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PhRMA

July 24, 2007

VIA E-MAIL AND U.S. MAIL

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

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

Dear Mr. Kuhn:

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

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

* * * *

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

I. Subpart D – Benefits and Beneficiary Protections

Part D Drug- Morbid Obesity

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

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

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

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

[5] SSA § 1860D-2(e)(2).

[6] SSA § 1860D-2(e)(2)(A).

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

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

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

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

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

(1) Agents When Used for Weight Gain

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

(2) Agents Used For Cosmetic Purposes or Hair Growth

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

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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.

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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

Government Affairs Division

Baxter Healthcare Corporation
1501 K Street, N.W.
Suite 375
Washington, D.C. 20005
202.508.8200
Fax: 202.508.8201

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Rec'd 7/23/07

Baxter

July 24, 2007

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

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

Dear Herb Kuhn:

Baxter Healthcare Corporation (Baxter) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed regulation, "Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit,"[1] released May 25, 2007, and issued pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Baxter is a manufacturer of innovative medical devices, pharmaceuticals and biotechnology therapies that make a meaningful difference in patients' lives. Baxter assists healthcare professional and their patients with treatment of complex and chronic medical conditions, including infectious diseases, cancer, hemophilia, immune disorders, kidney disease and acute trauma. We are committed to the patients we serve and to their ongoing ability to access their chosen therapy options in the location that best fits with their needs.

As the manufacturer of many critical therapies used by Medicare beneficiaries in the home, Baxter is particularly concerned about beneficiary access to the full range of home infusion therapies. We appreciate CMS' efforts in the Proposed Rule to strengthen the availability of home infusion pharmacies within Part D pharmacy networks as well as to propose a timeframe for the delivery of home infusion therapies upon discharge from an acute care setting. Home infusion therapy is a cost-effective alternative for patients who otherwise would receive care in hospitals, outpatient clinics, or physician offices. Meaningful access to home infusion therapies can reduce

[1] 72 Fed. Reg. 29,403 (May 25, 2007).

unnecessary hospital stays and better facilitate patient access to medically necessary infusion therapies rather than in overburdened or overscheduled hospital clinics and physician offices. It is critical that reimbursement for home infusion therapies – and the professional services and supplies necessary to administer these therapies – be available in a manner that does not disrupt Medicare beneficiaries' ongoing treatment regimens or limit the choice of treatment options for patients seeking to make the transition from an acute care setting to their home.

While certain drugs and biologicals necessary for home infusion therapy are available for coverage under Medicare Part D's prescription drug plan formularies, neither the Part D benefit nor fee-for-service Medicare provides coverage for the equipment, supplies, and professional services necessary to administer the infusion and provide related care. The lack of reimbursement for the professional services and supplies necessary for home infusion jeopardizes access to this care for many patients, given the underlying financial status of many Medicare beneficiaries.

Under Medicare Part B, a limited set of home infusion therapies are covered under the durable medical equipment (DME) benefit when an external electronic infusion pump that qualifies as DME is used and strictly controlled infusion of the medication is deemed to be medically necessary, particularly high risk medications or parenteral nutrition. Also, the Part A home health benefit may provide payment assistance with nursing services for a limited group of homebound beneficiaries. For many beneficiaries, however, Medicare payment is not available for the professional services, such as a nurse to calibrate doses and administer a drug, or the ancillary supplies, such as IV tubing or disposable infusion pumps that must be in place in order to administer the drug to the patient. As a result, the beneficiary must pay for these supplies and services out of pocket or choose to forego home-based therapy where such out-of-pocket expenditures are not feasible.

When home infusion providers are required to compound certain Part D medications such as anti-cancer chemotherapies, disposable infusion devices are both efficient and economical in providing patients with ease of use, minimal calibration/manipulation and accurate delivery of medications while enhancing patient's comfort and tolerance. Such patient-friendly infusion devices are also often filled in the home infusion pharmacy with a broad variety of therapies including antibiotics, such as vancomycin or ceftriaxone, steroids such as prednisone or methyprednisolone, or pamidronate for the treatment of hypercalcemia associated with some types of cancer. A subset of Medicare beneficiaries are perfectly capable of self-

administering these therapies when such infusion devices are used; others can do so with the assistance of a spouse or other non-paid caregiver.

It is not reasonable that Congress should have had to specify each and every possible method of administration of Part D drugs ranging from eyedroppers to syringes in order for drug delivery devices to be covered under Part D, just as Congress did not specify each drug or biologic. It would be economically prudent for CMS to assure full coverage via Part D plans of infusion drugs and their presentations for use in the home such as found in a premix container or prefilled disposable infusion device.

We have commented on each of CMS' specific proposals related to home infusion below, with respect to the three proposed criteria for home infusion pharmacies within Part D pharmacy networks, and on CMS' proposed timeframe for the provision of home infusion therapies.

ADEQUATE ACCESS TO HOME INFUSION PHARMACIES

1. Proposed Requirement: Part D plans ensure that home infusion pharmacies are capable of delivering home infused drugs in a form that can be administered in a clinically appropriate fashion.

Baxter strongly supports this proposal. Baxter has long been an innovator in the provision of therapies that can be delivered to the patient's home in a form that is fully ready for administration. We have developed a broad range premixed parenteral nutrition and medication solutions, in which drugs and diluents are carefully combined and provided to the patient in a stable and ready-to-administer form. This promotes accuracy in dosing, reduces the potential risk of contamination and infection, and enhances patient safety.[2] Because manufacturer prepared premix formulations do not require that the doses be calculated or manipulated further by a pharmacist or a nurse, the use of these formulations eliminates manual admixing, and simplifies preparation and administration and fosters a safer clinical environment by reducing medication errors and improving therapy compliance.

Given the lack of adequate Medicare coverage for the professional services and ancillary supplies necessary to administer home infusion therapies, it is particularly important that home infusion therapies be delivered in the most economically efficient manner possible – this

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[2] Bates D, et al. Consensus Development Conference Statement on the Safety of Intravenous Drug Delivery Systems: Balancing Safety and Cost. Hospital Pharmacy. 35(2):150-155, 2000.

includes, where available, therapies that do not require detailed preparation in the patients' homes such as manufacturer prepared premix products and extends to products that are subcutaneously administered.

Baxter urges CMS to require Part D plans to provide adequate access to these therapies on their formularies. This includes monitoring compliance with the agency's stated expectations that Part D plan sponsors both ensure appropriate beneficiary access to home infusion drugs via formulary inclusions[3] and not implement policies that could potentially delay or restrict beneficiary access to home infusion therapies, including that any prior authorization or utilization management edits imposed on home infusion therapies be handled in an expedited manner in order to facilitate a timely and efficient hospital discharge.[4] One of the reasons that delays can occur is through inappropriate denials of coverage of drugs that might also be provided in Part B. Enforcement of CMS coverage instructions will aid in ensuring that home infusion pharmacies will be able deliver therapies in the most clinically appropriate fashion.

2. Proposed Requirement: Part D plans ensure that home infusion pharmacies are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

Baxter also supports CMS' proposal that a home infusion network pharmacy be capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies. As a company that has developed a wide range of critical therapies appropriate for home administration, one of the greatest challenges we see is in ensuring adequate access to these therapies. The capability of home infusion pharmacies is tied to their ability under the Part D formularies to provide the range of therapies to support a wide range of clinical needs.

We appreciate CMS efforts to provide a comprehensive Part D benefit, but we urge CMS to continue to work toward a resolution of the gaps in home infusion coverage. Given that part D costs are so much lower than initially predicted, Medicare should and could support seniors' access to the most clinically appropriate setting by providing appropriate payment for all of the components necessary to provide infusion therapies to patients in their home.

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[3] Prescription Drug Benefit Manual, Ch. 6, § 10.11.
[4] Id.

3. Proposed Requirement: Part D plans ensure that home infusion network pharmacies ensure that the professional services and ancillary supplies necessary for infusion therapy are in place before dispensing Part D home infusion drugs.

Baxter supports CMS' proposal that a Part D plan ensure that the professional services and ancillary supplies necessary for infusion therapy are in place before a home infusion pharmacy dispenses Part D home infusion drugs. This requires a Part D plan to obtain assurances from the dispensing home infusion pharmacy that the necessary services and supplies are provided through Medicare Parts A, B, or C, or through a third party insurance plan or some other arrangement, including self-pay, prior to dispensing the therapies. It is critical that these services and supplies be in place in order for the infusion therapies to be administered in the home, and we support CMS' proposal to require Part D plans to receive assurances that these therapies can be properly administered prior to dispensing.

As discussed above, however, many Medicare beneficiaries do not have the insurance coverage or the financial ability for out-of pocket coverage for the professional services and ancillary supplies that are necessary to ensure that home infusion is administered safely and effectively. We believe that CMS should study and report on the effect of the lack of coverage on patient access and satisfaction and out-of-pocket costs for beneficiaries.

4. Proposed Requirement: Part D plans ensure that home infusion pharmacies provide delivery of home infusion drugs within at least 24 hours of discharge from an acute setting.

Baxter supports CMS' efforts to ensure that Part D plans provide for the delivery of home infusion drugs promptly following a patient's discharge from an acute care setting. If home infusion therapies are not available promptly upon a patient's discharge from an acute care setting, Medicare beneficiaries who could be safely and cost-effectively treated in their homes likely will need to stay in the hospital to receive necessary therapies (paying out of pocket for the care if no longer medically necessary), or must travel to their physician's office to receive their infusion. We support CMS' efforts to establish a clear timeframe for the delivery of home infusion therapies. This will help to reduce overall Medicare program and out of pocket costs.

We urge CMS to establish a timeframe – whether 24 hours or another timeframe – that appropriately reflects the most efficient provision of home infusion therapies. For example, the appropriate systems must be in place to allow hospital discharge personnel to make the necessary determinations of a patient's Part D coverage, as well as for Part D plans to provide information in a timely manner to home infusion pharmacies, for these pharmacies to make the necessary arrangements to deliver the home infusion therapies to the patient, and for the necessary assurances regarding the availability of professional services and ancillary supplies to be in place. Baxter supports the many steps that CMS already has taken to facilitate timely access to home infusion therapies, including efforts to ensure that a wide range of home infusion therapies are available on formularies without restriction, or, where restrictions such as prior authorization are in place, that such restrictions are resolved in an expedited manner. Baxter encourages CMS to facilitate these processes in a manner that makes a 24-hour turn-around time a viable option for hospitals, Part D plans, and home infusion pharmacies.

Conclusion

In conclusion, Baxter appreciates this opportunity to comment on the Proposed Rule. We urge CMS to continue to work towards providing Medicare beneficiaries with meaningful access to home infusion therapies rather than a "double doughnut hole" of uncovered costs for services and items needed for care in the home. We believe that there are reasonable steps that could be taken to increase access to home infusion services through requiring coverage of manufacturer prepared premix products, and patient friendly single-use pumps that do not require a highly trained professional to deliver the services. This would be entirely consistent with previously issued Part D formulary guidance requiring contracted pharmacy networks to deliver home infused drugs in a form that can be administered in a clinically appropriate fashion. Thank you for your attention to this very important matter for beneficiaries.

Sincerely,

Sarah Creviston
Vice President
U.S. Government Affairs &
Public Policy

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Omnicare

Omnicare, Inc.
1600 RiverCenter II
100 East RiverCenter Boulevard
Covington, Kentucky 41011
859/392-3300
859/392-3333 Fax

July 24, 2007

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-4130-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Comments on Proposed Regulation: Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Ms. Norwalk:

Omnicare is one of the nation's leading providers of pharmaceutical care for the elderly, serving residents in long-term care facilities and other chronic care settings, comprising approximately 1.4 million beds in 47 states and the District of Columbia. We appreciate the opportunity to comment on the proposed regulations, as published in the *Federal Register* on May 25, 2007 at 72 FR 29403. Our comments will follow the format and organization of the proposed rule as published.

A. Subpart B—Eligibility and Enrollment

1. Approval of Marketing Materials and Enrollment Forms

CMS proposes to clarify inconsistencies between its description of permissible provider "marketing" in the preamble to the Final Rule and the provisions of the Marketing Guidelines issued by CMS. CMS also proposes to amend its regulation at 42 CFR 423.50(f)(1)(v) requiring providers, provider groups and pharmacies to accept and display materials from all Part D plan sponsors when the sponsors use providers, provider groups and pharmacies to distribute printed information comparing the benefits of different Part D plans.

The restrictions on provider activities which CMS has purported to impose under the policies referenced by CMS are beyond the statutory authority which Congress has granted to CMS, and consequently must be modified to reflect these statutory limitations.

Specifically, CMS states at 72 FR 29404 (May 25, 2007), "*[t]he Guidelines* require Part D plan sponsors to ensure that their contracted providers agree to refrain from 'marketing' to beneficiaries, as that term is defined by *The Guidelines* (that is, steering or attempting to steer an undecided beneficiary toward a plan based on the provider's financial interest). ...we wish to emphasize our consistent policy: providers and pharmacies that are contracted with plan sponsors may not 'market' to beneficiaries, as the term is defined in *The Guidelines*." [1]

[1] We note that CMS has inaccurately described the definition of "marketing" under the Marketing Guidelines. The Marketing Guidelines actually define "marketing" as "[s]teering, or attempting to steer, an undecided potential enrollee

CMS's policy exceeds its authority because, under the most expansive possible reading of CMS's statutory authority, it is entitled only to establish rules for the conduct of plan sponsors, and not rules of conduct for providers acting independently of plan sponsors. Accordingly, CMS has no authority to require that plan sponsors "ensure" that the providers with which they contract not engage in certain activities, when those activities are not undertaken by the providers on behalf of the plan sponsors as part of those sponsors' marketing activities.

Specifically, in the portion of the preamble to the Final Rule for Part D which discusses 42 CFR 423.50, CMS cites Section 1860D-1(b)(1)(B)(vi) of the Social Security Act (the "Act") as directing CMS "to use rules similar to those established under Section 1851 of the Act to review PDPs' marketing materials and application forms." 72 FR at 4221 (January 28, 2005). Section 1860D-1(b)(1) provides in relevant part as follows:

> (b) Enrollment process for prescription drug plans.—
>
> (1) Establishment of process.—
>
> (A) In general.—The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans consistent with this subsection.
>
> (B) Application of MA rules.—In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA-PD plan under the following provisions of Section 1851:
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> * * *
>
> (vi) Marketing Material and Application Forms.—Section 1851(h), relating to approval of marketing material and application forms."

Section 1851(h) of the Act provides as follows:

> (h) Approval of marketing material and application forms.
>
> (1) Submission. No marketing material or application form may be distributed by a Medicare + Choice organization to (or for the use of) Medicare + Choice eligible individuals unless--
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> (A) at least 45 days (or 10 days in the case described in paragraph (5)) before the date of distribution the organization has submitted the material or form to the Secretary for review, and
>
> (B) the Secretary has not disapproved the distribution of such material or form.
>
> (2) Review. The standards established under section 1856 shall include guidelines for the review of any material or form submitted and under such guidelines the Secretary shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.

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towards a plan, or limited number of plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities. 'Assisting in enrollment' and 'education' do not constitute marketing." Accordingly, the Marketing Guidelines definition of "marketing" is limited to situations involving compensation from a plan, not just steering "based upon the provider's financial interest". Further, the Marketing Guidelines' limitations on provider activities are not limited to situations in which a provider "steers" a beneficiary based upon the provider's financial self-interest; they also restrict "steering" "to further the financial or other interests of the provider", Marketing Guidelines at 127, and elsewhere are not limited at all based upon a benefit to the provider: "Providers also cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific plan." Marketing Guidelines at 123-4.

(3) Deemed approval (1-stop shopping). In the case of material or form that is submitted under paragraph (1)(A) to the Secretary or a regional office of the Department of Health and Human Services and the Secretary or the office has not disapproved the distribution of marketing material or form under paragraph (1)(B) with respect to a Medicare + Choice plan in an area, the Secretary is deemed not to have disapproved such distribution in all other areas covered by the plan and organization except with regard to that portion of such material or form that is specific only to an area involved.

(4) Prohibition of certain marketing practices. Each Medicare + Choice organization shall conform to fair marketing standards, in relation to Medicare + Choice plans offered under this part, included in the standards established under section 1856. Such standards--

(A) shall not permit a Medicare + Choice organization to provide for cash or other monetary rebates as an inducement for enrollment or otherwise, and

(B) may include a prohibition against a Medicare + Choice organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual.

(5) Special treatment of marketing material following model marketing language. In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

Accordingly, the statute only provides for rules limiting distribution "by a Medicare + Choice organization" of marketing materials or application forms not approved by CMS, and for "fair marketing standards" which a Medicare + Choice organization must conform to, as part of the standards promulgated under Section 1856 of the Act. Section 1856 in turn provides, in relevant part, as follows:

Section 1856. Establishment of standards.

(a) Establishment of solvency standards for provider-sponsored organizations.

(1) Establishment.

(A) In general. The Secretary shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter III of chapter 5 of *title 5, United States Code*, standards described in section 1855(c)(1) (relating to the financial solvency and capital adequacy of the organization) that entities must meet to qualify as provider-sponsored organizations under this part.

* * *

(b) Establishment of other standards.

(1) In general. The Secretary shall establish by regulation other standards (not described in subsection (a)) for Medicare + Choice organizations and plans consistent with, and to carry out, this part. The Secretary shall publish such regulations by June 1, 1998. In order to carry out this requirement in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(2) Use of current standards. Consistent with the requirements of this part, standards established under this subsection shall be based on standards established under section 1876 to carry out analogous provisions of such section.

* * *

Accordingly, Section 1856 only authorizes CMS to establish "standards ... for Medicare + Choice organizations and plans" which are consistent with Part C. Nothing in this statutory language or elsewhere in Part C authorizes restrictions on <u>providers</u>, rather than plans. Further, the "standards established under Section 1876 to carry out the analogous provisions of such section" also contain

only restrictions on plan marketing activities, not restrictions on providers when they act independent of plans. See 42 CFR Part 417, particularly 42 CFR 417.428 (Marketing Activities).

The regulation for MA plans at 42 CFR 422.80, upon which CMS based 42 CFR 423.50, includes the following relevant provisions:

> (e) Standards for MA organization marketing. (1) In conducting marketing activities, MA organizations may not:
> * * *
> (vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all MA organizations involved and have received prior approval by CMS. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.
> * * *
> (ix) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

Once again, the only limitations are on what an MA organization may or may not do, not on the activities of providers when acting independent of the plan. Here is what CMS said in adopting Section 422.80(e)(1)(vi):

> *Comment*: Some commenters asked that we clarify the role of physicians in the marketing of M+C products to their patients. The commenters also requested further guidance regarding whether physicians are allows to counsel patients about their health insurance choices. Commenters both supported and opposed allowing physicians to advise potential enrollees and beneficiaries about M+C plan options.
> *Response*: We agree that the role of physicians should be clarified. Accordingly, we are amending the standards for marketing to add a new §422.80(e)(1)(vi) that permits provider groups and individual providers to distribute health plan brochures (exclusive of applications) at a health fair or in their own offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans. While this discussion is entirely appropriate within the doctor-patient relationship, M+C organizations may not use providers/provider groups to distribute printed information comparing the benefits of different health plans, unless the materials have the concurrence of all organizations involved and have received prior approval from us. Physicians and other providers may not accept plan applications. We are also adding a new §422.80(e)(1)(vii) that prohibits M+C organization representatives from accepting applications in provider offices or other places where health care is delivered.

65 FR 40170, 40196 (June 29, 2000). Once again, under the regulation for MA organizations, CMS had restricted only the activities of the plans when they use providers in the plans' marketing activities. The only statement about provider activities affirmatively indicates that providers may discuss the relative benefits of different health plans when asked by their patients, as "entirely appropriate within the doctor-patient relationship". There is absolutely nothing which prohibits provider activities, particularly "steering", when the provider is acting independent of the plan.

We do not object to the language of the amended Section 423.50 as proposed by CMS, since, like the existing regulation, it includes the introductory language "In conducting marketing activities, a Part D plan may not". We do, however, object to the policy which CMS has adopted and sought to

enforce pursuant to Section 423.50(e)(1), referred to by CMS at 72 FR 29404-5 of this release—specifically, the extraordinary restrictions on providers when acting independently of any Part D plan sponsor.

In particular, CMS should clarify that, consistent with CMS's limited statutory authority, its policies should not be deemed to restrict providers from communicating with Part D beneficiaries and potential beneficiaries about Part D plan alternatives, so long as the providers are not doing so as part of a Part D plan sponsor's marketing activities. Further, CMS should amend the Marketing Guidelines to provide that all of the restrictions contained therein are on what Part D plan sponsors may use providers to do on their behalf, and do not restrict providers acting on their own, independent of the plan. The portions of the Marketing Guidelines which exceed CMS's statutory authority include, but are not limited to, the following:

1. Page 123 of the Marketing Guidelines: "Following are requirements associated with provider activities. The plan sponsor shall ensure that any provider contracted with the plan (and its subcontractors) complies with these requirements." Consistent with the limitations on CMS's statutory authority, all restrictions on providers should apply only to the extent a Part D plan sponsor is using the given provider to conduct marketing activities on its behalf.

2. Pages 123-4 of the Marketing Guidelines: "Providers also cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific plan." This statement, as well as variations on it contained elsewhere in the Marketing Guidelines, should be expressly modified to provide only that Part D plan sponsors may not engage providers to direct, urge or attempt to persuade beneficiaries to enroll in their plan, and to also expressly state that it does not restrict the ability of providers to engage in any activities independent of a Part D plan sponsor.

3. Page 125 of the Marketing Guidelines: "Any affiliation communications materials that describe plans in any way (e.g., benefits, formularies) must be approved by CMS." It is not clear what CMS means by "affiliation communications materials." CMS should clarify that it is not purporting to restrict providers from preparing and distributing materials describing plans (e.g., benefits, formularies) which are not provided by a Part D plan sponsor, but which instead have been prepared or obtained by the provider independent of such sponsor.

4. Page 125 of the Marketing Guidelines: "Providers may distribute printed information comparing the benefits of different plans (all or a subset) in a service area when the comparison is done by an objective third party." CMS should revise this to indicate that it is not restricting the ability of providers to distribute materials comparing the benefits of different plans, whether prepared by the provider or an independent third party, unless such activity is undertaken pursuant to an arrangement with one or more Part D plan sponsors as part of a sponsor's marketing activities.

5. Restrictions on "steering" in the Marketing Guidelines: The Marketing Guidelines include various statements prohibiting providers from "steering" beneficiaries to a given plan "to further the financial or other interests of the provider." (E.g., see page 127 of the Marketing Guidelines). These are vague and overbroad; the only limitation on providers in this regard should be on steering "for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities" on behalf of the plan, as set forth in the Marketing Guidelines definition of "marketing".

As indicated above, we do not take issue with the language of the regulation itself. Our issue is with the Marketing Guidelines' unauthorized restrictions on provider activities independent of Part D plans' marketing activities, which were issued after the Final Rule had been adopted. We believe

CMS is obligated to comply with statutory limitations on its authority. The restrictions on provider activities contained in the current Marketing Guidelines clearly go beyond such limitations, and must be revised as we have indicated above.

SubPart C—Benefits and Beneficiary Protections

1. Definitions

b. ***Long-Term Care Facilities***: CMS proposes, in this section, to include institutions for mental disease in the definition of long-term care facilities. We support the inclusion of these facilities in the definition of long-term care facilities.

CMS should also expand the definition of long-term care facility to include assisted living facilities. With respect to how these terms are used in the Part D rules, we believe that it is appropriate to treat assisted living residents the same as nursing facility residents. In particular, residents of assisted living facilities usually require delivery of their medications by long-term care pharmacies, generally in the same types of specialized packaging which are used for nursing facility residents. As such, in order for CMS to ensure that assisted living residents have appropriate access to their Part D drugs, it is essential that Part D plans be required to provide access to long-term care pharmacies for such residents.

The two main impacts of this change would be (1) to mandate that Part D plans pay long-term care pharmacies dispensing fees in accordance with normal long-term care rates for assisted living facility residents (under current CMS subregulatory guidance, this is permitted , but not required), and (2) application of the same network adequacy tests that currently apply with respect to nursing homes to assisted living facilities. With respect to any concern that CMS may have about defining the specific assisted living facilities which would be taken into account in applying the network adequacy tests, this data is readily available from the states, and relevant trade associations would also be able to provide assistance.

3. Access to Covered Part D Drugs

b. ***Adequate Access to Home Infusion Pharmacies***: We appreciate CMS' attention to this important benefit with the framework of Part D. Adequate access to home infusion is critical, both is providing appropriate services to beneficiaries, as well as in providing cost effective care within the Medicare program.

CMS proposes to codify the standard that the plan must be able to assure the provision of infusion services within 24 hours of discharge from an acute care facility. We believe the more appropriate standard is that plans be required to assure provision of services for the next scheduled dose. As beneficiaries are discharged from acute care settings more expeditiously, care must be taken that access to required services is not interrupted by the hospitals' desire to discharge the beneficiary within a specified time frame.

We urge CMS to require that plans are able to provide for the administration of infusion services at the next scheduled time of administration.

F. Subpart J—Coordination of Part D Plans with Other Prescription Drug Coverage

b. ***Coordination of Benefits with Part D Plans and Other Payers***: During much of 2006 LTC pharmacies were burdened with beneficiary plan assignments that were not static, despite beneficiaries not having exercised their special enrollment period options within the LTC setting. Frequently, the pharmacy submitted an E-1 query and received a response that a beneficiary was assigned to a particular plan. Many of these beneficiaries were subsequently assigned an incorrect cost sharing status. Pharmacy attempts to re-submit claims to recover incorrectly withheld co-pay amounts frequently resulted in claim denials based on the fact that the beneficiary was not assigned to that plan.

With respect to the plan-to-plan reconciliation process that CMS established for 2006, CMS states that "[g]iven the volume of drug claims that pharmacies would need to re-adjudicate as a result of incorrect Part D enrollment information available at the point-of-sale, re-adjudication would have imposed a significant administrative and financial burden on pharmacies." This lead to the development of CMS's payer-to-payer reconciliation process for 2006.

CMS states "[i]t is important to note that an essential element of the plan-to-plan reconciliation process as designed precludes plan use of claim denials or edits in the transition period." .Further, "[p]ayments made by the Part D plans as part of this reconciliation process would be made without regard to the plan's formulary or drug utilization review edits."

We agree with CMS's proposal to codify a requirement that this plan-to-plan reconciliation continue past 2006. However, in reconciling incorrectly withheld cost-sharing amounts for low-income subsidy eligible beneficiaries withheld from payments to long-term care pharmacies, many plan sponsors have required pharmacies to engage in the very process of reversal and rebilling of claims that CMS proposes to prohibit under the new Section 423.464(f)(6). As a consequence, pharmacies which filled scripts in good faith based upon information provided at the point of sale would be required to go at risk for a retrospective denial of the entire claim based upon a new application of the plan's formulary and other edits, in order to obtain the withheld cost-sharing amounts as CMS has specified in guidance, consistent with 42 CFR 423.800(c).

We believe that plans should be charged with reconciling these inaccurate cost sharing amounts without requiring pharmacies to reverse and re-bill claims. Accordingly, consistent with CMS's policy under Section 423.464, CMS should modify Section 423.800(c) to prohibit Part D plans from requiring pharmacies to reverse and rebill claims as part of such reconciliation process.

H. Subpart M—Grievances, Coverage Determinations and Appeals

1. Definitions

a. ***Appointed Representative***: CMS proposes to clarify that an appointed representative may file a grievance on behalf of the beneficiary. We agree with that proposal, but urge CMS to go further. For residents of long-term care facilities, many of whom lack the cognitive ability to participate in medical decision making, it is critical that CMS grant appointed representative status to caregivers in the employ of the certified facility in which they reside.

Experience with Part D plans demonstrate that primary caregivers are frequently not aware of the claim status (prior authorization requirements, necessity to request medical exception) that the plan requires. Beneficiaries frequently don't understand communications sent to their attention by the PDP. Meanwhile, necessary interventions are not undertaken.

2. Expediting Certain Coverage Determinations: For ambulatory Medicare beneficiaries, the CMS requirement that they receive written notice within 3 calendar days for refusal to expedite coverage determinations is appropriate. For residents of long-term care facilities, we believe CMS must go further and require Part D plans to provide duplicate notice to the dispensing pharmacy from which the claim originated.

Beneficiaries in LTC settings are frequently unable to participate in their care and may receive notices from plans that beneficiaries are unable to comprehend or act upon. In these cases the beneficiary's dispensing pharmacy must be aware of the plan's position and be empowered to respond.

CMS has required plans to provide emergency supplies of drugs for beneficiaries while their coverage determinations are being reviewed. The pharmacy needs to be aware of the beneficiary's status when a request for an expedited coverage determination has been denied.

Conclusion: Omnicare appreciates the opportunity to comment on this important regulation. We look forward to more opportunities to work with CMS to ensure that this critical Medicare benefit is implemented in a manner consistent with Congressional intent and the interests of the frail elderly residing in long-term care facilities.

Respectfully submitted,

Paul Baldwin
Vice President
Public Affairs

astellas
Leading Light for Life

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Rec'd 7/23/07

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

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.

* * *

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 (michael.ruggiero@us.astellas.com).

Sincerely,

Michael Ruggiero /MB

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

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AstraZeneca

July 24, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4130-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: AstraZeneca Comments on Proposed Rule CMS-4130-P

Dear Ms. Norwalk:

AstraZeneca Pharmaceuticals LP ("AstraZeneca"), one of the world's leading pharmaceutical companies, is engaged in the research and development of new medicines. We are committed to the discovery of drugs that will allow patients to lead longer, healthier and more productive lives.

We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule making policy and technical changes to the Medicare prescription drug benefit, published in the *Federal Register* on May 25, 2007 (Proposed Rule CMS-4130-P).

We reviewed the proposed rule in detail, and commend CMS for taking action to clarify the agency's policies on important issues that affect Medicare beneficiaries' access to prescription drugs. Specifically, we are pleased that CMS included the following provisions in the proposed rule:

- Negotiated Prices. We are pleased that CMS proposes to revise the definition of "negotiated prices" to base beneficiary cost-sharing on the price received by the pharmacy. This change is consistent with commercial business practices. We commend CMS for publicly acknowledging that the price at the pharmacy counter does not necessarily reflect the discounts and rebates that pharmaceutical manufacturers negotiate with plans and pharmacy benefit managers.

- Marketing Guidelines. We also commend CMS for clarifying that providers and pharmacies may educate beneficiaries about the Medicare drug benefit and assist them with enrollment, and that these activities do not constitute illegal steering of beneficiaries. Providers and pharmacies play a key role in outreach to Medicare beneficiaries; this clarification helps ensure their continued participation.

- Nominal Copays Charged by Manufacturer Patient Assistance Programs. AstraZeneca appreciates CMS' efforts to clarify policies regarding the treatment of nominal copayments charged by manufacturer patient assistance programs operating outside of the Medicare Part D benefit. We believe that permitting those copayments to count towards beneficiaries' true out of pocket (TrOOP) threshold allows beneficiaries to receive proper credit for cash payments that they make during periods where they have a gap in coverage. We recommend that CMS codify this policy in the final rule.

We identified issues that we believe deserve further consideration by CMS. AstraZeneca recommends CMS make the following changes in the final rule:

- Recommendation A: Negotiated Prices - We recommend that CMS add language such as "point of sale" or "the point of dispensing" to the term "negotiated price" to reflect the fact that it is a price at the pharmacy, not a price negotiated with manufacturers.

- Recommendation B: We ask that CMS codify additional protections for beneficiary access to needed treatments in the final rule: codifying the six classes of clinical concern; limiting cost-sharing for drugs in these classes, including additional cancer treatments and extended release products as part of the classes of clinical concern; changing the cut-off date for plan consideration of drugs in the six classes of clinical concern; and allowing beneficiaries to request exceptions on drugs in specialty tiers.

We discuss these recommendations in more detail in the following pages. If you have any questions or need further information about these comments, please do not hesitate to contact me at 202.350.5525 or by electronic mail at Sandra.Leonard@astrazeneca.com.

Sincerely,

Sandra Leonard
Director, Government Reimbursement

Recommendation A: We recommend CMS add "point of sale" or "point of dispensing" to the term "negotiated price" to reflect that it is a price at the pharmacy, not a price negotiated with manufacturers.

We commend CMS for changing the definition of negotiated prices to include prices for covered Part D drugs negotiated between plan sponsors and providers. This change acknowledges that the prices found on the Medicare Drug Plan Finder tool and at the pharmacy counter do not necessarily reflect the negotiations between pharmaceutical manufacturers and plans. Because plans may elect to use rebates to lower beneficiary out-of-pocket costs, the price negotiated between plans and pharmacies is a more accurate base for determining beneficiary cost-sharing.

We recommend the definition of the "negotiated price" be further revised to read "point-of-sale negotiated price" so prices negotiated between plans and pharmaceutical manufacturers are clearly distinguished from the pricing beneficiaries see at the point of dispensing.

Recommendation B: We ask that CMS include in the final rule additional protections for beneficiary access to needed treatments.

Codify the Six Classes of Clinical Concern: For 2006, 2007 and 2008, CMS maintained a policy requiring Part D plans to cover "all or substantially all" drugs in six drug classes, including drugs used to treat serious mental health conditions and cancer.[1] This policy ensures Medicare beneficiaries with serious chronic conditions can access a broad range of therapies. We are concerned that CMS has not proposed to codify this important policy in regulation. This final rule represents a prime opportunity for CMS to ensure that this important policy remains in place in 2009 and future years. CMS should codify the six protected classes in the final rule.

In addition, we recommend that CMS modify the six classes of clinical concern in the final rule to further protect beneficiary access. Specifically, we recommend the following changes:

- Monitor Tier-placement and Limit Cost-sharing for Classes of Clinical Concern: Patients taking drugs in one of the six classes of clinical concern are likely to require intensive clinical treatment. This treatment, in addition to the cost-sharing required of the prescription drug plan, may negatively impact compliance and persistency or even the patient's ability to start medically necessary drug therapy. We respect the need of plan sponsors to have flexibility in designing their plans, but also recognize that beneficiary access is vital for the health of beneficiaries and the Part D program.

[1] CMS Final Part D Call Letter for CY2008 released April 19, 2007.

Analysis of CMS data shows that brand–name cancer drugs are covered on higher cost-sharing tiers than generic cancer drugs, thus creating a financial barrier for those patients who would benefit from the most advanced therapy. Additionally, plans using coinsurance structures generally place cancer drugs on the highest tier with a median coinsurance of 25 percent. This arrangement creates a sizable financial burden on beneficiaries who are already bearing the high costs of medical care.[2]

We encourage CMS to impose a limit on the amount of cost-sharing beneficiaries must pay for drugs in the six classes of clinical concern (as well as other anti-cancer agents, which should be included as discussed below), and also recommend that CMS apply stricter monitoring of tier placement for drugs in these classes.

- Add Cancer Treatments as a Class of Clinical Concern: Additionally, CMS should consider hormonal agents such as anti-androgens that are primarily used in the treatment of cancer as eligible for the same class protection as antineoplastics. We ask that CMS consider expanding the classes of clinical concern to protect beneficiaries that are using hormonal agents as part of their prostate cancer treatment.

  The standard of care for many cancers (e.g. breast cancer and prostate cancer) includes treatment with specific antineoplastic hormonal agents. While USP categorized aromatase inhibitors and antiestrogens under the Therapeutic Category of antineoplastic agents, anti-androgens are currently categorized under the USP Therapeutic Category entitled "Hormonal Agents, Suppressants." We recommend CMS protect patient access to those drugs by considering them included in the "Antineoplastics" category of drugs for which plans must cover "all or substantially all" of the drugs in the class, given their usage exclusively within oncology.

  The vast majority of prostate cancer is initially hormone sensitive (responds to hormonal therapies such as LHRH-agonists and antiandrogens). The goal of hormone therapy is androgen deprivation and thus hormonal therapy is a standard of care in the treatment of patients with prostate cancer.[3] The most commonly used drug in the antiandrogen class is, at present, only indicated (in combination with an LHRH agonist) for the treatment of metastatic prostate cancer or locally advanced prostate cancer in combination with radiation therapy.[4]

[2] J. Bowman et al. *Access to Cancer Drugs in Medicare Part D: Formulary Placement and Beneficiary Cost Sharing in 2006.* September/October 2006, http://content.healthaffairs.org/cgi/content/full/25/5/1240 (Accessed 2 July 2007)
[3] Comprehensive Textbook of Genitourinary Oncology, Vogelzang et. al. Chapter 35 p. 565.
[4] AstraZeneca Pharmaceuticals Inc., full prescribing information for bicalutamide (Casodex).

- Expanding Classes of Clinical Concern to Permit Extended Release Products: Per CMS, the intent of the six classes of clinical concern and the "all or substantially all" guidance is to provide uninterrupted access to all drugs in that class. As such, we strongly believe that CMS should adjust the criteria to account for the clinical need for access to extended release products. Extended release products should not be limited from coverage when they offer a patient benefit such as adherence.

- Change Cut-off Date for Classes of Clinical Concern to January 1, 2008: We would like to convey our concerns with the arbitrary cut-off date included in the "all or substantially all" section of the 2008 Call Letter, which is April 17, 2007. Since beneficiaries with chronic conditions need access to a broad array of drugs in the six classes, we recommend that CMS require plans to cover new drugs that enter the market into one of the six classes of clinical concern, regardless of when during the plan year the drug enters the market. At a minimum, CMS should extend this April 17, 2007; deadline to require plans to cover any drugs in the six classes that are FDA-approved prior to January 1, 2008 for ease and consistency for patients and plans.

- Allow Cost-sharing Exceptions for Specialty Tiers: CMS' existing regulations and guidance allow plans to place drugs on a specialty tier. We are concerned that CMS has not proposed any changes to those rules in this proposed regulation.

  According to independent analysis of plan features, specialty tiers have become more prevalent in 2007. In 2006, 54% of Prescription Drug Plans (PDPs) had formularies with four or more tiers; this frequency rose to 84% PDPs in 2007. The trend was the same for Medicare Advantage Prescription Drug plans (MA-PD) with a dramatic increase from 66% of MA-PD plans in 2006 to 78% in 2007.

  AstraZeneca is concerned that CMS' existing rules, which do not allow beneficiaries to obtain a cost-sharing exception for drugs on a specialty tier, create access problems for chronically ill Medicare beneficiaries. AstraZeneca recommends that beneficiaries have the ability to file for an exception to the cost-sharing for drugs placed on a specialty tier. This change, if included in the final rule, would ease the cost burden of these drugs on beneficiaries on a case-by-case basis, while still encouraging appropriate utilization.

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

George Paz
Chairman, CEO
Express Scripts, Inc.

Mark Merritt
President & CEO

July 24, 2007

Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

File Code: CMS-4130-P

Dear Acting Administrator:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Notice of Proposed Rulemaking (NPRM) with regard to the Policy and Technical Changes to the Medicare Prescription Drug Benefit.

Overview:

It is our belief that Part D Plans should continue to have the broadest possible choice in designing their prescription drug benefits, in order to ensure the lowest possible cost for beneficiaries. As such, PCMA fully endorses the continued flexibility to allow Part D Sponsors the choice of using either the lock-in or pass-through model in calculating drug costs on EOBs and PDE records.

The proposed rule would mandate a "pass-through" pricing model, thereby undermining Part D plans' ability to achieve the greatest possible savings, often generated with the "lock-in" pricing model. In fact, both models are available in the commercial market and the PBM industry believes that both models should be maintained for the Medicare Part D benefit as well.

This proposal takes a "single approach" to calculating negotiated prices under the Part D benefit, namely, "based upon the price ultimately received by the pharmacy."[1] PCMA has concerns with this approach for several reasons:

- The proposed rule is contrary to legislative intent, which was to model the drug benefit after the competitive model of the commercial market.

- The proposed rule is also in direct contradiction to the final Part D rule, upon which many Part D plans based their current Medicare business models.

[1] Federal Register / Vol. 72, No. 101 at 29407 / Friday, May 25, 2007 / Proposed Rules

- The proposed rule would treat PBMs differently than every other provider in the pharmacy supply chain.

In establishing the Medicare drug benefit, Congress explicitly supported a market-based competitive approach to ensure the lowest possible cost of drugs for Medicare beneficiaries. The noninterference language of the MMA (Sec. 1860D-11(i)(2)) clearly states, "In order to promote competition under this part and in carrying out this part, the Secretary [of HHS] ...**may not** require a particular formulary or **institute a price structure** for the reimbursement of covered Part D drugs." CMS acknowledged this point in the preamble to the final Part D Rule, which states, "Given this market-based approach envisioned by Congress, we are wary of regulating negotiations between private parties particularly regarding the specifics of price negotiations so as to ensure that enrollees receive competitive prices on their covered Part D drugs."[2] However, in just 18 months since the implementation of the Part D benefit, and even before first year performance results are available, CMS seeks to dictate which model should be used by Part D sponsors.

Unlike the pass-through model, the lock-in model aligns incentives to reduce overutilization and to promote more cost-effective alternatives. A key to lowering trend in prescription drug spending, and therefore lowering drug costs for plan beneficiaries, is to have PBMs use their cost-saving innovations to the fullest extent possible, such as utilization of preferred brands over non-preferred; lower cost generic drugs; and mail order pharmacy. That's why "lock-in" pricing is far more commonly chosen by plans in the private sector than the "pass-through" model.

The consequence of the proposed regulation is that it would eliminate the "lock-in" pricing option, thereby eliminating the market model that is preferred by most MA-PDs and PDPs as delivering lower drug costs to plans and beneficiaries alike. The result will be lower generic utilization, less competition among "me-too" brands, weaker mail service penetration rates and other deficiencies. These facts will mean higher costs for the Medicare Part D program and its beneficiaries, while offering no corresponding upside to either.

Our specific concerns are as follows:

B. Subpart C—Benefits and Beneficiary Protections
a. Part D Drug, (4) Vaccine Administration Fee

CMS proposes to amend the definition of Part D drugs to include a reference to vaccine administration on or after January 1, 2008, as dictated by the Tax Relief and Health Care Act of 2006. In guidance issued earlier this year, CMS indicated that the negotiated price for a Part D vaccine will be comprised of the vaccine ingredient cost, a dispensing fee (if applicable), and a vaccine administration fee.

[2] Federal Register / Vol. 70, No. 18 at 4244 / Friday, January 28, 2005 / Rules and Regulations

While it is understood that CMS is codifying the recent statutory provisions relating to vaccine administration, PCMA remains concerned with the potential problems with implementing coverage for vaccine administration under Part D. In their June Report to Congress, MedPAC highlighted these issues, including the potential adverse effect on beneficiary access and the administrative burden of establishing direct billing relationships between physicians and Part D plans.

According to MedPAC, "if more vaccines become eligible for Part D, physicians are likely to have problems billing plans." In addition, "If beneficiaries have to pay the full payment rate for vaccines and then seek reimbursement from their plans, physicians are concerned that the out-of-pocket cost will discourage beneficiaries from seeking preventive care when appropriate vaccines are available."[3] For these reasons, MedPAC recommended that Congress move coverage for certain preventive vaccines back to Part B.

PCMA Recommendation: *PCMA shares MedPAC's view that coverage for certain vaccines and vaccine administration should be under Part B. However, given the statutory mandate moving coverage of vaccine administration to Part D, PCMA will reiterate our previously stated position on how to best implement coverage under Part D.*

While Part D plans will do everything necessary to ensure that beneficiaries have broad access to vaccines and vaccine administration in 2008, we recommend that CMS proactively take steps to ease the logistics of implementing this new process, such as the creation of a billing webportal or contracting with a common processor. This will help ensure a workable, patient and provider friendly solution to the issue of out-of-network providers.

PCMA supports allowing Part D plans to treat vaccine administration in the same manner as they do a Part D drug. Part D plans should have the flexibility to put in place a system that permits vaccine (drug) and vaccine administration (VA) claims to be processed as one transaction from the pharmacy, or as two non-linked claims from the pharmacy or from the pharmacy and the out-of-network provider who administers the vaccine. For pharmacy-administered vaccines, claims should continue to be filed using NCPDP electronic submission, as is the case with all other Part D drugs. We believe this efficient and flexible model will allow plans to work within established CMS policies on the wide range of processes that vaccine administration affects such as benefit design, billing, processing and adjudication of claims, and relationships with providers – both in- and out-of-network.

NEGOTIATED PRICES

CMS is proposing to amend the definition of "negotiated prices" to be effective for Part D contract year 2009, to require that beneficiary cost sharing must be based upon the price ultimately received by the pharmacy or other dispensing provider.

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[3] Medicare Payment Advisory Commission. "Report to Congress: Promoting Greater Efficiency in Medicare" June 2007 p.166

However, Section 1860d-2(d)(1)(B) states only that "negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs." Nowhere does the statute define negotiated price as the amount ultimately received by the pharmacy. Rather, in developing the drug benefit, Congress left the flexibility to Part D sponsors to determine what their negotiated price would be and how much of the price concession to pass on to beneficiaries based on the competitive market model.

In the final Part D rule, CMS acknowledged that Part D plans may not pass through all negotiated price concessions and therefore interpreted the definition of negotiated price as "requiring Part D plans to pass on to enrollees **some, but not necessarily all**, of these price concessions."[4] In addition, in response to concerns about how price concessions would be passed through the pharmacy, CMS stated, "Given the market-based approach envisioned by the Congress, we are wary of regulating negotiations between private parties particularly regarding the specifics of price negotiations so as to ensure that enrollees receive competitive prices on their covered Part D drugs."[5]

PCMA Recommendation: *CMS should maintain the current policy, which allows Part D plan sponsors to base beneficiary cost-sharing not on the price ultimately charged by the pharmacy for the drug, but on the price the sponsor paid for a drug, including payment to a PBM or other intermediary. The definition of negotiated prices should continue to reflect this flexibility.*

ADEQUATE ACCESS TO HOME INFUSION PHARMACIES (§423.120(a)(4))

In addition to codifying previous guidance relating to home health infusion, CMS is also proposing to add a new requirement that would mandate that a Part D plan's contracted pharmacy network also provide delivery of home infusion drugs within 24 hours.

While we can understand the need to assure continuity of care through access to necessary home infusion drugs, the new requirement CMS proposes is decidedly unfair if it were interpreted to apply directly to the Part D plan itself. Not only would the requirement be administratively burdensome, but it would also be extremely difficult to enforce. For example, a stand-alone PDP does not have visibility into the medical side of beneficiaries' care, so therefore it would have no means to access medical claims data to make sure that these drugs were provided. Consequently, plans would be forced to build costly reporting processes and protocols to police their contracted pharmacies in order to ensure compliance.

PCMA Recommendation: *CMS should clarify that Part D sponsors are in compliance with this provision if they include it in their network pharmacy contracts. Plans should make every effort to work with pharmacies to modify existing contracts to incorporate*

[4] Federal Register / Vol. 70, No. 18 at 4244 / Friday, January 28, 2005 / Rules and Regulations
[5] *ibid*

this new requirement and to incorporate it into contracts moving forward. Any failure to adhere to this contract provision could penalize a pharmacy by potentially disenrolling them from the contracted pharmacy network. Provision of home infusion drugs within 24 hours of discharge from an acute setting should be contingent on the pharmacy being notified of the discharge by the enrollee or acute care provider prior to discharge.

***D. Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage,* 1. Definitions and terminology (§423.308)**

ADMINISTRATIVE COSTS

In the newly-proposed definition of administrative cost, CMS states, "When an intermediary acts on behalf of a Part D sponsor to negotiate prices with dispensing entities such as pharmacies, any profit retained by the intermediary contracting organization as a result of such negotiation (through discounts, manufacturer rebates, or other direct or indirect price concessions) is considered an administrative cost to the Part D sponsor and not a drug cost."[6]

The cost to purchase drugs (versus paying for a service) is a drug cost, regardless of from whom the drug is purchased. Administrative costs are not defined to include the margin retained by a wholesaler over the wholesale acquisition cost or a pharmacy's margin over the pharmacy acquisition cost, and the same should be true for PBMs.

To remove PBMs from the drug supply chain in this manner so that they bear no drug price risk would effectively relegate PBMs to claims processors, and as such they would have little incentive to utilize their cost savings tools such as generic substitution, formulary management and drug utilization management. This would in turn increase drug utilization and cost, thereby increasing costs for both beneficiaries and the federal government.

PCMA Recommendation: *Retain the traditional definition of "administrative costs" as described in the preamble to the Part D rule. Under this definition, profit or loss incurred by an intermediary contracting organization as a result of lock-in pricing would remain excluded from the definition of administrative costs.*

GROSS COVERED PRESCRIPTION DRUG COSTS

As CMS concedes in the proposed rule, "Many interpreted the term "intermediary" [under the January 28, 2005 final rule] to mean PBM (rather than agent). Using this definition, many plan sponsors reported the prices they negotiated with their PBMs, rather than the prices that were agreed upon as the amount to be received by the pharmacies."[7] CMS now seeks to exclude the differential retained or lost by a PBM from the definition of gross covered prescription drug cost, instead considering it to be an administrative cost.

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[6] Federal Register / Vol. 72, No. 101 at 29420 / Friday, May 25, 2007 / Proposed Rules

[7] Federal Register / Vol. 72, No. 101 at 29409 / Friday, May 25, 2007 / Proposed Rules

CMS has previously clarified that it expects "Part D plans and pharmacies to account for pharmacy profit as part of negotiated prices—either as part of overhead costs accounted for in dispensing fees or in the reimbursement rates for ingredient costs negotiated with pharmacies."[8] In fact, in each step of the drug supply chain, whether a drug is purchased directly from the manufacturer, a wholesaler, or pharmacy, the price of the drug would include a mark up by that entity which could include both the cost of delivering the drug and related service, as well as any margin retained by that entity.

When a Part D sponsor purchases a drug, the price it pays for the drug represents its actual cost (i.e. ingredient cost). CMS clearly accepts this when the drug is purchased from the pharmacy, even though the ingredient cost includes a pharmacy profit margin or mark-up that causes it to be higher than the pharmacy's acquisition cost for that drug. It should be no different if the Part D sponsor purchases the drug through a PBM instead of the pharmacy, and the ingredient cost includes the PBM mark-up.

There is no basis for treating PBMs any differently from any other entity in the supply chain. At each link along the supply chain – from the manufacturer to the wholesaler to the pharmacy to the PBM to the plan – there is a mark-up in the price of the product to account for the seller's overhead and profit in selling the product. This becomes embedded in the actual price paid for the product by the next buyer in the chain. CMS is not requiring the carve-out of this embedded mark-up for any other entity in the supply chain, and accepts that this is an integral part of the product cost to the buyer at the next level. If a PBM procures a drug and assumes the financial risk and responsibilities of that, the price it charges a Part D sponsor for that drug should be treated in the exact same way as the price charged by any other entity in the supply chain.

PCMA Recommendation: *Profit or loss retained by a PBM as result of lock-in pricing is a legitimate cost tied into the drug supply chain. As such, it should not be excluded from the definition of gross covered prescription drug cost.*

F. Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage
COORDINATION OF BENEFITS WITH PART D PLANS AND OTHER PAYERS

CMS explains that it developed the payer-to-payer reconciliation procedures in large part to alleviate the "significant administrative and financial burden" that would otherwise be placed on pharmacies to reverse and re-adjudicate claims based on incorrect information accepted by pharmacies "in good faith." CMS also states, "unforeseeable future events" may create the need for further reconciliation processes when a payer other than the correct Part D plan pays as primary, and that Part D plans will be required to coordinate benefits with these payers "on a timely basis."

While we support CMS' efforts to mitigate the burden placed on pharmacies, and also understand and support the requirement that Part D plans coordinate benefits with other payers, we are concerned that CMS does not address or even allude to the significant

[8] Federal Register / Vol. 70, No. 18 at 4236 / Friday, January 28, 2005 / Rules and Regulations

burdens – financial as well as operational -- placed on Part D plans by these processes, even though the Part D plans too, have relied in good faith on information provided to them by CMS. We are also concerned that CMS requires Part D plans to coordinate benefits with other payers "on a timely basis," but makes no provision on behalf of Part D plans to require pharmacies or other payers to submit COB claims to the plan on a timely basis, particularly in situations where these entities may have obtained or been in possession of the correct payer information for some period.

Based on this year's experience, we are particularly concerned that in adding new COB obligations on Part D plans, CMS does not address the payment reconciliation process and deadlines for submitting PDE claims and adjustments, or provide any indication of how it plans to adjust this process to allow Part D plans to receive reinsurance and risk corridor payments for claims received after the end of the coverage year. In the preamble to the current Part D Rule, CMS noted that its definition of the term "coverage year" was intended to "provide timely closure for payment determination processes such as reinsurance, risk corridor and employer subsidies" and that a three-month close-out window was warranted due to "highly automated and point of sale nature of prescription drug claims processing."[9] CMS added that it believed that "the number and value of claims that will potentially be missed will be immaterial, consisting primarily of paper claims."[10] CMS then went on to quote industry statistics that at least 98% of drug claims are paid within three months of submission, pointing out that, in addition to this three month claims run-out period, plans would have six months to submit data, thus giving plans "the extra time necessary to compile the data necessary for retroactive reconciliation."[11]

Clearly, and as CMS indicates in the proposed rule, it did not anticipate the various post-point-of-sale ("POS") reconciliation processes between Part D plans and other payers, including other Part D plans, SPAPs, states and even long-term care facilities. Thus, it is no longer the case that non-POS claims are immaterial. Indeed, it appears likely that these will be a significant and ongoing aspect of the Part D program for the foreseeable future. In any event, whatever the period for which Part D plans must continue to accept claims for processing, CMS clearly recognized in the preamble that plans should be provided at least three months from date of submission to pay those claims, and at least six months from the date of final claims submission to compile the data necessary for retroactive reconciliation. In order that Part D plans be able to receive the reinsurance and risk corridor payments to which they are entitled under the MMA, CMS must extend the deadlines for claims and data submission by three and six months respectively after the last date on which such claims may be submitted to the Part D plan for payment by other parties.

PCMA Recommendation: *CMS should add a provision in the Rule extending the time period for Part D sponsors to (i) submit claims for payment reconciliation to three months after the last date on which Part D plans are required to accept such claims from*

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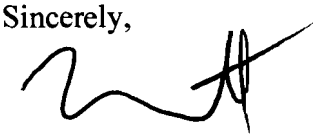
[9] Federal Register / Vol. 70, No. 18 at 4309 / Friday, January 28, 2005 / Rules and Regulations
[10] *ibid*
[11] *ibid*

other parties, and (ii) submit other data for reconciliation to six months from the last date on which Part D plans are required to accept claims for payment from other parties. This will ensure that Part D sponsors are provided the three and six month time periods that CMS intended for them to be able to submit claims and other data for payment reconciliation so that they are able to obtain the reinsurance and risk corridor subsidy payments on these claims as Congress directed.

On behalf of PCMA, I appreciate the opportunity to comment on proposed rule CMS-4130-P. PCMA looks forward to continuing to work with CMS to ensure a successful Part D benefit.

Sincerely,



Mark Merritt
President and Chief Executive Officer

LTC
Long Term Care
Pharmacy Alliance

July 24, 2007

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-4130-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Comments on Proposed Regulation: Policy and Technical Changes to the Medicare Prescription Drug Benefit

Dear Ms. Norwalk:

The Long Term Care Pharmacy Alliance, which represents long term care pharmacies serving over one million of the nation's nursing home residents, is pleased to present the following comments on the CMS proposed rule, CMS-4130-P, published in the Federal Register on May 25, 2007. While we appreciate the context in which CMS is proposing "technical corrections" to the January 2005 Part D Final Rule, the proposed changes, accompanied by the CMS "statement of intent" related to the CMS Marketing Guidelines, goes far beyond what the Administrative Procedures Act and law permit the Agency to do. Thus, we respectfully request that CMS withdraw its "statement of intent," and work to revise the Marketing Guidelines themselves. We have also provided comments on other aspects of the Rule below.

Comments on Section II A. Subpart B – Eligibility and Enrollment (Marketing Guidelines)

Background – The Proposed Rule: In this section, appearing at 72 Fed. Reg. 20403, 29404-29405 (May 25, 2007), CMS addresses two related but distinct issues regarding the "marketing" of Part D plans by pharmacies and providers: (1) plan selection advice and assistance given to beneficiaries by providers; and (2) marketing materials presented to beneficiaries by providers. In the first part of this section, CMS attempts to resolve the conflict between the Part D Final Rule which states it is "appropriate to allow providers and pharmacies to *market* to beneficiaries" and its subregulatory guidance Marketing Guidelines which prohibit *marketing* by providers defined as "[s]teering or attempting to steer an undecided potential enrollee towards a plan, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities."

CMS recognizes that by requiring Part D plans to enforce the *marketing* prohibitions of the subregulatory Marketing Guidelines on its subcontractor pharmacies, it has technically instructed plans to act in conflict with the language of Part D Final Rule, which allows *marketing* by pharmacies. (Of course, the Final Rule

was promulgated through notice and comment rulemaking.) In this notice, CMS attempts resolve this problem by stating that the subregulatory Marketing Guidelines prohibition on "marketing" and the Marketing Guideline's definition of "marketing" is its actual policy, now being codified in rulemaking.

CMS then goes on to clarify its "intent' that the Marketing Guidelines definition of *marketing* does not prohibit providers and pharmacies from "assisting in enrollment" or "education" and that the Guidelines "encourage providers to assist beneficiaries in objective assessments of the beneficiaries needs, and education." While CMS concludes by stating it is seeking to "clarify this policy in this proposed rule so as to avoid any confusion...," CMS does not explain why it is necessary to make this change via notice in a different rulemaking, rather than amending or clarifying its subregulatory Marketing Guidelines.

The CMS Marketing Prohibitions Are Unworkable In Long Term Care: Like the Marketing Guidelines. The CMS clarification also suffers from being unworkable in long term care. Most long term care (LTC) or nursing home residents are Medicare and Medicaid "dual eligibles' who because of their poor physical and mental condition, did not choose their own Part D prescription drug plan (PDP). Instead, most were auto-enrolled randomly into any one of number of Part D plans based on the sole criteria that a plan be below the financial cost "benchmark" determined by Center for Medicare & Medicaid Services (CMS). Because the auto-enrollment process did not attempt to match beneficiaries with the below benchmark plans that best covered their medications, many were assigned plans that do not cover all of their drugs or impose particularly burdensome requirements such as filing for exceptions and appeals; or working through drug utilization management tools such as prior authorization, step therapy or "fail first" policies to receive drug coverage.

Part D was primarily designed with the non-institutional senior population in mind. For the most part, it does not take into consideration the frail mental and physical condition which limits nursing home beneficiaries' capacity to "shop" for a Part D plan. Consider the special needs of nursing home Part D beneficiaries as analyzed in-depth by University of Washington professors Nancy Morden and Louis Garrrison in a 2006 article published in the journal *Health Affairs*:[1]

> *The 1.6 million dual eligibles residing in nursing homes are the sickest subset of beneficiaries. Six-to eight-tenths of these residents are mentally impaired. In contrast to the community-dwelling population, whose dominant mental disorders are psychiatric, mental impairment in this generally older population is largely the result of organic brain conditions such as Alzheimer's disease and other dementias. In 2000, average health spending for institutionalized dual eligibles was more than four times that of their community-dwelling counterparts ($44,600 versus $10,900). In the same year, nursing home residents in general received, on average, 9.4 medications per day, almost twice the number (5.0) used by those in the community with drug coverage. ...*
>
> *Under Medicaid, except for a minority in managed care, dual eligibles did not choose their prescription plans: They received the one plan offered by their state. Under Part D they may select a PDP. To ensure that there is no temporal gap in prescription coverage, the CMS automatically and randomly enrolled dual eligibles in a PDP in September 2005. The transition of benefits occurred 1 January 2006. Dual eligibles may change plans at any time under the special enrollment period (SEP) provision. Although random enrollment initially minimized the opportunity for favorable selection by PDPs, negative effects could result from the complexity of ongoing plan selection and the fact that initial plan assignment was random, with no consideration of current or future medication needs.*

[1] Nancy Morden and Louis Garrison, Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare, *Health Affairs*, March 2006

Beneficiaries with limited mental abilities will likely need ongoing assistance evaluating and selecting plans. If the process of selecting and changing plans proves prohibitively complex, dual eligibles may remain with the plan to which they were initially assigned, leaving their coverage match to chance.

Alternatively, if plan enrollment and disenrollment are easy, the SEP provision could result in frequent plan changes by dual eligibles in response to confusion, prescription needs, or access hurdles designed to encourage disenrollment and achieve favorable deselection.

For the institutionalized, transition and access concerns are magnified. The prevalence of mental limitations and high rates of polypharmacy complicate the plan selection process and augment PDPs' incentive to avoid this population.

Under Part D, nursing homes continue to manage drug purchase and procurement from pharmacies on behalf of beneficiaries. Beneficiaries or their guardians, however, must manage plan selection. Debilitated nursing home residents will be challenged by choosing a plan and may consequently keep their random plan assignment, however appropriate the match. For this frail population, medication changes and interruptions are especially disruptive. The elderly are more susceptible to and less tolerant of medication side effects than other populations are. They are more likely than others to be adversely affected by access restrictions that limit their options or require a trial of drugs with greater potential for side effects or interactions with other drugs. (emphasis added)

A January 2006 report issued the U.S. Department of Health and Human Services Office of the Inspector General (OIG)[2] found that plan offerings for dual eligible beneficiaries vary widely:

Prescription drug plan formularies include between 76 and 100 percent of the commonly used drugs we reviewed. The PDP formularies vary in their inclusion of the 178 common drugs in our review that are eligible for PDP coverage. Therefore, random assignment to PDPs may affect the number of dual eligibles who take a specific drug that is not included on their PDP's formulary. Formulary inclusion of the 178 commonly used drugs ranges from a low of 135 drugs (76 percent) to a high of 178 drugs (100 percent). Nineteen percent of formularies include all 178 of the Part D eligible drugs we reviewed; an equal proportion include 151 or fewer (less than 85 percent). By formulary, the average rate of inclusion is 92 percent of these commonly used drugs.

It is important to note that dual eligibles who take drugs not included by their PDP's formulary may obtain a prescription for a different drug that treats the same condition, apply for an exception if the nonformulary drug is medically necessary, or switch to a PDP that includes their drug. CMS has urged PDPs to cover a one-time supply of the nonformulary drug to aid in this transition. Nationally, almost one-fifth of dual eligibles (18 percent) are assigned to PDPs that include all 178 drugs in our review. On the other hand, almost one-third of dual eligibles (30 percent) are assigned to plans that include less than 85 percent (151 or fewer) of the 178 commonly used drugs. In every PDP region, at least one plan uses a formulary that includes all 178 of the high utilization drugs in our review. This means that every dual eligible has the opportunity to enroll in a plan that includes all of these commonly used drugs. (emphasis added)

In February, 2007 LTCPA released an analysis[3] of how well all below benchmark plans cover a common set of drugs prescribed in the LTC setting. Like the OIG, LTCPA found that a beneficiary randomly assigned a plan was more likely to be enrolled in a plan that did a poor job of covering their medications, while in each region there are plans available that would do a very good and much better job of covering a

[2] Office of the Inspector General, U.S. Department of Health and Human Services, Dual *Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs.* January 2006

[3] Long Term Care Pharmacy Alliance, State by State Formula Variability in Medicare Prescription Drug Plans for Auto-Assigned Long-Term Care Residents, February, 2006, www.ltcpa.org

beneficiary's medicines than the plan to which they were auto-enrolled. Simply put, the marketing limitations imposed by CMS are simply inappropriate for the long term care population which CMS purports to be serving.

CMS Has Failed to Acknowledge that the Marketing Guidelines Continue to Have A Negative Impact On the Cost and Effectiveness of the Part D Program:

CMS has failed to recognize that the Marketing Guidelines also negatively impact the Part D Program, both financially and from a program integrity perspective. Although the Part D program caps the cost for duals by only paying for plans that are below a financial benchmark, the added costs assumed by PDPs and care providers as a result of problems creating by the failure of beneficiaries to be matched to the below benchmark cost plans offering the best coverage for a particular beneficiary will ultimately be passed on to the Part D program and the people who fund it, the taxpayers. Also, when nursing home beneficiaries do not receive the best medication in a timely matter, the end result can be even more costly to the program and the beneficiary, such as requiring a hospital visit.

The failure to match nursing home duals with the best matching plan has resulted in unequal and often inadequate drug coverage for many nursing home residents. It has put severe financial and administrative strain on providers such as LTC pharmacists, nursing homes, and physicians who have stepped in and assumed the burden of working through the difficult administrative procedures required to get drug coverage approved; or when approval is not granted, to assume financial liability for uncovered drugs. It has also driven up the cost of the Part D program to have PDPs engage in unnecessary administration of drug utilization management tools or require them to cover drugs for which they have not negotiated best prices with drug manufacturers. As a result, everyone – beneficiaries, care providers, and the Part D program would benefit by matching beneficiaries with the below benchmark plan that best matches the beneficiaries drug usage.

The biggest obstacle to this happening is the CMS Marketing Guidelines which prohibit those most familiar with LTC beneficiaries' drug usage – their care providers – from assisting beneficiaries in choosing and enrolling in a plan that best matches their drug usage. Many of Part D problems could be avoided if beneficiaries had access to substantive advice and assistance from their care providers in choosing and enrolling in the Part D plan that best meets their needs.

The Marketing Guidelines Undermine Congress' Design of a Market Driven Part D Program.

Congress designed the Part D program to use beneficiary choice and free market forces rather than government intervention in the marketplace to reduce costs and provide better service. For a number of reasons, those factors are absent from the nursing segment of the Part D population:

- Being primarily duals, nursing home beneficiaries do not pay for their coverage and have no financial stake in which plan they are enrolled in.
- Given their frail physical and mental condition, most nursing home residents lack the capability to "shop" for a plan on their own.
- One of the most important things to understand about a plan – its drug utilization tools – are not readily available or would be difficult for most beneficiaries to understand without the aid of their care providers.

- Generally, when problems arise with drug coverage, it is providers rather than beneficiaries who typically assume the administrative and financial responsibility for dealing with the problems.

For the most part, plans did not compete for nursing home beneficiaries; they received them automatically and randomly. As a result, there has been little incentive to tailor a plan to meet the needs of nursing home beneficiaries and there is little opportunity for plans to effectively market to them. Thus, there is essentially no market mechanism in the nursing home segment of Part D as a result of the Marketing Guidelines. Further, because PDPs also have little opportunity to either gain or lose nursing home beneficiaries under the current CMS marketing restrictions, there is little market incentive for plans to provide better customer service to either beneficiaries or their care providers. In fact, with little risk of losing a beneficiary, the financial incentive for a plan is to make drug coverage less available.

Market discipline – the likelihood of gaining or losing customers based on cost and service – is absent for the nursing home segment of Part D. In the absence of market discipline, the federal government via CMS has had to step into try to resolve problems and micromanage the administration of the program. Stated differently, if care providers were allowed to assist nursing home beneficiaries, it would bring market forces into play. With the ability of duals to switch plans monthly, plans would have to be more responsive to beneficiaries and their care providers. They would have incentives to solve problems that currently necessitate government intervention. It would also create an opportunity for plans to better market their products to care providers, thus facilitating a better match-up of plans with beneficiaries' needs within the financial benchmark set by CMS.

In sum, the CMS Marketing Guidelines remove the very market forces Congress intended the Part D program use in place of government regulatory action.

The Proposed Rule Fails to Solve These Problems, And Instead Perpetuates an Unworkable Catch-22:

As CMS acknowledges in putting forth this proposed rule, its policies prohibiting care providers from assisting beneficiaries with plan selection and enrollment directly contradicts the January 2005 Final Rule. The Agency's belated attempts to 'clarify" its intent are a transparent effort to shoehorn the Marketing Guidelines into the Final Rule, and harmonize two conflicting requirements which cannot be reconciled. LTCPA requests that in the Final Rule CMS explicitly acknowledge that the Final Rule text has its ordinary and plain meaning, and that the Marketing Guidelines restrictions only apply when providers are acting directly as agents of Part D plans. Only by doing so will CMS eliminate the confusion that has resulted in care providers being uncertain and wary to the point of generally feeling their hands are tied, and that they are unable to provide the LTC residents with the assistance they need in selecting and enrolling in a plan that adequately covers their medications. We expand upon this request below.

Unfortunately, while CMS states in this rule that it is seeking to "clarify this policy in this proposed rule so as to avoid any confusion..." this proposed rule fails to do this. The fundamental problem with CMS's Marketing Guidelines policy, further advanced in this proposed rule, is that it does not address the unworkable conflict between CMS "intent' that the Marketing Guidelines encourage care providers in "assisting in enrollment" and "education" and "encourage providers to assist beneficiaries in objective assessments of the beneficiaries needs, and education," – and its prohibition on *marketing* defined as "[s}teering or attempting to steer an undecided potential enrollee towards a plan, and for which the

individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities."

Paraphrased, CMS' policy this rule is intended to clarify essentially says that it's OK for a provider to assist a resident as long as it doesn't "steer" beneficiaries into plans for which the provider has any financial interest. CMS fails to acknowledge that the beneficiary's clinical interest and the provider's financial interest typically align. Because the provider runs the risk of not getting paid for drugs dispensed that are not covered by a Part D plan, it has an indirect financial interest in seeing the beneficiary enrolled in the plan that best covers the beneficiary's drugs.

Another problem with the proposed rule language from the Marketing Guidelines is the prohibition on compensation provided "directly or indirectly" to providers by plans. Direct compensation of providers for enrolling beneficiaries in a particular plan – i.e. kickbacks – are currently prohibited by law and can be clearly defined based on existing law. LTCPA supports that prohibition as do most providers. However, "indirectly" is far too vague a term. If, for example, a pharmacy or nursing home "steers" or assists a beneficiary in enrolling in a the plan that best covers their medicines, it receives the "indirect" financial benefit of not having to risk dispensing an uncovered medication. Likewise, it could be argued that a care provider has an indirect interest in seeing a beneficiary enrolled in a plan with fewer restrictions to access to medications, thus less administrative costs and problems. In such cases, the beneficiary's needs would be served by the care provider also acting in its own interest – a very "market" solution to a problem.

Similarly, the admonition of the CMS Marketing Guidelines that pharmacies can provide "objective" information is similarly vague and made meaningless by the prohibition on recommending plans for which the provider has an "indirect" interest. As long as that prohibition exists, the provider will likely fear running afoul of the Marketing Guidelines by even providing "objective" information, education and assistance to the beneficiary in enrolling in a plan that also serves the providers interest seeing the beneficiary's drugs best covered.

In sum, the current policy, which CMS appears to be attempting to codify in this proposed rule, creates the following Catch-22: the policy urges care providers to provide assistance to ensure the beneficiary is enrolled in a plan that best meets their needs, but then prohibits them from providing such assistance if it also indirectly benefits the care provider, thus prohibiting care providers from assisting beneficiaries in enrolling in plans that best cover their medicines, which, of course, is also in the financial interest of the care provider.

The end result of this policy – and this rule - is to allow confusion to continue, thus effectively prohibiting care providers from assisting beneficiaries in selecting and enrolling in the best available plan, resulting in hundreds of thousands of Part D beneficiaries being unnecessarily left in plans that fail to cover their medicines – even when such plans are readily available to be enrolled in under the Part D program rules.

Recommendations:

CMS should withdraw the Marketing Guidelines restrictions on care providers.. At a minimum, CMS should modify the Marketing Guidelines and its policy to clarify and clearly state that providers can assist beneficiaries in evaluating, choosing and enrolling in a Part D plan, unless there is a direct financial conflict

of interest as defined by the current federal anti-kickback law.[4] It should also clarify the that the Marketing Guidelines restrictions do not apply when the provider is not acting on behalf of a Part D plan.

Issue 2: Legal Objections to the Marketing Guidelines, and the CMS Policy "Clarification"

In addition to its policy flaws, the Marketing Guidelines restrictions on providers also suffer from multiple legal insufficiencies, any one of which would require that they be withdrawn (and, taken together, illustrate their patent illegality). There are at least three legal reasons why the Marketing Guidelines are in violation of law: (1) they are not authorized by the MMA; (2) they are in conflict with the First Amendment Free Speech Guarantees; and (3) they were not promulgated under notice and comment rulemaking. Each of these points is addressed below.

a. The Marketing Guidelines Are Not Authorized by Law. The Agency's preamble addresses 42 CFR 423.50, which itself is predicated upon MMA Section 1860D-1(b)(1)(B)(vi) of the Social Security Act (the "Act"), which directed CMS "to use rules similar to those established under Section 1851 of the Act to review PDPs' marketing materials and application forms." 72 FR at 4221 (January 28, 2005). Section 1860D-1(b)(1), and correspondingly Section 1851, however, required Marketing Guidelines for Medicare + Choice (today Medicare Advantage) plans consistent with the standards set out in Section 1856, which only allowed CMS to establish "standards ... for Medicare + Choice organizations and plans" which are consistent with Part C. Importantly, there is no statutory language or any other provision of Part C that allowed CMS to implement restrictions on providers, rather than plans. Further, the statutory "standards established under Section 1876 to carry out the analogous provisions of such section" contain only restrictions on plan marketing activities, not restrictions on providers when they act independent of plans. See 42 CFR Part 417, particularly 42 CFR 417.428 (Marketing Activities). Indeed, the preamble to the regulation makes explicit that the Meedicare+Choice marketing guides are restricted to only plans, and do not affect providers. 65 FR 40170, 40196 (June 29, 2000). Indeed, the regulatory preamble makes clear that providers may discuss the relative benefits of different health plans when asked by their patients, as "entirely appropriate within the doctor-patient relationship". There is absolutely nothing which prohibits provider activities, particularly "steering", when the provider is acting independent of the plan.

LTCPA has no objection to the language of the amended Section 423.50 as proposed by CMS, since, like the existing regulation, it is explicitly addressing Part D plans, and not providers. However, LTCPA strongly objects to the unauthorized expansion of the Marketing Guidelines to providers as well – particularly when providers are acting independently of any Part D plan sponsor. For that reason, we request that CMS clarify, consistent with its statutory authority, that its do not restrict providers from communicating with Part D beneficiaries and potential beneficiaries about Part D plan alternatives, so long as the providers are not doing so as part of a Part D plan sponsor's marketing activities. Further, CMS should amend the Marketing Guidelines to provide that all of the provider restrictions are eliminated so long as they are activities independent of a part D plan.

b. The Marketing Guidelines Conflict with Constitutional Free Speech Guarantees: As CMS is well aware, its clarification of existing regulation is required due to the Marketing Guidelines' extensive limitations on the types of statements that pharmacies, including long term care pharmacies, may make concerning the PDP Plans for which they are (or are not) in network. However, the Guideline's provider limitations also conflict with Constitutional free speech principles. *Thompson v. Western States Medical Center ("Western States")*, 535 U.S. 357 (2002). The Supreme Court's *Western States'* rationale is directly applicable to the

[4] 42 U.S.C. 1320a-7b(B).

Marketing Guidelines restrictions, in that the federal restriction is overbroad, and is not narrowly tailored to the federal interest. Indeed, CMS's articulated and explicit rationale for the Guidelines' restrictions is precisely the type of "paternalistic" considerations that courts routinely reject in commercial free speech cases. Thus, the provider limitation should be withdrawn for this additional reason as well.

The First Amendment's Free Speech clause[5] limits CMS's ability to restrict commercial free speech. *Western States, supra; Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980); *Virginia St. Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976) (striking prohibition on pharmacy drug price advertising). In *Western States*, for example, the Supreme Court rejected Congress' compounded drug advertising ban based upon Congressional concerns that such drugs had not undergone FDA approval and therefore ought not to be widely available. In a 5-4 decision, the Court found that the FDAMA's advertising ban was too broadly drawn to meet the legitimate government concern, and therefore was unconstitutional.

LTCPA is aware of CMS's view that the "potential" for misleading speech justifies its restrictions -- in the words of the Guidelines, there is the risk that provider might offer "recommendations that do not address all of the concerns or needs of a potential Plan enrollee." (Guidelines at page 125.) CMS, however, has not cited to any actual false statements, and its sweeping limitations prohibit true speech just as they prohibit misleading speech. Thus, while CMS's rationale is sufficient to support prong two, and to demonstrate that CMS has an interest in regulating the speech at issue, the Guidelines do not present any actual misleading or false speech that CMS has prohibited. There is no dispute that marketing PDPs is a lawful activity and can be done in ways that are not misleading. Indeed, the PDPs themselves are allowed to undertake precisely such marketing activities, even through the same potential "misleading" of beneficiaries exist. Thus, the first two prongs will likely be answered affirmatively here.

Importantly, the *Western States* decision emphasized that that the suppression of commercial free speech in the name of "protecting" patients or paternalism would not stand. The Court demonstrated a strong preference for the use of disclosure (more speech) as a less restrictive alternative to resolve concerns that a speech may be misleading or inherently self-serving. Clearly, the majority believed that disclosure could cure potentially misleading speech:

> Even if . . . FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. Aside from the fact that this concern rests on the questionable assumption that doctors would prescribe unnecessary medications . . . [it] amounts to a fear that people would make bad decisions if given truthful information . . . . *We have previously rejected the notion that the Government has an interest in preventing the*

[5] "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of people peaceably to assemble, and to petition the Government for a redress of grievances." U.S. Constitution, Amendment I. The First Amendment applies to agency actions as well as Congressional enactments. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1990) (rejecting on First Amendment grounds mandatory FDA disclaimers imposed by regulation).

dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.

535 U.S. at 374.

In the case of the Guidelines, CMS has not demonstrated that there are no other alternative means of prohibiting pharmacies from 'steering" beneficiaries based upon financial motive or health information. In fact, CMS has correctly pointed to the numerous statutory and regulatory prohibitions on precisely that conduct. (Guidelines at pages 125-29) (referencing the anti-kickback statutes and HIPAA, among others). Further, the Guidelines prohibit a qualified long term care pharmacy from properly educating its possible enrollees with true information that would best assist them to ensure a timely receipt of their medications. While CMS expresses concern that qualitative information from providers might "confuse the beneficiary," the Supreme Court has rejected that concern as sufficient to deny speech: "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Western States* at 374; *see also Kitsap County v. Mattress Outlet*, 153 Wash.2d 506 (2005) (striking zoning ordinance restricting businesses from offset advertisements); *Walker v. Flitton*, 364 F. Supp. 2d 503 (M.D. Pa. 2005) (striking prohibition on unlicensed funeral directors marketing funeral services). Thus, applying a *Western States/Central Hudson* analysis, the Guidelines are an impermissible infringement on the free speech rights of both pharmacies and nursing homes.

This Rule is Another Example of CMS' Attempt to Regulate by Subregulatory Guidance and Contracting Requirements Rather than Clear, Direct Rulemaking:

Not only are the Marketing Guidelines prohibitions advanced by this proposed rule inherently contradictory, confusing and counterproductive, the process by which they have been advanced and enforced is of tremendous concern as well. As noted in the rule itself, CMS feels it must file this proposed rule because the language of its own subregulatory guidance, the Marketing Guidelines, conflicts with the official Final Rule of the Medicare Program. It is not clear why CMS would be using rulemaking to correct its subregulatory guidance. Changing such guidance does not require changing the Final Rule. On the other hand, if the intent of CMS in proposing this rule is to codify a significant regulatory policy that only exists in the subregulatory Marketing Guidelines, then this it is clearly not a "technical correction" but a highly significant change that should be fully outlined in detail and fully subject to public notice and comment.

A proposed rule is not an appropriate venue to address the Marketing Guidelines. Under the Administrative Procedures Act, CMS is prohibited from promulgating enforceable policies through subregulatory guidance documents. Rather, to the extent that CMS is articulating enforcement policies, they can be adopted only following notice and comment rulemaking in compliance with the Administrative Procedures Act. 5 U.S.C. § 551, *et seq. see also Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C.Cir.1997) ("[I]nterpretative rules and policy statements are quite different agency instruments. An agency policy statement does not seek to impose or elaborate or interpret a legal norm. It merely represents an agency position with respect to how it will treat--typically enforce--the governing legal norm."). Thus, in compliance with law, CMS should delete any references to the Marketing Guidelines or any other subregulatory guidance as enforceable legal norms. Under the law, as exemplified by the conflict they create with existing promulgated rules, the Marketing Guidelines cannot prevail, much less constitute enforceable rules.

This need for this proposed rule highlights the frequent and excessive use by CMS of enforcement of subregulatory guidance on third and even fourth party subcontractor providers, such as pharmacies and nursing homes by means of CMS's contracting with PDPs. As noted, pharmacies, other providers and beneficiaries have had the Marketing Guidelines restrictions – a subregulatory guidance – held over their heads by CMS since the fall of 2005 when enrollment in the new program began, even though CMS now acknowledges in this proposed rule that the Guidelines conflict with the official Part D final rule – thus the need for this "technical correction."

CMS has gone even further in attempting to enforce these guidelines on nursing homes, which do not have contracts with Part D plans. In a May 2006 letter to State Survey Agency Directors, the CMS Survey and Certification Director instructed state nursing home regulators that:

> "Under no circumstances should a nursing home require, request, coach, or steer any resident to select or change a plan for any reason. Furthermore, a nursing home should not knowingly and/or willingly allow the pharmacy servicing the nursing home to require, request, coach, or steer any resident to select or change a plan [42 C.F.R. §483.12(d)]. Nursing homes may, and are encouraged to, provide information and education to residents on all available Part D plans. ...[6]

In this case, CMS is using state nursing home regulators to enforce on nursing homes a subregulatory guidance, the Marketing Guidelines, which it acknowledges by this rule conflicts with its own Part D Final Rule, on nursing homes, which do not receive any funding directly or indirectly from the Part D program. Further it is attempting to force nursing homes – which again do not receive compensation from the Part D program, to enforce CMS subregulatory guidance on other providers such as pharmacies or physicians.

In this rule, CMS appears to be trying to formalize part of its Marketing Guidelines, rather than subjecting the entire policy to scrutiny. That violates good rule making practice and appears to be an indirect attempt to use formal rulemaking to indirectly validate subregulatory guidance. The Marketing Guidelines themselves have not been subject to formal notice and comment rulemaking, and have not been subject to formal public input. Nor have they been subject to the level of review and comment by the Office of Management and Budget's Office of Information and Regulatory Affairs that they would receive if they were formal rules. Although as "guidance" the ability of CMS to actually enforce them on providers directly is uncertain, CMS has avoided this scrutiny by forcing PDPs to force providers to adhere to them via their contracts. To comply with its legal obligations, CMS should withdraw the Guidelines and the "clarification" in its proposed rule.

Second Part of Section II A. Part B: Marketing Materials Presented to Beneficiaries by Providers.

As noted earlier, the Marketing Guidelines have been a tremendous obstacle to providing LTC beneficiaries with the information and assistance they need to enroll in an appropriate Medicare Part D plan. For that reason, we appreciate the fact that CMS has taken the first small step in recognizing that providers, in presenting materials and information about plans with which the provider does not have a contract, are not obligated to provide information on all plans, but instead just the plans with which they contract. Clearly, in the nursing home setting, where there is typically only one pharmacy servicing the facility, it would not make sense for CMS to require for a provider to assist or encourage a beneficiary in enrolling in a plan that does not have a contract with the pharmacy used by the facility. In that regard, this is an improvement over the current guidance.

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[6] See CMS memo "Nursing Homes and Part D," CMS Director of Survey and Certification Group, May 11, 2006.

However, the language in this section refers to the Marketing Guidelines restrictions as enforceable guidelines on educating beneficiaries in the health care setting. It specifies instances where a Part D plan uses providers to provide information and comparisons about Part D plans. The bigger problem is this section of the Marketing Guidelines is that it also asserts it applies to nursing homes, medical directors and other long term care providers which are not in fact Part D contractors or do not act on behalf of a plan:

> *As used in specific guidance about provider activities, the term "provider" refers to all providers contracted with the plan and their sub-contractors, including but not limited to: pharmacists, pharmacies, physicians, hospitals, and long-term care facilities. The plan sponsor shall ensure that any provider contracted with the plan (and its sub-contractors) or agent (or its sub-contractors) performing functions on the plan sponsor's behalf related to the administration of the plan benefit, including all activities related to assisting in enrollment and education, agrees to the same restrictions and conditions that apply to the plan sponsor through its contract, and shall prohibit them from steering, or attempting to steer an undecided potential enrollee toward a plan, or limited number of plans, offered either by the plan sponsor or another plan sponsor, based on the financial interest of the provider or agent, (or their subcontractors). (Marketing Guidelines page 123)*

It is a far-reaching abuse of CMS regulatory enforcement to attempt to enforce subregulatory guidance not only on Part D subcontractors, but sub-sub-contractors as well. Indeed, it presumptively characterizes the Guidelines as illegally promulgated regulations. In this case, CMS is using its contracts with PDPs to attempt to enforce subregulatory policies not only on pharmacy subcontractors which have contracts with Part D plans, but on the nursing homes which have a contract with a pharmacy, but not a PDP, and physicians which typically have neither a contract with a Part D plan or a pharmacy, and in many cases don't even have a contract with a nursing home.

CMS has no authority under the Medicare Modernization Act, particularly in light of the non-interference clause, to extend its regulatory reach that far, especially for subregulatory guidance.

Recommendation: CMS should further clarify that the Marketing Guidelines prohibitions do not apply if a provider is not acting on behalf of Part D plan. It should also be further clarified that nursing homes, medical directors and other providers which do not receive direct compensation from Part D plans are not subject to the Marketing Guidelines restrictions.

ADDITIONAL COMMENTS

Subpart C

Definition of Long Term Care Facilities. (page 29406 of the notice)
LTCPA supports CMS' proposal to include institutions for mental disease (IMD) in the definition of Long Term Care Facilities. LTCPA also recommends CMS make the appropriate changes necessary to ensure that residents of assisted living facilities also receive the benefits granted to long term care residents under the Part D program.

Adequate Access to Home Infusion (page 29408 of the notice). LTCPA is pleased CMS is acting to guarantee access to home infusion under Part D. LTCPA believes it would be better to require that beneficiaries have access to home infusion by the time their next dosage is due, rather than within 24 hours as proposed in by this rule.

Thank you for your consideration of our comments.

Sincerely,

Darrell McKigney
Executive Director
Long Term Care Pharmacy Alliance
1776 Massachusetts Avenue, Suite 410
Washington, D.C. 20036
(202) 386-7559
dm@ltcpa.org

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One Express Way
St. Louis, MO 63121
314-692-1991

July 24, 2007

Leslie Norwalk
Acting Administrator
Center for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

File Code: CMS-4130-P

Dear Acting Administrator Norwalk:

Express Scripts appreciates the opportunity to submit comments in response to the Notice of Proposed Rulemaking (NPRM) with regard to the Policy and Technical Changes to the Medicare Prescription Drug Benefit.

Express Scripts, Inc. is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to over 50 million patients through facilities in 13 states and Canada. Express Scripts serves thousands of client groups, including managed-care organizations, insurance carriers, third-party administrators, employers and union-sponsored benefit plans. Express Scripts is headquartered in St. Louis, Missouri.

Comments on: NEGOTIATIED COSTS, ADMINISTRATIVE COSTS, and GROSS COVERED PRESCRIPTION DRUG COSTS

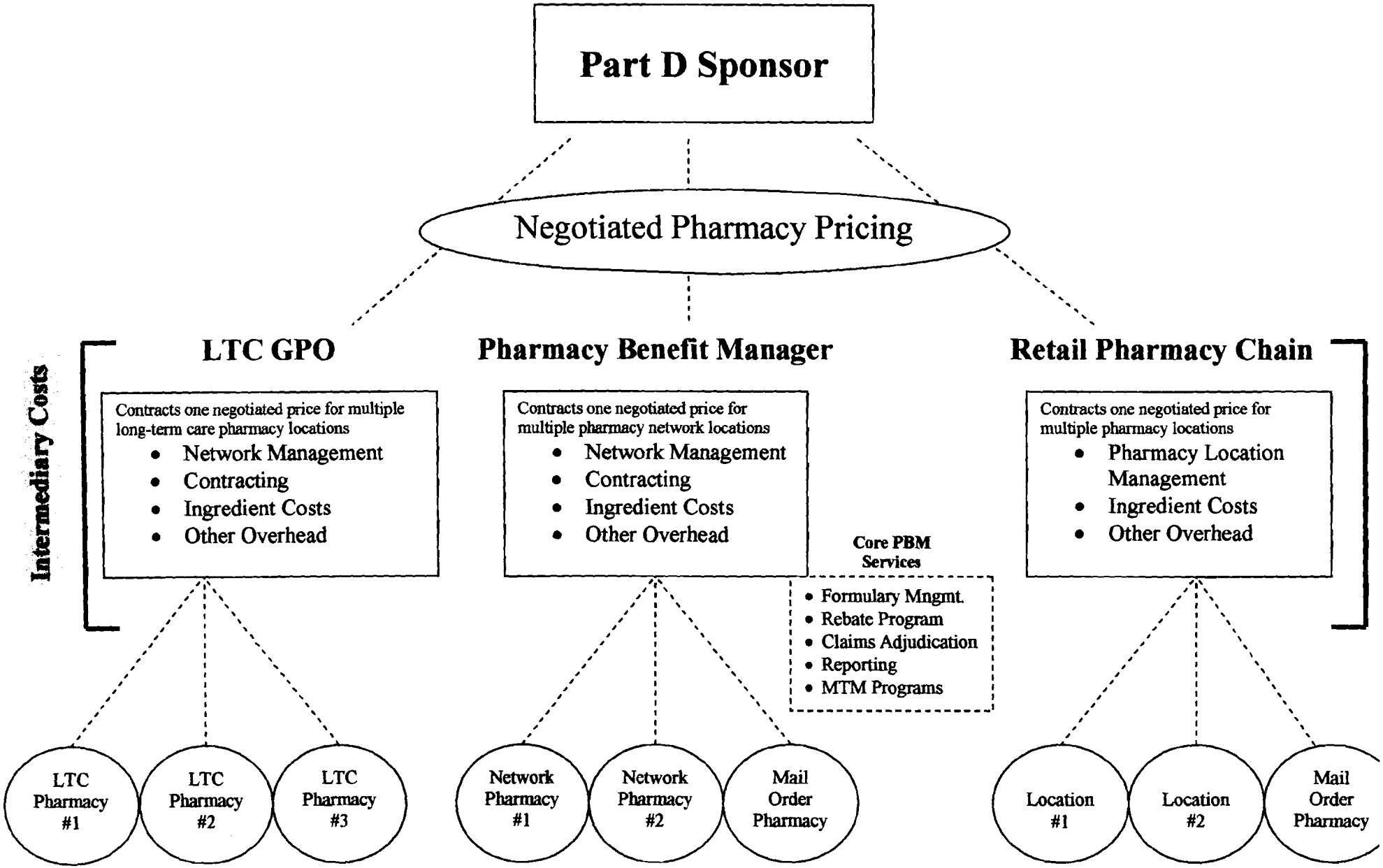
Express Scripts is commenting on all three of these areas in tandem because they all relate to CMS's proposal to eliminate Part D plans sponsors from using the "lock-in" method when contracting for its retail network. While we sympathize with CMS' desire to clarify to PDP plan sponsors what is administrative versus drug costs so that the Part D sponsor can appropriately exercise their authority and responsibility to accurately report drug costs, for the reasons stated below, we strongly oppose the policy change CMS proposes in this rule.

CMS proposes in the rule to implement a definition of "gross covered prescription drug costs" that would only allow actual amounts paid to the pharmacy to be counted as allowable costs. Specifically, the proposed rule would disallow PBM's core network contracting function to be allowed as a drug cost and would require that it be accounted for in the administrative costs. In essence, CMS is proposing that PBM lock-in pricing be considered part of the administrative

part of a Part D sponsor's bid. While there are commercial prescription drug benefit plans that are administrative/pass-through models, the overwhelming majority of the commercial marketplace continues to use a lock-in PBM pricing model. In fact, for Express Scripts' largest commercial clients, 96% have availed themselves of lock-in pricing. And, for good reason: it is financially better for the plan sponsor and it properly incents the PBM to work on behalf of its client to continue to reduce prescription drug costs. As Congress established the Medicare Part D program to operate similar to commercial, competitively-bid prescription drug plans, we strongly believe that mandating an administrative pass-through model would be contrary to the intent of Congress and would increase the costs of the Medicare program in the long term.

A PBM performs several services for its clients: both core PBM services such as formulary management, rebate reporting, claims adjudication, and MTM programs; as well as services that are akin to a GPO such as network management, contracting, ingredient costs and other overhead. Clearly the core PBM services are defined in the Medicare statute as being administrative in nature. However, when a PBM is contracting for one negotiated price for multiple pharmacy network locations, it is functioning similar to a long-term care GPO or a large retail pharmacy chain. In short, the "spread" or markup between the rates negotiated by pharmacies in a PBM's provider network, on one hand, and the rates negotiated between a PDP and its contracted PBM, on the other hand, should not be characterized as administrative costs but should, instead be viewed as part of the drug supply chain cost. This cost markup is analogous to the markup charged by a wholesaler to a retailer – it simply becomes part of the total drug cost as it passes through the supply chain.

MARKET RELATIONSHIPS



Should CMS mandate that this markup be included in the administrative costs of a plan bid, it will:

- Increase beneficiary premiums and federal government direct subsidies;
- Lead to de facto pass-through retail pricing, removing incentives for PBMs and Part D plans to continuously contract for better rates;
- Once the market is pass-through pricing, create perverse incentives for plans to leverage Medicare business to obtain more aggressive commercial rates at the expense of Medicare; and
- Have a disproportionately negative impact on smaller Part D plans and independent community pharmacies.

CMS has a reasonable alternative to promulgating this sweeping policy change. Specifically, CMS can continue its current policy of allowing plans to confidentially attest whether they are using pass-through or lock-in pricing in their bid. CMS could then monitor the bids over time and compare the lock-in model to the pass-through model to ensure the lock-in model does in fact lead to lower overall costs to the program without picking a business model winner in the marketplace. Such reasonable alternative would cause no disruption in the marketplace.

Proposed Policy Will Increase Beneficiary Premiums and Direct Subsidy Payments

As noted by CMS in its June 22, 2006, guidance regarding its May 19th Q&A on PDEs, under a pass-through approach, "the total amount of the [PDP's] bid will likely increase." This is because, in order to realize an appropriate profit for its services, a PBM will increase its fixed charges to the PDP if it can not retain the economic value of the difference between its pharmacy network rates and its client's negotiated rates for ingredient costs. The increased fixed charges will fall into the administrative fees category which will directly increase the premium charge for all beneficiaries, supplemented by CMS through the direct subsidy payments. In the short run, particular beneficiaries will realize lower cost-sharing payments where the pharmacy network rates are lower than the PDP's rates, which should, in turn, reduce the federal reinsurance payout slightly. However, the PDP bid increases will exceed the potential cost reductions, due to the fact that beneficiary cost sharing will be reduced, thereby negatively impacting the CMS budget. In addition, beneficiaries are far more price sensitive to premiums when choosing a plan. Even modest increases in premium will cause healthy beneficiaries to forgo coverage thereby negatively impacting the risk pool, which could perpetuate further increases in premiums.

In the following charts, we illustrate how moving pharmacy lock-in costs from the drug ingredient costs to administrative costs will increase both the direct subsidy costs to the government as well as increase premiums.

Direct Subsidy and Beneficiary Premiums Will Increase Due to Decrease in Copays

	Current Bid	Intermediary Changes	Proposed change
Gross Drug Spend	$ 200.00	$ (10.00)	$ 190.00
Beneficiary Cost Sharing (Copays, Deductibles, Donut Hole)	$ (100.00)		**$ (95.00)**
Rebates	$ (10.00)		$ (10.00)
Federal Reinsurance (net of rebates)	$ (15.00)		**$ (14.25)**
Net Drug Cost	$ 75.00		$ 70.75
Administration Expenses	$ 10.00	$ 10.00	$ 20.00
Target Profit (PDP)	$ 5.00		$ 5.00
Total Bid for Assumed Population	$ 90.00		
Estimated Part D Risk Score	$ 0.94		$ 0.94
Total Bid at 1.00 Risk Score Population	$ 95.31		$ 101.40

6.38% Incr.

Direct Subsidy	$ 71.01	$ 75.54
Estimated premium	$ 24.30	$ 25.86

Increases Could be Greater for Intermediaries Aggregating More Expenses into Drug Costs

	Current Bid	Intermediary Changes	Proposed change
Gross Drug Spend	$ 210.00	$ (20.00)	$ 190.00
Beneficiary Cost Sharing (Copays, Deductibles, Donut Hole)	$ (100.00)		**$ (90.48)**
Rebates	$ (10.00)		$ (10.00)
Federal Reinsurance (net of rebates)	$ (15.00)		**$ (13.57)**
Net Drug Cost	$ 85.00		$ 75.95
Administration Expenses	$ 10.00	$ 20.00	$ 30.00
Target Profit (PDP)	$ 5.00		$ 5.00
Total Bid for Assumed Population	$ 100.00		
Estimated Part D Risk Score	$ 0.94		$ 0.94
Total Bid at 1.00 Risk Score Population	$ 105.90		$ 117.50

10.95% Incr.

Direct Subsidy	$ 78.90	$ 87.54
Estimated premium	$ 27.00	$ 29.96

CMS and Beneficiary Economic Impact

- Potential increase of $2.2B - $3.8B in CMS costs, assuming budget of $35.0B*
- Beneficiary premiums could increase by up to $20 - $35 per year.
- Potential decrease in beneficiary participation and potential for adverse selection, due to premium increases

* Source: CBO's Cost Estimate for the Medicare Prescription Drug Benefit, Fiscal Years 2004 to 2013, (Estimate for Year 2007)

Proposed Policy Will Lead to De Facto Pass-Through Retail Pricing, Removing Incentives for PBMs and Part D Plans to Continuously Contract for Better Rates

The ability to lower trend in prescription drug spending lies in incenting PBMs to use their cost-saving tools to the fullest extent possible. That's why lock-in pricing is far more commonly chosen by clients in the private sector than the pass-through model. The unintended consequence of the proposed policy is that it would maintain the lock-in pricing option in name only while eliminating the very incentives PDPs have to use it. This would lead to lower generic utilization, less competition among "me-too" brands, weaker mail service penetration rates and other deficiencies that will mean higher costs for the program and seniors while offering no corresponding upside.

Technically, while the PDP must calculate and report the covered drug cost amounts on its PDEs using the pass-through method, this requirement does not, by itself, preclude the PBM from negotiating a financial arrangement with its PDP client such that the PBM will continue to retain the value of the spread between its negotiated pharmacy network rates and the rate paid to the PBM by its PDP.

Unfortunately, this attempt to separate the PDE reporting methodology used from the financial arrangement agreed to between a PDP and its PBM ignores the fact that PDPs receive reimbursement from CMS based on the PDE reported drug cost. Thus, if a PDP pays its PBM at a higher rate than the PBM is paying the network pharmacies, but receives Part D cost reimbursement based on the lower "drug cost" rates paid to the pharmacies, ever lower network pharmacy rates will continue to widen the gap between what a PDP pays out to its PBM and what it gets back through Part D reimbursement. Consider the following example:

[PDP-PBM rate = AWP-10%; PBM-pharmacy rate = AWP-15%; and the PDP agrees to let the PBM keep all the spread.]

On a $100 (AWP) drug, the PDP in this scenario will pay the PBM $90 but will report a "cost" of only $85 on its PDE. CMS will base the PDP's reimbursements on the lower PDE amount. Moreover, every effort made by the PBM to deepen its pharmacy network discount rates will exacerbate this loss of reimbursement to the PDP relative to its actual costs. A PDP in this predicament will quickly decide to revise its arrangement with the PBM such that its actual cost to the PBM matches exactly with the "costs" it must report for reimbursement purposes. Therefore, this proposed policy change may result in some first year savings (if PDPs do not react quickly), however in the following years, there are no savings and no pressure for rates to do anything but increase.

In light of the forgoing, it is easy to understand how the pass-through PDE reporting requirement will force all PBM/PDP arrangements toward a similar pass-through structure. Ultimately, this will result in a PBM market that, for Part D clients, competes only on the basis of the lowest possible fixed administrative fee. In this "commodity" market structure, PBMs will lose all incentive to invest valuable and limited time, energy and resources into efforts to obtain deeper pharmacy discounts for Part D clients.

If, on the other hand, a lock-in model continues to remain a viable option for Part D plans, PBMs can further negotiate pharmacy rates to lower overall program costs.

Proposed Policy Will Create the Perverse Incentive of Having Medicare Subsidize the Commercial Market

As stated above, if Medicare moves toward a pass-through pricing program, plans will compete on fixed administrative costs, and there will be little incentive to negotiate aggressive rates with pharmacies. However, it will also create the perverse incentive for large PDP sponsors to focus all efforts in their negotiations with pharmacies on getting the best price for their commercial books of business—at the expense of Medicare. For example, a large PDP sponsor could aggressively negotiate AWP-20% for commercial business in exchange for the pharmacy naming their preferred price on the Medicare population. In essence, the Medicare Part D program would be subsidizing the commercial market—the exact opposite intent of Congress.

This is of particular concern with larger PDPs that have ability to move market share. Pharmacies may feel they can not they can not afford to be out of their networks. We have been informed by some of our smaller, mid-sized clients that this alone could make their Medicare bid uncompetitive vis-à-vis the larger plans.

Proposed Policy Will Have a Disproportionately Negative Impact on Independent Community Pharmacies

Currently PBMs contract with tens of thousands of pharmacies at many different rates, but negotiate a standard plan rate with the PDP sponsor. Therefore, a PDP's beneficiaries pay the same negotiated plan rate as long as they use a network pharmacy (retail chain or independent).

By and large, PBMs are able—indeed, are willing—to negotiate more aggressive rates with larger retail pharmacy chains than with smaller, independent pharmacies for a variety of reasons (scale, presence, community, etc.) If the proposed policy takes affect, PBMs will have to allocate actual costs per pharmacy to their PDP clients whereas in the lock-in method, one plan rate covers the overages and underages of network contracting with pharmacies. The affect of this is that small, independent pharmacies will immediately be exposed to PDP clients as high-cost pharmacy providers. It naturally follows that PDP sponsors will want PBMs to narrow their networks as much as allowed by law to remove these high-cost providers or design their plans to pass on the burden of high cost providers to beneficiaries. The brunt of this network narrowing will be borne by the smaller, independent pharmacies. Combined with the impact of the latest changes in Medicaid reimbursement, independent pharmacies may be forced out of business.

Regulatory Impact Analysis

Pursuant to the Regulatory Flexibility Act (P.L. 96-354), agencies must assess the impact of regulations on small businesses, must solicit their concerns and must entertain significant alternative proposals which could achieve the objectives of the proposed rule at a lower cost to small entities. CMS in its rule states that such a regulatory flexibility analysis is not required as

this merely is implementing its previous policy, and since a full regulatory impact analysis was performed in 2005, that should suffice.

This logic is flawed. The disallowance of PDP sponsors to use a lock-in model for 2009 represents a significant policy change from previous bid years as illustrated by:

- CMS first issued this as guidance in May of 2006, just before bid submissions, but ended up retracting the guidance because they were rightfully concerned that it would disrupt the impending June bid submissions;
- In this proposed rule, CMS states its opinion that PDPs misinterpreted the definition of "intermediary" to include PBMs, thereby acknowledging many in the marketplace were using a lock-in versus pass-through pricing methodology; and
- CMS' 2005 regulatory impact analysis never addressed the issue of how this policy will impact smaller versus larger health plans' competitiveness, nor the market impact on small, independent community pharmacies.

It is therefore, inappropriate for CMS to rely on its 3 ½ year old regulatory flexibility analysis. Even a conservative analysis would trigger the $100 million threshold. Moreover, this impact needs to be compared with the reasonable alternative of maintaining the current policy of allowing PBMs to utilize either lock-in or pass-through models. This status quo accomplishes CMS' goal of ensuring the government is getting the best value for its Medicare dollar without impacting the market place.

Recommendation: ***CMS should maintain its current policy of allowing PBMs to use either the lock-in or pass-through pricing methodology, as long as the PDP confidentially attests to CMS which methodology they are using. Allowing this choice and flexibility in designing prescription drug benefits is key to ensuring the lowest possible cost for beneficiaries. Moreover, maintaining the status quo policy does not sacrifice CMS' ability to continue to monitor the market place to ensure it is getting the best value for the program—all without favoring a particular business model in the market place.***

In closing, Express Scripts appreciates the opportunity to comment on these critical issues. U.S. Secretary Michael Leavitt most recently reiterated his support for allowing market forces to drive Medicare pricing in his July 17th testimony U.S. House of Representatives Budget Committee. We believe maintaining the current policy will further that policy objective.

Regards,

Janice Forsyth
Vice President and Deputy General Counsel
Express Scripts, Inc.

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