

CMS-4130-P-1

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

Submitter : DAWN RIVERA-SMITH

Date & Time: 06/08/2007

Organization : MOBTS

Category : Academic

Issue Areas/Comments

Data Match

Data Match

I have had an extremely difficult time getting my prescription medications covered, in fact I was denied on many occasions. As it is I only receive 3 tablets of anti-nausea medication while I am taking 5 doses of chemotherapy. I would strongly suggest that something be done about this!

Gross Covered Prescription

Drug Costs

Gross Covered Prescription Drug Costs

I have had an extremely difficult time getting my prescription medications covered, in fact I was denied on many occasions. As it is I only receive 3 tablets of anti-nausea medication while I am taking 5 doses of chemotherapy. I would strongly suggest that something be done about this!

Submitter : Mr. raymond matthews

Date: 06/17/2007

Organization : matthews pharmacy

Category : Pharmacist

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

would love to be able to negotiate a pbm contract and i feel for the continued success of pharmacy, which is 149 years old. is a must.

GENERAL

GENERAL

for 20 years, i, a third generation pharmacist practicing in our independent that is 149 years old, found it enjoyable to come to work and truly work with people and help them manage their health care. there are now so much inconsistency in medicare part d plans that the enjoyable experience is quickly fading. the difficulty is the inconsistency and variations on how data is entered and transmitted for the 100's of plans. pharmacy has lobbied for a universal rx card. each to contain the same info and the same data. the second issue is that some plans really have it together. when submitting a claim at point of service, if a drug is not covered they will return useful info such as what med would be covered if submitted drug is not, what tel number to call if a pa is needed, this is ideal because one could then pickup the telephone and communicate with a doctor and resolve the issue. the majority of plans do not return this data and just say that this drug is not covered, this delays any assistance a pharmacist can give to a patient. delays mean patients give up on taking medicine for suffer while they call their plan to find out why then cannot get the medicine their doctor ordered. each plan should be mandated to return useful info if a claim is rejected. with the 100's of plans out there today not once has sent a pharmacy a written formulary to refer to. pharmacists are experts on drug use and medication management. as we all know pharmacist saved this program when it first began in jan 06. but are not reimbursed for managing insurance issues but are expected to. the pbm could make the process of helping easier by returning useful data to resolve a claim they are rejecting. the patient and the govt pay for this pharmaceutical service from the pbm's but are being shortchanged. this should not happen in healthcare in the united states.

Submitter : Amy Moon
Organization : Golden Clinical Services
Category : Long-term Care

Date: 07/16/2007

Issue Areas/Comments

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

In a skilled nursing facility, a resident typically applies for Medical Assistance(MA)during their Medicare skilled stay, but chooses not to enroll in a Med D PDP plan until the MA application has been approved, to avoid incurring any out-of-pocket monthly premium costs. When retroactive MA eligibility is approved, and the Medicare skilled stay has been exhausted, the primary payer changes from would-be private pay to a dual eligible status (with a new Med D PDP plan and state wrap-around coverage). **Related to the payer to payer reconciliation and the disallowment of claim denials or edits in the transition period, please clarify that a PDP may also not reject retro claims due to formulary denials or edits when the claims, at the time of dispense, were billed NOT to another PDP plan (with a different formulary, edits, etc), but rather, to a private payer or to a long term care facility.

It is common for a long term care pharmacy provider to hold these claims in a "pending status" during the time that a Medical Assistance (Medicaid) application is in process (since billing them to the private payer will typically result in collection challenges). Upon MA application approval (typically with retro eligibility) and a PDP on record to bill these claims to, the pharmacy then adjudicates these claims to a plan for the first time, unaware of any formulary restrictions at the time of dispense. Does this example apply to transition period disallowment of claim denials, as well?

And if the PDP is required to disclose instructions on how a beneficiary may submit retro claims for reimbursement, how can the long term care facility also be notified, because it is often the LTC facility that ends up paying the Private/MA pending resident's pharmacy bill, when the MA pending time is lengthy and the pharmacy threatens to stop providing the meds because a resident's credit line is exhausted. Can all of the instructions, forms, etc.. for claim reimbursement be required to be posted on-line for the LTC facility to have access to, as well?

Submitter : Mr. Charles Moore
Organization : Charlie's U-Save Pharmacy
Category : Pharmacist

Date: 07/18/2007

Issue Areas/Comments

GENERAL

GENERAL

Eliminating the exemption for Physician generated faxes as a communication of prescriptions to pharmacies would impose an extra cost burden to the already low rates of reimbursement that pharmacies now receive. Pharmacies have to bear the cost of the transmission of the electronic prescription from the doctor, which is now 23 cents per prescription, compared to the cost of the fax, which is simply the cost of a piece of paper. The errors are no less in the electronic prescription, than on a faxed one, since they are both generated by the physician on their computer! Every day we are having to call back physicians offices about the faxed or electronic prescriptions we receive, when the data on them is wrong. Forcing the prescriptions to all be sent electronically just adds another level of complexity to the error spotting process, and slows our systems down!

Submitter :

Date: 07/18/2007

Organization :

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#5

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

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

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

Submitter : Ms. Debbie Hamilton

Date: 07/18/2007

Organization : clients complaining about the so called dount hole

Category : Congressional

Issue Areas/Comments

Data Match

Data Match

where do clients go to get help once they have reached their "dount hole" most of the programs available refuse to assit these people because they are considered insured....even through they have to pay 100% for their medications till they reach \$2600 before their enrollment kicks back in....how do I help them with finding coverage to fill the gap?

you may reach me at home 570-320-1181 or email sapphire1109@yahoo.com

Submitter : Dr. Robert Ratner

Date: 07/19/2007

Organization : Dr. Robert Ratner

Category : Physician

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

Dear Ms. Norwalk:

I am the Vice-President of Scientific Affairs for the MedStar Research Institute, the research center of MedStar Health, the Baltimore-Washington area's largest health care delivery system. I also serve on the steering committee of the National Diabetes Education Program (NDEP) and am a principal investigator for the Diabetes Prevention Program and DPP Observational Study of the NIH.

As a board-certified endocrinologist specializing in diabetes, it is important to me that patients have every option available to them in managing their diabetes. I commend the agency for recognizing the necessity of providing patients with access to inhaled insulin therapy and am generally very pleased with the proposal that it be covered by Medicare Part D. I am concerned, however, by two aspects of the proposal.

First, I fear that each time a new insulin delivery method is introduced, Medicare patients will not have coverage until CMS undergoes a similar rule-making process which potentially could cause a long delay. There are quite a few advances in insulin delivery expected in coming years. I would hope that patients will be able to access them soon after they become available.

Second, I am discouraged that CMS expects Part D plans to apply utilization management tools to inhaled insulin supplies. UM tools such as prior authorization and step therapy place a burden on providers and delay implementation of effective therapies. Successful diabetes management is achieved through a plan that meets each individual patient's needs. Rather than encouraging utilization management by plans, I hope that CMS will encourage physicians to work with patients to devise a diabetes management plan incorporating all available therapies and encourage Part D plans to make all therapies available.

I appreciate your consideration of my comments.

Robert E. Ratner, MD
6495 New Hampshire Avenue
Suite 201
Hyattsville MD 20783

Submitter : Ms. Justine Coffey

Date: 07/19/2007

Organization : American Society of Health-System Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-8-Attach-1.DOC



American Society of
Health-System Pharmacists
7272 Wisconsin Avenue
Bethesda, Maryland 20814
(301) 657-3000
Fax: (301) 664-8877
www.ashp.org

July 19, 2007

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

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

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Medicare Program; Policy and Technical changes to the Medicare Prescription Drug Benefit. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP commends the Centers for Medicare & Medicaid Services (CMS) for publishing this proposed rule which provides clarification regarding approval of marketing materials and enrollment forms, covered home infusion drugs within 24 hours of discharge from an acute-care setting, and Part D coverage for supplies associated with the inhalation of insulin. However, ASHP has some concerns with the proposed rule, and recommends that CMS waive the penalty for late enrollment for low-income subsidy individuals, and also address the issue of the lag in information transfer between Part D plans and other agencies.

Approval of Marketing Materials and Enrollment Forms

ASHP applauds CMS's clarification of its consistent policy that providers and pharmacies that are contracted with plan sponsors may not "market" to beneficiaries, as the term is defined in *The Guidelines*, but providers and pharmacies may assist in enrollment, including participating in provider promotion activities within the parameters established in *The Guidelines*, and educate beneficiaries. Additionally, ASHP is pleased

that CMS clarified that providers, provider groups, or pharmacies are not obliged to accept and display any comparative information regarding those Part D plans with whom they do not contract.

Benefits and Beneficiary Protections, Definitions, Part D Drug

Morbid Obesity

ASHP understands that, in this proposed rule, CMS is clarifying existing policy that agents, when used for anorexia, weight loss, or weight gain, are specifically excluded from the definition of Part D drugs. However, ASHP continues to be concerned by this exclusion and the impact this lack of coverage has on patients, particularly those with non-cosmetic indications for these drugs, such as morbid obesity or wasting. Patients who suffer from these indications will continue to be unable to access necessary drugs under Part D. Additionally, while CMS does note that Part D plans that wish to continue coverage of weight loss agents may do so as a supplemental benefit through enhanced alternative coverage, dual eligibles will not benefit from these enhanced benefits, since they receive the equivalent of the standard drug benefit.

Insulin Inhalation Drugs and Supplies

ASHP is pleased that CMS has determined that supplies associated with the inhalation of insulin meet the definition of a Part D drug, and that Part D sponsors may decide whether or not to place these products on the formulary, thus allowing access to inhaled insulin supplies for Part D beneficiaries.

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

ASHP is aware that this section is a clarification of existing policy, however, the Society does not support this policy since many safety-net providers are fully or partially funded through government grants, and are therefore considered government-funded health programs. As a result, these safety-net providers are unable to have any waiver or reduction of cost-sharing their pharmacies apply to Part D enrollees' Part D cost-sharing count as an incurred cost. This policy leaves many individuals who are most in need of the coverage unable to reach catastrophic coverage under Part D.

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

ASHP applauds CMS's proposed requirement that Part D plan sponsors provide covered home infusion drugs within 24 hours of discharge from an acute-care setting, since the need for home infusion therapy is often of an urgent nature.

Gross Covered Prescription Drug Costs

ASHP applauds CMS amending the definition of 'gross covered prescription drug costs' to ensure that when a beneficiary is paying 100 percent cost sharing, and the beneficiary obtains a covered Part D drug at a network pharmacy for a lower price than the plan's negotiated price, the beneficiary's out-of-pocket costs are counted toward both TrOOP

and total drug spending. Additionally, the Society is pleased that nominal Patient Assistance Programs (PAPs) copayment amounts may count toward TrOOP. However, ASHP recommends that CMS consider adding a provision to allow for electronic submission of cash payment for prescriptions or copayments, since beneficiaries must submit documentation of these payments directly to their plans, and electronic submission would be less burdensome.

Coordination of Benefits with Part D Plans and Other Payers

ASHP agrees that a number of issues associated with the implementation of Part D have created challenges for Part D plans in coordinating benefits with other entities providing prescription drug coverage. In particular, the lag in information transfer between Part D plans and other agencies such as state Medicaid agencies has created continuing problems at the pharmacy, particularly pharmacies with a high proportion of dual eligible beneficiaries. These pharmacies continue to have problems with plans that do not accept documentation of a beneficiary's Medicaid eligibility as proof of dual status. ASHP strongly recommends that CMS address this issue with the Part D plans and the state Medicaid agencies to ensure these issues are resolved.

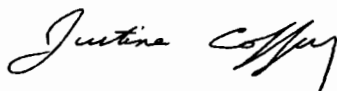
Additionally, regarding the plan-to-plan coordination process and CMS-developed reconciliation process, ASHP is pleased that the current process is designed not to require pharmacy reversal and re-adjudication of claims. Any reconciliation process should not involve pharmacies, but should occur at the plan-to-plan or plan-to-state level.

Premiums and Cost-Sharing Subsidies for Low-Income Individuals; Premium Subsidy for late Enrollment Penalty

ASHP agrees that low-income subsidy individuals should be subsidized for the late enrollment penalty; however, the Society strongly recommends that the penalty should either be fully subsidized, or waived, for all low-income subsidy individuals up to 150% of federal poverty level. A penalty is a disincentive for these individuals to sign up for Medicare Part D, and discourages those most in need from signing up for prescription drug coverage.

ASHP appreciates this opportunity to present its written comments on the proposed policy and technical changes to the Medicare Prescription Drug Benefit. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs

Submitter : Ms. Marissa Schlaifer
Organization : Academy of Managed Care Pharmacy
Category : Pharmacist

Date: 07/23/2007

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

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

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

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

Administrative Costs

Administrative Costs

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

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

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

Application Timing

Application Timing

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

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

GENERAL

GENERAL

See attachment

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



July 23, 2007

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

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

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

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

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

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

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

President
Richard A. Zabinski, PharmD
United Health Group
Golden Valley, MN

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Insulin Inhalation Drugs and Supplies

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

Negotiated Prices

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

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

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

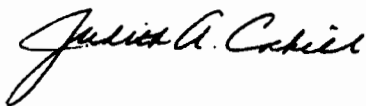
Adequate Access to Home Infusion Pharmacies

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

Sincerely,



Judith A. Cahill, CEBS
Executive Director

Submitter : Dr. Mary Hager
Organization : American Dietetic Association
Category : Dietitian/Nutritionist

Date: 07/23/2007

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

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



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

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

Ronald S. Moen
Chief Executive Officer

July 23, 2007

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

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

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

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

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

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

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

General Comments

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

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

Conclusion

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

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

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

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

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

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

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

Sincerely,



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



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

Submitter : Mr. Steven Wojcik
Organization : National Business Group on Health
Category : Consumer Group

Date: 07/23/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Insulin Inhalation Drugs and Supplies

Insulin Inhalation Drugs and Supplies

See Attachment

Negotiated Prices

Negotiated Prices

See Attachment

Noncalendar Year Plans

Noncalendar Year Plans

See Attachment

CMS-4130-P-11-Attach-1.DOC

NATIONAL BUSINESS GROUP ON HEALTH

50 F Street, NW • Suite 600 • Washington, D.C. 20001

202.628.9320 • Fax 202.628.9244

www.businessgrouphealth.org*Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow*

July 23, 2007

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

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

Dear Sir or Madam:

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

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

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

The Business Group offers the following comments and recommendations:

Retiree Drug Subsidy Application Timing

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

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

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

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

Data Match

We support the proposed change, provided:

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

Medicare Supplemental Adjustment

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

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

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

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

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

No comment.

Submission of Actuarial Attestation Upon Material Change

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

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

Sincerely,



Steven Wojcik
Vice President, Public Policy

Submitter : Mr. Steven Tucker
Organization : UnitedHealth Group
Category : Health Plan or Association

Date: 07/23/2007

Issue Areas/Comments

Administrative Costs

Administrative Costs

See Attachment.

Application Timing

Application Timing

See Attachment.

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

Coordination of Benefits with Part D Plans & Other Payers

See Attachment.

Data Match

Data Match

See Attachment.

GENERAL

GENERAL

See Attachment.

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



July 23, 2007

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

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

Dear Mr. Kuhn

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

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

We participate in the Medicare program in the following ways:

- Traditional fee-for-service -- Our Medigap offerings provide supplemental insurance on behalf of AARP to nearly three million of its members.
- Medicare Advantage -- We provide health care coverage to more than 1.3 million people through health plans, Preferred Provider Organizations (PPOs), private fee-for-service, and group health plans operating in diverse geographic areas ranging from Omaha to New York.

- Medicare Part D -- The nation's leading source of prescription drug coverage for over 5.8 million Medicare beneficiaries and the only provider of Medicare Part D plans endorsed by AARP.
- Evercare -- Evercare serves more than 150,000 people nationwide through Medicaid, Medicare, and private-pay health plans, programs and services. Evercare is also a leading provider of Special Needs Plans designed to help people who are chronically ill, dual eligible or living in an institutional setting stay as healthy and independent as possible.

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

ADMINISTRATIVE COSTS, NEGOTIATED PRICE, GROSS PRESCRIPTION DRUG COSTS

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

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

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

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

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

Sincerely,

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

**CMS-4130-P, Policy and Technical Changes
To the Medicare Prescription Drug Benefit**

**Comments Submitted by
UnitedHealth Group/Ovations
July 23, 2007**

NEGOTIATED PRICES

Section 423.100, p 29407

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

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

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

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

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

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

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

ADMINISTRATIVE COSTS

Section 423.308, p 29420

Issue: The definition of “administrative costs” is confusing.

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

Rationale: Currently the definition of “administrative costs” states:

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

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

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

ADEQUATE ACCESS TO HOME INFUSION PHARMACIES

Section 423.120(a)(4), p 29408

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

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

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

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

PREMIUM SUBSIDY FOR LATE ENROLLMENT PENALTY

Section 423.780(e), p 29414

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

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

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

Submitter : Mr. Matthew Insley
Organization : Ohio Northern University
Category : Academic

Date: 07/23/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

DATE: July 22, 2007

TO: CMS

FROM: Matthew Insley
PharmD Candidate
Ohio Northern University

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

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

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

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

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

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

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

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

Submitter : Dr. John A. Gans
Organization : American Pharmacists Association (APhA)
Category : Pharmacist

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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



American Pharmacists Association®

Improving medication use. Advancing patient care.

July 23, 2007

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

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

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

Dear Sir/Madam:

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

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

42 CFR Part 422

Provisions of the Proposed Regulations

Section 442.2 – Definitions

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

Section 422.503 and 423.504 – General Provisions

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

42 CFR Part 423

Provisions of the Proposed Regulation

Subpart B – Eligibility and Enrollment

Section 423.50 – Approval of Marketing Materials and Enrollment Forms

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

Subpart C - Benefits and Beneficiary Protections

Definitions

Section 423.100(a)(3) - Insulin Inhalation Drugs and Supplies

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

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

Section 423.100 (d) Negotiated Prices

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

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

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

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

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

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

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

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

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

Section 423.308(a) – Administrative Costs

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

Section 423.308(b) – Gross Covered Prescription Drug Costs

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

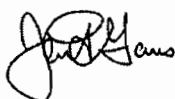
APhA Comments on Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit
July 23, 2007

Section 423.464(f) – Coordination of Benefits with Part D Plans and Other Payers

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

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

Sincerely,



John A. Gans, PharmD
Executive Vice President

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

Submitter : Mr. Howard Bedlin
Organization : National Council on Aging
Category : Other

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Howard Bedlin
Organization : National Council on Aging
Category : Other

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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



July 24, 2007

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

RE: File Code CMS-4130-P

To Whom It May Concern:

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

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

Sincerely,

Howard Bedlin
Vice-President
Public Policy & Advocacy
NCOA

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

1. Sec. A. Subpart B—Eligibility and Enrollment

1. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

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

2. Sec. B. Subpart C—Benefits and Beneficiary Protections

1. Definitions

a. Part D Drug

(2) Morbid Obesity

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

3. Sec. B. Subpart C—Benefits and Beneficiary Protections

1. Definitions

a. Part D Drug

4. Vaccine Administration Fee

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Submitter : Mr. Russell Bodoff
Organization : National Home Infusion Association
Category : Health Care Provider/Association

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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



August 31, 2007

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

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

Dear Ms. Norwalk:

The National Home Infusion Association (NHIA) submits these comments on the proposed rule clarifying and codifying the Center for Medicare and Medicaid Services' (CMS') policies associated with the Medicare Prescription Drug Benefit, as issued in the Federal Register on May 25, 2007.¹ We specifically focus our comments on Section 3.b. of the preamble, Adequate Access to Home Infusion Pharmacies, and the relevant proposed regulation § 423.120(a)(4).

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

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

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

¹ 72 Federal Register 29403 (May 25, 2007).
100 Daingerfield Road • Alexandria, VA 22314 • Phone: 703-549-3740
• Fax: 703-683-1484 • www.nhianet.org

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

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

In this proposed rule, CMS seeks to codify its previous, sub-regulatory policy² that Part D plans must require their contract network pharmacies to ensure that the necessary professional services and ancillary supplies required for home infusion therapy are in place before dispensing home infusion drugs. NHIA applauds CMS for recognizing that the provision of such supplies, equipment and professional services is critical to the safe and efficient administration of home infused drugs to Medicare beneficiaries. Without the availability of these services and supplies, there cannot be true access to clinically-intensive infusion therapy in the home.

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

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

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

³ 72 Fed. Reg. at 29408.

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

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

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

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

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

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

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

⁵ 72 Fed. Reg. at 29408.

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

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

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

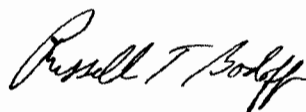
In addition, access problems for dual eligibles have increased since these patients were transitioned to Part D drug coverage from Medicaid coverage of infusion drugs, which in many states includes at least some home infusion services and supplies. "Sixty-three percent of hospital discharge planners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

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

* * * *

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

Sincerely,



Russell T. Bodoff
Executive Director

⁷ NHIA Survey Report, *Discharging Dual Eligibles Needing Home Infusion Therapy Under Medicare Part D: National Survey of Hospital Discharge Planners* (Nov. 15, 2006) 1-2, at <http://www.nhianet.org/documents/DchgPlnrSrvyReportFinal111506.pdf>.

⁸ *Id.* at 2.

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

¹⁰ *Id.*

Submitter :

Date: 07/24/2007

Organization : MAPRx Coalition

Category : Consumer Group

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See Attachment

Administrative Costs

Administrative Costs

See Attachment

Application Timing

Application Timing

See Attachment

Coordination of Benefits with Part D Plans & Other Payers

Coordination of Benefits with Part D Plans & Other Payers

N/A

Data Match

Data Match

See Attachment

GENERAL

GENERAL

See Attachment

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

See Attachment

Insulin Inhalation Drugs and Supplies

Insulin Inhalation Drugs and Supplies

See Attachment

Negotiated Prices

Negotiated Prices

N/A

Noncalendar Year Plans

Noncalendar Year Plans

N/A

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



July 24, 2007

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

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

Dear Mr. Kuhn:

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

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

Section II. A. Subpart B – Eligibility and Enrollment

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

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

1. Definitions, a. Part D Drug

(2) Morbid Obesity

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

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

(3) Insulin Inhalation Drugs and Supplies.

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

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

(4) Vaccine Administration Fee

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

1. Definitions, b. Long Term Care Facilities

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

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

1. Definitions, d. Negotiated Prices

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Definitions, a. Appointed Representative

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

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

2. Expediting Certain Coverage Determinations

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

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

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

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

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

Sincerely,

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

#79.

CMS-

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

Submitter : Joseph Devaney

Date: 07/24/2007

Organization : sanofi-aventis

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

#20



July 24, 2007

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

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

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

Dear Mr. Leavitt and Ms. Norwalk:

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

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

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

I discuss these comments in detail below.

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

Obesity is the second leading cause of preventable death in the United States, causing about 112,000 deaths per year.³ Obesity, defined as a body mass index (BMI) equal to or greater than 30 kg/m², is for many individuals a serious and life-threatening condition, often leading to increased risk of hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, arthritis, respiratory problems, and endometrial, breast, prostate, and colon cancers. The prevalence of obesity among Americans has increased sharply over the past thirty years, and as the baby boomer generation ages, the costs of this disease increasingly will be borne by the Medicare program. One estimate found that 90 percent of the increases in the cost of the Medicare program can be attributed to people entering the program with diabetes and other diseases associated with obesity.⁴

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

² See the attached legal opinion from Hogan & Hartson.

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

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

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

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

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

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

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

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

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

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

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

Several well established clinical practice statements and guidelines support the use of pharmacotherapy as one of a number of important tools for the treatment of obesity. In 2004, the American Heart Association issued a “Statement for Professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism” that supported the use of drug therapy for obesity using a definition of obesity as patients with “a BMI 30 kg/m² or a BMI between 27 and 29.9 kg/m² in conjunction with an obesity-related medical complication in patients with no contraindications for therapy.”¹¹ Consensus treatment guidelines developed by the National Heart, Lung, and Blood Institute in 1998 call for physician management of obese patients and regular clinical assessments every 6 months. Further, those guidelines call for the use of “...drugs that have been approved by the FDA for long-term use as ‘adjuncts to dietary therapy and physical activity for some patients with a BMI of 30 with no concomitant risk factors or diseases, and for patients with a BMI of 27 with concomitant risk factors or diseases.’”¹²

⁸ SSA § 1927(d)(2)(D).

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

¹⁰ See the attached legal opinion from Hogan & Hartson.

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

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

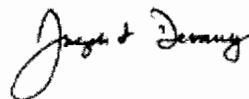
IV. CMS Should Withdraw Its Proposed Rule Denying Coverage of Drugs that Treat Obesity and Instead Should Reaffirm that Such Drugs Are Covered Under Part D

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

V. Conclusion

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

Respectfully Submitted,



Joseph F. Devaney
Vice President
Market Access Operation

July 24, 2007
Page 6 of 6

cc:

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

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

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

The Honorable Charles Grassley
United States Senate
Washington, DC 20510

HOGAN & HARTSON

MEMORANDUM

From: Sheree R. Kanner

Date: July 18, 2007

Re: Coverage for Obesity Medications Under Medicare Part D

We have been asked to analyze whether treatments for obesity must be excluded from coverage under Medicare Part D.¹ In the Centers for Medicare & Medicaid Services (CMS) proposed rule regarding policy and technical changes to the Medicare prescription drug benefit, published in the Federal Register on May 25, 2007 (the Proposed Rule),² CMS characterizes its statements in the 2005 Part D final rule³ as “erroneous” and “clarifies” that a “weight loss agent, even when not used for cosmetic purposes, is still ‘an agent used for anorexia, weight loss, or weight gain,’ for purposes of the exclusion from the definition of Part D drug.”⁴ We disagree with the agency’s statements in the Proposed Rule that its policy, as described in the 2005 final rule, is erroneous or that the Proposed Rule is not a change to current policy. As explained below, CMS reached the correct legal conclusion in the final rule: The statute permits coverage of obesity drugs under Medicare Part D. Moreover, such coverage serves the policy purposes intended by Congress when it enacted Part D.

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

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

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

¹Sanofi-Aventis requested this legal opinion.

²72 Fed. Reg. 29,403 (May 25, 2007).

³70 Fed. Reg. 4194, 4230 (Jan. 28, 2005).

⁴72 Fed. Reg. at 29,405.

⁵Id.

⁶Social Security Act (SSA) § 1860D-2(e)(1), referring to § 1927(k)(6).

list includes “agents when used for anorexia, weight loss, or weight gain,”⁷ but it does not prohibit coverage of drugs indicated for “obesity” or “weight management” because these indications are different from simple weight loss or weight gain.

In reaching the erroneous conclusion that obesity drugs must be excluded, CMS appears to have equated weight loss and weight gain, symptoms that do not define a disease, with obesity, which is a serious disease in its own right. Obesity has been widely recognized as a disease, distinct from weight loss or weight gain, by both the medical community⁸ and the federal and state governments. For example, the FDA distinguishes obesity from weight loss or weight gain by regulating obesity agents under the part of the Federal Food, Drug, and Cosmetic Act that applies to drugs used to treat a disease, while regulating weight loss or weight gain agents under a different part of the law.⁹

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

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

⁸Medical literature has defined obesity as a chronic disease with multiple causes, including genetics, environment, metabolism, and behavior. See, e.g., Rippe J., Crossely S, Ringer R. Obesity as Chronic Disease: Modern Medical and Lifestyle Management. J Am Diet Assoc. 1998 Oct; 98 (10 Suppl 2):S9-15; Stunkard A. Current Views on Obesity. Am J Med. 1996 Feb; 100(2):230-6. The National Heart, Lung, and Blood Institute at the National Institutes of Health describes obesity as a “complex, multifactorial chronic disease that develops from an interaction of genotype and the environment.” National Institutes of Health/National Heart, Lung, and Blood Institute. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. NIH Pub. No. 98-4083. 1998, at xi. Following this definition, the International Classification of Disease, 9th Edition, Clinical Modification (ICD-9-CM) coding system, created by CMS and other parts of the Department of Health and Human Services (HHS), identifies obesity as a disease in the “other metabolic and immunity disorders” section of the system and assigns unique codes to this condition. International Classification of Diseases, Clinical Modification, Ninth Revision, codes 278.01 (morbid obesity), 278.00 (unspecified obesity). In contrast, the ICD-9-CM identifies weight loss and weight gain as mere symptoms of other conditions. ICD-9-CM codes 783.1 (symptoms concerning nutrition, metabolism & development: abnormal weight gain) and 783.21 (symptoms concerning nutrition, metabolism & development: loss of weight).

⁹Products making obesity claims “are covered by section 201(g)(1)(B) of the [Federal Food, Drug, and Cosmetic Act] because obesity is now considered a disease,” but products making claims for “conditions, like overweight, that are not considered diseases, but that affect the structure or function of the body” are covered by section 201(g)(1)(C) of the Act. 65 Fed. Reg. 999, 1027 (January 6, 2000). The FDA also distinguishes weight management drugs from drugs used for weight loss. Weight management is more than weight loss. According to the FDA, a weight management indication would incorporate weight loss and weight maintenance, and it includes the “goal of reduced morbidity and mortality through quantifiable improvements in biomarkers such as blood pressure, lipids, and HbA1c.” Draft Guidance for Industry Developing Products for Weight Management, FDA, Center for Drug Evaluation and Research, February 2007.

¹⁰<https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=57> (announcing revision to Coverage Issues Manual § 35-26); subsequently reissued by Transmittal 23, October 1, 2004 (revising National Coverage Determinations Manual § 40.5). The revised policy now states: “Obesity may be caused by medical conditions such as hypothyroidism, Cushing’s disease, and hypothalamic lesions or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these medical conditions” <https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=57> (announcing revision to Coverage Issues Manual § 35-26); subsequently reissued by Transmittal 23, October 1, 2004 (revising National Coverage Determinations Manual § 40.5).

and to die prematurely.”¹¹ CMS Administrator Mark McClellan said, “What matters is whether there’s scientific evidence that an obesity-related medical treatment improves health.”¹² Consistent with these statements from those in charge of Medicare, the program has recognized that obesity is a significant health risk by covering bariatric surgery for treatment of comorbidities associated with morbid obesity¹³ and by identifying obesity as a complication and comorbidity for other illnesses under the proposed inpatient hospital payment rule for 2008.¹⁴

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

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

Because obesity is widely recognized as an illness distinct from weight gain, a drug that is used for the “medically accepted indication” of treatment of obesity or weight management²⁰ would not be precluded from coverage under Part D. The Act defines “medically accepted indication” as “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act” or a use of a covered outpatient drug that “is supported by one or more citations included or approved for inclusion” in any of certain specified compendia.²¹ Therefore, if use of a drug to treat obesity is included in the FDA-approved label or is supported by a citation in the compendia, it is not excluded under Part D. This is because the drug would be used for a medically accepted indication – treatment of obesity – which is distinct from mere weight loss. That is, while the drug might produce weight loss, it would treat obesity.

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

¹¹News Release: HHS Announces Revised Medicare Obesity Coverage Policy, July 15, 2004.

¹²*Id.*

¹³Medicare National Coverage Determinations Manual, § 100.1.

¹⁴72 Fed. Reg. 24,680, 24,698 (May 3, 2007).

¹⁵67 Fed. Reg. 57,859, 57,863-64 (September 12, 2002).

¹⁶67 Fed. Reg. at 57,860-61.

¹⁷Rev. Rul. 2002-19, 2002-1 C.B. 778 (2002).

¹⁸26 U.S.C. § 213(d)(1)(A).

¹⁹Rev. Rul. 2002-19, 2002-1 C.B. 778 (2002).

²⁰See *supra* note 8.

²¹SSA § 1927(k)(6).

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

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

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

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

Fourth, CMS has determined that vitamin D analogs and prescription niacin products are not affected by the statutory exclusion of prescription vitamins. CMS has determined that prescription niacin products, although composed of vitamin B₃, are different from the vitamins used for nutritional supplementation that are excluded under the statute because they are used at higher doses and for different purposes than the other vitamin products.²⁷ In the case of vitamin D analogs, "CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D₂) and/or cholecalciferol (vitamin D₃),"²⁸ but does not provide any explanation for this interpretation. CMS should apply the same logic it used to conclude that the plain language of the statutory exclusion of coverage for prescription vitamins allows coverage of vitamin D analogs and prescription niacin to permit coverage of

²²5 U.S.C. § 706.

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

²⁴*Id.*

²⁵*Id.*

²⁶*Id.*

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

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

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

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

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

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

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

As previously noted, in the Proposed Rule, CMS says that it “erroneously” stated in the January 2005 final rule that drugs for morbid obesity may be covered under Part D. This simply is not the case. CMS was legally correct in concluding that these drugs can be covered when used for a “medically accepted indication,” as described above. Furthermore, the January 2005 final rule was issued in response to specific comments, including those submitted by Sanofi-Aventis, recommending that Part D cover the use of drugs for morbid obesity. CMS addressed these specific comments in the final rule, further suggesting that CMS’s decision to cover drugs for morbid obesity was not a minor, technical error that can be corrected without notice and comment. If CMS wishes to change policy established in a final rule, it must clearly state that it intends to do so in order to allow stakeholders meaningful opportunity to comment on any changes.

Finally, CMS describes its statements in the Proposed Rule as “clarifying existing policy” and “not expanding or changing current policy regarding the exclusion of agents used for weight loss from the definition of Part D drug.”²⁹ In fact, CMS’s current binding policy statements are found in the Part D final rule issued in January of 2005, and thus CMS is

²⁹ 72 Fed. Reg. 29,405.

proposing a significant policy change in this Proposed Rule. Although CMS has issued subregulatory guidance that differs from the January 2005 final rule, these subregulatory statements are not binding and cannot be applied to limit Medicare coverage of drugs without further rulemaking. The proposed interpretation of coverage of obesity drugs set forth in the Proposed Rule is not simply a technical correction, but is instead a significant proposed policy change to which comments must be reviewed and considered before any change in policy may be adopted through a new final rule.

Submitter : Ms. Jane Galvin
Organization : BlueCross and BlueShield Association
Category : Health Plan or Association

Date: 07/24/2007

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies
see attachment

Administrative Costs

Administrative Costs
see attachment

Application Timing

Application Timing
see attachment

Coordination of Benefits with Part D Plans & Other Payers

Coordination of Benefits with Part D Plans & Other Payers
see attachment

Data Match

Data Match
see attachment

GENERAL

GENERAL
see attachment

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs
see attachment

Insulin Inhalation Drugs and Supplies

Insulin Inhalation Drugs and Supplies
see attachment

Negotiated Prices

Negotiated Prices
see attachment

Noncalendar Year Plans

Noncalendar Year Plans
see attachment

CMS-4130-P-21-Attach-1.DOC



BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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

July 24, 2007

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

Attention: CMS-4130-P

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

Dear Mr. Kuhn:

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

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

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

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

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

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

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

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

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

Sincerely,

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

Attachment



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

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**Blue Cross and Blue Shield Association
Comments**

**“Medicare Program: Policy and Technical Changes to the Medicare
Prescription Drug Benefit” (Part D Technical Rule)
(72 Fed. Reg. 29403, May 25, 2007)**

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

A. Erectile Dysfunction Prescription Drugs

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

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

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

B. Insulin Inhalation Drugs and Supplies

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

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

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

C. Vaccine Administration Fee

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. *Dispensing Fees*

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

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

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

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

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

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

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

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

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

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

5. *Direct and Indirect Remuneration.*

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

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

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

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

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

BCBSA Recommendations:

1. CMS should consider requiring reporting of PBM profits attributable to their role as intermediaries with dispensing pharmacies, without characterizing all such amounts as Part D sponsor administrative costs.
2. CMS should define the term “drug costs,” used in the first sentence of the definition.
3. CMS should clarify in the first sentence of the definition that dispensing fees are excluded from administrative costs.
4. If CMS proceeds with the second and third sentences of the definition, CMS should clarify that Part D sponsors will not automatically be liable for fraud or penalties if they exercise reasonable monitoring and oversight and are unaware that data is inaccurate or incomplete despite these efforts. Part D sponsors should be entitled to rely on the PBM supplied data without fear of penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

³ 72 Fed. Reg. at 29412.

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

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

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

CMS-

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

Submitter : Ms. Lisa Goldman

Date: 07/24/2007

Organization : Pfizer Inc

Category : Drug Industry

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See attached document.

GENERAL

GENERAL

See attached comment letter.

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

Submitter :
Organization : MAPRx Coalition
Category : Consumer Group

Date: 07/24/2007

Issue Areas/Comments

Adequate Access to Home Infusion Pharmacies

Adequate Access to Home Infusion Pharmacies

See Attachment

Administrative Costs

Administrative Costs

See Attachment

Application Timing

Application Timing

See Attachment

Coordination of Benefits with Part D Plans & Other Payers

Coordination of Benefits with Part D Plans & Other Payers

N/A

Data Match

Data Match

See Attachment

GENERAL

GENERAL

See Attachment. This is an UPDATE to comment number 191456.

Gross Covered Prescription Drug Costs

Gross Covered Prescription Drug Costs

See Attachment

Insulin Inhalation Drugs and Supplies

Insulin Inhalation Drugs and Supplies

N/A

Negotiated Prices

Negotiated Prices

N/A

Noncalendar Year Plans

Noncalendar Year Plans

N/A

CMS-4130-P-26-Attach-1.DOC



July 24, 2007

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

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

Dear Mr. Kuhn:

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

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

Section II. A. Subpart B – Eligibility and Enrollment

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

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

1. Definitions, a. Part D Drug

(2) Morbid Obesity

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

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

(3) Insulin Inhalation Drugs and Supplies.

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

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

(4) Vaccine Administration Fee

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

1. Definitions, b. Long Term Care Facilities

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

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

1. Definitions, d. Negotiated Prices

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Definitions, a. Appointed Representative

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

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

2. Expediting Certain Coverage Determinations

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

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

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

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

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

Sincerely,

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

Submitter : Lynn Rolston
Organization : California Pharmacy Association
Category : Health Care Professional or Association

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

Sec attached.

CMS-4130-P-27-Attach-1.DOC

CALIFORNIA PHARMACY ASSOCIATION

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August 1, 2007

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

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

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

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

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

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

Negotiated Prices

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

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

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

Adequate Access to Home Infusion Pharmacies

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

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

Administrative Costs

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

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

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

Conclusion

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

If you have any questions or need any additional information, please do not hesitate to contact Lynn W. Rolston, Chief Executive Officer of the California Pharmacy Association, at (916) 779-1400 ext. 400 or via email at lrolston@cpha.com .

Sincerely,

Lynn W. Rolston
Chief Executive Officer
California Pharmacy Association

Submitter : Mrs. Tracy Baroni Allmon

Date: 07/24/2007

Organization : SilverScript Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4130-P-28-Attach-1.DOC

July 24, 2007

Submitted as an attachment via
www.cms.hhs.gov/eRulemaking

Re: CMS - 4130-PComments on Part D Proposed Rule "Medicare Program: Policy and Technical Changes to the Medicare Prescription Drug Benefit"

Dear Sir or Madam:

SilverScriptSM Insurance Company (SSIC), a national Medicare Part D Sponsor, and SilverScript, Inc. (SSI), a Part D pharmacy benefit management company (PBM), both affiliates of Caremark Rx, Inc., a leading PBM company, appreciate the opportunity to provide comments on the draft 2008 Reporting Requirements.

SSIC is one of only 10 national PDPs servicing the Medicare Part D market. We have united with distribution partners, including health plans and Medicare Supplement providers, in the sales of our products nationwide. We bring substantial prescription drug benefit management experience through operating our own PDP (SSIC) as well as through our affiliate (SSI), a PBM offering prescription drug management services to Part D plans. SSI supports over 30 of our health plan clients, which have a combined membership of two million lives in Medicare Advantage and PDP programs.

I. General Comments

The proposed rule makes major revisions in the Part D Rule ("Rule") to reflect CMS' stated intent to require Part D plans to utilize a "single approach" to drug pricing. Rather than merely "refining" certain definitions, the proposed rule signals a major policy shift in the Part D program -- little more than a year after its implementation and before the results of the first year performance are available -- from a market-based model in which competition between private parties drives pricing and purchasing decisions, to a quasi-government model under which CMS dictates these decisions.

The freedom to make pricing and purchasing decisions is the underpinning of a market-based competitive model. The proposed rule's restrictions on the Part D sponsor's ability to choose what it believes to be the most effective drug management and pricing model will result in an increase in both drug costs and premiums, to the ultimate detriment of beneficiaries and the Part D program. Most importantly, the proposed rule's departure from a market-based approach is directly contrary to the Medicare Modernization and Prescription Drug Improvement Act of 2003 (MMA), and Congress' clearly stated intent in enacting it. CMS fails to articulate any basis or rationale for this major policy change, or to explain how it is consistent with the statute. As such, the proposed change is beyond CMS' authority.

Below we discuss these general concerns in greater detail, and then provide comments to specific sections of the proposed rule.

1. The proposed rule violates the MMA by departing from a market-based model and exceeds CMS' authority by substituting CMS' view for that of Congress.

The proposed rule institutes a "single approach" to Part D pricing, namely, "pass-through" pricing. This designation by CMS of a single acceptable pricing structure is contrary to the MMA and Congressional intent. Congress made clear in enacting the MMA that it intended to establish a market-based model under which "the private sector negotiate their incentives for insurers to get lower costs," and the marketplace works to "squeeze costs and get efficiency out of the system" rather than have CMS "dictate prices for everybody."¹ CMS acknowledges this repeatedly in the preamble to the Part D Rule, stating that that Congress structured the Part D benefit to be a "market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs."² Section 1860D-11(i)(2) of the MMA also specifically states that CMS may not institute a "pricing structure for the reimbursement" of Part D drugs. By specifying a "single approach" to drug pricing that requires the plan to charge beneficiaries the amount paid to pharmacies, CMS is depriving Part D plans of the ability to make their own drug purchasing choices, directly interfering with the market mechanism that underpins the Part D benefit, and instituting a pricing structure. This is contrary not only to Congressional intent, but also to the express prohibition in the MMA against the institution of a pricing structure by CMS.

Absent any ambiguity or conflict, it is a cardinal rule of statutory construction that the plain meaning of a statute be followed. In addition, when a statute may be interpreted to abridge long-held rights, or make a large policy change, courts *will not* interpret the statute to make the change unless the legislature clearly states it. This rule of construction is based on the assumption that the legislature would not make major changes in a vague or unclear way. This is known as the "clear statement" rule. Congress was keenly aware of the role of pharmacy benefits managers (PBMs) in the prescription benefit market when it passed the MMA, and both Congress and CMS (in the current Rule's preamble) repeatedly state that it was Congress' intent that the Part D benefit mirror the operation of drug benefit programs in the commercial market.

The lock-in pricing approach was the dominant pricing model in the commercial drug benefit market at the time the MMA was passed and it still is today. Applying the "clear statement" rule of construction, if Congress had intended to disallow this model for Part D purposes, it would have done so clearly and explicitly. Indeed, the fact that Congress' own definitions of several key terms as stated in the MMA must be substantially amended, and a new defined term added which is contrary to its well-understood meaning³, demonstrates that CMS is substituting its views for those of Congress in mandating the model under which Part D should operate. This fundamental principle, namely, whether Part D should be a market-based or government-directed program, was vigorously debated in Congress before it decided clearly and unequivocally to adopt a market-based model. We believe that only Congress can change this model, not CMS.

Congress decided that Part D sponsors should have the choice, as they do currently in the commercial market and under Part D, to decide which model works best for them and which delivers the best results. By dictating the purchasing and drug pricing methods that must be used by Part D sponsors, CMS is substituting the judgment of the government for that of the market, and assumes that the

¹ Congressional Record, November 24, 2003, S15670.

² 70 Fed. Reg. at 4320.

³ The new defined term "administrative costs" is contrary to the explanation of this term in preamble to the current Part D rule (see 70 Fed. Reg. at 4289-90), and contrary to the standard use of this terms for accounting and financial purpose.

government knows better than Part D sponsors how best to provide a high quality benefit with low drug costs. This assumption was explicitly rejected by Congress in enacting the MMA, when Congress noted that “private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.”⁴

It is notable that CMS provides no rationale for the proposed rule changes. It cites no harm to the program and no harm to beneficiaries. Indeed, it would be hard pressed to do so, not only because it has not even completed the first year payment reconciliation process and so does not know the full financial results for the year, but because it has pronounced the program a “resounding success” in testimony before Congress. Specifically, Acting Administrator Leslie V. Norwalk stated:⁵

Part D, enacted with passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implemented in January 2006, has been a resounding success. To date, more than 90 percent of Medicare beneficiaries have prescription drug coverage through Part D or another creditable source, including nearly 10 million low-income individuals receiving coverage with low or zero premiums and nominal cost-sharing. Beneficiary satisfaction with Part D is consistently at 75 percent or higher, exceeding 90 percent among low-income beneficiaries receiving extra help. Equally important, Part D premiums and estimated program costs have been declining steadily thanks in part to market forces encouraging strong competition among plans and smart choices by beneficiaries and in part because of lower-than-expected growth in prescription drug spending.

Yet it is these very market forces that CMS proposes to override with the proposed rule, and without providing any explanation or rationale whatsoever. As courts have stated:⁶

[W]hen an agency reverses its course, a court must satisfy itself that the agency knows it is changing course, has given sound reasons for the change, and has shown that the rule is consistent with the law that gives the agency its authority to act. In addition, the agency must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection, sufficient to allow for meaningful judicial review. Although there is not a “heightened standard of scrutiny . . . the agency must explain why the original reasons for adopting the rule or policy are no longer dispositive.” Even in the absence of cumulative experience, changed circumstances or judicial criticism, an agency is free to change course after reweighing the competing statutory policies. But such a flip-flop must be accompanied by a reasoned explanation of why the new rule effectuates the statute as well as or better than the old rule.

In this case, CMS has provided no explanation for how its proposed change effectuates the MMA better than the prior rule. It has cited no harm or mischief either to beneficiaries or the program as a result of the current policy, nor has it attempted to justify the change as more consistent with either the

⁴ Conference Report to the MMA, p.302.

⁵ Testimony before the House Energy and Commerce Subcommittee on Health, April 18, 2007.

⁶ Fox Television Stations, Inc. et.al. vs. Federal Communications Commission, Docket Nos. 06-1760-ag (L), 06-2750-ag (CON), 06-5358-ag (CON), 2nd Circuit Court of Appeals, June 4, 2007, quoting from N.Y. Council, Ass’n of Civilian Technicians v. Fed. Labor Relations Auth., 757 F.2d 502, 508 (2d Cir. 1985).

language of the MMA or Congressional intent. CMS itself has repeatedly touted the success of the program, and has from the outset emphasized the Congressional requirement that it be market-based. By departing from Congressional intent and the language of the MMA without any explanation, CMS is acting beyond its authority.

2. The proposed rule will deprive Part D sponsors of the best drug management practices available in the private sector today, ultimately causing drug costs to rise for beneficiaries and the program.

By effectively prohibiting⁷ the price risk or “lock-in” pricing model, CMS will be departing from Congress’ and its own goal of leveraging market- based best practices. Drug management techniques have evolved in the marketplace over the past 25 years from a claims processing pass-through model where PBMs do not participate in the drug purchasing and supply process to the lock-in model, where PBMs are an integral part of the drug supply chain. This model, developed in response to market demand, requires PBMs, like any other drug suppliers, to be at risk for their drug purchasing decisions, and to assure plans a drug price that is not conditioned on the costs at which the PBM obtains the drugs. Competition and aligned incentives drives PBMs to negotiate for the best pricing on drugs from pharmacies, resulting in lower drug prices for plan sponsors/clients and consumers and, under Part D, the government.

The proposed rule, by shifting drug costs to administrative costs and thus beneficiary premiums, will constrain Part D plans from utilizing the more innovative clinical drug management services and tools available in the market today. It will effectively reduce plans to using PBMs primarily for claims processing, where the pharmacy price is passed through as given, and the PBM is paid based simply on claims volume i.e. the number of claims processed. Plans will be less willing to implement more intensive, high-cost clinical interventions that have been developed by PBMs over time to improve medical outcomes and quality of care and, to the extent any drug management is implemented, the focus will become simply to ratchet down the use of drugs. Since drug costs cannot ultimately be lowered without improving health outcomes, the effect will be not only less drug cost trend management, but also inferior medical outcomes and lower beneficiary satisfaction.

While it is possible for Part D sponsors to institute performance guarantees in an attempt to better align incentives to retain better drug management tools, as Congress itself made clear by its choice of risk-based Part D model rather than a government-run plan, placing entities directly at risk for drug costs is far more effective than adjusting compensation through performance guarantees that attempt to mimic the incentives of true at-risk participants.

The lock-in model directly aligns the PBM's incentives with that of the plan and the Part D program to shift drug utilization to: (i) preferred brands from non-preferred brands; (ii) lower cost generic drugs; (iii)

⁷ While the proposed rule does not explicitly prohibit lock-in pricing, CMS does so implicitly by imposing a “single approach” to beneficiary cost sharing. Under Part D, beneficiaries and Part D sponsors share the cost of a drug in different proportions, depending on the phase of the benefit. Thus, if the beneficiary’s cost sharing is based on a certain drug cost (e.g. 25% of \$100) and the plan’s cost sharing that may be included in gross covered prescription drug costs must be based only its drug costs up to that amount (i.e. \$100 -\$25), then it is not possible, by definition, for Part D sponsors to pay a drug supplier either more or less than \$100 in total drug costs. In addition, while it would theoretically be possible to base subcontractor compensation on putative lock-in pricing, this would differ from lock-in pricing in the same crucial respect as purchasing on one’s own account differs from purchasing as an agent of another – any differential would be fully disclosed and so simply become a range for determining administrative fees. As such, it would be a pointless exercise and the parties would move to simply setting administrative fees. Thus, lock-in pricing would be eliminated, both in calculating allowable drug costs and for purposes of setting administrative fees.

mail order pharmacy alternatives. This is because, under the lock-in model, PBMs typically take risk (and routinely lose money) on brand drug pricing, and make money on generic pricing. Therefore, PBMs are incented to promote cost effective preferred brand drugs, and encourage beneficiaries to move from higher cost brand drugs to generic drugs when clinically appropriate. Utilization of lower cost alternatives, such as preferred brands and generics, aligns with CMS' goals and beneficiary desires for lower drug costs. In contrast, pass-through pricing does not directly align a PBM's incentives with that of the plan or the Part D program. Pass through pricing provides no incentive to the PBM to lower overall drug costs through the use of preferred brands, generics and mail pharmacies. By basing PBM reimbursement directly on costs and number of drugs dispensed, the pass-through model would ironically reward PBMs for higher utilization.

3. Pass-through pricing is less equitable and more confusing to beneficiaries as they lose the benefit of consistent drug pricing across pharmacies and across different regions of the country.

Under a lock-in model, plans are able to provide uniform drug pricing for beneficiaries, irrespective of where they live or the pharmacy they choose to use. This is positive for beneficiaries in two respects. First, it protects beneficiaries who live in less competitive or underserved areas. This is because the price charged to the beneficiary is not directly tied to the price that the pharmacy is reimbursed, and so plans are able to negotiate a single fixed price with PBMs, irrespective of various prices at which PBMs are able to negotiate the purchase of drugs from different pharmacies. The highest negotiated pharmacy reimbursements are generally seen in rural and underserved areas where there is less competition and lower volume. In the lock-in model, the PBM absorbs these spikes and variations in pharmacy pricing, and provides all beneficiaries a standard, uniform price. Beneficiaries are thus not unfairly penalized for living in a less competitive market with fewer pharmacy choices.

Second, the lock-in model provides consistency and simplicity to beneficiaries, allowing them to better predict and budget for their out-of-pocket drug costs. This is particularly important for the elderly, many of whom are on fixed incomes with little flexibility or financial cushion to absorb price spikes or significant variations. It is particularly onerous for seniors to have to "pharmacy shop" to find the cheapest pharmacy, especially in the case of those who have long-established relationships with certain, sometimes smaller and less competitive, pharmacies. In addition, for many of the elderly who are "snowbirds" that spend significant parts of the year in different parts of the country, it is a major benefit and comfort to know that their medications will cost the same, regardless of which pharmacies they use.

In contrast, under a pass-through model, plans have no ability to shield beneficiaries from the variations in drug pricing as a result of different drug price reimbursement rates negotiated with different pharmacies. As a result, beneficiaries' drug prices will vary not only by geographical region, but even pharmacy to pharmacy. In competitive (usually urban) markets where there are many pharmacies in close proximity to one another, these variations will likely be small and of little consequence, but in rural and less populated areas, where beneficiaries have fewer pharmacy options, these variations are likely to be significant. As a matter of equity, beneficiaries outside urban areas should be able to benefit equally from the PBM's national reach and negotiating power, and should not face higher drug costs because of where they choose to live.

4. The proposed rule impermissibly disallows a portion of Part D sponsors' legitimate drug costs.

The proposed rule substantially amends three definitions and adds a fourth for the purpose of excluding a portion of Part D sponsors' legitimate drug costs from the definition of "allowable" drug costs under the Rule. CMS has created a definition of "administrative costs" that is based not on the nature of the

costs incurred, but on the entity from which the drugs are purchased. While there is no definition of the term “administrative costs” in the statute or the current Rule,⁸ the generally recognized accounting and financial distinction, and that made elsewhere by CMS itself, is between the acquisition cost for the drugs or the “product purchased” as opposed to the costs or fees associated with administrative tasks, such as marketing, customer services, claims administration and other administrative services.⁹ While it is within CMS’ purview to examine whether certain costs are in fact for the purchase of drugs and not for the provision of services, as long as a Part D sponsor is paying for drugs, these costs should be recognized as drug costs to the plan and included in “allowable” drug costs under the Rule .

Throughout the MMA and the proposed rule, “administrative costs” are not defined to include the margin (positive or negative) a manufacturer charges over its production costs, or the margin a wholesaler charges over the wholesale acquisition cost, or the margin a pharmacy charges a PBM over the pharmacy acquisition cost. It is only the last transaction in this chain - the margin a PBM charges a Part D sponsor - that CMS disallows as part of the Part D sponsor’s drug costs. In the preamble to the Rule, CMS explicitly acknowledges that a pharmacy may include a profit element in the amount it charges for drugs.¹⁰ Similarly, if the plan purchases the drug directly from the wholesaler, manufacturer, or pharmacy, the price would include a mark-up by each of those entities and, in each case, the mark-up would not be identified as an “administrative” cost, even though in each case it would clearly include an increment to cover the cost of delivering the drug and related services as well as an element for profit. This is no different. Disallowing a portion of a Part D sponsor’s drug costs by changing the definition of “administrative costs” is without any support in the MMA .

II. Specific Comments

Below are specific comments on certain of the proposed changes in the rule, including some of the changes discussed more broadly above.

A. Marketing Materials

CMS clarifies that contracted providers are not required to accept and display comparative materials of all Part D plans, but only those with which they contract, and that they may simply inform prospective enrollees where they can obtain information on the full range of plans available. CMS explains that its reason for this limitation is to avoid confusing prospective enrollees who might otherwise believe or expect that the provider is a network provider to all these plans. We appreciate this clarification, but believe that it does not go far enough in terms of addressing beneficiary confusion with the array of plans presented to them in the provider setting. When the Part D program was implemented, few expected there to be as many plans as there currently are. The result is that many providers have contracts with dozens of plans, from major national plans to smaller regional or local plans, and so are

⁸ The preamble does provide a list of costs that may generally be included as “administrative costs” in a plan sponsor’s bid. See 70 Fed. Reg. at 4289-90. This list includes crossover fees paid to obtain information from other payers, MTMP expenses, marketing and sales, customer service, billing and claims administration, accounting operations, actuarial, legal and human resources, etc., none of which relate to the price paid to a PBM for drug costs. The bid instructions list the same types of administrative services.

⁹ See 70 Fed. Reg. at 4289-90. See also 70 Fed. Reg. at 4398 (referring to the “actual costs” as the costs for “acquisition of drugs”) and 4491 (describing the costs incurred by Part D plans in “administering the benefit”).

¹⁰ 70 Fed. Reg. at 4236 (“In addition, we clarify that we expect 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.”)

often inundated with plan materials. Requiring providers to accept and display the materials from all these plans puts an undue burden on providers that have limited display space. Providers have no choice but to simply pile up the materials, with the result that the materials are often not easily accessible, not necessarily the most recent information available for all the plans involved, and frequently overwhelming to prospective enrollees by the sheer volume of material and number of plans presented.

Instead of requiring providers to display information of every plan with which they've contracted, we recommend that providers be permitted to display information of a reasonable cross-section of plans with which they have contracted, as long as they also post a notice clearly stating that the materials represent only a cross-section of the plans with which they have contracted, and informing prospective enrollees where they can obtain the full range of plans available to them.

Recommendation: Modify the requirement that providers accept and display materials from all contracted plans to state that providers may accept and display materials from reasonable cross-section of contracted plans, as long as the provider posts a notice informing beneficiaries that the material represents only a subset of contracted plans, and explaining where beneficiaries may obtain information on the full benefits available to them.

B. Vaccine Administration Fee

CMS proposes to amend the definition of Part D drug to include a reference to vaccine administration on or after January 1, 2008 in order to conform the definition to the statutory change made by the Tax Relief and Health Care Act of 2006. While we understand that coverage changes would require Congressional action, we would like to reiterate the concerns we have previously expressed to CMS regarding the operational aspects of implementing this change.

Specifically, there is currently no mechanism in place for physicians to bill PDPs directly, or for PDPs to pay physicians directly for this fee. Indeed, since physicians lack the information systems or contractual relationships to bill Part D plans directly, the coverage of vaccine administration fees under Part D is fundamentally at odds with the real time nature of the Part D program. This disconnect is exacerbated by CMS' stated expectation that when the vaccine and its administration fee are billed separately, Part D plans must ensure that "there is a reasonable correlation of prescription drug event (PDE) records for vaccines dispensed to PDE records for vaccine administration." Since any separate vaccine administration fee claim will be a paper claim, this takes the program further away from its real time nature, and will require that costly manual processes be instituted by Part D plans. This imposes yet more costs and administrative burdens on all the parties involved, including beneficiaries who must pay out-of-pocket for the administration and seek reimbursement afterwards. While various billing and payment methods are being considered, as MedPAC has stated,¹¹ these methods are largely untested and none is without operational challenges. In addition, given the relatively small number of vaccine claims from physicians that are processed under Part D, it is not efficient for either physicians or plans to build the technical or administrative infrastructure that would be required in order for physicians to be able to bill Part D plans directly for these few claims.

In light of these difficulties, we strongly endorse the recommendation of MedPAC to permit the coverage of certain vaccines under Part B instead of Part D.¹² In addition, given that the statutory

¹¹ MedPAC Report to the Congress, "Promoting Greater Efficiency in Medicare", June 2007, p.166.

¹² Although the MedPAC recommendation was limited to preventative vaccines, MEDPAC stated:

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change takes effect only on January 1, 2008 and that the operational issues have not yet been fully teased out, let alone satisfactorily resolved, we urge CMS to consult closely with Part D sponsors before mandating any particular approach, and to allow Part D sponsors the maximum operational flexibility in handling these claims transactions so that they can provide the coverage with as little disruption to beneficiaries as possible. In particular, we urge CMS to allow Part D plans to treat the vaccine administration fee as if it were a drug, and to bill for it accordingly. In addition, CMS should allow Part D plans the maximum flexibility to process the vaccine itself and the administration fee as one transaction or two non-linked transaction at their discretion, and should not require that plans track and tie the two transactions together. Aside from the administrative burden involved to do this, it is monitoring a situation that is highly unlikely to occur, since few physician would administer a vaccine other than from their own stock, given the risks associated with administering a vaccine that has been outside the physician's control, including the risk of tampering, spoilage, and temperature damage, to name a few.

Recommendations: 1. Work with Congress and MedPAC to change the law to permit coverage of vaccines under Part B instead of Part D. 2. Work closely with Part D sponsors to develop the most efficient and cost-effective approach to billing and paying for vaccines and vaccine administration fees under Part D. This approach should, at a minimum, (i) treat the vaccine administration fee in all ways as if it were a separate Part D drug, and (ii) permit Part D sponsors as much operational flexibility as possible in handling these claims, and not require that the claim for the vaccine itself and the claim for the administrative fee be linked or otherwise correlated or tracked.

C. Long-Term Care Facilities

CMS clarifies that institutions for mental disease ("IMDs") fall within the definition of a "long term care facility" in 42 CFR 423.100. We appreciate this clarification, which is consistent with prior CMS guidance, but wish to point out that, as a practical matter, very few IMDs appear interested in contracting with Part D plans. We solicited state IMDs in all 50 states to participate in our Part D LTC network, but only about 10 have responded and are negotiating contracts. We are therefore concerned that the CMS standard does not take into account that entering contracts with IMDs requires the cooperation and interest of the IMDs too, and states simply that Part D plans must "ensure that they provide convenient access to network LTC pharmacies...for all their enrollees who are inpatients in a hospital" that qualifies as an IMD. The most that Part D plans can do is make a good faith effort to contract with the IMDs, and they cannot require or "ensure" that IMDs contract with them.

Recommendation: Clarify that Part D plans meet the "convenient access" requirement for LTC facilities that are IMDs if they make a good faith effort to contract with the IMDs, even if the contracts are ultimately not entered into with the IMDs.

D. Negotiated Prices

CMS states that it is requiring "a single approach for calculating beneficiary cost sharing, based upon the price ultimately received by the pharmacy" or other dispensing provider. CMS provides no rationale for requiring plans to determine their drug prices to beneficiaries exclusively on their reimbursement rates to pharmacies, and there is nothing in the statute to support this requirement. On the contrary, and as

Although this section relates only to preventive vaccines, beneficiaries might have better access to some other drug products under Part B than under Part D. CMS is studying whether some drugs should be moved from one part of the program to the other. The Commission also will study potential cases in future work. Any significant shift of drugs from one part of the program to the other should consider the time needed for drug plans to take the changes into account before submitting their bids to CMS for the following year.

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CMS later clarifies, section 1860D-2(d)(1)(B) of the MMA specifically states 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.” Since Part D sponsors may elect to pass through all or none of the price concessions negotiated with manufacturers, pharmacies or others, negotiated prices do not, nor are they required to, equal the price ultimately received by the pharmacy, and the MMA clearly contemplates that Part D sponsors will have the flexibility to determine and set their negotiated prices as they deem appropriate to be competitive.

As CMS itself states in the preamble to the Rule in discussing negotiated prices “How a Part D sponsor nets out negotiated price concessions in its negotiated prices is at the discretion of the Part D sponsor, but we expect that competition will create incentives for Part D sponsors to offer reasonable negotiated prices.”¹³ Similarly, “[t]he Part D benefit was established by the MMA as a market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs. Given the market-based approach envisioned by the Congress, we are wary of regulating negotiations between private parties....”¹⁴ Yet this is precisely what CMS seeks to do in changing the definition of “negotiated price” to limit how Part D sponsors set their prices. It is analogous to requiring a retailer to limit the amount it charges consumers for a product to the cost paid to the supplier by the retailer. Instead, a retailer may choose to mark up or lower the price as competition demands. Similarly, a Part D sponsor may choose to charge a lower price than the reimbursement rate to the pharmacy or a higher price that does not pass through any of the pharmacy or manufacturer discounts at POS, and instead take them into account in setting lower enrollee premiums or improving enrollee services.

The freedom to make these types of pricing decisions is at the heart of a market-based model, and the revised definition of “negotiated prices” seeks to limit that freedom by dictating how negotiated prices are to be set. This is in direct violation of the noninterference provision of the MMA, which states that CMS may not interfere with price negotiations or “institute a price structure for the reimbursement of covered Part D drugs.”¹⁵ As Congress made clear in the Conference Report to the MMA, this provision operates more broadly to prohibit CMS not only from “from interfering in any way with negotiations between prescription drug plan sponsors and ... and drug manufacturers, wholesalers, or other suppliers of covered drugs” but also from:

“...otherwise interfering with the competitive nature of providing prescription drug coverage through such entities and organizations. These negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.”¹⁶

Recommendation: Retain the current definition of “negotiated prices” in the Rule, which allows Part D sponsors to determine the drug price to charge enrollees, as required by the MMA, instead of seeking to limit drug prices to the reimbursement rate to pharmacies or other dispensing providers.

E. Administrative Costs

¹³ 70 Fed. Reg. at 4245.

¹⁴ 70 Fed. Reg. at 4244

¹⁵ MMA §1860D-11(i).

¹⁶ Conference Report to the MMA, p.302.

CMS proposes to define “administrative costs” as the Part D sponsor’s costs “other than those incurred to purchase or reimburse the purchase of Part D drugs.” However, CMS then adds that administrative costs include sponsor costs “that exceed the amount paid by or on behalf of the Part D sponsor to a pharmacy or other entity that is the final dispenser of the drug under the Part D plan.” Lest there be any doubt as to its intent, CMS adds in the preamble “For example, the profit retained by a PBM that negotiates prices with pharmacies on behalf of a Part D sponsor is considered an administrative cost and not a drug cost.”

We agree that administrative costs are costs other than those to purchase or reimburse the purchase of Part D drugs, since this is consistent with the traditional and well-understood meaning of the term. However, we strongly oppose CMS’ attempt to broaden the term to include any amount paid to entities other than the dispenser as administrative costs, irrespective of the nature of the payment. CMS is in effect using the definition of “administrative costs” to dictate from whom a Part D sponsor is permitted to buy drugs by recognizing only those drug purchases from dispensers as legitimate drug costs. A cost is either a drug cost or an administrative cost based on whether the cost is to buy drugs or pay for services. If the cost is to purchase drugs, then it is a drug cost, irrespective of the party from whom the drug is purchased. In addition, CMS specifically requires that rebates negotiated with manufacturers reduce drug costs, even though these amounts are not received from the final dispenser of the product. Thus, CMS proposes to allow only drug costs paid to the pharmacy to count as drug costs under Part D, but at the same time to require that all drug discounts -- irrespective of whether these are received from the pharmacy or any other entity – to count as a reduction in drug costs. This asymmetrical treatment of drug costs and drug cost discounts, as well as the arbitrary exclusion from Part D drug costs of those drug costs incurred in the purchase of drugs from parties other than the final dispenser is arbitrary and capricious, and without any support in the MMA. Instead of the outright banning of the purchase of drugs from certain entities, which would be a clear violation of the noninterference language in the MMA, CMS has sought to do this indirectly by defining administrative costs to include these drug sales. Thus, by definition, the purchase of drugs from any party other than the final dispenser is an administrative cost.

Recommendation: Revise the definition of “administrative costs” to read: “Administrative costs” means costs incurred by a Part D sponsor in complying with the requirements of this Part for a coverage year and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs.” Everything after this first sentence should be deleted.

F. Gross Covered Prescription Drug Costs (“Gross Drug Costs”)

CMS proposes to rectify what it characterizes as conflicting definitions of the term Gross Drug Costs by requiring Part D sponsors to report as GCPDC “the amount ultimately received by the pharmacy, other dispensing provider, or agent (as opposed to the amount paid to an intermediary contracting organization that does not serve as an agent, such as a PBM).” CMS then proceeds to add back into Gross drug Costs various costs in addition to those ultimately received by the pharmacy,” such as amounts paid to physicians and other dispensers, amounts paid to other plans, amounts paid by an enrollee outside the benefit in certain circumstances, including nominal cost sharing paid to patient assistance programs (“PAPs”) and when the enrollee obtains a lower price than the negotiated price when responsible for 100% cost sharing. Gross Drug Costs therefore include amounts paid by the Part D sponsor for drug costs to:

- pharmacies
- physicians

- other dispensers
- other Part D plans
- SPAPs
- other payers
- enrollees

Excluded from Gross Drug Costs are amounts paid by the Part D sponsor for drug costs to:

- PBMs

As with the definition of “administrative costs”, we believe that this definition is arbitrary and capricious in that it is based not on the nature of the costs, but on the party to whom they are paid. Without any justification or rationale, CMS seeks, by definition, to preclude the purchase of drugs by Part D sponsors from certain entities. There is no support for this in the MMA, where Congress defined Gross Drug Costs as:

...the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.¹⁷

This is mirrored in the Conference Report, which defines Gross Drug Costs as follows:

Gross covered drug costs would be defined as costs (not including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded basic coverage and regardless of when the payment for the drugs was made.¹⁸

Thus, all that the MMA requires is that the costs be (i) for drugs, and (ii) incurred under the plan. There is no support in the MMA for imposing limitations on a Part D sponsor’s ability to purchase drugs from whom it chooses, and to do so is directly contrary to the noninterference clause in the MMA which prohibits CMS from interfering in negotiations between Part D sponsors and others and from seeking to impose a pricing structure. Limiting from whom Part D sponsors may purchase Part D drugs and mandating a single pricing approach flies in the face not only of Congressional intent, but the express language of the MMA, and it is no less a violation because it is achieved indirectly through definitions than directly through an outright prohibition.

Recommendation: Revise the definition of “gross drug costs” to reflect the definition in the MMA, namely, the amount incurred by the Part D sponsor for Part D drugs.

¹⁷ MMA §1860D-15(b)(3).

¹⁸ MMA Conference Report , p.47.

G. Waiver or Reduction of Part D Cost-Sharing by Pharmacies

CMS states that although it will “generally allow waivers or reductions of Part D cost-sharing by pharmacies to count toward incurred costs, this will not be the case for pharmacies affiliated with entities whose wraparound coverage does not count as incurred cost.” While we understand that CMS is focused here particularly on safety-net providers that are considered government-funded health programs under 42 CFR 423.100, we are concerned that the broad and undefined terms “affiliated” and “wraparound coverage” that “does not count as incurred costs” could be misconstrued to disallow waivers by pharmacies that are affiliated with Part D sponsors that provide enhanced coverage. We recommend that CMS clarify that this prohibition on counting cost-sharing reductions by pharmacies applies only if the reduction is in fact part of the coverage provided by a health plan or other third party payment arrangement, and not a waiver funded by the affiliated pharmacy itself.

Recommendation: Clarify that only cost-sharing reductions that are in fact paid for by group health plans, government-funded health programs or other third party payer arrangements will not count toward “incurred costs” and that cost sharing waivers by a pharmacy, even if the pharmacy is affiliated with a payer, will count toward “incurred costs”.

H. Adequate Access to Home Infusion Pharmacies

The proposed rule states that plans must “ensure” that HI network pharmacies, “at a minimum” are capable of meeting the four requirements specified by CMS regarding HI drug delivery, including the requirement to ensure that the professional services and ancillary supplies are in place before dispensing and that drugs are delivered within at least 24 hours of discharge from an acute setting. We are concerned that, as written, this suggests that Part D plans have greater control and involvement in these activities than they in fact do. All that a Part D plan can do is to contractually require that HI network pharmacies meet these requirements to the extent that they are in control of these issues and then, as appropriate, audit the pharmacies for compliance with all their contractual obligations. While Part D plans can contractually require that HI pharmacies be capable of delivering home infusion drugs within 24 hours of discharge from an acute setting, the pharmacy must in turn rely on the hospital’s discharge staff notifying it beforehand of the discharge to coordinate this, and Part D plans cannot themselves effectively assume the role of the hospital’s discharge staff or require that HI network pharmacies do so.

Recommendations: CMS should clarify that Part D sponsors meet their obligations with respect to the requirements in proposed section 423.120(a)(4) (i)-(iv) by including these requirements in their contracts with HI pharmacies, and that the requirement to deliver HI drugs within 24 hours of discharge from an acute setting is contingent on the HI pharmacy being informed of the discharge by the enrollee or hospital staff before it occurs.

I. Coordination of Benefits (“COB”) 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 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 it 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 our experience this year, 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 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 3-month close-out window was warranted due to "highly automated and point of sale nature of prescription drug claims processing." 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."¹⁹ CMS then went on to quote industry statistics that at least 98% of drug claims are paid within 3 months of submission, pointing out that, in addition to this 3 month claims run-out period, plans would have 6 months to submit data, thus giving plans "the extra time necessary to compile the data necessary for retroactive reconciliation."²⁰

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.

Recommendations: 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 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

¹⁹ 70 Fed. Re. at 4309.

²⁰ *Id.*

they are able to obtain the reinsurance and risk corridor subsidy payments that on these claims as Congress directed.

We appreciate the opportunity to provide these comments. If you have any questions or would like discuss our comments, please do not hesitate to contact me at 202-772-3501.

Sincerely,

Russell C. Ring
SVP, Government Relations

Submitter : Howard Schiff
Organization : Maryland Pharmacists Association
Category : Pharmacist

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Roger Schwartz
Organization : National Association of Community Health Centers
Category : Health Care Provider/Association

Date: 07/24/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Thank you.

CMS-4130-P-30-Attach-1.PDF



**National Association of
Community Health Centers, Inc.**

July 24, 2007

[If by electronic means]

<http://www.cms.hhs.gov/eRulemaking>

Herb Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

Attention: **CMS-4130-P**

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

Dear Administrator Kuhn:

The National Association of Community Health Centers, Inc. ("NACHC") is pleased to respond to the above-cited solicitation from the Department of Health and Human Services ("DHHS") Centers for Medicare & Medicaid Services ("CMS") for comments on the proposed rules related to the Medicare Prescription Drug Benefit ("Part D") technical changes published at 72 Fed. Reg. 29403 (May 25, 2007).

NACHC is the national membership organization for federally supported and federally recognized health centers (hereinafter interchangeably referred to as "health centers" or "FQHCs") throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization.

I. Background

There are, at present, approximately 1100 FQHCs nationwide serving close to 16 million patients. More than one million of these FQHC patients are Medicare recipients. Most of these FQHCs receive Federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b) from the Bureau of Primary Health Care ("BPHC"), within the Health Resources and Services Administration ("HRSA") of DHHS. Under this authority, health centers fall into four general categories:

MAIN OFFICE
7200 Wisconsin Ave, Suite 210
Bethesda, MD 20814
301-347-0400
301-347-0459 fax

FEDERAL AND STATE AFFAIRS OFFICE
1400 Eye Street NW, Suite 330
Washington, DC 20005
202-296-3800
202-296-3526 fax

(1) those centers serving medically underserved areas (invariably poor communities), (2) those serving homeless populations within a particular community or geographic area, (3) those serving migrant or seasonal farm worker populations within similar community or geographic areas, and (4) those serving residents of public housing.

§ 423.120 ACCESS TO COVERED PART D DRUGS

NACHC is pleased to see health center pharmacies listed as a non-retail pharmacy that Part D plans may count toward the standards for convenient access to network pharmacies. Health centers serve approximately 1.2 million Medicare beneficiaries, many of whom experience multiple chronic diseases. Because the vast majority of them are low-income, health centers serve a disproportionate share of dual-eligibles. Medicare Part D has been a tremendous help for many health center patients. The low-income subsidy (LIS or “extra help”), has expanded the number of health center patients with close to fully-subsidized drug coverage. This benefit helps many health center patients purchase their drugs ultimately improving their overall health. Listing health center pharmacies as non-retail pharmacies that Part D plans may count toward their convenient access standards encourages Part D plans to coordinate with health centers to better serve Medicare patients; particularly those with fewer resources and often greater health care needs.

§ 423.100 DEFINITION OF GOVERNMENT-FUNDED HEALTH PROGRAM

NACHC appreciates the opportunity to raise the issue of CMS’ designation of FQHCs as a “government-funded health program” for the purpose of excluding health center cost-sharing from counting towards Part D beneficiaries’ true-out-of-pocket expenditures. We strongly urge CMS to reconsider its interpretation of the law and allow health centers’ cost-sharing to count towards a Part D enrollee’s TrOOP requirement. The current regulation defines a government-funded health program as “any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, *which uses public funds*, in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs. 42 C.F.R § 423.100 [Emphasis added]. FQHCs are not listed in the rule as a “government-funded health program” along with the Medicaid program, the Indian Health Service program and the veterans’ health care program however the preamble identifies FQHCs as a “government funded health program.”

Thus, insurance or otherwise encompasses not just traditional health insurance coverage that is not considered a group health plan, but also government programs and entities (including the Department of Veterans Affairs (VA), IHS, Federally Qualified Health Centers (FQHC), Department of Labor (DOL) Federal Workers’ Compensation Program), government insurers (including Medicaid, Medicaid 1115 demonstrations, and the State Children’s Health Insurance Program (SCHIP)), and government-sponsored funds (including black lung benefits, Ryan White CARE Act funds, and State special funds that assist certain

individuals with their medical costs such as a special fund for AIDS patients). 70 Fed. Reg. 4241, Jan. 28, 2005.

Unlike the other programs listed in the preamble, FQHCs do not necessarily use government funds to pay the cost of Part D drugs. Rather, FQHCs are non-profit charitable corporations that rely on a variety of sources to provide health care services, including revenue from private payers, public charitable donations, and State Pharmaceutical Assistance Programs. Moreover, so-called FQHC “look-a-likes” do not receive any federal grant funds under Section 330 of the Public Health Service Act despite meeting the qualifications for eligibility for such grant funds. The other “entities” on the excluded list are distinctly federally-funded health care programs. In contrast to such federal programs, FQHCs are a type of provider entity that must meet rigorous federal requirements to qualify for certain benefits and to become eligible for grant funding.

Moreover, CMS’ recent decision to allow Disproportionate Share Hospitals (DSH) funds to count towards a beneficiaries TrOOP requirements further supports allowing beneficiaries to count health centers’ cost-sharing towards their TrOOP requirement. Section 30.4 of the Chapter 5 Medicare Part D Prescription Drug Manual (Pharmacy Waiver/ Reduction of Cost-Sharing and Applicability toward TrOOP) provides:

Receipt of Medicaid or Medicare Disproportionate Share Hospital (DSH) payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a “government-funded health program.” We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services, and not akin to government grants and funding that are used, in whole or in part, to provide to (or pay on behalf of) an individual the costs of Part D drugs.

As a result Medicaid and Medicare DSH payments do not automatically designate a hospital as a TrOOP-excluded entity. Applying this same logic to FQHC provider types, the receipt of any source of federal funding should not automatically result in excluding health center cost-sharing from TrOOP expenditures.

§423.464 COORDINATION OF BENEFITS WITH PART D PLANS AND OTHER PAYERS

As CMS establishes methods for more effective coordination of drug benefits, we ask that CMS revise its current statutory interpretation disallowing health center expenditures for a Part D beneficiary to count towards his or her TrOOP requirement. The Medicare Part D final rule reads, “A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold.” 42 C.F.R. § 423.464(f)(2). CMS lists FQHCs among other health plans and payers as entities “that provide other prescription drug coverage.” 42. C.F.R. § 423.464(f)(1). We strongly disagree with CMS’ decision to include health centers in that definition.

As you know, Congress provided for a new exception in the anti-kickback statute that permits pharmacies to waive or reduce the co-pay for Part D drugs under certain conditions and allowed the result of such expenditures to count toward the beneficiary's TrOOP calculation in limited circumstances. However CMS' treatment of health center expenditures for the purposes of TrOOP requirements significantly harms health centers financial viability and serves as an obstacle to low-income Medicare beneficiaries. Specifically, some patients who have had their cost sharing waived by the health center pharmacy may never move out of the coverage gap because of the CMS rule. As a result, health centers will perpetually be required to use their resources to help their low-income seniors access their much needed drugs, further taxing the health center's finances. NACHC urges CMS to change its interpretation of health center expenditures as it applies to Part D TrOOP requirements.

We appreciate the opportunity to comment on the proposed regulations, and we would welcome the opportunity to further discuss these concerns. If you have questions, please contact, Roger Schwartz, Legislative Counsel and Senior Director of State Affairs, at 202.298.3800.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Roger Schwartz". The signature is fluid and cursive, with the first name "Roger" and last name "Schwartz" clearly distinguishable.

Roger Schwartz, Esq.
Legislative Counsel and
Senior Director of State Affairs