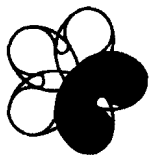

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July 18, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
(410) 786-6041

Dear Sir or Madam:

The National Kidney Foundation (NKF) appreciates the opportunity to respond to the Proposed Rule, "Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit," published in the ***Federal Register*** on May 25, 2007. NKF has mobilized a kidney community education initiative to facilitate utilization of the Part D benefit by enhancing the understanding of the program by Medicare beneficiaries who have kidney disease as well as the health care professionals who serve their needs. See, for example, the dedicated web site that NKF hosts, www.kidneydrugcoverage.org We understand that the Proposed Rule attempts to strike a delicate balance by, on the one hand, crafting adjustments in the Medicare Prescription Drug Program in response to Part D experience, and to reflect emerging beneficiary needs, while avoiding the fiscal consequences of expansion of the Part D benefit, on the other. For example, NKF endorses the draft revision insuring that enrollee's appointed representative may request a grievance on enrollee's behalf, and also the proposed decision to cover insulin inhalation drugs and supplies under Part D. On the other hand, we have two areas of concern.

423.120 Access to covered Part D drugs

ADEQUATE ACCESS TO HOME INFUSION PHARMACIES

NKF agrees that Part D Sponsors need to provide home infusion drugs in a timely manner after discharge from an acute setting. Industry best practices involve the availability of infusion drugs by either the next required dose or within 24 hours. CMS has proposed a requirement that PDP sponsors provide home infusion drugs within 24 hours. However,

patients that are discharged on home infusion therapy that is administered more frequently than at 24 hour intervals may not receive their drugs in a clinically acceptable timeframe if CMS uses "within 24 hours" as the criterion for the timelines. Thus, NKF advocates that CMS uses a stricter requirement of providing home infusion drugs by the next required dose.

In addition, as section 423.10 is drafted, it is not clear which entity is ultimately responsible for ensuring that Part D beneficiaries receive both the IV home infusion drug plus associated supplies and services in a clinically appropriate fashion. Is it the Part D plan? Is it the home infusion pharmacy? The language should clearly state that Part D plans are ultimately responsible for making sure that Part D beneficiaries receive both the IV drug as well as ancillary services and supplies from the home infusion pharmacy by the next required dose.

423.308 Definitions and Terminology

GROSS COVERED PRESCRIPTION DRUG COSTS

The NKF agrees that Part D enrollees that purchase a covered Part D drug at a network pharmacy for a reduced price during the coverage gap, without using the Part D benefit, should have that drug cost count towards TrOOP and total drug spending. On the other hand, we believe that it is onerous to make the enrollee responsible for submitting documentation to his/her Part D plan in the case where the enrollee uses an in-network pharmacy. When the enrollee uses an in-network pharmacy, the network pharmacy should have the responsibility for submitting this information to the Part D plan. Conversely, if the patient uses an out-of-network pharmacy, it would be reasonable to require that the enrollee be responsible for submitting the information to the PDP.

Thank you for your consideration of these comments.

Sincerely,

Allan J. Collins, MD
President
National Kidney Foundation, Inc.

NAASO
THE OBESITY
SOCIETY

July 23, 2007

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

RE: Medicare Program: Policy and Technical Changes to the
Medicare Prescription Drug Benefit, Federal Register, May 25, 2007

Dear Sir:

We are pleased to be able to comment on the above-referenced proposed rule.

Under the Medicare Prescription Drug Improvement and Modernization Act, the Centers for Medicare and Medicaid Services (CMS) reimburses prescription drug plans for a broad collection of drugs approved by the Food and Drug Administration that are used to treat "medically accepted indications." Section 1860D-2(e) (2) (A) of the Act excludes those drugs excluded in Section 1927(d) (2) of the Act covering the Medicaid program. That section excludes "agents when used for anorexia, weight loss, or weight gain" as well as agents for relief of coughs and colds and vitamins.

In Section II. B.1.a.2 of the proposed rule, the CMS addresses the term "Part D drugs" which excludes drugs for "anorexia, weigh loss, or weight gain and agents when used for cosmetic purposes or hair growth." The Federal Register proposed rule states, "However, in the preamble we erroneously asserted that to the extent that a drug was dispensed for a "medically accepted definition"...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."

The Obesity Society requests that the Centers for Medicare and Medicaid Services delete this language. Furthermore, we urge CMS to convene a special panel to discuss coverage of drugs for the treatment of obesity for the following reasons:

1. Obesity is one of, if not the most important, health care conditions affecting Medicare beneficiaries.
2. Obesity is a medically accepted indication.
3. Current Medicare coverage of obesity treatment is woefully inadequate and inconsistent with professional guidelines and those of the National Heart, Lung and Blood Institute of the National Institutes of Health.

4. The statutory language ambiguously lumps together weight loss treatments (which may be used by persons who are not obese) with patients who are obese or have morbid obesity.
5. CMS has created wholesale exceptions to similar exclusions in other important areas of public health.

1. Obesity is one of the most important, health care conditions affecting Medicare beneficiaries.

On June 21, 2007, Peter R. Orszag, Director of the Congressional Budget Office, in testimony before the Committee on the Budget of the United States Senate, addressed the growing problem of obesity for the Medicare program. Dr. Orszag states,

> The health of the American public, on average, is lower than it could be because steps that can foster better health – such as preventive medicine – appear to be underused, and various types of unhealthy behavior – in particular, those contributing to recent increases in obesity – remain relatively common...
>
> Obesity is associated with many serious medical conditions, including diabetes, heart disease, and high blood pressure. According to another recent study, obese people incurred medical costs in 2001 which were 37% higher than those for people of normal weight – a difference of about $1,000 per person. That study also found that the increased prevalence of obesity between 1987 and 2001 accounted for 12 percent of the overall growth in real (inflation-adjusted) medical spending per capita that occurred over that period. Another study found even more significant implications for Medicare. The share of spending attributable to obese enrollees increased from about 9 percent in 1987 to about 25% in 2002, a substantially larger increase than was seen in the obesity rate for the Medicare population.

Also in June, 2007, the Medicare Payment Advisory Commission, an independent federal body reported to Congress in *Promoting Greater Efficiency in Medicare* (accessed online June 30, 2007). It addressed the growing prevalence of chronic conditions among the Medicare population. The report identifies four reasons for the increased prevalence of chronic conditions, the first was obesity. The Report states,

> Higher rates of obesity – defined as a body mass index (BMI) of 30 or higher – likely have increased the prevalence of conditions such as diabetes, hyperlipidemia, and hypertension. Recent data suggest that the obesity rate among the elderly is at a historically high level...The impact of obesity on the prevalence of chronic conditions may become even stronger in the coming decades because the prevalence of obesity is higher among the population age 40 to 59 than among those age 60 or older.

The other three reasons were advance technology and the change in clinical definitions of some diseases, notably the metabolic syndrome, which is driven largely by obesity. The report further states,

> Increased obesity rates among the Medicare population have not only increased the treated prevalence of chronic conditions, they have likely played a role in the spending increase over the last two decades because many obese people have multiple conditions such as hyperlipidemia, diabetes and hypertension. Data from the Agency for Healthcare Research and Quality (AHRQ) indicate that the share of Medicare spending attributable to obese beneficiaries nearly tripled from 9.4 percent in 1987 to 24.8 percent in 2002.
>
> Obesity is a particularly important risk factor because it has spread across all age groups and segments of society, and research indicates that it tends to reduce life expectancy. Over the last three decades, improvement in risk factors such as smoking, high blood pressure, and drinking have increased life expectancy. However, increased obesity rates have offset part of these gains. Moreover, continued increases in obesity rates would further erode the gains from improvements in other risk factors.
>
> However, research also suggests that the effect of obesity on life expectancy may decline with age and even may have no effect once people reach age 70. This finding may reflect a complicated relationship in which obesity can have very different effects on longevity depending on an individual's medical circumstances. For example, it is plausible that the age at which an individual becomes obese may affect life expectancy. More research on this issue may help clarify the effect of age on the association between obesity and longevity.
>
> Irrespective of its effects on longevity, obesity increases disability rates. Obese beneficiaries spend a greater amount of their lifetimes with a limitation in one or more activities of daily living (ADLs) than beneficiaries who are the recommended weight (the list of ADLs includes eating, bathing, dressing, transferring from bed to chair, walking, and using a toilet). Obese 70-year-olds can expect to spend 40 percent more of their remaining years with a limitation in one or more ADLS than 70-year-olds of recommended weight. Moreover, obesity increases the likelihood of having several chronic conditions including diabetes, gallbladder disease, hypertension, and osteoarthritis; it also increases the likelihood of need dialysis.
>
> The increased limitations in ADLs, presence of chronic conditions, and need for dialysis among the obese translate to higher annual spending on health care. To the extent that the effect of obesity on life expectancy declines as people age, research suggests that lifetime Medicare spending is much higher (34 percent) among obese than among those of recommended weight.

Both the CBO and MPAC reports support programs to encourage lifestyle changes in diet and exercise. It should be pointed out, however, that Food and Drug Administration approved medications for obesity, require a showing of weight loss over and above that achieved by diet and exercise. Thus, for the Medicare program, FDA approved medications can result in greater weight loss than diet and exercise alone, by definition.

2. Obesity is a "Medically Accepted Indication"

The International Classification of Diseases (ICD-9-CM) lists, as a condition, disorder, or disease, both "morbid obesity" (278.01) and obesity (278.00). The Food and Drug Administration approves "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals" and, accordingly, has approved drugs for the treatment of obesity. FDA has stated that merely being overweight is not a disease.

3. Current Medicare coverage for treating obesity is woefully inadequate.

Current Medicare coverage for one of the most prevalent, fatal, chronic diseases affecting its beneficiaries (both the elderly and the non-elderly disabled population) is extremely limited.

In October, 2004 CMS removed language in the Medicare Coverage Manual which stated, "obesity itself cannot be considered an illness." Subsequently, Medicare examined bariatric surgery. In response to a petition for a new National Coverage Determination, CMS, in February 2006, expanded coverage of bariatric surgery. However, Medicare still does not cover physician or dietician counseling to reduce obesity. The proposed regulation would exclude coverage of approved drugs for obesity. Therefore, regarding one of, if not the most, important public health crises of our time, CMS has restricted beneficiaries to surgery only.

Current Medicare coverage and reimbursement policy creates a treatment gap with only bariatric surgery as a treatment option for patients who are severely obese. Additional options for clinicians are needed.

4. The statutory language is ambiguous on two counts.

CMS relies on statutory language defining the term, "Part D drug." Section 1860D-2(e)(1) of the act allows for coverage of drugs for a "medically accepted indication."

The Act excludes from that definition "drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under

sections 1927(d) (2 or (d) (3) of the Act, exception for smoking cessation agents. The list of excluded drugs included agents when used for "anorexia, weight loss or weigh gain and agents when use for cosmetic purposes or hair growth." It is clear from the statutory language that Congress was concerned about cosmetic weight loss and possibly about the use of weight loss agents by persons outside of the definition of "obesity" as used by the Food and Drug Administration for the approval of drugs for "weight loss." It should be clear that Congress did not, and would not, exclude drugs approved by the FDA as safe and effective for one of the most prevalent and costly conditions of Medicare beneficiaries. It is frankly inconceivable that Congress would have excluded a safe and effective treatment if they had considered the issue.

Secondly, we note that the Medicaid exclusion is quite porous. States can and have petitioned for exemption from this exclusion. Some 39 state Medicaid programs in 2006 covered drugs for the treatment of obesity and distinguished when use was for medical indications and when for cosmetic purposes.

5. CMS has created wholesale exceptions to similar exclusions in other important areas of public health.

CMS might be allowed to make this distinction if they rigidly adhered to the other exclusions in the section quoted above. In fact, CMS has taken an appropriate view of public health needs in interpreting these exclusions in other cases. For example, CMS specifically allows for prescription drugs to treat cachexia or AIDs although weight gain is the desired outcome of such interventions. Prescription antihistamines/decongestant combinations are covered under Part D when the relief of coughs and colds could prevent further injuries, such as broken bones.

In conclusion, obesity is a major health problem facing the Medicare program, current Medicare coverage of surgery but not physician counseling or FDA approved drugs is inadequate to address the problem, the statutory language CMS relies on is ambiguous and CMS has made more liberal decisions in similar areas of comparable public health impact. Therefore, the language in the above referenced proposed rule is contrary to the statute act and to act in a reasonable fiduciary manner to protect Medicare expenditures. We recommend that CMS delete the language on the coverage of drugs to treat obesity and convene an appropriate advisory group to address this specific issue.

Sincerely,

Eric Ravussin,
President
The Obesity Society

vna
More than a century of caring ...since 1885

Visiting Nursing Association of WNY, Inc.

VNA Home Care Services

July 23, 2007

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

Re: Adequate Access to Home Infusion Pharmacies

Dear Mr. Kuhn:

On behalf of the staff and patients of the Visiting Nursing Association of Western New York (VNAWNY), I appreciate the opportunity to comment on the proposed rule, ***Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit (CMS-4130-P).*** The VNAWNY is the oldest in the country, beginning services in 1885, and serves over 10,000 Medicare patients annually in a variety of areas, including home infusion. In addition to being the largest home health agency (HHA) in the five western counties of New York State, we are also the largest home infusion provider. My comments are restricted to the section entitled, "Adequate Access to Home Infusion Pharmacies."

I would like to thank CMS for raising the issue of access to home infusion under the Medicare Prescription Drug Benefit. Other payers have long recognized the cost efficiency of providing infusion therapy in the home as opposed to more costly inpatient or clinic settings. In addition, the home is the setting where patients want to be cared for, a fact that is verified by our very high levels of patient satisfaction with our services. We survey patient satisfaction with each discharge, and benchmark ourselves nationally. Our overall satisfaction level is 4.85 on a 5-point scale, testimony to the high quality we routinely deliver.

The Coverage Gap in Part D for Home Infusion

Unfortunately, current Part D recipients are still unable to take advantage of this highly cost-effective, quality care because of significant coverage gaps in the program. The policy changes CMS are proposing do not go far enough in filling that gap. There is no coverage under Medicare Part D for either the supplies that are integral to home infusion, nor the skilled monitoring services needed to safely manage the therapy in the home. Part D coverage is restricted to the actual drug—a serious problem since the drug itself cannot be administered without an array of products and services that are currently not covered.

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Williamsville, NY 14221

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www.vna-wny.com

Because of the gap in coverage, the VNAWNY home infusion pharmacy did not sign any straight Part D contracts, recognizing we would not be able to provide safe, effective home infusion therapy without coverage for ancillary supplies and services. We did sign contracts with Medicare Advantage plans, which supply coverage for both the drug and ancillary supplies and services through a per diem payment. As things stand now, Medicare Advantage plans generally offer full home infusion coverage, something not available to Traditional Medicare beneficiaries with Part D.

CMS attempts to address this gap in your proposed rule by stating, "...while we do not expect Part D plans to provide or pay for supplies, equipment, or the professional services needed for home infusion therapy, we do expect Part D sponsors' contracted pharmacy networks to deliver home infused drugs in a form that can be administered in a clinically appropriate fashion." Left unsaid in your policy statement is who is expected to pay for these supplies and services to ensure safe administration. In our market, the home infusion providers who have signed Part D contracts are unwilling to provide these supplies and services. They expect the discharging hospital, or the HHA providing nursing services to provide them, with no reimbursement from the Medicare system. Without that assurance, the Part D pharmacies routinely refuse to take on the case.

It is the opinion of many in our industry that the Medicare Prescription Drug Benefit was designed to cover medications filled by a retail drug store, not home infusion therapy. Almost nothing about how a home infusion prescription is written, dispensed, delivered or administered is like that of a retail medication drug prescription.

When a physician initiates home infusion for a patient, he or she is initiating far more than the dispensing of a product, but rather the initiation of a whole host of products and services that comprise home infusion therapy. These products and services include the diluents required to dilute the dry powders or highly concentrated liquids that comprise the drugs as delivered by the manufacturer. This process must be completed under a pharmacist's direction and in a sterile clean room with mathematical precision.

The nature of infusion means there is an IV line invasively placed in the patient and through which the ordered medication enters the patient's body. An integral part of home infusion services involves the maintenance of these lines through the use of flushes to keep them clear, clean, prevent blood clots, infection and other problems.

Home infusion prescriptions change frequently, based upon changes in the patient's condition, weight, blood chemistries, and reactions. It is the job of the home infusion pharmacist to monitor the effectiveness of a particular therapy on a patient, and report any significant findings to the prescribing physician. That frequently triggers a change in the therapy. Clinical monitoring in home infusion more closely approximates the work done in a hospital setting rather than a retail setting, and is far more intensive than the dispensing work done by retail pharmacists.

The deliveries of home infusion medications are time sensitive. Physicians frequently prescribe medications for same-day dosing. The drugs are often unstable and require refrigeration. The costs of maintaining a high quality home infusion delivery service are substantial and far in excess of the mailing costs of a retail or mail order pharmacy.

For all of these reasons, we implore CMS to institute a comprehensive fee to cover the cost of providing these services. Without these services, the actual drug that Part D currently covers is useless and cannot be safely administered.

Medicare Advantage patients are currently enjoying full home infusion benefits, as the commercial payers have long recognized the cost-effectiveness and the distinctions involved in home infusion therapy. It is time for traditional Medicare beneficiaries with Part D coverage to receive the same coverage.

The Timely Delivery of Home Infusion Drugs

We do not believe your proposed requirement of providing covered home infusion drugs within 24 hours is adequate in many cases. As indicated above, the VNAWNY infusion pharmacy frequently gets physician orders that require dosing in a matter of hours. It is the job of any professional infusion pharmacy to meet the needs of the patient as written by the physician. We would propose that you change the rule to read, "within the time frame prescribed by the physician, not to exceed 24 hours."

The two issues addressed above are related, as the arrangement of non-covered supplies and services is often time-consuming and may involve communication with several different pharmacies and nursing agencies before the prescription can be filled and delivered. In our market, delays in patient acute discharges are common when the patient has Part D coverage and requires home infusion. Adding a comprehensive fee to cover these costs would also improve the timeliness of the care.

Thank you for giving me the opportunity to comment on the proposed rules. If you have any questions or require more information, please do not hesitate to contact me.

Sincerely,

Lawrence J. Zielinski
President, VNA of WNY

4

July 24, 2007

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

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

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

Dear Mr. Leavitt and Ms. Norwalk:

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

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

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

I discuss these comments in detail below.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[8] SSA § 1927(d)(2)(D).

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

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

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

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

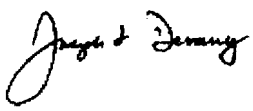
IV. CMS Should Withdraw Its Proposed Rule Denying Coverage of Drugs that Treat Obesity and Instead Should Reaffirm that Such Drugs Are Covered Under Part D

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

V. Conclusion

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

Respectfully Submitted,



Joseph F. Devaney
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cc:

The Honorable Charles B. Rangel
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The Honorable Jim McCrery
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