher premiums, further exacerbating the financial burdens this policy will have on beneficiaries with chronic diseases and disability. With or without this policy change, MAPRx strongly urges CMS to aggressively monitor Part D plans' formulary practices, pricing and co-payment structure and actual beneficiary experience regarding access to medications to accurately evaluate the success of Part D in meeting the prescription needs of America's most vulnerable beneficiaries.

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

3. Access to Covered Part D Drugs, b. Adequate Access to Home Infusion

MAPRx commends CMS for requiring that Part D enrollees receive adequate access to Part D-covered home infusion therapy. This policy provides enhanced safety for immuno-suppressed beneficiaries by reducing exposure to harmful pathogens outside their home environment and provides for greater efficiency of healthcare management for these individuals and the health system at large.

In response to CMS' request for guidance on the timeliness of delivery of home infusion drugs under Part D, it is MAPRx's position that the 24-hour standard proposed in this rule is inadequate. For patients discharged from an acute setting on home infusion therapy, some of whom may require more than one dose per 24-hour period, the only reasonable standard CMS can establish is one that allows for a beneficiary to receive therapy by the next required dose.

In addition, MAPRx is concerned about the lack of clarity regarding access to the supplies, equipment, or the professional services required for beneficiaries to safely receive home infusion therapy. What is the most efficient coverage system for ensuring that the necessary mechanisms/services are in place to effectively deliver this drug benefit? MAPRx advocates that CMS establish, similar to the vaccine administration policy (referenced above), a policy that Part D plans are responsible for the home infusion drug and ancillary services and supplies to deliver this therapy (Part D versus Part B coverage) in a home infusion environment.

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

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

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

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

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

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

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

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

1. Definitions, a. Appointed Representative

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

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

2. Expediting Certain Coverage Determinations

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

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

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

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

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

Sincerely,

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

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

**Organization :** **Virginia Pharmacists Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-4130-P-19-Attach-1.DOC

#19


# VIRGINIA PHARMACISTS ASSOCIATION

5501 Patterson Avenue, Suite 200 Richmond, Virginia 23226
Phone: (804) 285-4145 Fax: (804) 285-4227
E-Mail: vpha@vapharmacy.org www.vapharmacy.org


*Pharmacists helping pharmacists to improve patient care.*



August 31, 2007

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

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

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

**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**

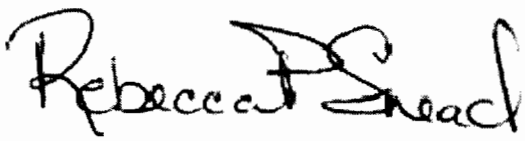
In summary, VPhA strongly supports CMS' proposes policy and technical changes to the Medicare Prescription Drug Benefit plan. Given the changing nature of the practice of pharmacy and the ever-increasing reliance on federal guidance, VPhA appreciates CMS' effort to clarify and codify the areas addressed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

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

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

Sincerely,



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

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

**Organization :** **sanofi-aventis**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4130-P-20-Attach-1.DOC

#20

sanofi aventis

Because health matters

July 24, 2007

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: Access to Obesity Treatment Therapies Under Medicare Part D; CMS-4130-P (Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit)**

Dear Mr. Leavitt and Ms. Norwalk:

I am writing on behalf of sanofi-aventis, a leading, research-based pharmaceutical company, to request your assistance with ensuring that Medicare beneficiaries have access to treatments approved by the Food and Drug Administration (FDA) for obesity, a serious disease that imposes significant personal and financial costs on Medicare beneficiaries and the Medicare program. Sanofi-aventis is a global pharmaceutical company with over 18,000 employees in the United States and a leader in developing innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. We are pursuing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines. Our mission is to discover, develop, and make available to physicians and

their patients innovative, effective, well-tolerated, high quality and safe treatments that fulfill vital health care needs.

This access to FDA-approved therapies to treat obesity is seriously threatened by a proposed rule, CMS-4130-P, which was published by the Centers for Medicare and Medicaid Services (CMS) on May 25, 2007, and purports to restate the CMS position that weight loss drugs are excluded from the definition of a Part D drug "even when not used for cosmetic purposes." 1/ If finalized, this proposed policy will limit patient access to dozens of new compounds that may ultimately be approved to treat obesity. Further, it will leave in place the obesity "treatment gap" by limiting physicians' ability to treat obese Medicare beneficiaries according to well established clinical practice guidelines. **We urge CMS to reject its proposed policy and allow for coverage of FDA-approved drugs for the medical management of obese patients.** Coverage of such treatments is completely consistent with language of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[2] congressional intent, the medical community's and government's definition of "obesity," and medically accepted standards of high quality clinical practice.

I discuss these comments in detail below.

## I. Obesity Imposes Significant Financial and Medical Costs on the United States

Obesity is the second leading cause of preventable death in the United States, causing about 112,000 deaths per year.[3] Obesity, defined as a body mass index (BMI) equal to or greater than 30 kg/m$^2$, is for many individuals a serious and life-threatening condition, often leading to increased risk of hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, arthritis, respiratory problems, and endometrial, breast, prostate, and colon cancers. The prevalence of obesity among Americans has increased sharply over the past thirty years, and as the baby boomer generation ages, the costs of this disease increasingly will be borne by the Medicare program. One estimate found that 90 percent of the increases in the cost of the Medicare program can be attributed to people entering the program with diabetes and other diseases associated with obesity.[4]

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

2 *See* the attached legal opinion from Hogan & Hartson.

3/ Fact Sheet: CDC Efforts to Reduce or Prevent Obesity, Centers for Disease Control and Prevention, April 19, 2005, http://www.cdc.gov/od/oc/media/pressrel/fs050419.htm.

4 Steven Reinberg, "Obesity Driving Medicare Costs Higher," HealthDay News, Aug. 22, 2006, http://www.healthfinder.gov/news/newsstory.asp?docID=534510.

## II. Congress Intended for Part D to Cover Drugs for Obesity

Medicare can and must help reverse this alarming trend by providing America's seniors with access to treatment options they need to effectively combat this disease. When Congress enacted the MMA, it intended for Medicare to make available to America's seniors the broad range of prescription drugs they need to fight disease and live healthier lives. The statute excludes coverage of a very small number of drugs, or their uses, but drugs used to treat obesity are not on the list of excluded drugs. Instead, the statute excludes from coverage only drugs "when used for weight loss or weight gain"[5] (emphasis added) which are not uses inherently limited to people who are obese, may be unnecessary, and which are clinically distinct from managing obesity.

When CMS issued the final rule for Part D, it clearly understood the distinction between medically necessary uses of a drug that are covered – such as when used for the treatment of obesity – and other uses – such as for simple weight loss or weight gain – that are excluded from coverage. The preamble to the final rule states that "weight loss agents may be covered for the treatment of morbid obesity."[6] Since the publication of the final rule, however, CMS has indicated in informal guidance that these agents should be excluded from Part D coverage. CMS has again taken this position in the proposed rule.

In expressing this view, CMS appears to have equated weight loss and weight gain, symptoms that do not define a disease, with obesity which is a serious disease in its own right.[7] The statutory exclusion prevents Medicare payment for drugs when they are used for something other than treatment of a medical condition, but

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[5] Social Security Act (SSA) § 1860D-2(e)(2), referring to SSA § 1927(d)(2). This language has engendered some confusion. Although it would appear to mean that a drug used to *treat* weight gain or weight loss is excluded from coverage, many interpret the coverage exclusion to apply to drugs used to *induce* weight gain or loss. Under the latter construct, a drug used to treat obesity is a "weight loss" drug. For discussion purposes only, this letter describes obesity products as inducing weight loss rather than treating weight gain.

[6] 70 Fed. Reg. 4194, 4230 (Jan. 28, 2005).

[7] Obesity has been widely recognized as a disease, distinct from weight loss or weight gain, by both the medical community and the federal and state governments. Medical literature has defined obesity as a chronic disease with multiple causes, including genetics, environment, metabolism, and behavior. Following this definition, the International Classification of Disease, 9th Edition, Clinical Modification (ICD-9-CM) coding system, maintained by CMS and other parts of the Department of Health and Human Services, identifies obesity as a disease. In contrast, the ICD-9-CM identifies weight loss and weight gain as mere symptoms of other conditions. Similarly, the Food and Drug Administration (FDA) distinguishes obesity from weight loss or weight gain by regulating 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. Forty state Medicaid programs also cover drugs used to treat obesity, and some of those programs do not cover drugs "used for weight loss," but make an exception for certain agents used to treat obesity and other disease states. In addition, CMS itself implicitly acknowledged that obesity is a disease when it revised its national coverage determination manual to delete the statement, "obesity itself cannot be considered an illness." Finally, even if CMS were to conclude that obesity is not a disease, a drug indicated for and used to treat obesity should nevertheless be covered under Part D. This is because the drug would be used for a medically accepted indication – treatment of obesity – which is distinct from mere weight loss. That is, while the mechanism of action might be weight loss, the drug would treat obesity.

allows coverage when the same drug is used to treat an illness. For example, Medicare does not cover drugs used simply to allow patients to gain weight, but it does cover drugs that are used to treat cachexia (a disease marked by progressive emaciation and weakness), although those drugs are prescribed to help patients gain weight. Additionally, while the statute excludes from coverage medications when used for "the symptomatic relief of cough and colds,"[8] CMS permits coverage of these drugs when relief of cough and colds prevents other illnesses or injuries, such as reducing the risk of broken bones in a patient with severe osteoporosis or minimizing or eliminating shortness of breath or induced respiratory spasm in a patient with severe asthma.[9] There are additional examples where CMS has allowed the coverage of a certain drug under Part D when "used for" a medically necessary purpose but not when "used for" a purpose that is on the excluded list.[10] Similarly, drugs that treat obesity may produce weight loss, but they are prescribed to treat a medical condition or disease – obesity – and not simply for cosmetic or non-medically necessary reasons. Therefore, these drugs should be covered by Part D.

## III. Coverage Is Consistent with Good Medical Practice and Clinical Practice Guidelines

Several well established clinical practice statements and guidelines support the use of pharmacotherapy as one of a number of important tools for the treatment of obesity. In 2004, the American Heart Association issued a "Statement for Professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism" that supported the use of drug therapy for obesity using a definition of obesity as patients with "a BMI 30 kg/m$^2$ or a BMI between 27 and 29.9 kg/m$^2$ in conjunction with an obesity-related medical complication in patients with no contraindications for therapy."[11] Consensus treatment guidelines developed by the National Heart, Lung, and Blood Institute in 1998 call for physician management of obese patients and regular clinical assessments every 6 months. Further, those guidelines call for the use of "...drugs that have been approved by the FDA for long-term use as 'adjuncts to dietary therapy and physical activity for some patients with a BMI of 30 with no concomitant risk factors or diseases, and for patients with a BMI of 27 with concomitant risk factors or diseases.'"[12]

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[8] SSA § 1927(d)(2)(D).

[9] Q&A # 7827, "Does the exclusion of cough and cold medications extend to all clinical indications of these drugs?" http://questions.cms.hhs.gov.

[10] *See* the attached legal opinion from Hogan & Hartson.

[11] Clinical Implications of Obesity with Specific Focus on Cardiovascular Disease: A Statement for Professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism: Endorsed by the American College of Cardiology Foundation. *Circulation* 2004; 110: 2952-2967.

[12] National Heart Lung and Blood Institute guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. NIH Publication No. 98-4083. September 1998.

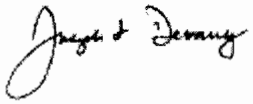
## IV. CMS Should Withdraw Its Proposed Rule Denying Coverage of Drugs that Treat Obesity and Instead Should Reaffirm that Such Drugs Are Covered Under Part D

CMS has described its decision to eliminate Part D coverage for obesity drugs as "clarifying" existing policy and the agency's "erroneous[] assert[ion]" in the preamble to the original Part D rule that such drugs could be covered if dispensed for a medically accepted indication. In our view, this description mischaracterizes CMS's prior statements and actions. CMS received comments on the original proposed Part D rule that urged the agency to adopt precisely the interpretation contained in the preamble to the final rule. For CMS now to say that it "erroneously asserted" that obesity drugs could be covered is inaccurate. Accordingly, we ask CMS to follow the correct analysis that it laid out in the original Part D final rule stating that drugs used to treat obesity are covered under Part D. When Congress passed the MMA, it understood that providing seniors with appropriate outpatient drugs could prevent progression of chronic diseases and save seniors from costly hospitalization and long-term care. Obesity is just such a disease which is frequently the cause of additional serious conditions, such as Type 2 diabetes, dyslipidemia, hyperinsulinemia, hypertension, cardiovascular disease, and impaired glucose tolerance. Denying coverage for drugs that treat obesity is not in the best interests of beneficiaries nor is it consistent with the language of the statute and the widespread recognition of obesity as a disease by the medical community and state and federal government agencies. The Social Security Administration and the Internal Revenue Service recognize obesity as a disease for purposes of disability benefits and the tax deduction for medical care costs. CMS should do the same for Part D.

## V. Conclusion

We thank you for your consideration of these comments on the proposed rule and hope we can continue to work with you to advance Medicare beneficiaries' access to innovative and life-saving therapies. Please contact Jon Spear, Associate Vice President, Federal Government Affairs, at (202) 628-0500 if you have any questions regarding these comments. Thank you for your attention to these important issues.

Respectfully Submitted,



Joseph F. Devaney
Vice President
Market Access Operation

cc:

The Honorable Charles B. Rangel
Chair, House Committee on Ways and Means
United State House of Representatives
Washington, DC 20515

The Honorable Jim McCrery
United States House of Representatives
Washington, DC 20515

The Honorable Max Baucus
Chair, Senate Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Charles Grassley
United States Senate
Washington, DC 20510

HOGAN & HARTSON

**MEMORANDUM**

**From:** Sheree R. Kanner

**Date:** July 18, 2007

**Re:** Coverage for Obesity Medications Under Medicare Part D

We have been asked to analyze whether treatments for obesity must be excluded from coverage under Medicare Part D.[1] In the Centers for Medicare & Medicaid Services (CMS) proposed rule regarding policy and technical changes to the Medicare prescription drug benefit, published in the Federal Register on May 25, 2007 (the Proposed Rule),[2] CMS characterizes its statements in the 2005 Part D final rule[3] as "erroneous" and "clarifies" that a "weight loss agent, even when not used for cosmetic purposes, is still 'an agent used for anorexia, weight loss, or weight gain,' for purposes of the exclusion from the definition of Part D drug."[4] We disagree with the agency's statements in the Proposed Rule that its policy, as described in the 2005 final rule, is erroneous or that the Proposed Rule is not a change to current policy. As explained below, CMS reached the correct legal conclusion in the final rule: The statute permits coverage of obesity drugs under Medicare Part D. Moreover, such coverage serves the policy purposes intended by Congress when it enacted Part D.

## I. The Medicare Statute Permits Part D Coverage of Drugs Used for Obesity

### A. The Statute Excludes Only Certain Categories and Uses of Drugs, and Obesity Is Not on this List

In the Proposed Rule, CMS interprets the Medicare statute and the implementing regulations at 42 C.F.R. § 423.100 as excluding coverage of drugs used to treat morbid obesity.[5] This interpretation is incorrect. By statute, Medicare Part D covers drugs approved for marketing by the Food and Drug Administration (FDA), as well as "medically accepted indications" of those drugs that are supported by citations in certain compendia.[6] Only specific classes of drugs and uses of certain drugs are statutorily excluded from coverage. This narrow

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[1]Sanofi-Aventis requested this legal opinion.
[2]72 Fed. Reg. 29,403 (May 25, 2007).
[3]70 Fed. Reg. 4194, 4230 (Jan. 28, 2005).
[4]72 Fed. Reg. at 29,405.
[5]Id.
[6]Social Security Act (SSA) § 1860D-2(e)(1), referring to § 1927(k)(6).

list includes "agents when used for anorexia, weight loss, or weight gain,"[7] 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.

In reaching the erroneous conclusion that obesity drugs must be excluded, CMS appears to have equated weight loss and weight gain, symptoms that do not define a disease, with obesity, which is a serious disease in its own right. Obesity has been widely recognized as a disease, distinct from weight loss or weight gain, by both the medical community[8] and the federal and state governments. For example, the FDA distinguishes obesity from weight loss or weight gain by regulating 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.[9]

In addition, CMS itself has implicitly acknowledged that obesity is a disease by revising its national coverage determination manual to delete the statement, "obesity itself cannot be considered an illness."[10] In announcing this change, both the then-Secretary of HHS and Administrator of CMS issued statements supporting expanded coverage for treatment of obesity-related conditions. Secretary Tommy Thompson said, "Obesity is a critical public health problem in our country that causes millions of Americans to suffer unnecessary health problems

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

[8]Medical literature has defined obesity as a chronic disease with multiple causes, including genetics, environment, metabolism, and behavior. See, e.g., Rippe J., Crossely S, Ringer R. Obesity as Chronic Disease: Modern Medical and Lifestyle Management. J Am Diet Assoc. 1998 Oct; 98 (10 Suppl 2):S9-15; Stunkard A. Current Views on Obesity. Am J Med. 1996 Feb; 100(2):230-6. 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. Following this definition, the International Classification of Disease, 9th Edition, Clinical Modification (ICD-9-CM) coding system, created by CMS and other parts of the Department of Health and Human Services (HHS), 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. ICD-9-CM codes 783.1 (symptoms concerning nutrition, metabolism & development: abnormal weight gain) and 783.21 (symptoms concerning nutrition, metabolism & development: loss of weight).

[9]Products making obesity claims "are covered by section 201(g)(1)(B) of the [Federal Food, Drug, and Cosmetic Act] because obesity is now 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 (January 6, 2000). The FDA also distinguishes weight management drugs from drugs used for weight loss. Weight management is more than weight loss. According to the FDA, a weight management indication would incorporate weight loss and weight maintenance, and it includes the "goal of reduced morbidity and mortality through quantifiable improvements in biomarkers such as blood pressure, lipids, and HbA1c." Draft Guidance for Industry Developing Products for Weight Management, FDA, Center for Drug Evaluation and Research, February 2007.

[10]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 diseases as well as diabetes and hypertension. Services in connection with the 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 . . . .
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).

and to die prematurely."[11] CMS Administrator Mark McClellan said, "What matters is whether there's scientific evidence that an obesity-related medical treatment improves health."[12] Consistent with these statements from those in charge of Medicare, the program has recognized that obesity is a significant health risk by covering bariatric surgery for treatment of comorbidities associated with morbid obesity[13] and by identifying obesity as a complication and comorbidity for other illnesses under the proposed inpatient hospital payment rule for 2008.[14]

Furthermore, forty state Medicaid programs cover drugs used to treat obesity, and some of those programs do not cover drugs "used for weight loss," but make an exception for certain agents used to treat obesity and other disease states. In addition, both the Internal Revenue Service (IRS) and the Social Security Administration consider obesity to be a disease. The Social Security Administration has identified obesity as "a disease that requires treatment"[15] and considers obesity to be an impairment that may allow an individual to qualify for disability benefits.[16] The IRS also has determined that obesity "is medically accepted to be a disease in its own right."[17] Costs of treatment for obesity qualify for deductions under the Internal Revenue Code,[18] while costs of weight loss treatment for "general health" and not "to cure a specific ailment or disease" are not deductible.[19]

### B. Treatment of Obesity Is a "Medically Accepted Indication" If the FDA Has Approved the Drug for that Purpose or that Use Is Identified as Accepted in One of the Compendia

Because obesity is widely recognized as an illness distinct from weight gain, a drug that is used for the "medically accepted indication" of treatment of obesity or weight management[20] would not be precluded from coverage under Part D. The Act defines "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act" or a use of a covered outpatient drug that "is supported by one or more citations included or approved for inclusion" in any of certain specified compendia.[21] Therefore, if use of a drug to treat obesity is included in the FDA-approved label or is supported by a citation in the compendia, it is not excluded under Part D. This is because the drug would be used for a medically accepted indication – treatment of obesity – which is distinct from mere weight loss. That is, while the drug might produce weight loss, it would treat obesity.

### C. In Light of CMS's Treatment of Other Drugs that Have a Use Excluded by the Statute or Are Categorically Excluded by the Statute, Obesity Drugs May Not Be Excluded from Part D

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[11]News Release: HHS Announces Revised Medicare Obesity Coverage Policy, July 15, 2004.
[12]Id.
[13]Medicare National Coverage Determinations Manual, § 100.1.
[14]72 Fed. Reg. 24,680, 24,698 (May 3, 2007).
[15]67 Fed. Reg. 57,859, 57,863-64 (September 12, 2002).
[16]67 Fed. Reg. at 57,860-61.
[17]Rev. Rul. 2002-19, 2002-1 C.B. 778 (2002).
[18]26 U.S.C. § 213(d)(1)(A).
[19]Rev. Rul. 2002-19, 2002-1 C.B. 778 (2002).
[20]See supra note 8.
[21]SSA § 1927(k)(6).

CMS has repeatedly interpreted the statute to permit coverage of classes and uses of drugs arguably excluded under section 1927(d)(2). To the extent that CMS had discretion to cover such drugs or their uses, CMS must possess the discretion to cover drugs used to treat obesity. Put simply, the legal bases for the agency's decisions to cover some of these drugs or their uses are somewhat unclear or tenuous, whereas a decision to cover obesity products is quite legally supportable. In view of this, CMS's exclusion of drugs used to treat obesity from Part D coverage would be arbitrary and capricious.[22]

In order to be consistent with CMS's treatment of other products that either fall into a category or have a use excluded under section 1927(d)(2), CMS must cover obesity drugs. For example, CMS provides coverage of drugs used for AIDS wasting and cachexia,[23] although those drugs are used to treat a disease marked by progressive weight loss and the drugs may cause weight gain. In its comments on why these products are covered, CMS notes that they are "not considered agents used for weight gain or agents used for cosmetic purposes."[24] Similarly, a drug used for the medically accepted indication of treatment of obesity would not be used for cosmetic purposes, should not be considered an agent used for weight loss, and should be covered by Part D.

Second, Medicare covers drugs used to treat acne, psoriasis, rosacea, or vitiligo because the agency has concluded that those treatments are not considered to be cosmetic.[25] Like these conditions, obesity is recognized as a medical condition that has effects that are not merely cosmetic. CMS possesses the discretion to conclude that, just like the treatments for these conditions, drugs used for treatment of obesity should be covered by Medicare Part D.

Third, CMS permits Part D coverage of cough and cold medications when used in "clinically relevant situations other than those of symptomatic relief of cough and colds,"[26] even when the medication is used in these situations to prevent a cough. CMS similarly could conclude that a drug that treats obesity is covered because it is being used in a "clinically relevant situation" other than weight loss.

Fourth, CMS has determined that vitamin D analogs and prescription niacin products are not affected by the statutory exclusion of prescription vitamins. CMS has determined that prescription niacin products, although composed of vitamin $B_3$, are different from the vitamins used for nutritional supplementation that are excluded under the statute because they are used at higher doses and for different purposes than the other vitamin products.[27] In the case of vitamin D analogs, "CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin $D_2$) and/or cholecalciferol (vitamin $D_3$),"[28] but does not provide any explanation for this interpretation. CMS should apply the same logic it used to conclude that the plain language of the statutory exclusion of coverage for prescription vitamins allows coverage of vitamin D analogs and prescription niacin to permit coverage of

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[22]5 U.S.C. § 706.

[23]Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.

[24]Id.

[25]Id.

[26]Id.

[27]Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.

[28]Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.

treatments for obesity, which also are used for different purposes from simple, cosmetic weight loss.

The above examples amply demonstrate that CMS can interpret – and has interpreted – the statutory exclusions of certain uses of drugs and categories of drugs to permit coverage of medically accepted uses of drugs when other uses of those drugs might be excluded. CMS should apply the same standards and cover drugs used for treatment of obesity and not conclude that these drugs are excluded by the statute's prohibition on coverage for agents used for weight loss or weight gain. To do anything else would be arbitrary and capricious.

## II. Congress Intended the Medicare Statute to Cover Drugs for Serious Medical Conditions, Such as Obesity

When Congress passed the MMA, it understood that providing seniors with appropriate outpatient drugs could prevent progression of chronic diseases and save seniors from costly hospitalization and long-term care. Obesity is just such a disease. Not only is it a serious illness on its own, but it also often is associated with other comorbid conditions, such as Type 2 diabetes, dyslipidemia, hyperinsulinemia, hypertension, cardiovascular disease, and impaired glucose tolerance. Failure to address these conditions can lead to heart attack, stroke, organ failure, and death. Congress also intended for Part D to help the Medicare program address the changing health care needs of America's seniors. As more and more beneficiaries struggle with obesity and these related conditions, there is all the greater need for Medicare to cover the drugs that treat this serious disease. Denying coverage for drugs that treat obesity would be inconsistent with Congress's intent, as well as with the clear language of the statute and the widespread understanding of obesity among the medical community and state and federal government agencies.

## III. CMS Has Not Provided Adequate Notice and Opportunity for Comment on the Proposed Change in Coverage Policy

As previously noted, in the Proposed Rule, CMS says that it "erroneously" stated in the January 2005 final rule that drugs for morbid obesity may be covered under Part D. This simply is not the case. CMS was legally correct in concluding that these drugs can be covered when used for a "medically accepted indication," as described above. Furthermore, the January 2005 final rule was issued in response to specific comments, including those submitted by Sanofi-Aventis, 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's 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 established 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.

Finally, 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."[29] In fact, CMS's current binding policy statements are found in the Part D final rule issued in January of 2005, and thus CMS is

[29] 72 Fed. Reg. 29,405.

proposing a significant policy change in this Proposed Rule. Although CMS has issued subregulatory guidance that 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 is instead a significant proposed policy change to which comments must be reviewed and considered before any change in policy may be adopted through a new final rule.

**Submitter :** Ms. Jane Galvin **Date:** 07/24/2007

**Organization :** BlueCross and BlueShield Association

**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-21-Attach-1.DOC

#21

**BlueCross BlueShield Association**

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

July 24, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
The Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Attention: CMS-4130-P

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

Dear Mr. Kuhn:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the proposed rule (the Proposed Rule) that would make certain policy changes and technical corrections to the Medicare Prescription Drug Program (the Program). BCBSA represents the 39 independent Blue Cross and Blue Shield Plans (Plans) that collectively provide Medicare prescription drug coverage to more than two million Medicare beneficiaries through stand-alone Medicare prescription drug plans (PDPs) as well as Medicare Advantage prescription drug plans (MA-PDs) (collectively, Part D Plans).

Our comments on the Proposed Rule are intended to help CMS make critical operational decisions necessary to make implementation of these policies and procedures a success for beneficiaries as well as Plans sponsoring Part D Plans. Accordingly we have focused on the practical result of the proposed modifications and the need for greater clarity in many areas. Many of the proposed changes create significant implementation issues as well as potential confusion and increased liability exposure for Plans.

In particular, BCBSA is concerned with CMS's revised definitions of administrative costs, gross covered prescription drug costs, and negotiated prices. BCBSA supports transparency in pricing and believes it would be appropriate to require disclosure of profits retained by an intermediary with which a sponsor of a Part D Plan (Part D sponsor) directly contracts. However, BCBSA is concerned that recharacterizing the entire amount of such profits as administrative costs artificially reduces Part D sponsors' drug costs reported to CMS, and may have unintended consequences in reducing incentives for cost control.

BCBSA is also concerned that the new proposed definitions may be confusing and difficult for Plans to implement. Specifically, BCBSA is concerned that the proposed definitions would require Plans to obtain and report data that may reside solely within the possession of third

parties, such as PBMs. Plans may not even be aware of this data. This is a significant potential liability concern for Plans, since under the Proposed Rule, such data would impact final payments to Plans. BCBSA looks forward to working with CMS to assure that Plans are able to understand and comply with CMS's interpretations and expectations for the Program.

The vaccine administration fee policy also creates new logistical and administrative burdens associated with processing claims for services provided by out-of-network providers. BCBSA encourages CMS to consider such operational implications prior to implementing these types of policies and also to monitor the effects post- implementation in order to minimize such burdens for Plans, providers, and pharmacies to the extent possible.

BCBSA also suggests that CMS reconsider the new addition to the home infusion therapy access requirements. BCBSA believes that the proposed obligation to coordinate or ensure provision of professional services falls outside the scope of Plans' responsibility to provide access to Part D Drugs.

We appreciate the opportunity to offer these comments and would be pleased to meet with you to discuss any of these concerns. If you have any questions about these comments, I can be reached at 202.626.8651.

We look forward to continuing to work with CMS as together Plans and your staff continue efforts to improve the Medicare Prescription Drug Program for beneficiaries.

Sincerely,

Jane Galvin
Director, Regulatory Affairs
Blue Cross and Blue Shield Association

Attachment

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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202.626.4780
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**Blue Cross and Blue Shield Association**
**Comments**
**"Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit" (Part D Technical Rule)**
**(72 Fed. Reg. 29403, May 25, 2007)**

## I. Definition of Part D Covered Drugs (Subpart C – Benefits and Beneficiary Protections, § 423.100)

### A. Erectile Dysfunction Prescription Drugs

**CMS Proposed Rule:** CMS addresses the coverage status of drugs prescribed for erectile dysfunction (ED), stating that such drugs are excluded from the definition of a Part D Drug based on the coverage exclusion under § 1927(d)(2) of the Social Security Act. Further, CMS clarifies that ED drugs do not meet the definition of a Part D Drug when prescribed for off-label use not approved by the U.S. Food and Drug Administration (FDA). Two exceptions exist for this coverage prohibition: (1) an ED drug may be covered by a Part D Plan when prescribed for a condition other than ED and such use has been approved by the FDA; and (2) the drug, when prescribed for ED, may be covered by a Part D Plan offering enhanced alternative coverage.

**Issue:** Several Blue Cross and Blue Shield Plans (Plans) have indicated that non-coverage determinations for ED drugs have been overturned by independent review entities (IREs), despite the coverage limitations articulated by CMS in the Proposed Rule.

**BCBSA Recommendation:** BCBSA recommends that CMS clarify, for both sponsors of Part D Plans (Part D Sponsors) as well as IREs and other entities that review coverage determinations and appeals, those circumstances in which an ED medication may be covered by a Part D Plan, including identifying the (non-ED) medical conditions for which ED drugs have been approved by the FDA as a *medication therapy*.

### B. Insulin Inhalation Drugs and Supplies

**CMS Proposed Rule:** CMS proposes to include within the definition of a Part D Drug inhaled insulin as well as the hand-held chamber and other supplies necessary to administer the medication. However, Part D sponsors retain the

authority to determine whether to include the inhaled version of insulin and the related supplies on their individual formularies.

**BCBSA Recommendation:** BCBSA supports CMS's decision to include inhaled insulin and related supplies necessary for administration in the definition of a Part D Drug as this policy should eliminate potential issues regarding whether the related supplies are covered under Medicare Part B versus Medicare Part D. BCBSA supports CMS's approach that permits Part D sponsors to determine whether to include inhaled insulin and related supplies on their formulary, rather than CMS mandating coverage conditions. CMS's deference to Part D sponsors is consistent with one of the underlying principles of the Program that lets Part D sponsors administer their Part D Plans in the most effective manner.

### C. Vaccine Administration Fee

**CMS Proposed Rule:** CMS proposes to amend the definition of a Part D Drug to include administration of vaccines covered under the Program, consistent with the recent amendment to the Section 1860D-2(e)(1)(B) of the Social Security Act and CMS's recent guidance regarding payment for such costs.

**Issue:** BCBSA supports CMS's proposal to amend the definition of a Part D Drug to include vaccine administration costs. However, this new policy gives rise to several operational issues and challenges, including the potential for double-billing of administration fees and increased administrative burden arising from processing and coordinating claims for related services from multiple providers. Additionally, because vaccine administration costs frequently are incurred by non-network providers (particularly with respect to PDPs), Plans must receive, process and pay claims for covered services provided by non-network providers. The potential for a vaccine administration to be covered by Medicare Part B or Medicare Part D further complicates these logistical difficulties.

**BCBSA Recommendation:** BCBSA recommends that CMS monitor billing and payment for vaccine administration fees over the next several months to identify and resolve issues that may arise with implementation of this new policy. We also suggest that CMS increase physician education with regard to this coverage policy. We also recommend consideration of MedPAC's recommendation to include more vaccines in Part B rather than Part D, which would be in the best interest of beneficiaries, providers, and Part D sponsors.

## II. Definition of Long-Term Care Facilities (Subpart C – Benefits and Beneficiary Protections, § 423.100)

**CMS Proposed Rule:** CMS proposes to clarify that the definition of long-term care (LTC) facilities includes institutions for mental disease (IMDs) as well as hospitals (including LTC hospitals) that receive payments under § 1902(q)(1)(B) of the Social Security Act. As a result, Part D sponsors will be obligated to ensure that Members residing in such facilities have convenient access to network LTC pharmacies to the extent that such Members require medications covered under Medicare Part D.

**Issue:** Although BCBSA supports providing Medicare beneficiaries residing in LTC facilities with convenient access to Part D Drugs through LTC pharmacies, there are significant practical implications to CMS's policy. For example, many Plans do not receive notice that their Members are patients at IMDs (or admitted to another LTC facility) until after prescriptions have been filled and claims submitted. The number of facilities that potentially could meet the definition of a LTC facility prohibits Plans from anticipating those facilities with which it should contract, and the utilization of IMD pharmacies within a Part D Plan's pharmacy network may be minimal. Additionally, most of these facilities rely on their in-house pharmacies to fill prescriptions and prohibit another LTC pharmacy from providing prescription drugs to their patients.

**BCBSA Recommendation:** BCBSA supports providing Medicare beneficiaries with convenient access to Part D Drugs via LTC pharmacies. However, BCBSA encourages CMS to consider the practical implications resulting from the automatic classification of IMDs and other facilities receiving payment under § 1902 of the Social Security Act as LTC facilities necessitating access to LTC pharmacies in accordance with the convenient access standards set forth in the regulations. BCBSA believes that Part D sponsors should continue to meet access standards with respect to such LTC pharmacies but should not be required to satisfy any heightened standard of access resulting from a few Members who are admitted to an IMD (or other LTC facility) unbeknownst to the Part D sponsor, unless those affected institutions proactively seek inclusion in a Part D sponsor's network under the "any willing pharmacy" provisions in order to assure the appropriate coverage for affected patients in advance of the need for services.

## III. Negotiated Prices (Subpart C – Benefits and Beneficiary Protections, § 423.100)

**CMS Proposed Rule:** CMS proposes to amend the definition of "negotiated prices," effective for the 2009 contract year, to be the prices that the network pharmacy ultimately receives for a Part D Drug. The negotiated price would be the total payment from the Part D Plan Sponsor net of any discounts or other remuneration and net of any dispensing fee. Beneficiary cost-sharing therefore would be based upon the price ultimately received by the pharmacy or dispensing provider, rather than the price ultimately paid by the Part D sponsor to an intermediary, if different.

**BCBSA Recommendation:** We have addressed issues related to the definition of negotiated prices under administrative costs below. If CMS proceeds with the revision, BCBSA supports CMS's proposal to make this new definition effective for the 2009 contract year. Many Plans will have to modify their operations, including their PBM contracts, to comply with the new definition.

BCBSA continues to support CMS's interpretation of the term "negotiated prices" as excluding those price concessions that, at the Part D sponsor's election, are not applied at the point of sale. BCBSA recommends that CMS further clarify that this interpretation would include any price concessions from any sources, including the dispensing provider. For example, if a network pharmacy's

payments are adjusted (up or down) based on its generic dispensing rate over a specific time period, any such adjustments would occur after the point-of-sale and would not be included in the determination of the negotiated price.

## IV. Adequate Access to Home Infusion Pharmacies (Subpart C – Benefits and Beneficiary Protections, § 423.120)

**CMS Proposed Rule:** CMS proposes to require that a Part D sponsor's pharmacy network include pharmacies that are capable of: (1) delivering home infused drugs in a form that can be administered in a clinically-appropriate fashion; (2) providing infusible Part D Drugs for both short-tem acute care and long-term chronic care therapies; (3) ensuring that professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing the home infused Part D Drugs; and (4) arranging the delivery of home infused drugs within 24 hours of a Member's discharge from an acute setting.

**Issue:** Although BCBSA supports Medicare beneficiaries having adequate access to home infusion drugs, "ensur[ing] that the professional services and ancillary supplies necessary for home infusion therapy are in place prior to dispensing Part D home infusion drugs" falls outside the scope of responsibilities of Part D sponsors and their contracted pharmacies.

Although certain professional services and ancillary supplies may be necessary for the clinically-appropriate administration of home infused drugs, ***such services and supplies are not covered Part D Drugs*** and do not otherwise fall within the scope of benefits that Part D sponsors are responsible for providing or coordinating. In fact, when CMS defined the scope of services to be covered under the Dispensing Fee (and thus within the purview of Part D sponsors' responsibility) in the Part D Final Rule, CMS specifically limited the scope of the covered services. CMS stated that the Dispensing Fee would include activities relating to the transfer of possession of the covered Part D Drug but not "amounts for the supplies and equipment necessary for the drugs to be provided in a [s]tate in which they can be effectively administered," nor "activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist...We believe that [the more narrow definition of dispensing fee] represents the best reading of the statute...[and] also note that where Congress wished for Plans to include the cost of supplies under Part D, it specifically directed us to do so."[1,2]

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[1] Centers for Medicare and Medicaid Services, "Medicare Program; Medicare Prescription Drug Benefit; Final Rule," 70 Fed. Reg. 4193, 4234 (Jan. 28, 2005). CMS also identifies other potential issues associated with requiring Part D sponsors to ensure the provision of professional services associated with the administration of Part D Drugs in the Final Rule, including potential for double-billing, in this same discussion.

[2] CMS's narrow interpretation of the dispensing fee and items and services covered by the definition of Part D Drugs is supported by Congress' subsequent enactment of legislation to provide coverage under the Program for vaccine administration, a cost previously not covered by the Program or imposed on Part D Plans.

**BCBSA Recommendation:** Plans will work with the appropriate home health agencies and other providers to meet CMS's proposed requirements that home infusion medications be available within 24 hours of a beneficiary's discharge from an acute setting if that timeline matches the physician's order for care.

However, CMS should not require that Part D sponsors (nor their contracted pharmacies) also be required to "ensure" that professional services and ancillary supplies necessary for such service be in place prior to dispensing Part D Drugs. That is the role of the home health agency or other provider who has responsibility for arranging for the actual administration of the covered items through discharge planning efforts. This is a clinical responsibility that should be undertaken and monitored by those health care providers that are responsible for providing such services, including hospitals, outpatient facilities, physician offices, home health agencies, etc. that have responsibility for implementation of continued care following the patient's discharge from an acute care setting.

## V. Administrative Costs (Subpart G – Payments to Part D sponsors, § 423.308)

**CMS Proposed Rule:** CMS proposes to adopt a new defined term for Subpart G, Payments to Part D sponsors for Qualified Prescription Drug Coverage, of the Program. "Administrative costs" would be defined as

> costs incurred by a Part D sponsor in complying with the requirements of [Medicare Part D] ... and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs. Administrative costs include sponsor costs that exceed the amount paid by or on behalf of the Part D sponsor to a pharmacy or other entity that is the final dispenser of the drug for the provision of a covered Part D drug under the plan. When an intermediary acts on behalf of the Part D sponsor to negotiate prices with dispensing entities such as pharmacies, any profit retained by the intermediary contracting organization as a result of such negotiation (through discounts, manufacturer rebates, or other direct or indirect price concessions) is considered an administrative cost to the Part D sponsor and not a drug cost.

**Issue:** BCBSA agrees that greater clarity is needed on the critical distinction between administrative costs and allowable drug costs. This classification has a direct impact on CMS's payments to Plans. As a result, these terms should be defined precisely and in a manner that allows Plans to report data accurately with a clear understanding of CMS's expectations.

### 1. *Treatment of PBM profits as administrative costs.*

BCBSA supports transparency in pricing, and believes it would be appropriate for CMS to require pharmacy benefit managers (PBMs) to disclose retained rebates to Part D sponsors, and for Part D sponsors to report that information to CMS for information purposes. However, BCBSA is concerned with CMS's proposal to recharacterize any such amounts as "administrative costs." BCBSA suggests that CMS consider requiring reporting in order to enhance transparency, much as

CMS has done with respect to rebates retained by long-term care pharmacies, *without* altering the calculation of drug costs/administrative costs.

CMS's proposal would turn Part D sponsors' actual payments to PBMs for drug into administrative costs and would remove them from calculations of gross covered prescription drug costs. The factual basis for CMS's assumption that PBM-retained profits are in their entirety substitutes for administrative costs is unclear.

BCBSA is also concerned that CMS's proposal may have unintended and negative consequences, by reducing or eliminating use of a "lock-in" method of pricing. Part D sponsors may select the lock-in method of pricing believing that it provides an incentive for PBMs to negotiate lower prices with pharmacies. When combined with the need to compete with other PBMs, this may serve to provide a balance of incentives that reduce Part D sponsors' and CMS's costs. Some Part D sponsors may wish to continue utilizing lock-in pricing for these or other reasons, and should be able to do so. As noted previously, BCBSA supports requiring transparency in the actual amount a PBM pays to pharmacies without recharacterizing the differential in payments as administrative costs.

BCBSA has similar concerns about PBM-retained rebates from pharmaceutical manufacturers. Any such amounts that are not passed along to Part D Sponsors should not be used to reduce Part D sponsors' drug costs. Again, BCBSA supports requiring PBMs to fully disclose these amounts.

In addition to this fundamental issue, the proposed definition of administrative costs raises a number of more technical issues.

2. *Lack of a Definition of "Drug Costs."*

The first sentence of the definition of "administrative costs" defines the term as those costs that are not "drug costs" incurred to purchase or reimburse the purchaser of Part D Drugs. However, the term "drug costs" is not a defined term under the Program, although "gross covered prescription drug costs" and "actually paid" are defined terms. CMS should clarify what the term "drug costs" is intended to refer to in the definition.

3. *Dispensing Fees*

CMS should clarify in the definition that dispensing fees are not administrative costs, consistent with CMS's approach elsewhere in the regulations.

4. *Narrative Describing Administrative Costs in Excess of the Negotiated Price.*

The proposed definition's narrative describes certain instances in which CMS believes that drug costs that a Part D sponsor pays to an intermediary organization should be characterized as administrative costs. BCBSA believes that if CMS proceeds with this aspect of its proposal, it is critical that Part D sponsors be able to anticipate how this definition will apply, so they can negotiate

for access to data necessary to comply with the requirements and accurately estimate costs for the 2009 bid submission.

BCBSA has several concerns as well as suggestions. The second sentence, for example, would require Part D sponsors to report negotiated prices as the amount ultimately paid to the dispensing provider, as CMS proposes elsewhere in the Proposed Rule. BCBSA supports transparency in pricing. However, BCBSA is concerned that Part D sponsors are entirely dependent on third parties to fully and accurately report and disclose this information. CMS should make clear its understanding that Part D sponsors will need to contract with third parties to obtain this information. Moreover, if Part D sponsors exercise reasonable monitoring and oversight and are unaware that data is inaccurate or incomplete despite these efforts, CMS should clarify that Part D sponsors will not automatically be liable for fraud or penalties. BCBSA believes that in such circumstances, Part D sponsors should be entitled to rely on the PBM-supplied data without fear of penalties.

In addition, BCBSA suggests that the second sentence of the definition be modified to clarify that "Administrative costs include sponsor costs paid to an intermediary that contracts with dispensing providers on the Part D sponsor's behalf that are characterized as drug costs, but that exceed the amount paid on behalf of the Part D sponsor to a pharmacy or other entity that is the final dispenser of the drug for the provision of a covered Part D drug under the plans."

The suggested phrase would promote enhanced compliance because it would clarify that Part D sponsors should look carefully at costs that may otherwise be characterized as drug costs. The additional language also makes clear that the amounts that are of concern and that may need to be reclassified as administrative costs are those the Part D sponsor pays to an intermediary entity that contracts for the Part D Drugs.

The third sentence in the "administrative costs" definition creates possible confusion as to the scope of the definitions because the sentence refers to profit retained by the intermediary contracting organization as a result of its role in negotiating prices with dispensing entities. CMS should clarify whether it intends to reach remuneration a PBM receives from pharmacies and whether it also reaches amounts a PBM receives from third parties, such as pharmaceutical manufacturers.

If CMS intends to include these amounts in the definition, a number of questions arise. For example, if a PBM sells aggregate data to pharmaceutical manufacturers, is some portion of those fees considered a "profit" to the PBM that must be deducted from Part D sponsors' drug costs and added to their administrative costs? What if the PBM obtains funding from pharmaceutical manufacturers for educational programs, medication management programs for formulary products, or other types of programs? Are these payments considered administrative costs? If so, what amount would be expected to be reported? The total payment to the PBM from the pharmaceutical manufacturer or only the amount of the 'profit' the PBM makes on these activities after accounting for its costs?

BCBSA is concerned that Part D sponsors may be required to obtain and report these types of information as a reduction in its allowable drug costs and an increase in administrative costs. Part D sponsors may not be aware of all of these relationships, even if they have tried to identify and report all of the relevant data.

5. *Direct and Indirect Remuneration.*

BCBSA is concerned that the concepts of direct and indirect remuneration (DIR) overlap with and are duplicative of the proposed new definition of administrative costs. CMS appears to be defining administrative costs in a manner that would require Part D sponsors to reclassify certain costs as administrative costs. However, in the CMS guidance on "Final Medicare Part D DIR Reporting Requirements for Payment Reconciliation," (Final DIR Guidance) CMS has described some of the same costs as DIR that must be applied against a Part D sponsor's allowed drug costs.

One important step would be to define direct and indirect remuneration. This definition should be developed in conjunction with CMS's proposed definition for administrative fees, so that there is a consistent and clear distinction between costs, expenses and remuneration that are treated as being related to the purchase or reimbursement of Part D Drugs, and those costs, expenses and remuneration that are treated as administrative in nature. The definition of DIR also should be limited so that it does not include amounts that have already been reclassified or reported as administrative costs.

Although BCBSA appreciates that CMS may be unable to adopt a "bright line" test for determining those price concessions or discounts that should be treated as DIR and those that should not be treated as DIR, CMS's effort to clearly distinguish between costs that are administrative versus those that are drug-related necessitates that a similar approach be taken with respect to price concessions and other discounts. A lack of consistency could result in costs related to a particular service being treated as administrative while the discounts are treated as DIR. This could result in the discounts being applied against allowable drug costs when, in fact, they should be applied against the administrative costs to which they are related. For example, performance bonuses paid to a PBM that achieves certain goals with respect to generic utilization rates or other utilization management techniques would be treated as administrative costs under the Proposed Rule's definition for "administrative costs." If a bonus payment is not paid, or if the PBM were to pay a penalty fee for failure to achieve another similar benchmark, such dollars similarly should be treated as administrative dollars, not DIR, and should not be applied against allowable drug costs. CMS should develop an approach to DIR that is closely related to the definition of administrative costs set forth in the Proposed Rule.

Although CMS is proposing to adopt the new definition of administrative costs for 2009, CMS stated in its Final DIR Guidance and other sub-regulatory guidance that rebates and remuneration a PBM receives from pharmaceutical manufacturers and does not pass on to Part D sponsors must be reported as DIR because it is, in essence, an administrative cost. However, the sub-regulatory

guidance applies this requirement beginning in 2007. BCBSA believes that this interpretation should be applied beginning in 2009, consistent with the effective date for the revised definition of administrative costs.

**BCBSA Recommendations:**

1. CMS should consider requiring reporting of PBM profits attributable to their role as intermediaries with dispensing pharmacies, without characterizing all such amounts as Part D sponsor administrative costs.

2. CMS should define the term "drug costs," used in the first sentence of the definition.

3. CMS should clarify in the first sentence of the definition that dispensing fees are excluded from administrative costs.

4. If CMS proceeds with the second and third sentences of the definition, CMS should clarify that Part D sponsors will not automatically be liable for fraud or penalties if they exercise reasonable monitoring and oversight and are unaware that data is inaccurate or incomplete despite these efforts. Part D sponsors should be entitled to rely on the PBM supplied data without fear of penalties.

In addition, BCBSA suggests that the second sentence of the definition be modified to clarify that "Administrative costs include sponsor costs paid to an intermediary that contracts with dispensing providers on the Part D sponsor's behalf that are characterized as drug costs, but that exceed the amount paid on behalf of the Part D sponsor to a pharmacy or other entity that is the final dispenser of the drug for the provision of a covered Part D drug under the plans."

CMS should clarify whether it intends to reach remuneration the PBM receives from pharmacies and whether it also reaches amounts a PBM received from third parties such as pharmaceutical manufacturers. If so, CMS should clarify the issues discussed above.

5. CMS should provide a consistent definition of direct and indirect remuneration that addresses the issues described above. In addition, CMS should delay implementation of the new policy for reporting of rebates retained by PBMs until 2009, consistent with these regulations.

## VI. Gross Covered Prescription Drug Costs (Subpart G – Payment to Part D Plan Sponsors, § 423.308)

**CMS Proposed Rule:** CMS proposes to revise the definition of "gross covered prescription drug costs" consistent with its proposal that all negotiated prices and allowable drug costs reflect the payment made to the final dispenser of the Part D Drug.

**Issue:** BCBSA is concerned about this proposal as described in Section V above. If CMS implements the proposal, BCBSA is concerned about Plans' ability obtain and submit accurate information regarding drug costs as CMS

proposes to define them. CMS's proposed definition requires Part D sponsors to depend heavily on information held exclusively by PBMs.

**BCBSA Recommendation:** If CMS proceeds with its proposal, CMS should clarify that Part D sponsors are expected to take reasonable efforts to obtain and submit accurate data regarding transactions between PBMs and third parties. However, CMS also should confirm that Part D sponsors that take such reasonable efforts would not ordinarily be subject to penalties or enforcement proceedings if data supplied by a PBM is inaccurate through no fault of the Part D sponsor. In such instances, enforcement efforts would more appropriately be directed to the entity that originated the incorrect data.

BCBSA agrees with CMS's proposal to clarify that "gross covered prescription drug costs" includes the amount of any beneficiary cost-sharing amounts where the beneficiary purchases drugs outside the Program as well as nominal co-payments assessed by patient assistance programs, if the Member provides the relevant information to the Part D sponsor, as instructed.

Finally, BCBSA agrees that amounts a Part D sponsor pays other than to a dispensing entity should be included in gross covered prescription drug costs, including payments to physician, payments under plan-to-plan reconciliation and pursuant to COB error.

## VII. Coordination of Benefits with Part D Plans and Other Payers (Subpart J – Coordination of Part D Plans With Other Prescription Drug Coverage § 423.464)

**CMS Proposed Rule:** CMS proposes to codify several existing procedures relating to the coordination of benefits (COB), including (i) clarifying that Part D sponsors must coordinate prescription drug coverage with other Part D sponsors; (ii) clarifying that Part D sponsors must coordinate benefits with other Part D sponsors through CMS's reconciliation processes in existence and that may be developed; and (iii) requiring Part D sponsors to coordinate benefits with CMS-developed reconciliation processes (when established) when "another entity providing prescription drug coverage when that entity has incorrectly paid as a primary payor for the covered Part D drug."[3]

**Issue:** BCBSA supports CMS's on-going efforts to develop and refine the COB and reconciliation processes, and agrees with CMS's proposed clarification to § 423.464(f) to require Plans to coordinate benefits with other Part D sponsors and to do so through the processes developed by CMS. However, CMS's third proposal, to require Plans to coordinate benefits with non-Part D sponsors, including commercial payers, using CMS-developed reconciliation processes raise several practical issues, including issues relating to the accurate reporting of TrOOP and PDE data and the reconciliation of allowable drug costs.

**BCBSA Recommendation:** BCBSA recommends that CMS consider modifying reconciliation processes with non-Part D sponsors to include claim level

[3] 72 Fed. Reg. at 29412.

reconciliation. The exchange of TrOOP information and PDE resolution handled by the Drug Data Processing System for Program Plan-to-Plan reconciliation is not available for COB with commercial payors. However, Part D sponsors need claim-level information to streamline reconciliation, more accurately identify Member TrOOP expenditures and appropriate PDE data, and enable the accurate determination of Part D sponsors' incurred costs for payment reconciliation purposes.

BCBSA appreciates CMS's sensitivities to Part D sponsors' exchange of large volumes of data, from which it might be possible to discern another Part D Plan's pricing structure. However, COB with commercial payors, which typically is sporadic and limited to a minimal volume of claims data, should not give rise to similar concerns. Moreover, as point-of-service coordination improves with continued developments in processes, procedures and computer systems, COB with commercial payors should only decrease in frequency and volume.

We urge CMS to consider requiring this claims-level information reconciliation for commercial payors to improve the efficiency, accuracy and speed with which Program claims data can be reconciled and beneficiary status and expenditures are monitored. We also request that CMS extend the time periods for claims submissions for payment reconciliations (three months after the last date on which Part D claims are required to accept such claims from other parties and six months from the last date on which Part D sponsors are required to accept claims for payment from other parties). These time periods will greatly assist Plans in their business operations.

**Submitter :** Mr. Rod Shafer **Date:** 07/24/2007

**Organization :** Washington State Pharmacy Association

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4130-P-22-Attach-1.DOC

#22

# wspa

**WASHINGTON STATE PHARMACY ASSOCIATION**

August 31, 2007

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

**Subject: 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 State Pharmacy Association (WSPA), the organization representing pharmacists in Washington, 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, WSPA 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. WSPA 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.



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**Negotiated Prices**

WSPA 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, WSPA 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.

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

WSPA 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. WSPA 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 WSPA has

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

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

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

**Conclusion**

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

The Washington State Pharmacy Association (WSPA) exists to support and advance the practice of pharmacy to ensure that the public receives optimal medication therapy management and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health.

If you have any questions or need any additional information, please do not hesitate to contact Rod Shafer, RPh, Chief Executive Officer WSPA, at (425) 228-7171 or via email at rshafer@wsparx.org.

Sincerely,

Rod Shafer

Rod Shafer, RPh.
CEO
Washington State Pharmacy Association

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

**Organization :** **Pfizer Inc**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**Adequate Access to Home Infusion Pharmacies**

Adequate Access to Home Infusion Pharmacies

See attached document.

**GENERAL**

GENERAL

See attached comment letter.

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

#23

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

July 24, 2007

**BY ELECTRONIC DELIVERY**

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

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

Dear Mr. Kuhn:

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

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

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

## I. Insulin Inhalation Drugs and Supplies

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

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

[2] *Id.* at 29,419

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

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

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

**II. Six Classes of Clinical Concern**

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

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

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

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

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

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

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[6] *Id.*

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

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

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

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

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

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

## III. Conclusion

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

Sincerely,

Lisa Goldman

Lisa Goldman

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

**Organization :** National Alliance of State Pharmacy Associations

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

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

#24


NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS
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PHONE: (804) 285-4431 FAX: (804) 285-4227 EMAIL: BECKY@NASPA.US
WWW.NASPA.US

August 31, 2007

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

**Subject: 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 National Alliance of State Pharmacy Associations (NASPA), the national organization representing all fifty state pharmacy associations, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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, NASPA 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. NASPA 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**

NASPA 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.

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

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

**Adequate Access to Home Infusion Pharmacies**

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

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

**Conclusion**

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

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

If you have any questions or need any additional information, please do not hesitate to contact Rebecca P. Snead, R.Ph., Executive Vice President and Chief Executive Officer NASPA, at (804) 285-4431 or via email at becky@naspa.us.

Sincerely,

Rebecca P. Snead, R.Ph
Executive Vice President and Chief Executive Officer
National Alliance of State Pharmacy Associations

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

**Organization :** **Minnesota Pharmacists Association**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment.

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

#25


August 31, 2007

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

**Subject: 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 Minnesota Pharmacists Association (MPhA), 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 (5) categories.

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**MINNESOTA PHARMACISTS ASSOCIATION**
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*www.mpha.org*

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MPhA 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, MPhA 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.

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

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

Reg. 29419 (2007) (to be codified at 42 C.F.R. § 423.120(4)(iii)) (proposed May 25, 2007) reasonable federal guidance. MPhA appreciates the willingness of CMS to again assert that adequate access to home infusions pharmacies is an expectation of the Part D plans.

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

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

**Conclusion**

In summary, MPhA 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, MPhA 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 Julie K. Johnson, Pharm.D., Executive Vice President and Chief Executive Officer MPhA, at (651) 789-3204 or via email at Julie@mpha.org.

Sincerely,

Julie K. Johnson, Pharm.D.
Executive Vice President and Chief Executive Officer
Minnesota Pharmacists Association