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

Organization : National Senior Citizens Law Center

Category : Attorney/Law Firm

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See Attachment

Administrative Costs

Administrative Costs

See Attachment

Application Timing

Application Timing

See Attachment

Data Match

Data Match

See Attachment

GENERAL

GENERAL

See attached re late enrollment penalty.

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

See Attachment

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

#31

Justice
Independence
Dignity
Security

National Senior Citizens Law Center

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July 24, 2007

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

Re: File Code CMS-4130-P

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

BENEFICIARIES AND BENEFICIARY PROTECTION

Drugs for Morbid Obesity (Sec. 423.100)

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

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

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

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

Insulin Inhalation Drugs and Supplies (Sec. 423.100)

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

Long Term Care Facilities (Sec. 423.100)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

GROSS COVERED PRESCRIPTION DRUG COSTS (Sec. 423.308)

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

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

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

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

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

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

Sincerely,

Georgia Burke
Staff Attorney
National Senior Citizens Law Center

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

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

Organization : **NC Association of Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

#32

North Carolina Association of Pharmacists
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www.ncpharmacists.org

August 1, 2007

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

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

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

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

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

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

Negotiated Prices

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

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

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

Adequate Access to Home Infusion Pharmacies

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

Administrative Costs

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

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

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

Conclusion

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

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

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

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

Sincerely,

Fred Eckel, RPh
Executive Director

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

Organization : **Astellas Pharma US**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

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

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

July 24, 2007

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

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

Dear Ms. Norwalk:

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

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

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

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

* * *

A. Benefits and Beneficiary Protections; Definitions; LTC Facilities

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

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

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2 42 C.F.R. § 423.100.

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

4 Id. at 29407.

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

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

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

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

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5 42 C.F.R. § 423.120.

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

7 72 Fed. Reg. at 29408.

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

Sincerely,

s/ Michael Ruggiero

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

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

Organization : Nebraska Pharmacists Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-34-Attach-1.DOC

This vision takes its point of origin in people with diabetes themselves – people who need help to live their lives free of diabetes-related complications. As we are committed to working actively to promote collaboration between all parties in the healthcare system in order to achieve our common goals, below we address two issues of great importance to persons with diabetes, and those at risk of developing diabetes.

First we discuss the legal authority that allows CMS to include drugs for the treatment of obesity in the Part D benefit, as well as the compelling public health reasons for doing so. Should CMS not adopt this approach despite legal authority and public health reasons, we then encourage CMS to clarify that drugs prescribed for the treatment of other conditions covered by Part D will not be excluded due to any weight-loss effect.

Second we encourage CMS not to limit the revised definition of Part D drug to supplies associated only with delivering insulin into the body through inhalation. Novo Nordisk recommends that CMS broaden the proposal such that it will include other mechanisms for delivering insulin directly into the body. Should CMS not adopt this approach, we urge CMS to make room for other forms of inhaled insulin delivery systems under the Part D drug benefit.

I. Definition of Part D Drug: Morbid Obesity

a. *CMS has the Legal Authority Not to Exclude Drugs for the Treatment of Obesity from the Part D Benefit*

Novo Nordisk urges CMS not to adopt its proposed interpretation of coverage for obesity drugs, under which agents used for treatment of obesity would be excluded from the definition of Part D drugs.[1] Instead, Novo Nordisk strongly encourages CMS to retain its policy, as set forth in its January 2005 final rule,[2] permitting Part D coverage of drugs used for the treatment of obesity. This January 2005 interpretation is consistent with the statute and with CMS' own interpretation of coverage of drugs used for other conditions, as well as with the commonly accepted view within the medical community and among government agencies that obesity is a serious disease and is distinct from weight loss.

[1] 72 Fed. Reg. 29,403, 29,405 (May 25, 2007).
[2] 70 Fed. Reg. 4193 (January 28, 2005).

Obesity is associated with many comorbid conditions, such as type 2 diabetes, hypertension, cardiovascular disease, and other life-threatening conditions that affect Medicare beneficiaries. Congress enacted the Part D prescription drug benefit in an effort to more fully address the health needs of America's seniors by making available coverage for medically appropriate outpatient drugs, including those that could prevent progression of chronic diseases and reduce costly hospitalization and long-term care. As more and more Medicare beneficiaries struggle with obesity and related conditions, it is critical that Medicare cover the drugs necessary to treat this serious disease and its comorbidities.

CMS proposes to preclude Part D coverage of obesity drugs generally, even where a drug is not used for cosmetic purposes.[3] Novo Nordisk disagrees with this proposed interpretation. Under the statute, Medicare Part D coverage is available for 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.[4] Only a limited list of drugs and uses of drugs are excluded from coverage under the law. This list includes "agents when used for anorexia, weight loss, or weight gain"[5] but does not exclude coverage of drugs indicated for obesity or weight management. As described below, there is an important distinction between obesity and weight management, on the one hand, and weight loss or weight gain, on the other.

CMS describes its proposed exclusion of obesity drugs as treating these drugs "[s]imilar to other excluded drugs contained in section 1927(d)(2) of the Act."[6] However, excluding obesity drugs from the definition of Part D drugs is inconsistent with CMS' treatment of other excluded drugs and categories described under §1927(d)(2). Under the statute, Part D drugs are defined as excluding the drugs or uses of drugs listed in §1927(d)(2) (except for smoking cessation agents). However, CMS has clarified that a number of drugs or uses of drugs that would seem to be excluded via §1927(d)(2), in fact may be covered as Part D drugs.

For example, CMS policy states that drugs used for AIDS wasting and cachexia are not excluded from Part D coverage, despite the fact that these

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[3] 72 Fed. Reg. 29,403, 29,405 (May 25, 2007).
[4] Social Security Act (SSA) § 1860D-2(e)(1), referring to § 1927(k)(6).
[5] SSA § 1860D-2(e)(2), referring to § 1927(d)(2).
[6] 72 Fed. Reg. 29,403, 29,405 (May 25, 2007).

drugs are used to achieve weight gain.[7] CMS explains that these drugs are eligible for coverage under Part D because they are "not considered agents used for weight gain or agents used for cosmetic purposes."[8] CMS also has stated that drugs used for treatment of acne, psoriasis, rosacea, or vitiligo are not used for cosmetic purposes and thus are not excluded from Part D coverage.[9] Similarly, CMS should interpret the same statutory language as permitting Part D coverage of a drug used for a medically accepted indication of obesity; a drug used for such an indication is not used for cosmetic purposes and should not be considered an agent used for weight loss.

CMS also has determined that vitamin D analogs and prescription niacin may be covered under Part D, despite the statutory exclusion of prescription vitamins. CMS explains that prescription niacin is different from vitamins used for nutritional supplementation – and thus excluded by statute – because prescription niacin is used at higher doses and for different purposes than vitamins used for nutritional supplementation.[10] CMS does not explain its rationale for covering vitamin D analogs.

CMS also permits Part D coverage of cough and cold medications to be covered when used in "clinically relevant situations other than those of symptomatic relief of cough and colds",[11] even when the medication is used in these situations to prevent a cough. CMS explains that these drugs, while excluded under the statute when used to relieve a cough and cold, are not excluded when used to prevent a cough in clinically relevant situations other than those of symptomatic relief of cough and cold.

As these examples demonstrate, CMS has concluded in a number of instances that certain uses of drugs are not excluded under Part D even where other uses of those same drugs or similar drugs may be excluded under the definition of Part D drugs. CMS should adhere to the same standards and recognize that drugs used to treat obesity are not excluded by the statutory exclusion of coverage for drugs used for weight loss or weight gain. CMS' interpretation of obesity drugs should be consistent with its treatment of drugs in these other categories.

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[7] Medicare Part D Manual, ch. 6, § 20.1 and Appendix B.
[8] Id.
[9] Id.
[10] Id.
[11] Id.

Obesity is widely recognized as a disease separate from weight loss or weight gain by numerous federal agencies and state governments. For example, FDA makes this distinction in how it regulates agents used to treat obesity as compared to those used for weight loss. Drugs used to treat obesity are regulated under the part of the Federal Food, Drug, and Cosmetic Act (FDCA) that applies to drugs used to treat a disease.[12] FDA explains that products making claims for obesity are covered under a separate section of the FDCA "because obesity is now considered a disease."[13] In contrast, 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 a different section of the FDCA.[14]

In recent draft guidance, FDA also distinguishes drugs used for weight management from drugs used for weight loss.[15] FDA explains that weight management incorporates weight loss and weight maintenance but also includes the "goal of reduced morbidity and mortality through quantifiable improvements in biomarkers such as blood pressure, lipids, and HbA1c".[16] A reduction in HbA1c is vital to the long-term health and reduction of complications for diabetic patients.

Obesity is treated as a disease in a number of ways within the Medicare program itself. For example, Medicare covers bariatric surgery for treatment of comorbidities associated with morbid obesity.[17] CMS also has identified obesity as a complication and comorbidity for other illnesses under the 2008 proposed inpatient hospital payment rule.[18]

Further, CMS implicitly acknowledged that obesity is a disease by revising its national coverage determination manual to remove the statement that "obesity itself cannot be considered an illness."[19] CMS replaced this language with a revised policy that 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

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[12] Federal Food, Drug, and Cosmetic Act § 201(g)(1)(B).
[13] 65 Fed. Reg. 999, 1027 (January 6, 2000).
[14] Id.
[15] Draft Guidance for Industry Developing Products for Weight Management, FDA, Center for Drug Evaluation and Research, February 2007.
[16] Id.
[17] Medicare National Coverage Determinations Manual, § 100.1.
[18] 72 Fed. Reg. 24680, 24698 (May 3, 2007).
[19] 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).

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."[20]

When CMS announced this revised policy, the then-Secretary of Health and Human Services Tommy Thompson said, "Obesity is a critical public health problem in our country that causes millions of Americans to suffer unnecessary health problems and to die prematurely."[21] Dr. Mark McClellan, then the CMS Administrator, said "what matters is whether there's scientific evidence that an obesity-related medical treatment improves health."[22]

Federal agencies outside of the Department of Health and Human Services also consider obesity to be a disease. For example, the Social Security Administration describes obesity as a disease requiring treatment[23] and considers obesity to be an impairment that may allow an individual to qualify for disability benefits.[24] The Internal Revenue Service (IRS) allows tax deductions for treatment of obesity.[25] Importantly, costs associated with weight loss treatment for "general health" and not "to cure a specific ailment or disease" are not eligible for deductions.[26] The IRS also has stated that obesity "is medically accepted to be a disease in its own right."[27] Furthermore, 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.

Novo Nordisk strongly urges CMS to maintain its January 2005 interpretation of coverage of obesity drugs, in which CMS stated that drugs may be covered under Part D for the treatment of morbid obesity.[28] Obesity is a major epidemic that warrants careful policymaking. In recent years, CMS has recognized obesity as a disease and issued a national coverage determination for bariatric surgery. These are steps in the right direction to addressing one of the most pervasive public health problems in this country. CMS should bring Part D coverage in line with the prevailing view of obesity as a serious and chronic disease. The statute clearly permits CMS to include

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[20] Id.
[21] News Release: HHS Announces Revised Medicare Coverage Policy, July 15, 2004.
[22] Id.
[23] 67 Fed. Reg. 57859, 57863-64 (September 12, 2002).
[24] Id. at 57860-61.
[25] 26 U.S.C. § 213(d)(1)(A).
[26] Rev. Rul. 2002-19, 2002-1 C.B. 778 (2002).
[27] Id.
[28] 70 Fed. Reg. 4193, 4230 (January 28, 2005).

coverage of drugs used to treat obesity within the definition of Part D drugs. We urge CMS to finalize an interpretation that permits coverage of obesity drugs.

b. *CMS not only has the Legal Authority - but also Compelling Public Health Reasons - Not to Exclude Drugs for the Treatment of Obesity from the Part D Benefit*

i. Prevalence of Obesity

Obesity is a growing global epidemic. In the United States alone, 140 million adults are considered overweight or obese,[29] a prevalence of 66.3%.[30] Among those 60 years or older, the prevalence increases to more than 70% with almost half of those considered obese.[31] The growth of this epidemic has been attributed to societal changes and worldwide nutrition transition, as well as economic growth, urbanization, and globalization of food markets.

ii. Health Impact of Obesity

While genetics plays a role in determining an individual's susceptibility to obesity, ultimately, obesity arises from an energy imbalance between dietary intake and energy expenditure over a prolonged period of time. The cause of this imbalance may be due to several factors, including individual behaviors, social, physiological and environmental factors, and genetics, the combination of which contributes to the complexity of this chronic disease.

Each year an estimated 300,000 deaths in the US are attributable to obesity.[32] In general, higher body weights are associated with increased mortality from all causes.[33] More specifically, overweight or obesity has been shown to increase the risk of morbidity from hypertension,[34] dyslipidemia,[35]

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[29] American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics - 2007 Update. Circulation 2007;115:69-171.

[30] Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999-2004. JAMA 2006;295:1549-55.

[31] Wang Y and Baydoun M. The Obesity Epidemic in the United States - Gender, Age, Socioeconomic, Racial/Ethnic and Geographic Characteristics: A Systemic Review and Meta-Regression Analysis. Epidemiologic Reviews; Vol. 29 2007; 8.

[32] Allison DB, Fontaine KR, Manson JE, Stevens J, VanItallie TB. Annual deaths attributable to obesity in the United States. JAMA 1999;282:1530-8.

[33] Calle EE, Thun JM, Petrelli JM, Rodriguez C, Heath CW. Body-mass index and mortality in a prospective cohort of U.S. adults. New England Journal of Medicine 1999;341:1097-105.

[34] Dyer AR, Elliott P, INTERSALT Co-operative Research Group. The INTERSALT study: relations of body mass index to blood pressure. J Hum Hypertens 1989;3:299-308.

type 2 diabetes,[36] coronary artery disease,[37] stroke,[38] gallbladder disease,[39] osteoarthritis,[40] sleep apnea and respiratory problems,[41] and cancers of the endometrium, breast, prostrate, and colon.[42] Furthermore, the prevalence of hypertension, high blood cholesterol, low HDL-C, and high total cholesterol to HDL-C ratio has been shown to increase with increasing body mass index (BMI).[43] Weight management is advantageous for patients with diabetes by reducing mortality risks and slowing progression of the disease, primarily by improving insulin resistance, beta cell function and the metabolic handling of glucose.[44]

In addition to the numerous medical risks associated with obesity, psychological and social effects arising from stigmatization and discrimination also contribute to the health burden associated with the disease. Such negative attitudes and stigmatization have been documented in settings of employment, education and healthcare and continue to impact the well-being of obese individuals.[45]

iii. Economic Impact of Obesity and Diabetes

The impact of obesity extends beyond the health effects on the individual. The annual cost of overweight and obesity in the U.S has been estimated to

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[35] Tchernof A, Lamarche B, Prud'Homme D, Nadeau A, Moorjani S, Labrie F, et al. The dense LDL phenotype. Association with plasma lipoprotein levels, visceral obesity, and hyperinsulinemia in men. Diabetes Care 1996; 19(6):629-37.

[36] Ford ES, Williamson DF, Liu S. Weight change and diabetes incidence: findings from a national cohort of U.S. adults. Am J Epidemiol 1997;146:214-22; and, Lipton RB, Liao Y, Cao G, Cooper RS, McGee D. Determinants of incident non-insulin dependent diabetes mellitus among blacks and whites in a national sample. The NHANES I Epidemiologic Follow-up Study. Am J Epidemiol 1993;138:826-39.

[37] Hubert HB, Feinleib M, McNamara PM, Castelli WP. Obesity as an independent risk factor for cardiovascular disease: a 26-year follow-up of participants in the Framingham Heart Study. Circulation 1983;67:968-77.

[38] Rexrode KM, Hennekens CH, Willett WC, Colditz GA, Stampfer MJ, Rich-Edwards JW, et al. A prospective study of body mass index, weight change, and risk of stroke in women. JAMA 1997; 277(19):1539-45.

[39] Stampfer MJ, Maclure KM, Colditz GA, Manson JE, Willett WC. Risk of symptomatic gallstones in women with severe obesity. Am J Clin Nutr 1992;55:652-8.

[40] Hochberg MC, Lethbridge-Cejku M, Scott WW Jr, Reichle R, Plato CC, Tobin JD. The association of body weight, body fatness and body fat distribution with osteoarthritis of the knee: data from the Baltimore Longitudinal Study of Aging. J Rheumatol 1995;22:488-93.

[41] Young T, Palta M, Dempsey J, Skatrud J, Weber S, Bards S. The occurrence of sleep-disordered breathing among middle-aged adults. New England Journal of Medicine 1993;328:1230-5.

[42] Chute CG, Willett WC, Colditz GA, Stampfer MJ, Baron JA, Rosner B, et al. A prospective study of body mass, height, and smoking on the risk of colorectal cancer in women. Cancer Causes Control 1991;2:117-24.

[43] Brown CD, Higgins M, Donato KA, Rohde FC, Garrison R, Obarzanek E, et al. Body mass index and the prevalence of hypertension and dyslipidemia. Obesity Research 2000;8:605-19.

[44] Aucott L, Poobalan A, Smith WCS, Avenell A, Jung R, Broom J, et al. Weight loss in obese diabetic and non-diabetic individuals and long-term diabetes outcomes - a systematic review. Diabetes, Obesity and Metabolism 2004;6:85-94.

[45] Puhl R, Brownell KD. Bias, discrimination, and obesity. Obesity Research 2001;9(12):788-805.

be $122.9 billion. Direct costs, including preventive, diagnostic, and treatment services, have been estimated at $64.1 billion, and indirect costs, including value of wages lost by people unable to work due to illness or disability, as well as the value of future earnings lost by premature death, at $58.8 billion. Not surprisingly, obese individuals incur on average a 25% greater cost to health care plans than non-obese individuals.[46]

The prevalence of pre-diabetes in the Medicare population is estimated to be 39%.[47] As obesity is a risk factor in the development of diabetes, obesity management could be an important factor in preventing the progression to diabetes in the pre-diabetic population. In 2005, the Medicare program spent more than $61 billion on treating diabetes and its complications.[48] CMS' own figures note that the 18% of Medicare beneficiaries with diabetes "account for 32 percent of Medicare spending."[49]

iv. Obesity Management

An epidemic number of individuals are obese and facing the medical and psychological consequences of this chronic disease. The reduction of excess weight and maintenance of a lower body weight are essential to controlling the risk factors associated with obesity. It is becoming clearer that obesity has many underlying causes, which may not be controlled by diet and exercise alone. While education and counseling on diet and physical activity remain the cornerstone for treatment, pharmacotherapy may often be necessary. The National Institutes of Health recommends pharmacotherapy as an adjunct to diet and physical activity for patients with BMI>30 kg/m^2 and without concomitant obesity-related risk factors or diseases or with BMI≥27 kg/m^2 who have concomitant obesity-related risk factors or diseases.[50] Health care providers are encouraged to play a greater role and more aggressively manage obesity in their patients, but to do so, more agents are needed that either address obesity directly or minimize weight

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[46] The Endocrine Society and The Hormone Society. The Endocrine Society Weighs In: A Handbook on Obesity in America. Available at: http://www.obesityinamerica.org/. Accessed July 16, 2007.

[47] Source: Cowie, C.C., et al. "Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population." Diabetes Care 29(2006): 1263-1268.

[48] Mathematica Policy Research, Inc. An Opportunity for Federal Leadership in Changing Diabetes: A Study of Federal Spending on Diabetes. June 2007. p. 14.

[49] U.S. Department of Health and Human Services. Centers for Medicare and Medicaid Services. (December 8, 2004). "Medicare Awards for Programs to Improve Care for Beneficiaries with Chronic Illnesses." CMS Office of Public Affairs. February 8, 2007. Available at: http://www3.cms.hhs.gov/apps/media/press/release.asp?Counter=1274.

[50] National Institutes of Health. The practical guide. Identification, evaluation and treatment of overweight and obesity in adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm. Accessed July 16, 2007.

gain. Such therapeutic agents should become integrated into the long-term treatment strategy for obesity, one that addresses nutritional, behavioral and metabolic aspects of the disease.

As the agency responsible for overseeing the healthcare of our nation's seniors, CMS should not prohibit access to effective treatments for obesity management.

c. If CMS Excludes Drugs for the Treatment of Obesity from the Part D Benefit, CMS Should Clarify that Drugs Prescribed for the Treatment of Other Covered Conditions are Included in the Part D Benefit Despite any Weight-Loss Effect

If CMS declines to maintain its January 2005 policy, we request that CMS clearly state that any interpretation the agency issues on obesity drugs will not affect coverage of drugs that may cause weight loss, but whose primary indication is not for obesity. One of the first companies to introduce insulin, Novo Nordisk has remained a world leader in diabetes care. We are committed to continuing to develop innovative treatments for individuals with diabetes. Type 2 diabetes is a growing condition among Medicare beneficiaries, and it is critical that beneficiaries continue to be able to access a broad range of diabetes therapies.

We are concerned that, should CMS preclude coverage of treatments for obesity under a theory that these drugs result in weight loss, CMS may inadvertently affect coverage of treatments for diabetes or other conditions. We urge CMS not to preclude coverage of obesity treatments under Medicare Part D; we do not believe that such a decision would be supported by the statute, nor is in the interest of public health. If, however, CMS finalizes its proposal that obesity treatments may not be covered under the standard Part D benefit, we urge CMS to clarify that drugs used for a medically accepted indication other than obesity remain covered under Part D, even where the drug may result in weight loss, or where weight loss is listed on the label as a possible side effect or as another medically accepted indication. Provided that the indication for which the drug is prescribed is diabetes or another condition for which Part D coverage is available, the drug should be covered under Part D without regard to any policy determinations on treatments for obesity. If CMS does not permit coverage of obesity treatments, we urge CMS to make clear that existing coverage of other drugs – including those that have an indication for weight loss or

obesity or simply have a weight loss effect – is maintained as long as the physician prescribes the drug for medically accepted indication other than weight loss or obesity.

II. Definition of Part D Drug: Insulin Inhalation Drugs and Supplies

a. CMS Should Not Limit the Revised Definition of Part D Drug to Supplies Associated with Delivering Insulin into the body through Inhalation but Broaden the Proposal to Include all Non-Durable Supplies that Deliver Insulin Directly into the Body

Novo Nordisk is extremely pleased that CMS has continued its efforts to ensure that people with diabetes are provided access to the life-saving medicines they need. Although diabetes is a chronic condition that can be controlled through the careful management of a patient's hyperglycemia, striking the optimal balance between insulin and glucose levels in a patient's blood is an inexact science.

Without a cure, medical emphasis must be on managing and avoiding costly short and long-term diabetes-related complications. Good diabetes care and management depend on a number of factors, foremost being the proper management and balance of insulin and glucose. People with diabetes often require special consideration and have special needs for access to a wide array of medications. A drug benefit that does not allow such access will be detrimental to America's diabetic seniors. Although careful glucose control can be achieved with combinations of diet, exercise and weight loss, various oral anti-diabetic drugs, and insulin use, non-compliance with therapeutic regimens continues to present one of the greatest challenges in battling this disease.

CMS' codification of the inclusion of the supplies associated with the delivery of inhaled insulin under the Part D benefit is very encouraging, in keeping with Congressional intent, and - we believe - good public policy.

The proposed revision would add the following paragraph (1)(vi) to the definition of Part D drug at §423.100:

> "[s]upplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin."

While we recognize CMS' responsibility to protect the Medicare program from inappropriate and wasteful expansion to medically unnecessary care, Novo Nordisk is concerned that the proposed language may inadvertently fail to encompass novel insulin delivery mechanisms as they become available – whether advances in inhaled insulin delivery or other mechanisms of delivery. The proposed approach may have an unintended effect of preventing Medicare beneficiaries from accessing the most appropriate insulin delivery system for their unique disease state, health status, and life circumstance.

While the dry powder inhaled insulin was the first insulin delivery system that presented an alternative to insulin injections, there are a number of insulin delivery systems that are in late stage development and that will likely gain market approval over the coming few years. These include other non-injectable forms insulin delivery from a variety of manufacturers, such as transdermal administration, intranasal delivery, and oral aerosol administration.

The limiting language in the proposed definition could result in widespread confusion regarding coverage and cost among patients, providers and Part D plan sponsors alike. The proposal could also create unfair commercial advantages for some manufacturers by limiting the ability of competitors with clinically comparable or superior products to contract with Part D plans.

Therefore, we suggest CMS revise the proposed paragraph (1)(vi) of the definition of Part D drug under §423.100 to simply read:

> "[s]upplies that are directly associated with delivering insulin into the body."

Novo Nordisk urges CMS to implement a change that would not again inadvertently circumvent Congress' intent that millions of Medicare beneficiaries have access to an alternative way to manage diabetes. By removing the language "through inhalation" and references to inhalation devices, CMS could prospectively provide a more clear and sound approach

to diabetes management without compromising the program. Of course, Part D plans will continue to have both the ability and the responsibility to make clinically and programmatically reasonable choices using standard P&T review mechanisms.

We understand that CMS can not predict which products will come to market or which will be most effective in treating Medicare patients, but allowing for the broad inclusion of insulin delivery systems on Part D plan formularies will enable the Part D plan sponsors to make the same reasoned decisions they make for all other drug classes based on clinical utility and efficacy rather than on potentially unclear regulation.

Providing access to the most effective insulin delivery systems appropriate to the needs and situation of individual beneficiaries may improve the quality of life of this vulnerable population and potentially reduce the costly effects of therapeutic noncompliance. The difficulties inherent in caring for Medicare beneficiaries with diabetes require a broad, rather than limited, range of treatment options and we strongly encourage CMS to finalize a broad, rather than limited, definition of Part D drug.

b. If CMS Limits the New Definition of Part D Drug to Supplies Associated with Delivering Insulin into the body through Inhalation, CMS Should be Certain that the Language Encompasses a Range of Insulin Inhalation Devices and Supplies

In the event that CMS does not modify the proposed changes to the definition of Part D drug in §423.100 to ensure the inclusion of all alternative insulin delivery methods as additional products receive marketing approval, Novo Nordisk strongly urges CMS to reconsider the inhaled insulin language in the proposed rule. Novo Nordisk is in late stage development of its own inhaled insulin system, AERx® iDMS, which will offer an alternative to the inhaled insulin delivery mechanism currently on the market. Among other features, the AERx® system is designed to deliver insulin only if the inhaled volume and air flow are in the appropriate range. And, although our product will fit within the expanded Part D drug definition as an insulin delivered to the body "through inhalation", we are concerned by the language "such as the inhalation chamber used to deliver the insulin," which misleadingly suggests that all inhaled insulin may be delivered using a mechanical chamber delivery device.

There are various proprietary methods of delivering inhaled insulin, including differences in the mode of inhalation and aerosol properties. The currently available inhaled insulin formulation uses a mechanical dry powder inhaler (DPI). It is our understanding that additional DPI delivery mechanisms are under development by other manufacturers and it is possible that these DPI may vary significantly from the one that is currently on the market.

Novo Nordisk's novel product, on the other hand, is delivered through an electronically guided inhaler that aerosolizes a liquid insulin formulation and does not include a "chamber". Moreover, while both methods of insulin delivery may effectively deliver insulin to the targeted alveoli, the systems differ greatly and each may offer advantages for particular patients that impact compliance, drug availability, and ultimately, disease management. We encourage you to view the photo of AERx® iDMS on page 16 of this letter so you will be aware of the differences between the currently available inhaled insulin delivery system and the AERx® iDMS.

Should CMS not adopt the approach to modifying the definition of Part D drug that we strongly recommend above, under which paragraph (1)(vi) of the definition of Part D drug would read:

> "[s]upplies that are directly associated with delivering insulin into the body,"

we suggest as an alternative that this paragraph (1)(vi) be revised to read:

> "[s]upplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber or any other component part(s) necessary to deliver inhaled insulin."

For optimal beneficiary and provider choice, as well as clarity and program integrity purposes, Novo Nordisk encourages CMS to ensure that all inhaled insulin delivery systems have equal opportunity for coverage under either the Part B or the Part D program so that Part D plan sponsors, providers and patients will be able to identify and access available treatment options as additional insulin inhalation delivery systems come to market.

III. Conclusion

We trust that we have provided the Agency with a solid legal framework under which to cover drugs for the treatment of obesity under the Part D benefit. Armed with legal authority, we believe it is vital to the public health for CMS to be a leader in curbing the growing obesity epidemic which is contributing to compromised health status in America's seniors, including the alarming prevalence of diabetes. Should CMS exclude drugs for the treatment of obesity from the Part D benefit, we ask that CMS clearly state in the final rule that drugs prescribed for the treatment of other conditions covered by Part D, such as diabetes, will not be excluded from coverage due to any weight-loss effect.

Further, we encourage CMS to broaden the proposed definition of Part D drugs relating to inhaled insulin to include other (non-inhalation) mechanisms for delivering insulin directly into the body. Should CMS not adopt this approach, we urge CMS to clearly provide coverage for other forms of inhaled insulin delivery systems under the Part D drug benefit.

Again, thank you for the opportunity to comment on this important proposal and we commend the Agency for recognizing the importance of providing patients with diabetes access to novel therapies. As we would be happy to discuss these matters further as CMS finalizes this rule, our contact information is provided below.

Sincerely,

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AERx® insulin Diabetes Management System (iDMS)

#36

CMS-

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

Submitter : **Ms. Erin Darling** **Date: 07/24/2007**

Organization : **Merck & Co., Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see Attachment.

CMS-4130-P-37-Attach-1.PDF

#37

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July 24, 2007

BY ELECTRONIC DELIVERY

Herb B. Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
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200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4130-P; Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit, Definitions: Part D Drug

Dear Acting Deputy Administrator Kuhn:

Merck & Co., Inc. ("Merck") is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule regarding policy and technical changes to the Medicare prescription drug benefit ("Proposed Rule").[1] Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve human health.

Merck appreciates the effort by CMS to incorporate certain Part D guidance into regulation and to make clarifying technical changes, which will be helpful to the Part D program's stakeholders. As explained below, however, we are concerned that the Proposed Rule could adversely affect an important group of Medicare beneficiaries who may need the option of pharmaceutical therapy. Specifically, Merck believes the preamble language excluding prescription drugs used to treat obesity from Part D coverage is incorrect as a legal matter and is counterproductive from a policy perspective. CMS previously has recognized correctly that the Medicare Modernization Act ("MMA") does not exclude drugs to treat obesity from Part D coverage, and we urge CMS to reaffirm that principle and withdraw the guidance denying coverage for obesity drugs in the Proposed Rule preamble.

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

CMS should differentiate between treating obesity and merely promoting weight loss for cosmetic purposes. This simple distinction is fundamental to delineating the proper scope of Part D coverage. Prescription drugs used to treat obesity, a chronic disease representing one of the country's most pressing public health concerns, must be distinguished medically and legally from agents used only for "weight loss" that are not covered under Medicare Part D. The treatment of obesity is not solely about effecting short-term weight loss, but is a combination of a period of clinically significant weight loss accompanied by an ensuing phase to prevent weight regain over the long term, as well as other systemic effects designed to reduce or eliminate the comorbidities that accompany obesity. Merck therefore urges CMS to reaffirm that prescription drugs used to treat obesity can qualify as "covered Part D drugs." This drug coverage can be a clinically important part of the Part D benefit package – and the overall Medicare benefit package – for certain Medicare beneficiaries who have serious health problems associated with obesity and limited treatment options. Our detailed comments on these issues are set forth below.

I. BACKGROUND

Any consideration of Part D coverage of obesity therapies must be informed by an understanding of the scope of the public health epidemic that obesity has become in this country, the implications for the physical health of Medicare beneficiaries, the burden of this serious medical condition on the long-term financial health of the entire health care system, and the regulatory history of the Medicare Part D program on these issues.

A. Obesity is a Costly, National Health Epidemic

Obesity is recognized as a serious disease that threatens patients' health and differs from simply desiring weight loss, as discussed more fully below. In the past twenty years, the prevalence of overweight and obesity has increased dramatically for both adults and children. Currently, more than 64% of American adults are either overweight or obese, according to results from the 1999-2000 National Health and Nutrition Examination Survey ("NHANES").[2] Additional data from two NHANES studies show that among adults aged 20–74 years the prevalence of obesity more than doubled from 15.0% (in the 1976–1980 survey) to 32.9% (in the 2003–2004 survey).[3] In the Medicare program in particular, the prevalence of obesity among beneficiaries has doubled in the last twenty years.[4] These increasing rates raise concern because of their implications for Americans' health. According to the Centers for Disease Control and Prevention ("CDC") and National Institutes of Health ("NIH"), obesity increases the risk of developing 35 major diseases and health conditions, including:

- Hypertension

[2] *See* http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese/obse99.htm.
[3] *See* http://www.cdc.gov/nccdphp/dnpa/obesity/.
[4] Kenneth E. Thorpe and David H. Howard, *The Rise in Spending Among Medicare Beneficiaries: The Role of Chronic Disease Prevalence and Changes in Treatment Intensity*, HEALTH AFFAIRS – WEB EXCLUSIVE, p. w378 (Aug. 22, 2006).

- Hyperlipidemia (e.g., high total cholesterol or high levels of triglycerides)
- Type 2 diabetes
- Coronary heart disease
- Stroke
- Gallbladder disease
- Osteoarthritis
- Sleep apnea and respiratory problems
- Certain forms of cancer (endometrial, breast, and colon)

In addition, the increasing prevalence of obesity creates a tremendous burden on the health care system and its limited resources. According to a 2003 study, about 9% of national health care costs in 1998 were attributed to excess weight, and nearly half of these were paid for by the Medicare and Medicaid programs.[5] In 2000, the total cost of obesity in the United States was $117 billion.[6] In the Medicare population, the share of spending incurred by obese beneficiaries has nearly tripled over the last two decades, to nearly 25% of total Medicare spending.[7] A recent Medicare Payment Advisory Commission ("MedPAC") report noted that lifetime Medicare spending for obese beneficiaries is much higher than among beneficiaries of a normal weight.[8] Further, research shows that the cost of medical care for severely obese elderly individuals (ages 50 to 69) is 60% higher than for elderly individuals with normal weight.[9] Experts suggest that this is most likely the result of increased spending on the comorbid conditions frequently associated with obesity.[10] Moreover, this trend is likely to continue and even intensify in the future since the prevalence of obesity is higher among individuals aged 40 to 59 than it is in the elderly population.[11] Efforts to promote weight management have the potential to create cost savings as a result of disease prevention, reduced utilization of health care services, and improved disease status or quality of life.[12]

B. History of Medicare Part D Coverage of Obesity Therapies

The MMA generally defines a "covered Part D drug" to include FDA-approved

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[5] *See* http://www.cdc.gov/nccdphp/dnpa/obesity/economic_consequences.htm; *see also*, Keith H. Buckman, M.D., *Obesity, Weight Management, and Health Care Costs: A Primer*, DISEASE MANAGEMENT, vol.10, no. 5, p. 130 (June 2007).

[6] HHS, *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity,* Rockville, MD: HHS, Public Health Service, Office of the Surgeon General (2001).

[7] Thorpe and Howard at w382; *see also*, Medicare Payment Advisory Commission, *Report to the Congress: Promoting Greater Efficiency in Medicare*, ch.1, p. 9 (June 2007) (hereafter referred to as "MedPAC Report").

[8] MedPAC Report at 9.

[9] Kenneth E. Thorpe et al, *The Impact of Obesity on Rising Medical Spending*, HEALTH AFFAIRS – WEB EXCLUSIVE, p. W4-480 (Oct. 20, 2004).

[10] *Id.* at W4-484; *see also*, Buckman at 129, 130; MedPAC Report at 9.

[11] MedPAC Report at 8.

[12] Buckman at 132.

prescription drugs and biologicals, when used for a "medically accepted indication."[13] The MMA's definition of covered Part D drugs excludes a limited subset of "drugs or classes of drugs, or their medical uses" described in § 1927(d)(2) of the SSA (except smoking cessation drugs).[14] SSA's § 1927(d)(2), a provision in the Medicaid rebate statute, provides that "[t]he following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted [under Medicaid]":

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require... that associated tests... be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.[15]

In the Part D final rule, issued on January 28, 2005, CMS recognized that the MMA's exclusion of "[a]gents when used for. . . weight loss" did not preclude Part D coverage of drugs used to treat morbid obesity:

> *Comment*: One commenter said that many of the categories of excludable drugs in section 1927(d)(2) of the Act refer to drugs when used for a specific purpose and that it is inappropriate to simply exclude these drugs when they may be covered depending on the specific clinical use. This

[13] Social Security Act ("SSA") §1860D-2(e)(1). The definition of "medically accepted indication" refers to FDA-approved indications and those indications supported by citations included (or approved for inclusion) in specified compendia. *Id.*

[14] SSA § 1860D-2(e)(2)(A). Drugs covered by Medicare Part A or B (when prescribed and dispensed or administered in circumstances where Part A or B coverage is available) also are excluded from Part D coverage. *Id.*, § 1860D-2(e)(2)(B).

[15] SSA § 1927(d)(2) (emphasis added).

> commenter recommended that we provide coverage for potentially excludable drugs when they are prescribed for a clinical use not covered by section 1927(d)(2) of the Act. Two examples provided were ''weight loss agents'' when used not for cosmetic purposes, but for the treatment of morbid obesity, and decongestant combination products, which while commonly prescribed to treat coughs and colds, could be used for the treatment of allergic conditions.
>
> *Response:* Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act, provided they otherwise meet the requirements of section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act. To the extent this is the case, and a drug is dispensed for a ''medically accepted indication'' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity . . . . Part D plans may establish utilization management processes in . . . order to ensure that such drugs are being prescribed for medically accepted indications that are not excluded under section 1927(d)(2)...[16]

Subsequently, CMS reversed its position in an FAQ indicating that Part D coverage excludes weight loss agents "used for the treatment of morbid obesity."[17] The May 25, 2007 proposed rule also takes this position, stating that:

> [I]n the preamble [to the Part D final rule] we erroneously asserted that to the extent that a drug was dispensed for a "medically accepted indication" (70 FR 4230) as described in section 1860D-2(e)(1) of the Act, weight loss agents could be covered for the treatment of morbid obesity. Therefore, we clarify here that agents, when used for anorexia, weight loss, or weight gain, are specifically excluded from the definition of Part D drugs. Thus, a weight loss drug, 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 drugs.[18]

This reversal in position is confusing as it fails to distinguish between the medical condition of obesity, which is a serious and increasingly prevalent chronic disease that left untreated will continue to progress, and merely desiring "weight loss." In addition, CMS has not provided a clear explanation for the troubling shift in position. Merck is concerned that the Proposed Rule would improperly constrict Part D coverage by failing to acknowledge a recognized medical distinction: between a disease associated with significant morbidity and

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[16] 70 Fed. Reg. 4194, 4230 (Jan. 28, 2005) (emphasis added).
[17] CMS Q&A No. 5279 (July 25, 2005).
[18] 72 Fed. Reg. at 29405.

mortality risks, on the one hand, and a status of simply desiring weight loss for whatever reason, on the other hand. Many people want or need to lose a modest (or even significant) amount of weight, but these individuals usually are not classified as having a medical need to lose weight due to the health risks associated with obesity. By conflating these two phenomena, CMS would severely limit the treatment options available to Medicare beneficiaries battling obesity. That result is not in accordance with the medical understanding of obesity; not consistent with many CMS precedents recognizing that certain drugs may have dual uses (some Medicare covered and some non-covered); not consistent with the MMA language excluding agents "when used for . . . weight loss"; and ultimately not a prudent policy for promoting good clinical outcomes and cost-effective care under the Medicare program.

II. OBESITY IS A SERIOUS CHRONIC DISEASE THAT IS DISTINCT FROM DESIRING WEIGHT LOSS FOR COSMETIC PURPOSES

As pertinent here, both the MMA's exclusion for the "covered Part D drug" definition and the underlying Medicaid provision in SSA § 1927(d)(2) relate to specific "medical uses" for drugs.[19] As a consequence, the key question in interpreting this statutory language is whether – from a medical perspective – agents "when used for . . . weight loss" differ from agents used to treat obesity. For reasons summarized below, both the medical literature and the Food and Drug Administration ("FDA") recognize a clear distinction between these two uses. Accordingly, when a prescription drug that otherwise qualifies as a covered Part D Drug is used to treat obesity, it cannot properly be excluded from Part D coverage on the theory that it has been prescribed merely to promote "weight loss."

A. Definition of Obesity as a Chronic Disease

The National Institutes of Health ("NIH")/National Heart, Lung and Blood Institute ("NHLBI") report entitled "Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity" defines obesity as a "complex multifactorial chronic disease that develops from an interaction of genotype and environment."[20] Obesity is a chronic disease with many manifestations and associated comorbidities, including cardiovascular disease, type 2 diabetes mellitus, hypertension, stroke, dyslipidemia, osteoarthritis, and some cancers.[21] As explained in a 2004 report on obesity prepared by RAND for the Agency for Healthcare Research and Quality ("AHRQ"):

> The health consequences of obesity include some of the most common chronic diseases in our society. Obesity is an independent risk factor for heart disease, the most common killer disease in most developed

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[19] That is, the pertinent provision in SSA § 1927(d)(2) refers to agents "when used for . . . weight loss" and thus relates to a particular "medical use" as opposed to a particular drug or class of drugs.

[20] National Institutes of Health/NHLBI Report, *Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity*, page xi (1998), *available at* http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf (hereafter referred to as "NIH Obesity Report"). This report, published in 1998, evaluated almost 400 randomized controlled trials.

[21] A. Must et al., *The Disease Burden Associated With Overweight and Obesity*, J. AM. MED. ASS'N, 282:1523-1529 (1999); NIH Obesity Report at xii.

> countries. Type II diabetes, hypertension and stroke, hyperlipidemia, osteoarthritis, and sleep apnea are all more common in obese individuals. . . .[22]

Obesity is a disease that lies to the right side of a continuum of increasing severity from underweight persons on the far left to the extremely obese on the far right. The NIH/NHLBI Report provides scientifically-based definitions of conditions along this continuum, according to an individual's body mass index ("BMI"), which categorizes weight relative to height for adults. BMI is calculated as weight (kg) divided by height in meters squared (m^2).

Classification of Overweight and Obesity by Body Mass Index (BMI)[23]

	Obesity Class	BMI (kg/m^2)
Underweight		<18.5
Normal		18.5-24.9
Overweight		25.0-29.9
Obesity	**I**	**30.0-34.9**
	II	**35.0-39.9**
Extreme Obesity	**III**	**≥ 40**

The risk and incidence of associated co-morbidities increase considerably once the BMI increases above 30, the level at which obesity is diagnosed. In addition, a BMI of 30 reflects the point at which obesity confers about a two-fold mortality risk in the general adult population.[24]

B. FDA Classifies Obesity as a Disease

Like clinical experts and other government agencies with a health-related mission, FDA has concluded that obesity is a disease. The FDA (in the preamble to its final rule on structure/function claims for dietary supplement labels) stated: "FDA agrees with these comments that obesity is a disease, and that obesity claims are not acceptable structure/function claims."[25]

It is therefore clear that the FDA considers obesity to be a disease, and that obesity agents are properly considered drugs under the disease-based definition. As the FDA explained in the preamble of a 2004 final rule regarding dietary supplements, "there was a paradigm shift in the 1990s, with the realization that obesity is a chronic disease requiring long-term treatment, both with behavior modification and long-term drug therapy, when appropriate, in addition to diet and

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[22] *Pharmacological and Surgical Treatment of Obesity*. Southern California Evidence-Based Practice Center, RAND Corporation for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, Chap. 1, p. 1 (July 2004) (footnotes omitted). The report also noted that today "nearly all clinical authorities agree that obesity is reaching epidemic proportions." *Id.*

[23] NIH Obesity Report at xiv.

[24] *See* AHRQ Health Technology Assessment Diagnosis and Treatment of Obesity in the Elderly, December 18, 2003, *available at* the Medicare coverage center on the CMS website.

[25] 65 Fed. Reg. 999, 1027 (Jan. 6, 2000) (emphasis added).

exercise."[26] In multiple instances in this preamble, the FDA states that obesity is "a disease with serious health consequences."[27]

C. The International Classification of Diseases System Classifies Obesity as a Disease

One of the critical tools used by CMS to define these medical terminology and medical concepts is the International Classification of Diseases ("ICD-9-CM") system. CMS and other divisions of the Department of Health and Human Services ("HHS") have responsibility for the ICD-9-CM system. Providers use this system to explain on Medicare claim forms and other clinical documentation why they have provided items and services, including drugs.

There is a fundamental distinction in the ICD-9-CM system between conditions, diseases, or disorders, on the one hand, and mere symptoms, on the other. Diseases and disorders are classified under separate groups of codes from those that are used to describe mere symptoms. The ICD-9-CM coding system identifies obesity as a disease in the "other metabolic and immunity disorders" section of the system and assigns unique codes to this condition.[28] By contrast, the ICD-9-CM identifies weight loss and weight gain as mere symptoms of other conditions. This point has been made for many years by clinical groups, including the American Academy of Family Physicians.[29] In addition, CMS reached the same conclusion when it revised the National Coverage Determinations Manual to remove the language stating that "obesity itself cannot be considered an illness."[30]

D. Treatment of Obesity is More than Mere Weight Loss

Treatment approaches differ for individuals who merely desire to lose weight for cosmetic purposes and patients within the different classes of obesity. Diet and exercise provide an important foundation for everyone above normal weight (BMI of 18.5-24.9), but obese patients usually need additional treatments for long-term risk and co-morbidity mitigation. Because obesity is frequently accompanied by one or more comorbid conditions, the treatment of obesity is not solely weight loss, but is a combination of weight loss and the prevention of regain as well as other systemic effects such that the comorbidities that accompany obesity are mitigated or eliminated. This basic tenet of obesity treatment is recognized both by clinical experts[31] and the FDA.

The FDA Obesity Working Group ("OWG") has stated that: "[T]he OWG recognizes that obese and extremely obese individuals are likely to need medical intervention to reduce weight

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[26] 69 Fed. Reg. 6787, 6820 (Feb. 11, 2004).
[27] *Id.* at 6819-20.
[28] INTERNATIONAL CLASSIFICATION OF DISEASES, CLINICAL MODIFICATION, NINTH REVISION, codes 278.01 (morbid obesity) and 278.00 (unspecified obesity).
[29] *See* AAFP Statement on Obesity, Classify Obesity as an Illness, December 5, 2003 (indicating that the support for the classification of obesity as an illness "includes ICD-9 codes classifying obesity among other metabolic and immunity disorders").
[30] MLN Matters Number MM3502 (Oct. 1, 2004).
[31] *See* M. Rosenbaum et al., *Obesity*, NEW ENG. J. MED., 337:396-407 (1997).

and mitigate associated diseases and other adverse health effects."[32] In fact, many studies have shown dramatic improvement in comorbidities (e.g., diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea) in obese patients treated with bariatric surgery[33] and other treatments. For example, many randomized controlled trials document the positive effect of obesity treatment on blood pressure, serum lipids, and blood glucose.[34] Therefore, obese patients benefit from treatment in many ways beyond weight loss. From a medical and scientific perspective, the treatment of this chronic disease cannot be confused with merely seeking "weight loss." Because the medical understanding of these terms must inform the interpretation of the statutory provisions on Part D coverage, the exclusion of agents when used for "weight loss" cannot properly be read as extending to the treatment of a chronic disease associated with significant increased morbidity and mortality risks.

III. CMS RECOGNIZES THAT DRUGS EXCLUDED FROM MEDICARE COVERAGE WHEN USED FOR ONE PURPOSE MAY BE COVERED WHEN USED FOR A DIFFERENT PURPOSE

In interpreting the scope of exclusions to Part D coverage, CMS generally has not embraced an unduly expansive reading of the exclusion (and an unduly narrow view of Part D coverage); instead, CMS has recognized that in many instances drugs can be excluded when used for one purpose but cannot be excluded when used for another purpose. Apart from its current position on the "weight loss" issue, CMS has adopted nuanced, careful interpretations that appropriately recognize and reflect medical distinctions between different uses of drugs. The best example – because it closely parallels the distinction between drugs used for obesity and drugs used for weight loss – is the distinction CMS has recognized since 1999 between drugs used for AIDS wasting and drugs used for "weight gain."

The same statutory provision that excludes from Part D coverage agents when used for "weight loss" also excludes agents when used for "weight gain" or for anorexia.[35] But CMS has long recognized the language in SSA § 1927(d)(2)(A) concerning "agents when used for . . . weight gain" does not encompass prescription drugs used to treat AIDS wasting or cachexia. As defined by the CDC, AIDS wasting means involuntary weight loss of greater than 10% of baseline body weight, plus either chronic diarrhea or chronic weakness and fever in the absence of a concurrent illness or condition other than HIV.[36] Drugs used to treat AIDS wasting cause weight gain – and act by causing weight gain – even though they are prescribed for AIDS

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[32] COUNTING CALORIES REPORT OF THE WORKING GROUP ON OBESITY, March 12, 2004, page 27 of 39, *available at* http://www.cfsan.fda.gov/~dms/owg-rpt.html#v.

[33] *See* H. Buchwald et al., *Bariatric Surgery: A Systemic Review and Meta-Analysis*, J. AM. MED. ASS'N, 292:1724-1737 (2004).

[34] NIH Obesity Report at xxi-xxiii.

[35] SSA § 1927(d)(2)(A).

[36] *1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults*, CDC Morbidity & Mortality Weekly Report (MMWR), Dec. 18, 1992, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm. Cachexia is defined as "general physical wasting and malnutrition usually associated with chronic disease." MERRIAM-WEBSTER ONLINE DICTIONARY, U.S. National Library of Medicine and the National Institutes of Health (2005), *available at* http://www2.merriam-webster.com/cgi-bin/mwmednlm?book=Medical&va=cachexia.

wasting and not merely to help a person gain weight. Yet CMS' current Part D guidance appropriately provides that: "[p]rescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain or agents used for cosmetic purposes, and therefore such products are NOT excluded... "[37]

CMS (then HCFA) first recognized this distinction in 1999, when the issue was whether the State of Texas could exclude a drug for AIDS wasting (Serostim) from Medicaid coverage. FDA supplied part of the rationale for CMS' ultimate decision when it stated in a letter to CMS that "Serostim is approved for the treatment of AIDS wasting, or cachexia, which is associated with increased morbidity and mortality."[38] Citing its discussions with FDA, CMS reversed its earlier position and announced in March 1999 that "we have revised our policy on Medicaid coverage of Serostim, which is indicated for AIDS wasting and cachexia. Accordingly, States should include the drug in their formularies."[39]

Thus, although "weight gain" is the intended outcome of using prescription drugs to treat AIDS wasting and cachexia, CMS does not interpret this as a statutory bar to Part D coverage (or, in the Medicaid context, as a permissive justification for non-coverage). The parallel with "weight loss" and prescription drugs used to treat obesity, which, like AIDS wasting, is associated with increased morbidity and mortality, is striking. CMS cannot appropriately and fairly reach opposite results in these two situations, nor would the interests of the Medicare program and its beneficiaries be well served by CMS attempting to rationalize such a dichotomy.[40]

Moreover, the carefully-considered AIDS wasting precedent represents the approach CMS repeatedly has taken in addressing this type of a "dual use" coverage issue. For example, Medicare covers bariatric surgery (under Part A) in certain circumstances involving morbid obesity;[41] and distinguishes such surgeries from cosmetic surgeries excluded from Part A and Part B coverage; Medicare covers botox injections (under Part B) when used for therapeutic purposes, such as strabismus (an eye disorder) or blepharospasm (a disorder causing involuntary facial movement), instead of being used for cosmetic purposes; and Medicare covers prescription niacin products (under Part D) even though "prescription vitamins" are excluded from Part D coverage because prescription niacin can be used at a high dosage to reduce cholesterol and, when used in this manner, does not serve as a nutritional supplement or to address vitamin deficiencies.[42]

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[37] CMS, Part D Drugs/Part D Excluded Drugs (updated April 19, 2006) (emphasis added).
[38] "NAPWA Applauds Ruling," The Body, News & Notes, May 1999 (quoting FDA correspondence with HCFA) *available at* http://www.thebody.com/content/art30648.html.
[39] "Medicaid Coverage of AIDS Drug - Serostim," Medicaid Drug Rebate Program Release #88 to the States, March 5, 1999.
[40] For reasons discussed below, the interests of Medicare and its beneficiaries would be better served by CMS recognizing (as it did in the Part D final rule) that in fact the MMA permits coverage of drugs when used to treat obesity, just as the MMA permits Part D coverage of drugs used to treat AIDS wasting.
[41] Discussed *infra,* Part IV.
[42] CMS, Part D Drugs/Part D Excluded Drugs (updated April 19, 2006).

CMS should draw the same type of careful distinction to reach a proper interpretation of the language excluding from Part D coverage agents "used for . . . weight loss." Such an approach would permit coverage for prescription drugs when used in appropriate circumstances, for medically accepted indications, to treat obesity and its comorbidities. This approach is most faithful to the statutory language, and it would also effectuate Congress' probable intent in incorporating the SSA § 1927(d)(2) exclusions into the new Part D benefit. That is, we believe that Congress would have specifically mentioned – and vigorously debated – any exclusion that it viewed as denying pharmaceutical treatment for a health problem that has now reached epidemic proportions and has become increasingly prevalent among the elderly. Likewise, it is doubtful that Congress would have envisioned the exclusion for "weight loss" drugs as sweeping in obesity treatments when the long-standing AIDS wasting precedent is directly analogous and points squarely to the conclusion that obesity treatments cannot be lumped together with products that merely promote "weight loss." It seems also unlikely that Congress would, through limiting access to prescription treatments for obesity and related comorbidities, intend to direct beneficiaries to the more expensive, invasive, and riskier treatment option of bariatric surgery when the only other options of diet and exercise have failed.

IV. THE PROPOSED RULE'S GUIDANCE ON OBESITY DRUG COVERAGE THWARTS OVERALL MEDICARE POLICY GOALS

In 2006, CMS determined that certain types of bariatric surgery were covered (under Part A) for Medicare beneficiaries with: (1) a BMI equal to or greater than 35; (2) at least one co-morbidity related to obesity; and (3) previous unsuccessful medical treatment for obesity.[43] In addition, facilities used to perform bariatric surgery must meet specific criteria.[44] Among the evidence CMS considered in making this National Coverage Determination was the Technology Assessment performed for AHRQ on *Diagnosis and Treatment of Obesity in the Elderly*.[45]

The AHRQ Assessment discussed how obesity has become extremely common among older U.S. adults. In 1999-2000, 33% of men and 39% of women aged 65-74 were classified as obese, as were 20% and 25%, respectively, above the age of 74.[46] The AHRQ Assessment cited obesity's societal cost, estimating direct obesity costs at that time of 5.7% of total U.S. health expenditures.[47] It also found that "the proportion of elderly with risk for diseases associated with obesity is considerable; if these risks improve with obesity treatment, intervention could have a large population effect."[48]

The prevalence and seriousness of obesity in the older population clearly influenced CMS' decision to cover bariatric surgery for certain obese beneficiaries. At the same time, CMS had concerns about the risks of bariatric surgery in the elderly population; CMS noted that

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[43] Decision Memo For Bariatric Surgery for the Treatment of Morbid Obesity, (CAG-00250R), Feb. 21, 2006.
[44] *Id.*
[45] U.S. Department of Health and Human Services Public Health Service, Agency for Healthcare Research and Quality, *Diagnosis and Treatment of Obesity in the Elderly*, December 18, 2003 (referred to hereafter as the "AHRQ Assessment").
[46] *Id.* at i.
[47] *Id.* at 3.
[48] *Id.* at 4.

"[e]xcluding high volume surgeon experience as a factor, overall mortality rates in the 65 and over population were 2.8 times higher at 30 days [after surgery], 3 times higher at 90 days and 2.85 times higher at one year, when compared to the population under age 65."[49] CMS also noted that given the relative risks and benefits of bariatric surgery and medical treatment for obesity (including dietary manipulation, behavior modification and medication, which had been tried both individually and in combination) medical treatment "should be routinely attempted and shown to be unsuccessful before considering a patient for bariatric surgery."[50]

Denying Part D coverage for drugs used to treat obesity would effectively limit most Medicare beneficiaries' access to obesity treatments to diet, exercise, and (for a small subset of obese patients) bariatric surgery. We are concerned that the guidance in the preamble to the Proposed Rule could create a situation where either no effective treatment is available or – perhaps worse – beneficiaries must wait until their condition progresses to the point where they become eligible for the more expensive, intrusive, and risky alternative of bariatric surgery before they can receive a Medicare-covered obesity treatment.[51]

CMS should avoid creating a situation where the only viable option for an obese patient may be surgery, because pharmaceutical treatment is an intermediate option that may be an effective solution for a number of Medicare beneficiaries. CMS should recognize that Part D coverage of obesity drugs could potentially reduce overall Medicare costs by avoiding the cost of bariatric surgery for some patients. Coverage could also provide the option of an intermediate treatment modality – and a more balanced menu of treatment options – for beneficiaries who are either ineligible for or hesitant to undergo bariatric surgery.

We understand that CMS may have concerns regarding increased costs that could result from offering Part D enrollees access to obesity drugs. However, CMS has previously noted Part D plans' ability to employ utilization management tools (such as prior authorization) to ensure that obesity drugs are only covered appropriately under Part D. Since the launch of the Part D benefit, Part D plans have developed considerable experience in using utilization management tools to contain costs while ensuring access to appropriate medicines; plans have established a good record in this regard. Based on this record, CMS can feel confident that permitting Part D plans to offer appropriate coverage for drugs used to treat obesity will not undermine Part D cost containment goals. At the same time, CMS could potentially reduce Medicare costs over the long term, as well as give Medicare beneficiaries who need treatment for obesity a Part D benefit package that better addresses their health care needs and that offers new tools to help improve outcomes for this important beneficiary population.

By acknowledging once again that the MMA permits Part D coverage of prescription drugs used to treat obesity – reaffirming the sound legal position on obesity drug coverage

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[49] Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (Feb. 21, 2006) at 22 (footnote omitted).
[50] *Id.* at 21.
[51] Medicare currently pays a mean cost of $17,000 per bariatric surgery; however, some individual surgeries can range as high as $250,000 or more. "Bariatric Surgery - The Right Call (WA0602)," Medicaid and SCHIP Promising Practices, Details for Obesity, Aug. 15, 2006.

articulated in the Part D final rule – CMS could help to advance its overarching policy goals for the Medicare program: spurring the delivery of cost-effective, high-quality, and appropriate care.

V. CONCLUSION

Merck recognizes that CMS fully appreciates the serious public health problems posed by obesity, especially for seniors. We are concerned, however, that the preamble guidance in the Proposed Rule would needlessly (and improperly) deny Medicare beneficiaries access to a lower cost, less intrusive, and less risky outpatient treatment option for this very serious disease. CMS need only refer to its precedents on closely analogous coverage issues, as well as its initial interpretation of coverage for obesity drugs under Part D, to withdraw the Proposed Rule's language relating to obesity treatments and give beneficiaries new options for battling obesity and its comorbidities.

Merck appreciates the opportunity to provide input on the Proposed Rule. Merck recognizes and appreciates the considerable effort that CMS put into the development of the Proposed Rule, and we hope that our comments will be useful to CMS as it finalizes this proposal. We look forward to further dialogue with CMS on these important issues. Please feel free to contact me if you have any questions or need additional information.

Sincerely,

Erin L. Darling

Erin L. Darling
Director and Counsel
Global Health Policy
Merck & Co., Inc.

Submitter : Ms. Margherita Giuliano **Date:** 07/24/2007

Organization : Connecticut Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

i.e. see attachment

CMS-4130-P-38-Attach-1.DOC

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August 1, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P, Mail Stop C4-2605
7500 Security Blvd
Baltimore, Maryland 21244-1850

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

On behalf of the Connecticut Pharmacists Association (CPA), the state pharmacy organization representing approximately 1000 pharmacists in Connecticut, 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.

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, CPA 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 the plans they contract with, 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. CPA 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

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expertise in helping their patients make informed decisions about their prescription drug plans. Pharmacists and pharmacy students in the state of Connecticut worked with the Department of Social Services to educate patients in the ConnPACE program and those that were dual eligibles on the various plans that met their needs. It not only saved the state financially, but it eased the concerns of many of our elderly patients.

Negotiated Prices

CPA 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, CPA 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.

CPA 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, and now other entities in the drug distribution system, the complexity of the rebate and price concession processes, and evolution of the marketplace requires CMS to continually address the methodologies used for basis pricing. CPA is pleased that CMS has again conceded that the benefits, rebates, price concessions, chargebacks and other contractual arrangements may not be shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors.

With regard to what is commonly referred to as 'spread pricing,' CPA 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). CPA 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 CPA's contention that spread pricing is most often employed for

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

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generic prescriptions; this, in turn, leads to higher brand utilization, unnecessarily creating higher overall costs. CPA 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

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

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

Conclusion

In summary, CPA strongly supports CMS' proposed policy and technical changes to the Medicare Prescription Drug Benefit plan. Given the changing nature of the practice of pharmacy

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and the ever-increasing reliance on federal guidance, CPA 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 Margherita R. Giuliano, R.Ph., CAE, Executive Vice President and Chief Executive Officer CPA, at (860) 563-4619 or via email at mgiuliano@ctpharmacists.org.

Sincerely,

Margherita R. Giuliano

Margherita R. Giuliano, R.Ph, CAE
Executive Vice President and Chief Executive Officer
Connecticut Pharmacists Association

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

Organization : Pharmaceutical Research and Manufacturers of Ameri

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please see our comments attached.

CMS-4130-P-39-Attach-1.DOC

#39

PhRMA

July 24, 2007

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

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

Dear Mr. Kuhn:

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

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

* * * *

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

I. Subpart D – Benefits and Beneficiary Protections

Part D Drug- Morbid Obesity

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

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

- Hypertension
- Dyslipidemia (for example, high total cholesterol or high levels of triglycerides)
- Type 2 diabetes
- Coronary heart disease
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- Some cancers (endometrial, breast, and colon)

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

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

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

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

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[5] SSA § 1860D-2(e)(2).

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(1) Agents When Used for Weight Gain

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

(2) Agents Used For Cosmetic Purposes or Hair Growth

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

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

(3) Antihistamines/Decongestant Combinations (RX)

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

(4) Botox®

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

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

Part D Drug- Vaccine Administration Fee

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

II. Gross Prescription Drug Costs (§ 423.308)

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

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

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

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

Incurred costs means cost incurred by a Part D enrollee for

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

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

(2) That are paid for...

Subpart M – Grievances, Coverage Determinations and Appeals

Projected Value (§ 423.560)

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

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

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

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

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

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

* * * * *

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

Sincerely,

/s/
Daniel T. Durham
Deputy Vice President

/s/
Ann Leopold Kaplan
Assistant General Counsel

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

Organization : **Texas Pharmacy Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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"See Attachment"

CMS-4130-P-40-Attach-1.DOC

#40

TEXAS PHARMACY ASSOCIATION

Serving Texas Pharmacy Since 1879

August 1, 2007

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

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

On behalf of the Texas Pharmacy Association and the approximately 20,000 pharmacists in Texas, we concur with the National Alliance of State Pharmacy Associations (NASPA), the national organization representing all fifty state pharmacy associations. We appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed 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

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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.

[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.

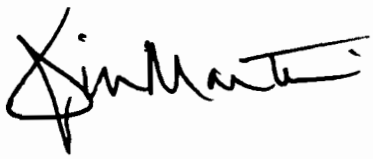
Conclusion

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 me at (512) 836-8350 ext 131 or via email at jmartin@texaspharmacy.org.

Sincerely,



Jim Martin, R.Ph.
Executive Director/CEO

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

Organization : Pharmaceutical Research and Manufacturers of Ameri

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Please see our comments attached.

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

#41

PhRMA

July 24, 2007

VIA E-MAIL AND U.S. MAIL
Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
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There are a number of areas where CMS has provided coverage for drugs with multiple uses when the drugs are used for covered conditions. There is no reason provided by CMS for treating the class of drugs that may be prescribed to treat obesity differently. The medical community distinguishes between medical uses that are therapeutic in nature and those that relate merely to cosmetic use or to non-specific symptoms that do not sufficiently indicate the presence or likely presence of a condition, disorder, or disease. Accordingly, the same analysis applies to drugs used to treat obesity. So long as a drug that treats obesity is being used for a purpose other than weight loss, it must be considered a covered Part D drug. Some examples of CMS' coverage of drugs with dual uses are as follows:

(1) Agents When Used for Weight Gain

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

(2) Agents Used For Cosmetic Purposes or Hair Growth

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

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

(3) Antihistamines/Decongestant Combinations (RX)

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

(4) Botox®

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

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

Part D Drug- Vaccine Administration Fee

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

II. Gross Prescription Drug Costs (§ 423.308)

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

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

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

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

Incurred costs means cost incurred by a Part D enrollee for

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

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

(2) That are paid for...

Subpart M – Grievances, Coverage Determinations and Appeals

Projected Value (§ 423.560)

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

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

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

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

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

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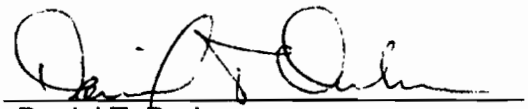
[17] As a related issue, CMS should mandate in the Chapter 18 of the Prescription Drug Benefit Manual (Part D Enrollee Grievances, Coverage Determinations and Appeals) that when a Part D beneficiary wins an appeal to an ALJ, the Part D plan must grant coverage of the drug in accordance with the ALJ decision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

* * * * *

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

Sincerely,



Daniel T. Durham
Deputy Vice President

Ann Leopold Kaplan
Assistant General Counsel

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

Organization : Nebraska Pharmacists Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

#42

Nebraska Pharmacists Association

August 1, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P, Mail Stop C4-2605
7500 Security Blvd
Baltimore, MD 21244-1850

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

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

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

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

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

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NPA
Nebraska Pharmacists Association

Negotiated Prices

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

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

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

Adequate Access to Home Infusion Pharmacies

NPA supports the proposed rule regarding home infusion pharmacies that codifies existing operational policies and imposes a new requirement that access to home infusion be offered within 24 hours of release from an acute setting. NPA continually works with its members to promote best practices in the pharmacy community. We agree that the

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

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NPA
Nebraska Pharmacists Association

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

Administrative Costs

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

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

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

Conclusion

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

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

Sincerely,

Joni Cover
Executive Vice President

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

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

Organization : **Pfizer Inc**

Category : **Drug Industry**

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See attachment.

GENERAL

GENERAL

See attachment.

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

#43

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

July 24, 2007

BY ELECTRONIC DELIVERY

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

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

Dear Mr. Kuhn:

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

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

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

I. Insulin Inhalation Drugs and Supplies

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

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

[2] *Id.* at 29,419
[3] *Id.* at 29,405.

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

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

II. Six Classes of Clinical Concern

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

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

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

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

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

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

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[6] *Id.*

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

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

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

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

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

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

III. Conclusion

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

Sincerely,

Lisa Goldman

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

Organization : **Pennsylvania Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

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

#44

PENNSYLVANIA PHARMACISTS ASSOCIATION

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

July 24, 2007

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

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

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

Subpart B – Eligibility and Enrollment
72 Fed. Reg. 29404 (2007) (to be codified at 42 C.F.R. § 423.50) (proposed May 25, 2007)
Approval of Marketing Materials and Enrollment Forms
As a general matter of public policy, PPA supports federal measures attempting to better inform our member pharmacists and their patients. As such, we wholeheartedly support a clarification of the pharmacists' educational and informational abilities with regard to Part D plans. Clarifying that the providers, provider groups, or pharmacies may supply printed information of Part D plan sponsors, provided that they offer similar material for all contracted sponsors, will limit confusion of available Part D sponsors while offering a more clearly defined mechanism to better educate the patient.

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

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

Negotiated Prices

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

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

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

Adequate Access to Home Infusion Pharmacies

PPA supports the proposed rule regarding home infusion pharmacies that codifies existing operational policies and imposes a new requirement that access to home infusion be offered within 24 hours of release from an acute setting. PPA continually works with its state association members to inculcate best practices in the pharmacy community. We agree that the 24-hour requirement is consistent with accepted best practices. Furthermore, we support the new

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

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

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

Gross Covered Prescription Drug Costs; Coordination of Benefits with Part D Plans and Other Payers; and Application Timing
With regard to these sections PPA, again, supports and appreciates the additional clarification and codification of CMS guidance.

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

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

Sincerely,

Patricia A. Epple, CAE
Executive Director

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

Organization : **Indiana Pharmacists Alliance**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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#45

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

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