

Submitter : Dr. Wayne Myers
Organization : Norland Avenue Pharmacy, LLC
Category : Pharmacist
Issue Areas/Comments

Date: 02/20/2007

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. (My pharmacy(s) is located in Chambersburg, Pennsylvania. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of Retail Class of Trade Removal of PBMs and Mail Order Pharmacies

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the general public. The more extensive comments submitted by Pennsylvania Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent.

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

4. Manufacturer Data Reporting for Price Determination Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, Pennsylvania Pharmacists Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on claw back from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Wayne G. Myers Pharm.D
Pharmacy Manager/Owner Norland Avenue Pharmacy

CMS-2238-P-1302

Submitter : Ms. JoAnn Smith
Organization : Family Planning Advocates of NYS
Category : Health Care Provider/Association

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1302-Attach-1.PDF



Family Planning Advocates of NYS
17 Elk Street
Albany, New York 12207-1002
Phone: (518)436-8408
Fax: (518)436-0004
Website: www.fpaofnys.org

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P/ RIN 0938-AO20

Dear Administrator Norwalk:

Family Planning Advocates (FPA) is a nonprofit organization that represents family planning providers in New York State, including the state's twelve Planned Parenthood affiliates, hospital- and non-hospital-based family planning health agencies, and a wide range of other health, community and social service organizations. New York's family planning agencies serve a vital role by providing quality, preventive health care to growing numbers of low-income patients in cost-efficient settings.

Family planning agencies provide a range of preventive health services such as routine gynecological exams; screening for breast and cervical cancers, high blood pressure, anemia, diabetes; health education; screening and treatment for sexually transmitted infections; pregnancy testing; prenatal care or referral as well as contraceptive care. One of the most important services our health centers offer is the provision of low cost oral contraceptive pills. Many women who could not otherwise afford the cost of contraceptives are able to obtain them from one of New York's family planning providers.

Many of the patients seen in New York's family planning health agencies are uninsured or underinsured, and for many patients, a family planning agency is their only source of health care. In 2005, 65.1% of the patients seen in New York's family planning agencies had income levels at less than 100% of federal poverty level, and 22.2% had income levels between 101-150% of federal poverty level. In 2005, 36.3% of patients seen in one of New York's family planning agencies were insured through the Medicaid program and almost 40% of the patients received services on a sliding scale basis.

New York's family planning providers have been able to serve as safety net providers and meet the needs of women in need of low-cost contraceptives because family planning providers have historically been able to purchase contraceptive drugs from manufacturers willing to provide them at nominal prices.

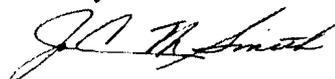
FPA is very concerned that the rule proposed to implement section 6001(d) of the Deficit Reduction Act of 2005 ("DRA") limits the ability of many vitally needed safety net providers to purchase nominally priced drugs. The proposed rule preserves the ability of only three kinds of providers to purchase drugs at nominal prices: (I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated nursing homes. We are very disappointed that CMS declined to identify other "safety net providers"--as authorized in section 6001(d)(IV) of the DRA--that would be eligible for the nominal pricing exception. We do not believe the proposed rule is sufficiently inclusive.

Almost all of New York's family planning health agencies are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured for the time being, but we are concerned that the rule could have a detrimental impact in the future. 340B status is not permanent and could be lost due to funding deficits in Title X or other programs that qualify health providers for 340B status. If 340B status is lost, family planning agencies still need protection as safety net providers. Additionally, we are aware that many family planning providers, including many Planned Parenthood affiliates across the nation are no longer eligible to purchase nominally priced drugs because of the failure to specifically define as safety net providers those who provide a significant level of health care services to uninsured, low-income and Medicaid patients. Clearly, the rule is not inclusive enough when health providers who serve as vital safety need providers for vulnerable patient populations do not meet the proposed definition of an entity eligible for the nominal price exemption.

We believe the proposed rule, unless changed, will have a negative impact on public health by constricting women's access to low-cost contraceptives. Family planning is a cost effective public health strategy and actually saves money by preventing costlier health problems. Unintended pregnancy can have wide ranging consequences for women and their families. When pregnancies are planned, the number of high-risk pregnancies and births are reduced, and infant and child health is improved. Expanding the proposed rule to include those safety net providers, including those who once were, but are no longer eligible for the nominal price exemption, will not have a negative impact on drug prices, and will serve to protect public health and prevent the need for health care expenditures associated with unintended pregnancy.

We urge CMS to amend the proposed rule by defining "safety net provider" or giving health providers who provide health care services to large numbers of uninsured, low-income and Medicaid patients the ability to purchase nominally priced drugs.

Sincerely,



JoAnn M. Smith
President and CEO

Submitter : Mr. Michael Koelzer
Organization : Kay Pharmacy & HME
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

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

Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer's price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Grand Rapids. Pharmacy is a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Definition of Retail Class of Trade Removal of PBMs and Mail Order Pharmacies

CMS should exclude pharmacy benefits managers (PBMs) and mail order pharmacies from the definition of retail pharmacy class of trade. PBMs and mail order pharmacies are not community pharmacies, which is where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the general public. The definition of retail pharmacy class of trade should include independent pharmacies, independent pharmacy franchises, independent chains, chain pharmacies, mass merchandisers and supermarket pharmacies.

2. Calculation of AMP Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade. Nursing home pharmacies, PBMs and mail order pharmacies receive discounts, rebates, and price concessions that are not available to the community retail pharmacies, making them a fundamentally different class of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacy for medications. Including these elements is counter to Congressional intent.

3. Removal of Medicaid Data
Including Medicaid data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. Medicaid, like the PBMs, does not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Inclusion of Medicaid data would have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs and, therefore, be excluded from AMP calculations in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination Address Market Lag and Potential for Manipulation

Reporting of AMP data by the manufacturers on a quarterly basis versus a monthly or weekly basis does not address the issue of price fluctuations when they occur. CMS needs to address this concern and create an exceptions and appeals process, similar to Medicare Part D, which would allow any provider, including a pharmacy, a mechanism to request a redetermination process for a FUL. The redetermination process should include a toll-free number that would be monitored by CMS and include a specific timeframe in which the redetermination process must occur and a procedure by which a redetermined FUL would be updated. This process would mitigate the risk of pricing lag and create a fair reimbursement mechanism for community pharmacy that is timely.

Collection of Information Requirements

Collection of Information Requirements

5. Use of 11-Digit NDC Versus Nine-Digit NDC

We believe that CMS should use the 11-digit NDC in the calculation of AMP since this is package size most commonly dispensed by retail pharmacies. The prices used to set the FUL should be based on the most common package size dispensed by retail pharmacies, not quantity sizes that would not be purchased routinely by a community pharmacy. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association regarding this proposed regulation. Please feel free to contact me with any questions.

Sincerely,

CMS-2238-P-1303

Copy: Members of Congress

GENERAL

GENERAL

Submitter : Mr. David Baloga
 Organization : Mr. David Baloga
 Category : Other Practitioner

Date: 02/20/2007

Issue Areas/Comments

Background

Background

The U.S. Government Accountability Office recently reported that on average the federal upper limits under the new Average Manufacturer Price (AMP) were "36% lower than average retail pharmacy acquisition costs" for the medications they reviewed. What business model allows someone to sell a product for 36% less than they are able to purchase it?

It is important to keep in mind that the GAO's findings were based on a reimbursement model of 250% of AMP, because the President's Fiscal Year 2008 budget proposes to further reduce reimbursement to pharmacists to 150% of AMP. This would be another \$1.2 billion in cuts from federal reimbursement, or over \$2 billion when combined with the corresponding state match. How are we supposed to continue to serve our patients with such devastating cuts to our reimbursement?

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It is without question that this ruling would impact many pharmacies, especially rural Medicare/Medicaid population serving pharmacies such as the one that I am affiliated with. Where will our patients turn when our pharmacy can no longer afford to fill their prescriptions because we are losing money? How will our government provide for these patients when they begin to increase the amount of emergency and hospital budget because they are not utilizing medications? THAT will increase the fiscal deficit more than paying for medications. Pharmacists provide more information about medications and how they impact disease states than physicians. They have little time to spend with their patients, and when they get to the pharmacy they are confused and looking for answers. CMS has benefited greatly over the years because pharmacists provide more than what they are paid for. Even with MTM and reimbursement programs, pharmacists are not being paid for all that they do for CMS patients as compared to physicians. Quite honestly, we will not be able to accept contracting with CMS for patients/community members if rates are based on what mail order and other entities can receive. We CANNOT buy prescription medications for the same price that other entities can. The policy mentions being able to buy medications at cost-effective bottle sizes. What about our HIV patients who do not remain on their medications for long periods of time, and we purchase medications just for them? What will we do with the remaining 150 tablets expiring on our shelf?

In addition, while CMS prepares to decrease reimbursement rates, nothing is discussed about increasing dispensing rates. How will pharmacies compensate when reimbursement decreases, and dispensing fees remain low. The average dispensing rate is \$10.50 per prescription. Current rates are less than four dollars. A major concern for me as an individual is the impact that this will have on my rural community. Community members will not be able to have access to necessary medications, because pharmacies will not be able to provide them. Essentially it is equivalent to asking pharmacists to start paying for CMS patients' medications.

This matter needs to be addressed in Congress. Pharmacies will not survive in rural areas where many retirees/indigent persons need care. Please revise this policy and provide patients with the care that they deserve through medications.

Thank you for your time. I will look forward to hearing how you will be changing this policy.

CMS-2238-P-1305

Submitter : Mr. michael fedida

Date: 02/20/2007

Organization : J&J Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

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see attachment

CMS-2238-P-1305-Attach-1.DOC

J&J Pharmacy
527 Cedar Lane
Teaneck, New Jersey 07666
201 836 7003

VIA ELECTRONIC SUBMISSION

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New Jersey serve a diverse Medicaid patient population for pharmacy care needs, I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacturers' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue provide Medicaid generic pharmacy prescription services to my Medicaid prescription patients without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.

Public Access Defines Retail Pharmacy Class of Trade

CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "publicly accessible." Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in calculating the AMP.

"Retail pharmacy class of trade" definition should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.

Inclusion in Best Price of PBM rebates, discounts and other price concessions.

Treatment of Manufacturer coupons with regard to Best Price.

Inclusion of Direct-to-Patient Sales with regard to AMP.

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.

For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.

PBM price concessions reporting to CMS.

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed - again through lack of regulation - to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufacturers supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-digit NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.

Impact on small pharmacies demonstrated by (General Accountability Office (GAO) findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. **It is also unlikely that states would set dispensing fees high enough to cover the average \$10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.**

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

Submitter : Dr. Gary Raines
Organization : Setzer Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS 2238-P Rin 0938-AO20

I wish to submit these comments to CMS regarding CMS's Dec 20, 2006 proposed regulations that would provide a regulatory definition of AMP as well as implement the new Medicaid FUL program for generic drugs. I am a pharmacy owner located in St Paul, MN. We are a major provider of phcy services in the community and your consideration of these comments is essential:

1. Remove PBM and Mail Order from Retail Class of Trade

- the creates consistency in the Regulation
- this conforms definition with market reality

2. Implement a Trigger Mechanism

- this would address severe price fluctuations
- it would also mitigate the risk of Pricing Lag

3. Use of 11 digit NDC versus 9 digit NDC

- this represents the most common package size dispensed in retail pharmacies

I support the more extensive comments that are being filed by the MN Pharmacist Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Gary Raines
Setzer Pharmacy
St. Paul, MN

Submitter : Ms. Darrah Johnson

Date: 02/20/2007

Organization : Planned Parenthood of San Diego & Riverside

Category : Health Care Provider/Association

Issue Areas/Comments

Background

Background

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Currently, PPSDRC's clinics are Title X clinics, and therefore 340B covered entities. For now, our 340B status allows us to purchase contraceptive drugs at nominal prices. However, having our eligibility for nominal prices tied to a federal funding source puts us in a vulnerable position. 340B is not a permanent designation. Given potential future funding constraints, our 340B status could be jeopardized and our eligibility for nominal drug pricing would subsequently disappear.

Planned Parenthood of San Diego & Riverside Counties serves as a key safety net provider to our communities. Our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define safety net provider or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will reconsider and exercise its authority to name other safety net providers that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. Planned Parenthood of San Diego & Riverside Counties is clearly a safety net provider and we strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient clinics like ours.

If Planned Parenthood of San Diego & Riverside Counties should ever lose its 340B designation and is not considered a safety net provider, it is likely that as many as 58,900 of our low-income clients would lose much needed care.

Respectfully submitted by,

Darrah D. Johnson
President & CEO
Planned Parenthood of San Diego & Riverside Counties

1075 Camino del Rio S.
San Diego, CA 92108
(619) 881-4500

GENERAL

GENERAL

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the President & CEO of Planned Parenthood of San Diego & Riverside Counties (PPSDRC) located in Southern California. We serve a three-county area that includes San Diego, Riverside and Imperial Counties. The area we serve comprises 16,000 square miles and 5 million people, a population larger than the state of Colorado. Our affiliate operates 19 not-for-profit outpatient clinics and serves approximately 250,000 patients annually in our three-county region. PPSDRC provides a range of reproductive health care services at low or no cost to the uninsured or underinsured population.

While PPSDRC, with 114,000 patients and 230,000 patient visits annually, is the largest reproductive health care community clinic in the area, there is still significant need for family planning services among the low-income populations. According to the California State Office of Family Planning (Family PACT), the unmet need for family planning services for people in California at or below 200% of the federal poverty level is 59% in San Diego, 66% in Riverside County and 70% in Imperial County.

70% of our patients are below the federal poverty level (FPL) and 94% of our patients fall below 200% FPL. All of these patients are eligible for public funding. The rest of our patients are low-income and uninsured but may not be eligible for public funding. We have a sliding scale for those clients who are uninsured.

Submitter : Mr. Mike Cantrell

Date: 02/20/2007

Organization : Longs Drug Stores

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1308-Attach-1.PDF

Longs Drugs

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Norwalk:

In response to CMS's proposed regulation associated with the definition of Average Manufacturers' Price (AMP) relative to the Deficit Reduction Act of 2005 (DRA), I ask that you kindly consider the following remarks.

- **Accurate Reflection:** Theoretically, AMP will closely approximate prices paid by retail pharmacies for medication. We are concerned that the proposed definition fails to satisfy that primary ambition. The United States Government Accountability Office's (GAO) report, dated December 22, 2006, addressed to Congressman Joe Barton tends to support our concern with its finding that when AMP-based FULs were applied, most drugs in the GAO's sample would be reimbursed at prices lower than average retail pharmacy acquisition costs. The final definition of AMP must accurately reflect prices paid for drugs in the retail class of trade.
- **Postpone Publication:** Given the importance and complexity associated with accurate and consistent AMP figures, CMS's decision in 2006 to delay the release of AMP data was prudent. Publication of a data set that has yet to be defined could result in tremendous confusion and misuse of that data. CMS's prudence sets the proper precedent—withhold publication of AMP data until such time as the final rule has been determined.

With the commencement of the Medicare Part D Drug Benefit, many Medicaid pharmacy claims migrated to a lower reimbursement schedule associated with Part D, having a dramatic adverse impact on many pharmacies. The DRA's change in the calculation of FUL prices will likely compound that deleterious effect.

Few dispute the value delivered by the pharmacy industry in response to hurricane Katrina. The presence of retail pharmacies in the ravaged area enabled countless victims to have access to life sustaining medications. The obvious benefits derived from that access is now threatened by the adverse consequences associated with the DRA's mandate of AMP adoption. Careful deliberation associated with the definition of AMP is of paramount importance to the retail pharmacy industry and the patients it serves.

Thank you for your kind consideration of these remarks.

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.



Michael Cantrell
Vice President Professional Services

MLC/me

Submitter : Walter Cwietniewicz

Date: 02/20/2007

Organization : Ellis Phy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Calculation of AMP shoul only include independent phy & ind chains & should exclude mail order. CMS should exclude rebates paid to PBM from AMP calculation-they aren't offered to retail phy!- AMP data must be reported weekly! AMP pricing must use 11 digit NDC-I can't buy in 100,000's.-Accounting firm of Grant Thornton LLP found dispensing fee shoul be 10.50 per rx -need this if lowering drug prices!!! WE need a fair reimbursement for our time & work-why can't this be done?????

Submitter :

Date: 02/20/2007

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1310-Attach-1.DOC

CMS-2238-P-1310-Attach-2.DOC

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 : Mrs. Amanda Stubblefield
Organization : University of Tennessee College of Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1311-Attach-1.DOC

February 20, 2007

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

**Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20**

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a student pharmacist at the University of Tennessee College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Longley Pharmacy, a community retail pharmacy located at 785 Chickamauga Avenue, Rossville, GA, and I am familiar with the challenges in retail pharmacy practice.

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

CMS is proposing an overly broad inclusive definition of "retail class of trade" for use in determining the AMP used in calculating the FULs. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the "open to the public" distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the "general public" and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL. The more extensive comments submitted by the Tennessee Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP – Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including the elements defined in the proposed regulations is counter to Congressional intent. Rebates and other concessions paid by manufacturers to entities such as mail order pharmacies and PBMs are not shared with community retail pharmacies and, thus, do not reduce the prices pharmacies pay for drugs and are not available to the "general public." These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

While the AMP data is not currently publicly available, so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I worked, where the majority of our business came from prescription drugs. What the “other sales” in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, the Tennessee Pharmacists Association (TPA) proposes a “trigger mechanism” whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the TPA comments on the lack of clarity on “claw back” from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Amanda Stubblefield
1613 W. 53rd Street
Chattanooga, TN 37409

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Zach Wamp

Submitter : Mr. James Cammarata

Date: 02/20/2007

Organization : Valley Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Historically and currently, community retail pharmacy has been THE leader in the health professions with regard to efficiencies in delivering health care to the general public. It is exactly because of these efficiencies (computer technology, robotics, etc) that pharmacy in particular has been targeted as a primary area to "cutback" reimbursements in order to control health costs.

Presently, retail pharmacy is existing on the thinnest of margins while offering the general public the best pharmacy care of all pharmacy service venues. It is NOT possible to reduce reimbursement levels to any further extent; to do so would eliminate retail pharmacy as it exists today.

The current proposed AMP-based FULs would significantly reduce reimbursement on generic drugs to the retail community pharmacy to the point where it will no longer be possible for these pharmacies to exist. The arrived at AMP-based FULs, according to the GAO, are predominately BELOW acquisition costs for the retail sector. AMP-based FULs for the retail class of trade must be derived from true acquisition for pharmaceuticals available to the retail class. An accurate determination of such acquisition costs plus an equitable fee will ensure that not only will retail community pharmacy remain to service the American public, but also ensure that the highest utilization of cost saving generic drugs will decrease significantly the overall cost to CMS with regard to pharmaceuticals. Under the current proposed AMP-based FULs, pharmacies would do better financially to dispense high-priced brand drugs whenever possible, as the product reimbursement would be higher. Do we want this scenario?

Under the present proposed provisions, it will not be long before most, if not all, independent and small chain pharmacies will be forced out of business. If CMS, our legislators, and the general public are willing to accept that scenario, then there is no need to change the proposed provisions.

CMS-2238-P-1313

Submitter : Mrs. Rebecca Tallent
Organization : Little Drugs
Category : Other Technician

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1313-Attach-1.DOC

February 15, 2007

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

**Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20**

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacy technician at Little Drugs, located at 510 South Main Street, Sweetwater, TN. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

CMS is proposing an overly broad inclusive definition of "retail class of trade" for use in determining the AMP used in calculating the FULs. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the "open to the public" distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the "general public" and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL. The more extensive comments submitted by the Tennessee Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP – Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including the elements defined in the proposed regulations is counter to Congressional intent. Rebates and other concessions paid by manufacturers to entities such as mail order pharmacies and PBMs are not shared with community retail pharmacies and, thus, do not reduce the prices pharmacies pay for drugs and are not available to the "general public." These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

While the AMP data is not currently publicly available, so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less

than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I work, where the majority of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, the Tennessee Pharmacists Association (TPA) proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the TPA comments on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Rebecca Tallent
206 Kinzalow Drive

Sweetwater, TN. 37874

cc: Senator Lamar Alexander
Senator Bob Corker
Jimmy Matlock

CMS-2238-P-1314

Submitter : Mr. Jack Painter

Date: 02/20/2007

Organization : Prasco, LLC

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attached Word Document, "Letter to Centers for Medicare & Medicaid Services" and PDF Document, "Mitchell Letter 1-30-07"

CMS-2238-P-1314-Attach-1.DOC

CMS-2238-P-1314-Attach-2.PDF



Via Electronic Posting to: <http://www.cms.hhs.gov/eRulemaking>

February 20, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-2238-P

Dear Sir/Madam:

Prasco, LLC appreciates the opportunity to offer comments on the proposed rules published on December 22, 2006 (71 FR 77174 *et seq.*) regarding implementation of the Deficit Reduction Act of 2005 ("DRA").

Prasco is a privately held generic pharmaceutical company that has become a leader in the authorized generic drug industry. Prasco is not owned, wholly or in part, by any brand-name drug company. Prasco is an independent organization that specializes in offering a broad range of authorized generic drug products from several brand manufacturers. Prasco markets authorized generic drug products during and after the 180-day exclusivity period and when there is no exclusivity period.

Prasco submits the following comments on the proposed rules:

1. 340B Program AMP Calculation

Recently, the Office of Pharmacy Affairs suggested that AMP be calculated differently for the 340B program than it is for the Medicaid program. *See* January 30, 2007 letter from J. Mitchell to 340B manufacturers, attached hereto. Competing and contradictory definitions of AMP (and presumably unit rebate amount) would be unduly burdensome and confusing for manufacturers, regulators and providers. (A manufacturer would have to calculate five different AMPs per NDC-9 per quarter.) We urge CMS to coordinate with HRSA and OPA to come up with a single calculation methodology for AMP and unit rebate amount for all programs.

2. Publication of AMP

We propose that CMS delay any requirement to post AMP on a public website for at least two full quarters after the publication of a final rule. Until the final rule is published and manufacturers adopt it, the variety of calculation methodologies currently in place among manufacturers will yield AMPs that cannot be accurately compared. This is likely to create unnecessary confusion among providers, consumers and manufacturers and will place many pharmacies in an untenable position due to inconsistency in the resulting reimbursement.

We also urge CMS to reconsider its decision to require publication of monthly AMPs. The DRA requires AMPs to be posted on a public website quarterlyⁱ. See §6001(b). The proposed rule, however, calls for publication both monthly and quarterly. We believe quarterly AMPs provide better information about actual average prices because they are subject to much less volatility than monthly AMPs.

3. AMP and Best Price Reporting

Under proposed regulation §447.506(b), a manufacturer of a branded drug product is required to “include the direct and indirect sales” of an authorized generic drug product in the branded product’s AMP calculation.

We propose that CMS clearly specify that the information to be provided by the authorized generic manufacturer to the brand manufacturer is limited to AMP and related units and does not include core transaction data. A requirement to furnish core transaction data would significantly increase the reporting and recordkeeping requirements above CMS’ current estimates in §447.510 and would significantly increase the antitrust concerns described in item 4 below.

We understand the approach taken by CMS to require the brand manufacturer to use the authorized generic manufacturer’s commercial sale price in calculating the best price for the branded drug product. We urge CMS, however, to explicitly exclude from the calculation of best price the transfer price at which the brand manufacturer sells to the authorized generic manufacturer. Such an exclusion would be consistent with the historical treatment of sales to repackagers and relabelers, which are excluded from best price.

4. Mitigation of Antitrust Risks

The proposed rules require the authorized generic manufacturer (including each independent authorized generic manufacturer) to share sensitive, proprietary pricing data with the manufacturer of the branded drug product, which could lead to unwarranted allegations of violations of antitrust laws.

We propose that CMS take the following steps to mitigate this risk:

- Clearly lay out the data sharing requirements to reduce the risk of unwarranted accusations of anticompetitive conduct.
- Formally request that the Federal Trade Commission and the Antitrust Division of the Department of Justice establish a safe harbor for data exchange under the proposed rules.
- Create an administrative outlet within CMS for initial consideration of claims of anticompetitive activity arising out of compliance with the rules.

Taken together, these steps will minimize the likelihood that manufacturers will be unfairly accused of violating the antitrust laws simply by complying with the government price reporting rules concerning authorized generics.

If you have any questions about the above comments, please contact Jack Painter at 513-618-3333, ext. 3507.

Submitted on behalf of Prasco, LLC by:

Jack Painter, Esq.
Legal Counsel to Prasco, LLC

Attachment

¹ While the preamble to the proposed rule suggests that the DRA requires the publication of AMP on a monthly basis (*see* 71 FR 77186, which states, “The statute does not specify that this exception [to the confidentiality provisions] only applies to monthly AMP...”), the text of the DRA actually suggests publication on a quarterly basis: “[T]he Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, *on at least a quarterly basis*, update the information posted on the website under subparagraph (D)(v).” §6001(b)(1)(B) (emphasis added).



DEPARTMENT OF HEALTH & HUMAN SERVICES

1314-2
Health Resources and Services
Administration

Healthcare Systems Bureau

JAN 30 2007

Rockville MD 20857

Dear Pharmaceutical Manufacturer:

The Office of Pharmacy Affairs (OPA), within the Healthcare Systems Bureau of the Health Resources and Services Administration, is charged with administering the drug pricing program established by Section 340B of the Public Health Service Act. Section 340B requires that participating pharmaceutical manufacturers charge covered entities a price for covered outpatient drugs that does not exceed the average manufacturer price decreased by the Medicaid rebate percentage (the "340B ceiling price") as specified in the statute.

OPA is writing to clarify for manufacturers the definition of Average Manufacturers Price that is used for 340B ceiling price calculations (340B AMP). Although the Deficit Reduction Act amended the statutory definition of Average Manufacturers Price for purposes of Medicaid by removing the deduction for customary prompt payment discounts, Section 340B(c) of the Public Health Service Act states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section." Accordingly, manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.

We welcome comments from all parties about how to best implement the 340B Program requirements in the wake of changes in related areas impacted by the DRA. Our goal would be to minimize the burden on pharmaceutical manufacturers in submitting the required data.

As part of OPA's efforts to improve the administration of the 340B Program as outlined previously in our letter to pharmaceutical manufacturers dated December 30, 2005, we also continue to invite all pharmaceutical manufactures that have signed 340B PPAs to voluntarily submit quarterly 340B price files on covered outpatient drugs to OPA.

Please feel free to contact LT Devin Williams of OPA at 301-594-4356 (email: DWilliams@HRSA.GOV) with any questions you may have. We appreciate your continued participation in and commitment to the 340B Program. Your cooperation will make a significant contribution to ensuring the fairness and integrity of the 340B Drug Pricing Program.

Sincerely,

Jimmy R. Mitchell, R.Ph, MPH, MS
Director
Office of Pharmacy Affairs

Submitter : Mr. Andrew Sperling
Organization : National Alliance on Mental Illness
Category : Consumer Group

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1315-Attach-1.TXT



February 20, 2007

Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Attention CMS-2238-P

Dear Sir/Madam:

On behalf of the 210,000 members and 1,200 affiliates of the National Alliance on Mental Illness (NAMI), I am writing in regards to the recently proposed rule under the Deficit Reduction Act of 2006 related to the calculation of Best Price (BP) used to determine rebates paid by pharmaceutical manufacturers to state Medicaid agencies.

In reviewing this proposed rule, it appears that CMS will be requiring manufacturers to include the value of coupons in BP calculations when they are redeemed by an entity other than the consumer. In addition, it appears that this proposed rule is being interpreted as requiring manufacturers to include in the BP, the value of coupons redeemed by pharmacies or third-party vendors that process these transactions.

NAMI is particularly concerned about the potential implications of this proposed rule on low-income individuals and families that participate in coupon programs to access discounted or free medications. At minimum, this rule could cause manufacturers to change their coupon programs in order to comply with these new guidelines, causing enormous disruption for low-income participants.

In addition, navigating how to use a new coupon program would likely prove difficult and time-consuming for low-income participants in these coupon programs – many of whom are living with a severe mental illness or a cognitive impairment. Confusion and frustration over how participate in a new coupon system would almost certainly result in many low-income participants these coupon programs to lose access to medications that they depend on serious chronic conditions and make already difficult challenges with treatment adherence all the more challenging.

NATIONAL ALLIANCE ON MENTAL ILLNESS
2107 Wilson Blvd., #300 * Arlington, VA 22201 * 703-524-7600 * www.nami.org

NAMI would strongly recommend that CMS avoid policy changes in this proposed rule that would disrupt access to these important coupon programs. NAMI urges CMS to pull this proposed rule back and integrate changes that would allow these assistance programs for low-income consumers to continue uninterrupted.

Thank you for your consideration on this important issue.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Fitzpatrick". The signature is written in a cursive style with a large initial "M" and "F".

Michael J. Fitzpatrick, M.S.W.
Executive Director

Submitter : Ms. Sarah Potter

Date: 02/20/2007

Organization : Ms. Sarah Potter

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1316-Attach-1.DOC

March 27, 2007

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

**Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20**

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in Sanford, North Carolina. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

- 1. Remove PBM and Mail Order from Retail Class of Trade**
 - (i) Creates consistency in the Regulation
 - (ii) Conforms definition with market reality

- 2. Implement a Trigger Mechanism**
 - (i) Addresses severe price fluctuations
 - (ii) Reduces risk of Market Manipulation
 - (iii) Mitigates Risk of Pricing Lag

- 3. Use of 11-Digit NDC versus 9-Digit NDC**
 - (i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by the North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Sarah S. Potter,
Doctor of Pharmacy Candidate,
Campbell University

Submitter : Mr. David Nova

Date: 02/20/2007

Organization : Planned Parenthood of the Blue Ridge, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Thank you.

CMS-2238-P-1317-Attach-1.DOC

February 20, 2007

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Ms. Norwalk:

As the President & CEO of Planned Parenthood of the Blue Ridge, Inc., I am submitting comments on behalf of our not-for-profit, 501(c)(3) agency and its Board of Directors regarding one of our four health centers. That center, based in Charlottesville, Virginia, is no longer eligible for nominal pricing on contraceptive products since implementation of the Deficit Reduction Act of 2006.

Our other Virginia sites in Roanoke, Blacksburg and Lynchburg receive limited federal funding as a 340B provider. Our Charlottesville health and education center receives no public monies from federal, state or local entities. That center relies entirely upon patient fees supplemented with private donations. Well over 90% of patients at our health center are either uninsured or underinsured. Many of these patients could not otherwise access affordable reproductive health care services – in particular, oral contraceptives – without our continued operation.

The other low-cost community provider of reproductive health care services are the municipal-based health department centers that operate under the auspices of the Virginia Department of Health. While they are able to provide subsidized care using Title X funding, the limitations of that funding are reflected in extremely limited hours for the provision of family planning services. Below are the current schedules for the Title X family planning clinics provided at the health departments of our Charlottesville Center's services area. (Please note that teens, women and couples in need of low-cost reproductive health care may only be served by the municipal health center in which they reside!):

- **Charlottesville/Albemarle County:** Wednesdays 8:30-10am, 1-4:20pm
- **Fluvanna County:** Monday (1st, 2nd and 4th weeks) 1-3pm
- **Nelson County:** Tuesdays, 12-4:30pm
- **Greene County:** Thursdays, 12:45-3:30pm

These brief clinical hours provide a very limited window of opportunity for those at risk of sexually transmitted infections and unintended pregnancy. For working women of limited means, and for adolescents attending schools, access to reproductive health care through the local health department centers is virtually impossible.

In order to address unmet need in these communities, we established our Charlottesville health center serving more than 1,000 patients from these aforementioned communities. To adequately meet the needs of working women and teens, we offer evening and Saturday family planning clinic hours, in addition to weekday hours during the day. We have tailored our hours of operation to meet the needs of these higher-risk populations. We have also been able to provide subsidized care by seeking private community support and by relying heavily on the discounted purchase of contraceptive products that had previously been available to our Charlottesville Center at nominal prices.

As you are aware, effective January 1, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Most other Planned Parenthood health centers, including the three other centers of Planned Parenthood of the Blue Ridge, receive Title X funding and, as a result, are 340B-covered entities. The ability to purchase oral contraceptives for these centers at very low prices is assured. However, our Charlottesville Center is not federally funded. We do not qualify as a 340B covered entity in Charlottesville.

Nevertheless, Planned Parenthood in Charlottesville serves as a key safety net provider to our community, and in particular, teens. Without government funding, we have maintained a monthly Free Teen Clinic that provides a full range of reproductive health care services plus three months of free contraceptives. We have been able to do so through a reliance on the purchase of contraceptive drugs at a nominal price. Our Free Teen Clinic is one primary example of a program serving hundreds of at-risk, sexually active patients that is now in jeopardy due to our inability to access nominally priced contraceptive services.

We are deeply disappointed that the Centers for Medicare and Medicaid Services did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, our Charlottesville Center does not qualify for the three categories listed above.

We sincerely hope that the Centers for Medicare and Medicaid Services will reconsider and exercise its authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. All four of our Planned Parenthood health centers in Charlottesville, Roanoke, Blacksburg and Lynchburg are clearly safety net providers. We strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient health centers like ours.

Sincerely,

David Nova
President & CEO

Submitter : Mr. John Chappuis

Date: 02/20/2007

Organization : MT Department of Public Health and Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1318-Attach-1.PDF

1318

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES



BRIAN SCHWEITZER
GOVERNOR

JOAN MILES
DIRECTOR

STATE OF MONTANA

www.dphhs.mt.gov

PO Box 4210
HELENA, MT 59604-4210

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Attention: CMS-2238-P

Re: Proposed Rule: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk:

The State of Montana, Department of Public Health and Human Services respectfully submits this comment letter on the Medicaid prescription drug benefit. Montana is commenting on the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS). Montana is committed to implementing the prescription drug related provisions of the Deficit Reduction Act of 2005 (DRA) and to the ongoing initiatives that seek to improve the efficiency of the Medicaid pharmacy benefit.

Medicaid's basic structure of a federal-state partnership necessarily means that Montana has a vested interest in the proposed regulation on prescription drugs. This rule must be easily implemented and cause minimal disruption to the ongoing operation of the Medicaid program. Montana is designated a frontier state; this requires the rules consider the special circumstances that we and other rural states face in the Medicaid pharmacy benefit. Through this rule, we must continue to be assured that pharmacies from all areas of the state be able to be reimbursed according to their acquisition cost of prescription drugs, not that of a PBM or mail order pharmacy.

Montana provides the following comments and suggestions based on the specifics of our state.

Determination of Average Manufacturer Price

In the proposed rule, CMS outlines its reasoning for the inclusion of mail order pharmacies in its definition of retail class of trade for purposes of calculating AMP. Mail order pharmacies are able to capitalize on their economies of scale by purchasing in bulk and dispensing in large quantities. Additionally, mail order and other large scale purchasers have access to discounts that are not available to rural or sole proprietorship pharmacies. Because of this disparity, mail order pharmacies should not be included in the AMP calculation. There are many areas of Montana who are served entirely by these sole proprietorship pharmacies. These providers will likely not have access to prescription drugs at the same pricing as the mail order or PBM pharmacies. It is essential that Medicaid clients and other Montanans continue to have access to pharmacies in their local communities. This can only be accomplished through a Medicaid reimbursement policy based on the pharmacy's actual acquisition costs.

Montana is one of many states that have implemented a Preferred Drug List (PDL) in recent years to contain costs in the Medicaid prescription drug benefit. We request that CMS consider the impact that the new AMP-based FUL will have on our PDL. We could also face challenges and unintended consequences on the level of savings expected to

"An Equal Opportunity Employer"

accrue from the new FUL if the net cost to the federal government and Montana is less than generic. Specifically, this could compromise supplemental rebate agreements that Montana has in place in situations where the federal rebate and supplemental rebate together produce greater savings than the new FUL.

Determination of Best Price

The proposed rule discusses why CMS feels it is appropriate to include all PBM rebates, discounts, or other price concessions for drugs provided to retail pharmacy class of trade for purposes of calculating AMP. While PBM rebates, discounts or other price concessions accurately reflect prices available to large scale purchasers, these prices are again not generally available to rural or sole proprietorship pharmacies and should not be included in the AMP calculation.

Requirements for Manufacturers

We believe that the DRA and this proposed rule begins to detail the important steps that will help to increase the access and simplicity of AMP data. However, Montana has identified several areas of concern with the proposed rule related to AMP.

Quality of Data

Montana strongly encourages CMS to consider the quality of the data that is available. This is likely to have a significant impact on the accuracy and appropriateness of our reimbursement methodology. CMS began providing Montana and other states with sample or "non-standard" AMP data in July of 2006, and, to date, we have only conducted a preliminary analysis of the AMP data. From this preliminary analysis, there are a significant number of terminated products or products that were not available in a certain geographic location that were included in the manufacturers' lists. In addition, we have recognized that there is significant fluctuation in AMP and that this inconsistency results in inaccurate estimates of the acquisition costs that providers pay.

Montana remains concerned by the lack of controls and accountability measures for manufacturers submitting AMP information. The previous experience of Montana suggests that existing CMS processes have been insufficient in monitoring and managing the prescription drug files submitted by manufacturers. This lack of updated data will undoubtedly result in inappropriate calculations. These erroneous calculations will impose an unforeseen burden on states to identify and subsequently report any inaccuracies to CMS. Montana urges CMS to implement systems checks and measures to hold manufacturers accountable for the quality of data they provide, including the reporting or not reporting of accurate data.

Dispensing Fee Adjustments

Montana understands that in making the changes proposed by this rule, we will retain the flexibility of increasing dispensing fees to providers. However, we believe that it is inappropriate for CMS to require Montana to increase the dispensing fees to compensate for the providers' loss of income on ingredient costs. In addition, while the proposed rule seeks to achieve Medicaid savings, these savings could be minimized or eliminated should states be required to increase their dispensing fees rather than maintain a reasonable, market-based reimbursement threshold. We urge CMS to examine the range of factors impacting the reimbursement methodology currently employed by Montana, not just the ingredient costs.

Implementation Timeline

Montana is concerned that the final regulation may not be published until July 1, 2007 and that many questions critical to implementation of the proposed rule are unknown. While we understand that this is the date specified in the DRA, we urge CMS to consider and account for the steps Montana will need to take in order to implement the final rule and meet this deadline.

Montana is unable to change our current processes and systems for a number of reasons. These include; 1) we must wait for CMS to finalize the provisions of this rule before we can modify our current systems and processes to implement it, otherwise, it may be necessary to make additional changes to reflect the changes and additional information CMS provides in the final rule; 2) the implementation timeframe is short and we do not have the ability to

draft and submit the required changes to our state rule which outlines the specific pricing methodology of our pharmacy program; and 3) although we received AMP data in 2006, this was only sample data. We have had insufficient time to evaluate the monthly fluctuations in AMP and determine the impacts this change will have on the pharmacy program. Because of the reasons stated above, Montana requests that CMS be open to the possibility that an extension may be necessary for Montana to comply with the proposed rule.

FFP: Conditions Relating to Physician Administered Drugs

As discussed in the proposed rule, Montana will now be required to collect NDC codes from physicians along with the Healthcare Common Procedure Coding System (HCPCS) or J-Codes. While J-Codes will require physicians to indicate an NDC, not all of the B-codes representing infusion therapy drugs within the HCPCS system are subject to the rebate legislation. In addition, there will be operational challenges associated with the NDC requirements for HCPCS prescription drugs.

There are two paper forms, the CMS 1500 and the UB04 that are used. The electronic 837 format for both the CMS 1500 and UB04 can accommodate the NDC, including the NDC quantity. However, currently the paper version of the UB04 does not have a space for this information. CMS has indicated that each state should develop its own unique form.

Montana urges CMS to reconsider this issue, particularly given the limited timeframe available to adopt a new form. Due to the administrative procedures and existing demands on state staff, Montana faces great challenges in meeting this requirement. Instead, Montana respectfully requests CMS develop a standard form available for use by all states. This will ensure uniformity across states and ensure that Montana collects all the required information. Furthermore, CMS needs to clarify whether FFP will be available to states for physician administered drugs where the reimbursed NDC is from a labeler who does not participate in the drug rebate program.

Provider education

Montana is concerned that the proposed rule does not take into account the extensive education and systems updates that will be required to ensure that providers can comply without placing an undue burden on either the state agency or the provider themselves. We believe that it would be an onerous requirement to mandate states – without any assistance from CMS – to work with providers to ensure that these codes are collected are for rebatable drugs. Montana expects the change in the billing system and practices to be an especially acute problem in situations of small provider groups or among providers that utilize separate contractors for their billing systems. Montana believes that CMS has significantly underestimated the burden of this provision on states if it is implemented as proposed.

As such, Montana requests that CMS inform providers of the National Drug Code (NDC) billing requirements. Without this information, providers may not know who is and is not a rebating labeler. At a minimum, CMS should revise its burden estimate to account for the extensive education and outreach that states will ultimately be required to undertake.

Thank you for the opportunity to comment on the proposed rule regarding prescription drug pricing. If you have any questions, please do not hesitate to contact me at (406) 444-4084.

Sincerely,



John Chappuis, State Medicaid Director
Montana Department of Public Health and Human Services

cc: Mary Dalton, Administrator, Health Resources Division
Duane Preshinger, Senior Medicaid Policy Manager, OPCA

CMS-2238-P-1319

Submitter : Mr. Jayson Slotnik

Date: 02/20/2007

Organization : Biotechnology Industry Organization (BIO)

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1319-Attach-1.PDF

February 20, 2007

Leslie V. Norwalk, Esquire, 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, DC 20201

Re: CMS-2238-P (Medicaid Program; Prescription Drugs)

Dear Administrator Norwalk:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding the treatment of prescription drugs under the Medicaid Drug Rebate Program (the Proposed Rule).¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. The Deficit Reduction Act of 2005 (DRA) includes a number of provisions that will impact the operation of the Medicaid Drug Rebate Program.² BIO supports CMS' effort to bring additional clarity to the calculations of Average Manufacturer Price (AMP) and Best Price, both of which determine Medicaid rebates, and in the case of AMP, federal upper payment limits (FULs) as well. The Final Rule has the potential to significantly impact patient access to drugs and biologicals, and BIO urges CMS to provide the additional guidance and clarity described below to ensure continued beneficiary access to important drug and biological therapies. In addition, BIO urges CMS to take steps to ensure that any State implementation of AMP-based reimbursement methodologies, which is not mandated by the Final Rule, also does not impede such access.

In this spirit we offer comments to the Proposed Rule. First and foremost, BIO strongly urges CMS to codify the statutory requirements that limit the amount of manufacturer rebates where a State Medicaid program is a secondary payor and the time

¹ 71 Fed. Reg. 77,174 (Dec. 22, 2006).

² See Deficit Reduction Act of 2005, Pub. Law No. 109-171, §§ 6001-04 (2006).

period in which States can submit rebate claims. BIO also comments regarding certain definitions in the Proposed Rule, including those for the retail class of trade, bundled sale, and bona fide service fee. BIO addresses the Proposed Rule's new guidance regarding patient and other transaction types as well. This letter then discusses the provisions relating to manufacturer recalculation of base date AMP and monthly reporting of AMP. Finally, BIO addresses a number of issues not directly reached by CMS in the Proposed Rule but that BIO believes are crucial to the effective administration of the Medicaid Drug Rebate Program. These issues are discussed in depth below, in the order in which they are addressed in the Proposed Rule.

I. CMS Should Clarify Certain Terms and Definitions Included in the Proposed Rule.

BIO applauds the Proposed Rule's attempt to "bring together existing and new regulatory requirements in one, cohesive subpart."³ Even with the additional guidance contained in the Proposed Rule, BIO has identified a number of key terms that the Proposed Rule either does not define, or includes but are in need of additional clarification. BIO requests that CMS address those issues in the Final Rule. Specifically, BIO urges CMS to clarify that drugs approved under a biologic license approval are single source drugs, to define the term "original NDA," to specify that the "United States" means the fifty states and District of Columbia, to clarify that "net sales" is not tied to a manufacturer's recognized revenue for financial accounting purposes, and, finally, to encourage States to include Medicare special add-on fees when setting dispensing fees.

1. CMS Should Clarify That Drugs Approved Under a Biologic License Application Are Single Source Drugs.

CMS proposes to define single source drug as a "covered outpatient drug that is produced or distributed under an original NDA . . . [or] approved under a product license approval, establishment license approval, or antibiotic drug approval."⁴ This definition is consistent with the Medicaid rebate statute and the Medicaid rebate agreement, but does not address products approved under a biologic license application (BLA).⁵ BIO asks CMS to clarify that drugs approved under a BLA are single source drugs, consistent with those products' designation under the Average Sales Price (ASP) calculation.⁶

2. CMS Should Define the Term "Original NDA" Consistent with the 1995 Proposed Rule.

The Proposed Rule does not contain a definition of "original NDA," although this term is a crucial component in the definition of single source drug. The term is not

³ 71 Fed. Reg. at 77,174.

⁴ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.502).

⁵ See Social Security Act (SSA) § 1927(k)(7)(A)(iv); Medicaid Rebate Agreement at I(z).

⁶ SSA § 1847A(c)(6)(D)(i).

defined in the Medicaid rebate statute, the Medicaid rebate agreement, or the Federal Food, Drug, and Cosmetic Act. CMS previously has recognized the need for a definition of this term.⁷ In the 1995 proposed rule, which never has been finalized, CMS defined the term as “an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act, or marketing exclusivity rights granted by the FDA.”⁸ CMS stated then that this definition was consistent with congressional intent to treat separately those drugs able to realize greater profits due to patent or marketing protection. BIO asks CMS to include this definition in the Final Rule.

3. CMS Should Clarify the Definition of Multiple Source Drug

CMS proposes implementation of section 6002 of the DRA, including the development of a top 20 multiple source drug list, in proposed 42 C.F.R. § 447.520. For purposes of that proposed regulation, CMS proposes in 42 C.F.R. § 447.502 to define “multiple source drug” consistent with the Medicaid statute - section 1927(k)(7)(A)(i). BIO agrees that this is the proper definition of “multiple source drug” to utilize in creating this listing, but believe that the top 20 multiple source drug listing is not consistent with either the pertinent statutory definition or the proposed regulatory definition. Specifically, the listing that CMS released in December includes two products - Factor viii recombinant and Factor viii - that do not meet the definition of “multiple source drug” because they are not listed in the Food and Drug Administration’s Orange Book. Accordingly, we ask CMS both to correct the top 20 multiple source drug listing to remove these two products and to ensure that the final rule makes clear that drugs that are not listed in the Orange Book cannot appear in the multiple source drug listing.

4. CMS Should Define the Term “United States” As the Fifty States and District of Columbia

The Proposed Rule defines AMP as the average price received by the manufacturer for the drug “in the United States.”⁹ Best Price is defined as the lowest price available from the manufacturer to “any entity in the United States.”¹⁰ The Proposed Rule does not define “United States,” although the agreement defines the term “states” as the fifty states and District of Columbia.¹¹ Consistent with this agreement definition, BIO asks CMS to define the full term “United States” as the fifty states and the District of Columbia.

⁷ See 60 Fed. Reg. 48,442, 48,453 (Sept. 19, 1995).

⁸ Id.

⁹ 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).

¹⁰ Id. at 77,197 (proposed 42 C.F.R. pt. 447.505(a)).

¹¹ 56 Fed. Reg. 7050 (Medicaid Rebate Agreement at 1).

5. CMS Should Clarify That the Term “Net Sales” Is Not Dependent on Revenue Recognition for Financial Accounting Purposes.

The Proposed Rule directs that AMP is to be calculated as “net sales divided by number of units sold.”¹² CMS proposes to define net sales as the “quarterly gross sales revenue less cash discounts allowed and all other price reductions . . . which reduce the amount received by the manufacturer” (emphasis supplied).¹³ BIO requests CMS to clarify that the term “revenue” in the “net sales” definition refers only to sales dollars associated with a transaction and not revenue recognized for a transaction for financial accounting purposes. This interpretation is consistent with the position CMS already has taken in the context of ASP reporting: that financial accounting principles are generally inapplicable in the price reporting context.¹⁴ For purposes of the AMP calculation, BIO believes it is appropriate to define net sales as a measure of actual sales made regardless of the financial accounting treatment of the transaction. BIO requests that CMS include this clarification in the Final Rule.

6. CMS Should Encourage States to Include Additional Fees Provided in the 2007 Physician Fee Schedule Final Rule When Establishing Dispensing Fees.

The Proposed Rule includes a general definition of dispensing fee to “assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers.”¹⁵ The Proposed Rule does not mandate that States use a specific formula or methodology for determining dispensing fees for Medicaid drugs, as it has in the Medicare context, but instead opts to provide the States with factors to consider in setting those amounts.¹⁶ As CMS knows, the Medicare program does provide additional or special fees for certain drugs that involve specific pre-administration processing or complicated dispensing procedures. For example, the 2007 Physician Fee Schedule (PFS) Final Rule mandates the additional payments for intravenous immune globulin (IVIG) preadministration-related services “to compensate physicians and hospital OPDs for extra resources expended on locating and obtaining appropriate IVIG products.”¹⁷ Although BIO recognizes that CMS is not required to set dispensing fee rates under the Medicaid statute, BIO does ask CMS to include these additional Medicare payments and fees in the dispensing fee definition as a specific factor for the States to consider when determining dispensing fee amounts.

II. CMS Should Clarify the Treatment of Certain Entities Under the New Definition of Retail Pharmacy Class of Trade.

¹² 71 Fed. Reg. 77,197 (proposed 42 C.F.R. pt. 447.504(i)(2)).

¹³ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.504(d)).

¹⁴ *See* 71 Fed. Reg. 69,624, 69,667 (Dec. 1, 2006) (explaining that the treatment of service fees for price reporting purposes may differ from the treatment of service fees for financial accounting or other purposes).

¹⁵ 71 Fed. Reg. 77,176.

¹⁶ *See id.*

¹⁷ 71 Fed. Reg. at 69,679.

Section 6001(c)(3) of the DRA requires the Secretary “to clarify the requirements for, and the manner in which, AMP is determined” in a formal regulation.¹⁸ AMP is defined as “the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the *retail pharmacy class of trade*” (emphasis supplied).¹⁹ The Proposed Rule defines retail pharmacy class of trade as “any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.”²⁰ CMS explained in the preamble to the Proposed Rule that “the retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services.”²¹ BIO welcomes the significant contribution that this definition and preamble guidance will have in standardizing the AMP calculation, but also requests that CMS clarify the status of certain additional entity types in the Final Rule, discussed below.

1. CMS Should Clarify the Retail or Non-Retail Status of Certain Entities.

The Proposed Rule and preamble specify the retail or non-retail status of a number of different entity types, including pharmacy benefit managers (PBMs), long-term care pharmacies, and mail order pharmacies. BIO appreciates this level of clarity and believes that it will aid in the effective and uniform implementation of the revised retail pharmacy class of trade definition. While BIO recognizes the impracticality of attempting to address every entity type in the Final Rule, the absence of a specific classification for a number of entity types, including but not limited to the physician class of trade, home health care providers (specialty pharmacies that provide for the home delivery and administration of product by health care professionals), prisons, and hospices is conspicuous. These entity types represent a significant portion of our members’ direct and indirect sales transactions, particularly in the case of physician sales, and merit individualized attention for that reason. BIO asks CMS to, at a minimum, clarify the retail or non-retail status of each of these entities in the Final Rule.

2. CMS Should Clarify the Treatment Of Contract Pharmacies That Serve Long Term Care Facilities.

The Proposed Rule clarifies that sales to nursing home pharmacies and long term care pharmacies are to be excluded from the calculation of AMP.²² CMS explained that under its proposed definition of the retail pharmacy class of trade, which requires that the entity dispense product to the general public, such pharmacies would not qualify as retail

¹⁸ See 71 Fed. Reg. at 77,175; Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c)(3).

¹⁹ 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).

²⁰ *Id.* (proposed 42 C.F.R. pt. 447.504(e)).

²¹ *Id.* at 77,178.

²² *Id.* at 77,178, 77,196 (proposed 42 C.F.R. § 447.504(h)(6)).

because they dispense to facility residents only. As CMS may know, many nursing home and long term care facilities do not maintain their own pharmacies, but rather contract with an outside pharmacy, often one that specializes in long term care facilities, to supply their residents with medications. The Proposed Rule does not specifically address the treatment of contract pharmacies that dispense product to nursing home and long term care facility residents, and BIO therefore requests that CMS clarify whether manufacturer sales to such contract pharmacies also should be treated as non-retail and excluded from the calculation of AMP.

3. CMS Should Clarify That Manufacturers May Treat Drugs Sold to Hospitals as Sales for Inpatient Use When Manufacturers Cannot Distinguish Between Units Purchased for the Inpatient Versus Outpatient Setting.

The Medicaid rebate agreement and Manufacturer Release 29 both direct that all sales to hospitals are to be excluded from the AMP calculation, without regard to whether the product sold was used in the inpatient or outpatient setting.²³ The Proposed Rule now distinguishes between those settings. CMS *includes* in AMP sales to hospitals “where the drug is used in the outpatient pharmacy,” while continuing to exclude sales to hospitals for inpatient use.²⁴ This distinction presumes that manufacturers can identify the setting in which the product that a hospital purchases is used. That typically is not the case. Manufacturers know only that a hospital has made a purchase, not the setting in which the product will be used. For this reason, BIO requests CMS to clarify that manufacturers may continue to exclude hospital sales from AMP when manufacturers cannot distinguish between units purchased for inpatient use and units purchased for use in the outpatient setting.

4. CMS Should Revise the Proposed Rule to Exclude State, County, and Municipal Entities from the Retail Pharmacy Class of Trade.

The Proposed Rule is silent regarding the retail status of state, county, and municipal-run entities. BIO believes that these entities, which include hospitals and mental health clinics, should be excluded from the retail pharmacy class of trade. As noted above, the retail pharmacy class of trade includes only those entities that sell or provide drugs “to the general public.”²⁵ Entities that are funded or run by states, counties, or municipalities provide or sell drugs to specific classes of persons who are eligible or qualify for their services; these entities do not provide or sell drugs to the general public. For this reason, BIO urges CMS to clarify that state, county, and municipal entities are excluded from the retail pharmacy class of trade.

²³ 56 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(a)); Medicaid Drug Rebate Program Release #29 for Participating Drug Manufacturers (1997).

²⁴ *Id.* at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(3), (h)(4)).

²⁵ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

5. CMS Should Clarify That All Rebates, Discounts, and Other Price Concessions Provided to a PBM Should Be Included in AMP.

The Proposed Rule clearly states that “[d]iscounts, rebates, or other price concession to PBMs associated with sales for drugs provided to the retail pharmacy class of trade” are included in AMP.²⁶ This provision is consistent with CMS’ conclusion that excluding such price concessions from AMP “could result in an artificial inflation of AMP.”²⁷ In the preamble however, there is language that could be read to limit the price concessions paid to PBMs that are to be included in AMP to those “that affect the net price recognized by the manufacturer” for drugs provided to the entities in the retail pharmacy class of trade, *i.e.* those price concessions passed on to retail pharmacies.²⁸ CMS itself noted in the preamble that manufacturers typically do not know what price concessions paid to PBMs are passed on to the PBM’s network pharmacies or member plans, and so BIO does not believe CMS intended to limit the requirement in this way.²⁹ BIO does not disagree with a requirement to include all PBM price concessions in AMP but asks CMS to clarify that this requirement applies to all such price concessions without regard to whether a PBM passes on any portion of those amounts to any other entity.

6. CMS Should Revise the Proposed Rule To Include Sales and Discounts to HMOs that Do Not Purchase or Take Possession of Product in the AMP Calculation.

The Medicaid rebate agreement explicitly excludes sales to health maintenance organizations (HMOs) from the AMP calculation,³⁰ and the Proposed Rule seeks to adopt this exclusion as well.³¹ The exclusion contained in the Proposed Rule does not distinguish between HMOs that purchase drugs and distribute them to members through the HMO’s own closed-door pharmacies, and HMOs that do not purchase drugs but rather act as third-party payors that reimburse retail pharmacies for drugs dispensed to members.³² The former type of HMO does not provide or sell drugs to the general public, only its own enrollees, and is appropriately excluded from the AMP calculation as non-retail. Sales to HMOs that are not purchasers, on the other hand, are more analogous to Medicaid sales, Medicare Part D sales, and sales to State pharmaceutical assistance programs (SPAPs). The preamble to the Proposed Rule explains that these entities are included in AMP because their sales “are determined by entities that are actually in the

²⁶ Id. (proposed 42 C.F.R. pt. 447.504(g)(3)).

²⁷ Id. at 77,179.

²⁸ Id.

²⁹ See Id.

³⁰ 56 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(a)).

³¹ 71 Fed. Reg. at 77,179.

³² See 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(5)).

sales chain” and “should not be backed out of the AMP calculation to the extent that such sales are included within sales provided to the retail pharmacy class of trade.”³³

CMS’ analysis is equally applicable to HMOs that do not purchase and take possession of drugs, but rather act as reimbursers to pharmacies that do. Inclusion of non-purchaser HMOs in AMP is consistent with CMS’ guidance regarding other reimbursing entities and also avoids the anomalous result of excluding non-purchaser HMO transactions from AMP where the HMO contracts directly with a manufacturer for discounts, but including such transactions in AMP where the HMO chooses to contract with a PBM to do so. BIO urges CMS to revise the Proposed Rule to specifically include in the AMP calculation sales and discounts to HMOs that do not purchase or take possession of product.

7. CMS Should Clarify That the Prices Negotiated By a Qualified Retiree Prescription Drug Plan for Its Retirees As Well As for the Retiree’s Dependents Are Excluded from Best Price.

CMS proposes to exclude from Best Price the price for covered Medicare Part D drugs negotiated by a qualified retiree prescription drug plan “on behalf of individuals entitled to benefits.”³⁴ This provision is also described by CMS in the preamble where the agency states that payments made by a qualified retiree prescription drug plan on behalf of “eligible individuals” are excluded from Best Price.³⁵ BIO supports this exclusion but notes that it does not address the treatment of prices on retiree dependent utilization. Manufacturer rebate contracts for qualified retiree plan utilization typically do not distinguish between the utilization of the retiree and his/her dependents, because the utilization data supplied by the plans does not distinguish between the two populations. The two groups are treated as a single population because they are both covered by the same benefit. BIO requests that CMS address this issue in the Final Rule.

8. CMS Should Revise the Proposed Rule to Exclude All Patient Transactions from the AMP and Best Price Calculations.

One of BIO’s central principles is ensuring patient access to biologic therapies. Our members employ a number of different mechanisms to make certain that patients maintain their access to needed therapies, including sales directly to patients, patient coupons, and patient assistance programs. The Proposed Rule for the first time addresses the treatment of such patient transactions in the AMP and Best Price calculations, and in the case of patient assistance programs, explicitly excludes them from the calculations.³⁶ BIO strongly supports the exclusion of patient assistance programs from these calculations, as these programs provide a crucial safety net for those patients lacking insurance coverage and without sufficient income to acquire needed medications.

³³ *Id.* at 77,180.

³⁴ *Id.* at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(5)).

³⁵ *Id.* at 77,182.

³⁶ *Id.* at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(9)).

The Proposed Rule also addresses direct patient sales and coupon programs but directs their inclusion in AMP and Best Price,³⁷ with one limited exception for patient coupons.³⁸ BIO is concerned that the Proposed Rule will have the unintended effect of endangering these critical programs. BIO does not interpret the Medicaid rebate statute to support the inclusion of these patient transactions in either calculation and also disagrees with CMS' stated rationale for doing so. BIO asks CMS to exclude these transactions from AMP and Best Price in the Final Rule.

A. Patient Sales. The Proposed Rule directs the inclusion of manufacturer direct sales to patients in the calculations of AMP and Best Price.³⁹ In the case of AMP, the Proposed Rule does so despite its explicit acknowledgment that such transactions do not involve a sale transaction to a retail entity, but rather a service arrangement with a distributor to provide storage, delivery, and billing services for product that the distributor ships to patients on the manufacturer's behalf.⁴⁰ CMS asserts that such distributors are acting as "wholesalers" and the sales are to the retail pharmacy class of trade.⁴¹

BIO believes that direct patient sales should be excluded from AMP and Best Price because, in the case of AMP, patients are not part of the retail pharmacy class of trade, and, in the case of Best Price, patients are not one of the entity types included in the statutory definition of Best Price.⁴² Only an entity that purchases drugs and "subsequently sells or provides the drugs to the general public" is retail under the Proposed Rule.⁴³ Patients, even as direct purchasers of drugs, obtain drugs for their personal medical use; they do not sell or provide drugs to the general public. Nor does the service arrangement with the distributor transform this arrangement into a retail sale, as the distributor never purchases the product at issue. CMS has not provided a basis for its conclusion that patients are retail and BIO can find no support for this position in the text of the rebate statute, rebate agreement, or Proposed Rule. As noted above, BIO also does not believe that patient sales are within the scope of the statutory definition of Best Price. BIO strongly urges CMS to revise its proposal regarding direct patient sales and exclude them from both calculations.

B. Patient Coupons. CMS also proposes to include in the AMP and Best Price calculations patient coupons redeemed by an entity other than the consumer.⁴⁴ BIO asserts that because patients are not part of the retail pharmacy class of trade, price

³⁷ Id. at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(11), .505(c)(12)).

³⁸ Id. at 77,197-98 (proposed 42 C.F.R. pts. 447.504(h)(9), .505(d)(8)).

³⁹ Id. at 77,180-81, 77,197 (proposed 42 C.F.R. pt. 447.504(g)(7)).

⁴⁰ Id. at 77,180-81.

⁴¹ Id.

⁴² SSA § 1927(c)(1)(C)(i) ("The term 'best price' means . . . the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States.").

⁴³ Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

⁴⁴ Id. at 77,181, 77,183.

concessions available to them should not be included in AMP or Best Price. To the extent that CMS is concerned that patient coupons redeemed by an entity other than the consumer affect the price realized by the entity that redeems the coupon to the manufacturer on the patient's behalf, BIO would like to take this opportunity to explain why that is not the case and to ask CMS to revise the Proposed Rule to exclude all patient coupon transactions from the AMP and Best Price calculations.

Manufacturers have a number of different types of patient coupon programs but they fall into three general categories. The first type is a mail-in rebate coupon. These coupons typically are submitted by the consumer directly to the manufacturer, along with proof of purchase, for a rebate. This type of coupon would be excluded from AMP and Best Price under the Proposed Rule because consumers redeem mail-in rebates directly to the manufacturer.⁴⁵ BIO asks CMS to clarify, however, that such coupons are excluded even when redeemed through a third-party vendor that does not purchase product but administers the coupon program on the manufacturer's behalf. The involvement of a non-purchasing third-party to administer the program creates no impact on price for any entity that does purchase product, and therefore should not prevent the exclusion of these types of programs from the calculations.

A second type of patient coupon is a copayment assistance or dollars-off coupon. These coupons are presented by consumers at the point-of-sale, entitling them to some amount off of their copayment or co-insurance obligation. If the consumer has no insurance, these coupons act to reduce the consumer's overall cost for the prescription. A retail pharmacy that honors such a coupon provides the coupon's discount directly to the consumer at the time of sale, and then submits the coupon to the manufacturer (or a third-party vendor) for reimbursement. The manufacturer then reimburses the redeeming pharmacy for its out-of-pocket expense, i.e., the face value of the coupon, and also a fair market value processing fee. This reimbursement does not affect the price realized by the pharmacy for the drug that was the subject of the coupon because the manufacturer only reimburses the pharmacy for its actual expenses. For these reasons, BIO asks CMS to clarify that copayment and dollars-off coupons are excluded from AMP and Best Price.

The final coupon type is a free goods coupon. These coupons offer a patient a certain number of units of a drug at no cost, and have grown in importance as a means of providing patients with a period of free "trial" or "sample" product where their prescriber is either unable or unwilling to store PDMA-compliant sample product from the manufacturer. A retail pharmacy accepting a free goods coupon will provide the drug at no cost to the patient and, as with co-pay assistance coupons, seek reimbursement from the manufacturer. A manufacturer may reimburse the redeeming pharmacy in one of two ways. First, the manufacturer may reimburse the pharmacy with replacement product and a fair market value dispensing fee. When the manufacturer reimburses the pharmacy in kind, there is no affect on the price realized by the pharmacy on the drug at issue because the pharmacy receives exactly that which it dispensed for free, and the transaction should be excluded from AMP and Best Price. A manufacturer instead may choose to reimburse

⁴⁵ See *id.* at 77,197-98 (proposed 42 C.F.R. pts. 447.504(h)(9), .505(d)(8)).

a pharmacy for the cost of the drug it dispensed, again with a fair market value dispensing fee. Manufacturers typically cannot determine a pharmacy's actual acquisition costs and so employ a formula to estimate that amount. Where the manufacturer uses such a formula, meant to approximate the pharmacy's acquisition price and therefore make the pharmacy whole, the transaction between the manufacturer and the pharmacy is revenue neutral and there is no effect on the price realized by pharmacy. CMS should clarify that such transactions are, therefore, excluded from AMP and Best Price.

The manner in which CMS handles patient transactions is crucially important. Manufacturers are able to provide significant benefits to patients through their patient sales and patient coupon programs. Without clear guidance from CMS on how these transactions are to be treated for AMP and Best Price purposes, such valuable programs are at risk of being curtailed. BIO therefore strongly encourages CMS to categorically exempt all patient transactions from the AMP and Best Price calculations to ensure their continued availability.

III. CMS Should Provide Additional Guidance Regarding the Treatment of Particular Transactions for AMP and Best Price Purposes.

CMS has taken the opportunity in the Proposed Rule to address the treatment of certain transaction types in the calculations of AMP and Best Price. BIO appreciates CMS' attention to these issues in the Proposed Rule and comments below regarding the proposed treatment of administrative and service fees, bundled sales, customary prompt payment discounts, nominal sales, and returned goods.

1. CMS Should Clarify that Administrative and Service Fees Paid to GPOs Are Excluded From AMP and Best Price.

The Proposed Rule revises CMS existing position regarding the treatment of administrative and service fees in the calculations of AMP and Best Price. CMS' long-standing position has been that such fees are included in the calculations to the extent they affect the price realized by an entity that is eligible for the calculations.⁴⁶ The Proposed Rule would require the inclusion of all fees that do not satisfy the definition of a bona fide service fee, even if the entity receiving the fee does not take title to product.⁴⁷

The preamble to the 2007 Physician Fee Schedule Final Rule included extensive substantive discussions of the bona fide service fee definition adopted in that Final Rule, and which CMS now proposes to adopt for purposes of the AMP and Best Price calculations as well. Should CMS proceed to include this definition in the Final Rule, BIO urges CMS to confirm that manufacturers may rely on that preamble discussion to interpret the definition for purposes of the AMP and Best Price definition. This

⁴⁶ Medicaid Drug Rebate Program Release #14 for Participating Drug Manufacturers (1994).

⁴⁷ *Id.* at 77,195, 77,197-98 (proposed 42 C.F.R. pt. 447.502, .504(i), .505(e)(1)).

clarification would ensure uniform application of the definition across calculations and facilitate manufacturer compliance with this new term.

In that preamble, CMS specifically declined to provide guidance with respect to the application of this definition to group purchasing organizations (GPOs), and instead directed manufacturers to continue to make documented, reasonable assumptions regarding their treatment of such fees.⁴⁸ BIO urges CMS to now address this issue definitively and specify that fees paid to GPOs are excluded from AMP and Best Price.

GPOs are entities that negotiate contracts with vendor manufacturers on behalf of their members that are health care providers, such as hospitals, clinics, nursing homes, and physician practices. GPOs, in general, do not themselves purchase drugs and biologicals, but instead negotiate contracts that providers use in making their own purchases. As GPOs are not purchasers, any fees paid by a manufacturer to a GPO should not be considered a price concession that is eligible for the AMP calculation.

The Office of Inspector General has studied GPOs and their relationships with their members and found that there are situations in which a GPO may share some portion of the fee paid by a manufacturer with its members, who are purchasers.⁴⁹ Manufacturers have no control over these arrangements and typically are unaware of the contractual terms between the GPO and its members.⁵⁰ Accordingly, even when the GPO shares some portion of a manufacturer fee with its members, those fees should not be considered discounts provided by the manufacturer to a purchaser.

A requirement to treat GPO administrative fees as a discount in either of the above situations also would face a significant practical hurdle. Specifically, manufacturers would have no basis for determining the amount of the fee that is shared with the member purchasers or to which product the fee should be attributed as a price concession. Without this information, manufacturers have no basis for including these fees in the AMP calculation.

BIO understands that the Health Industry Group Purchasing Association submitted comments (dated January 2, 2007) to CMS regarding their discussion of GPO fees in the preamble to the 2007 Physician Fee Schedule Final Rule. Section I of that letter is consistent and supportive of the positions articulated above and requests that

⁴⁸ Id. at 69,669.

⁴⁹ The Office of Inspector General (OIG) found in an audit conducted of three large GPOs that the GPOs retained a significant amount of the administrative fees and that their practices regarding passing on administrative fees to members differed. See Review of Revenue from Vendors at Three Additional Group Purchasing Organizations and Their Members, OIG Report A-05-04-00073 (May 2005).

⁵⁰ BIO recognizes, however, that where the contract between the manufacturer and the GPO directs the GPO to pass on service fees to the GPO's members, the manufacturer indirectly would be paying

fees to a purchaser, and, therefore, the bona fide service fee standard should be applied to the portion of the fee passed on to the members.

CMS create a calculation safe harbor for GPO fees. The proposed safe harbor, as modified to apply under the Proposed AMP Rule, would be included in the definition of bona fide service fee and read:

For purposes of 42.C.F.R. § 447.504(i) and 447.505(e), fees paid by a manufacturer to a bona fide group purchasing organization, as defined at 42 C.F.R. § 1001.952(j)(2), will not constitute a price concession by the manufacturer unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization.

BIO strongly supports the creation of such a safe harbor and urges CMS to include such a provision in the Final Rule.

2. CMS Should Refrain From Finalizing the Revised Definition of Bundled Sale At This Time.

The Medicaid rebate agreement currently defines a bundled sale as “the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.”⁵¹ The Proposed Rule now includes a new, revised definition of this term: “an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types . . . or some other performance requirement . . . or [] where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.”⁵²

This proposed definition of bundled sale represents a significant change from the definition provided in the Medicaid rebate agreement. CMS does not provide any explanation in the Proposed Rule for why it proposes to change the definition in this way or describe policy objectives the changes are intended to promote. Nor does CMS provide any guidance regarding the interpretation and application of the definition, which contains several new terms subject to multiple interpretations, or the methodology to be used to reallocate discounts included in bundled sales. The Proposed Rule does not even reference this term in the regulatory provisions governing the calculation of AMP and Best Price. BIO is unable to provide any meaningful comments on this new definition in the absence of such content and therefore requests that CMS refrain from finalizing the revised definition of bundled sale at this time. Should CMS wish to pursue this new definition, BIO requests that CMS provide additional information regarding the new

⁵¹ 71 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(e)).

⁵² 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. pt. 447.502).

definition and provide another opportunity for comment before the definition is finalized. In the interim, BIO strongly urges CMS to clarify that manufacturers may continue to rely on the definition of bundled sale included in the rebate agreement.

3. CMS Should Clarify That Manufacturers May Make Reasonable Assumptions in Applying the Proposed Definition of Customary Prompt Pay Discounts.

Section 6001(c) of the DRA amends the Medicaid rebate statute to exclude from the AMP calculation customary prompt pay discounts extended to wholesalers.⁵³ This language is included in the definition of AMP in the Proposed Rule and BIO supports its inclusion.⁵⁴ CMS has proposed to define customary prompt pay discounts as “any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time.”⁵⁵ BIO supports this definition but urges CMS to confirm that manufacturers may make reasonable assumptions in applying this definition to their AMP calculations and in their reporting of such discounts each quarter.

4. CMS Should Issue Any Further Guidance on Nominal Sales Through Notice-and-Comment Rulemaking and Clarify That Until Such Guidance Is Issued Manufacturers May Exclude Any Nominal Sales that Meet the DRA Definition From the Best Price Calculation.

The Medicaid rebate statute excludes from the Best Price calculation prices that are merely nominal in amount.⁵⁶ The Medicaid rebate agreement defines nominal as any price that is less than 10% of the AMP for the product in the same quarter for which Best Price is being calculated.⁵⁷ Section 6001(d)(2) of the DRA amended the Medicaid rebate statute to clarify that nominal prices are excluded from Best Price only when offered to a list of specifically identified “safety net” providers.⁵⁸ The DRA also authorized the Secretary to identify additional categories of safety-net providers that could be excluded from Best Price should they receive a nominal price.⁵⁹ CMS indicated in the preamble to the Proposed Rule that it was declining to exercise this authority at this time.⁶⁰

CMS also included in the preamble additional commentary regarding the nominal price exception. Specifically, CMS stated its concern that “the nominal price exclusion will continue to be used as a marketing tool” and indicated that it is considering issuing

⁵³ Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c).

⁵⁴ *Id.* at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).

⁵⁵ *Id.* (proposed 42 C.F.R. pt. 447.504(c)).

⁵⁶ SSA § 1927(c)(1)(C)(ii)(III).

⁵⁷ 56 Fed. Reg. at 7051 (Medicaid Rebate Agreement at I(d), (s)).

⁵⁸ Deficit Reduction Act of 2005, Pub. Law No. 109-171, §6001(d)(2).

⁵⁹ *Id.*

⁶⁰ 71 Fed. Reg. at 77,184-85.

additional guidance on this topic.⁶¹ BIO asks CMS to issue any further guidance on the use of nominal prices as a marketing tool through formal notice-and-comment rulemaking. BIO also asks CMS to clarify that until such guidance is issued, and in accordance with the DRA language itself, manufacturers may exclude from Best Price nominal price sales to entities listed in the DRA definition without regard to the manufacturer's intent in providing such prices.

5. BIO Supports Excluding Returns Made in Good Faith from the AMP Calculation.

CMS guidance currently requires manufacturers to include in AMP returned goods credited to the manufacturer.⁶² As CMS recognized in the preamble to the Proposed Rule, this position has generated problems for manufacturers by substantially reducing AMP or resulting in a negative AMP for the quarter in which the return is credited.⁶³ BIO supports CMS decision to exclude returns made in good faith from AMP⁶⁴ and urges the agency to retain this provision in the Final Rule. BIO also requests that CMS clarify that returns transactions also have no impact on the determination of Best Price.

IV. CMS Should Provide Additional Guidance Regarding the Various Requirements for Manufacturers in the Proposed Rule.

The Proposed Rule also addresses a number of "requirements for manufacturers." BIO supports CMS' decision to allow manufacturers to recalculate base date AMP and asks the agency to clarify that the recalculation should take into account the exclusion of customary prompt pay discounts from the AMP calculation. BIO also requests that CMS revise the new manufacturer price reporting form registration process, so that manufacturer personnel need not supply their Social Security Numbers in order to obtain access to that reporting route. CMS proposes to adopt the Medicare ASP certification requirement and language for Medicaid submissions, but BIO notes that the standards for imposing liability differs under the two programs and asks CMS to ensure that the certification requirement takes this into account.

1. BIO Supports CMS' Decision To Allow Manufacturers to Recalculate Base Date AMP and Asks CMS To Clarify That the Recalculation Should Take the Exclusion of Customary Prompt Pay Discounts into Consideration.

Section 1927(c)(2) of the Social Security Act requires manufacturers of single source and innovator multiple source drugs to pay an "additional rebate" when the AMP for a specific reporting period exceeds by a certain percentage the AMP calculated in the

⁶¹ *Id.* at 77,185.

⁶² *Id.* at 77,181.

⁶³ *Id.*

⁶⁴ *Id.* at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(13)).

product's base date quarter. To ensure that manufacturer liability for additional rebates does not increase due to changes in the definition of AMP, CMS has included a provision in the Proposed Rule giving manufacturers the option to recalculate their base date AMPs.⁶⁵ BIO supports this provision and asks CMS to include it in the Final Rule.

BIO also recommends that CMS apply the recalculated base date AMPs retroactively to the first quarter of 2007 for the calculation of rebates. CMS itself recognized the inherent inequity created by the change in the AMP definition and in the preamble on the recalculation issue stated, "We propose this amendment so that the additional rebate would not increase due to changes in the definition of AMP."⁶⁶ Further on, CMS states, "However, we decided that retaining the current base date AMP is unwarranted because it would create a financial burden on manufacturers that was not intended by Section 6001 of the DRA."⁶⁷ The only way to alleviate that additional financial burden is to apply the recalculated base date AMP retroactively to the first quarter of 2007 when the provisions of the DRA that changed the AMP definition first were effective. BIO understands that this may create additional workload due to restating prior periods, however we believe this is a necessary step to achieve the appropriate outcome.

The text of the recalculation provision states that the recalculation of base date AMP "must only reflect the revisions to AMP as provided for in § 447.504(e)."⁶⁸ That provision includes the new definition for the retail pharmacy class of trade, but does not address the new requirement to exclude customary prompt payment discounts from the AMP calculation.⁶⁹ We believe this was an oversight, as CMS stated in the preamble to the Proposed Rule that it was allowing recalculation to "reflect the changes to AMP as set forth in the DRA."⁷⁰ The DRA specifically changes the AMP calculation by excluding customary prompt pay discounts.⁷¹ BIO requests CMS to clarify that the recalculation of base data AMP should reflect not only the changes to the definition of the retail pharmacy class of trade, but also the exclusion of customary prompt pay discounts from the AMP calculation.

Finally, BIO asks CMS to confirm that manufacturers retain complete discretion regarding the decision to recalculate base date AMP figures, and may make that decision on a product-by-product basis. CMS itself recognized that manufacturers will need to evaluate the availability of data needed to perform any recalculation and weigh the administrative costs of doing so against the savings to be gained.⁷² Data availability and the related cost analysis of performing recalculations necessarily will vary by product,

⁶⁵ *Id.* at 77,198 (proposed 42 C.F.R. pt. 447.510(c)).

⁶⁶ *Id.* at 77,185.

⁶⁷ *Id.* at 77,194.

⁶⁸ *Id.*

⁶⁹ *Id.* at 77,196.

⁷⁰ *Id.* at 77,185.

⁷¹ Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c)(1).

⁷² 71 Fed. Reg. at 77,185.

and therefore manufacturers should be able to perform that analysis for each of their products individually. CMS' discussion of this issue in the preamble suggests that is CMS' intent, and BIO asks CMS to confirm the acceptability of this approach.

2. BIO Asks CMS to Allow Manufacturers to Submit Reports Using a Randomly Generated Identification Number Rather than an Individual's Social Security Number.

CMS has issued a new data reporting format and system for manufacturer submissions of rebate data – the Drug Data Reporting or DDR system. The instruction form for the application for access to this new reporting system requires that the manufacturer employee who will be accessing the system provide CMS with his/her social security number. This information is highly sensitive personal information and BIO requests that CMS remove this requirement from the application. The application requires the provision of other, less sensitive, personal information that still will enable CMS to identify the manufacturer personnel with access to the reporting system such that a social security number should not be necessary. BIO urges CMS to remove this requirement as soon as possible.

3. CMS Should Clarify That the “Knowledge” Requirement of the Medicaid Civil Money Penalty Provision Is Included for All Elements of AMP and Best Price Certification.

The Proposed Rule seeks to adopt for both monthly and quarterly manufacturer submissions the same certification that manufacturers currently must submit with their quarterly ASP figures.⁷³ BIO believes that the ASP certification language must be revised if used in relation to AMP and Best Price data because the civil monetary penalty standard applicable to the reporting of AMP and Best Price contains an explicit “knowing” requirement.

The civil money penalty provision of the Medicaid statute provides that manufacturers are subject to penalty only for “knowingly” providing false information to CMS.⁷⁴ BIO therefore believes that this knowledge requirement must modify all representations included in any certification. The full text of the ASP certification reads as follows: “I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.”⁷⁵ This certification does not clearly qualify the certification of “calculated accurately” with the “to the best of my knowledge and belief” language. As the Medicaid civil monetary penalty provision applies only to the knowing submission of false information, BIO believes any representation that the AMP and Best Price figures were

⁷³ *Id.* at 77,198.

⁷⁴ SSA § 1927(b)(3)(C).

⁷⁵ 69 Fed. Reg. 17,935, 17941 (April 6, 2004).

"calculated accurately" also should be explicitly qualified by the "to the best of my knowledge and belief" language. To accomplish this, BIO urges CMS to revise the certification to read:

To the best of my knowledge and belief, the reported Average Manufacturer and Best Prices were calculated accurately and all information and statements made in this submission are true, complete, and current. I understand that information contained in this submission may be used for Medicaid reimbursement purposes.

V. CMS Should Safeguard Immunosuppressives in the Federal Upper Limit Methodology.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the AMP for the least costly drug in each multiple-source group.⁷⁶ In implementing this provision, CMS has proposed to use its rulemaking authority to establish safeguards to ensure that the FUL is set at a price that is "adequate . . . to ensure that a drug is available for sale nationally as presently provided in our regulations."⁷⁷ Specifically, CMS has proposed not to include in a FUL calculation: (1) the AMP of an NDC that has been terminated; or (2) an AMP that is less than 30 percent of the next highest AMP in the relevant multiple source drug group.⁷⁸

BIO urges CMS to adopt an additional safeguard in the FUL methodology to ensure that Medicaid beneficiaries have access to anti-rejection immunosuppressives. Immunosuppressives must be taken by transplant patients to prevent organ rejection; therefore, access to these medications is critical. Missing even a few days of an anti-rejection immunosuppressive regimen can cause graft failure, resulting in loss of the organ and catastrophic consequences for the patient.

The special importance of access to immunosuppressives has prompted CMS to use its regulatory authority to establish safeguards under Part D for these therapies and five other drug classes of "clinical concern."⁷⁹ CMS has stated that this safeguard is "necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."⁸⁰ This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government

⁷⁶ SSA § 1927(e)(5).

⁷⁷ 71 Fed. Reg. at 77,187.

⁷⁸ *Id.* at 77,188. CMS proposed that the 30% outlier policy not apply when calculating the FUL for a multiple-source group that includes only the innovator and the first generic to enter the market.

⁷⁹ The other classes protected by this Part D safeguard are antidepressants, antipsychotics, anticonvulsants, HIV/AIDS drugs, and antineoplastics.

⁸⁰ Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines -- Formularies*, at 7.

Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.⁸¹

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives and other critical medications. We recommend that CMS base the FUL for immunosuppressive multiple-source drug groups on the lowest AMP that is not less than 70% of the next-highest AMP in the multiple-source drug group. In addition, we urge CMS to apply this safeguard to all FULs containing these critical medications, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor. Such a safeguard would ensure that implementing the new FUL methodology does not harm Medicaid beneficiaries' access to critical medications at the pharmacy level.

VI. CMS Should Address a Number of Additional Issues in the Final Rule That Are Crucial to the Operation of the Medicaid Drug Rebate Program.

BIO believes that there are additional issues related to the program that CMS should address in the Final Rule. These include the proportionality of rebate payments when Medicaid is a secondary payor, the period of manufacturer liability for rebate claims, the affect of the changes in AMP on Medicare reimbursement rates, the provision of additional payments for blood clotting factors, and the form of future guidance regarding the AMP and Best Price calculations.

1. CMS Should Limit Manufacturer Rebate Liability to the Proportion of a Claim Actually Paid by Medicaid.

Although not addressed by CMS in the Proposed Rule, BIO believes that the issue of proportionality for manufacturer rebate liability when Medicaid is a secondary payor is of crucial importance to the Medicaid Drug Rebate Program. Through various program releases over the years, CMS has articulated its position that "if a state Medicaid agency pays any portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug."⁸² BIO believes this position is inconsistent with the Medicaid rebate statutory language and legislative intent and also procedurally defective as it has never been subject to notice-and-comment rulemaking.

BIO understands it is CMS' position that the statute requires payment of the full rebate amount in all circumstances because of the statute's direction that the manufacturer pay the rebate amount defined in "subsection (c) of this section" for each unit of a drug for which payment was made under a State plan, and subsection (c) provides only for the full rebate amount.⁸³ This mandate, however, must also be read in

⁸¹ GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs (Dec. 22, 2006).

⁸² Medicaid Drug Rebate Program Release #54 for Participating Drug Manufacturers (May 7, 2002).

⁸³ Social Security Act § 1927(b)(1)(A).

conjunction with the statute's other requirement in the immediately following paragraph – that the rebate be considered “a reduction in the amount expended” – which clearly presumes the rebate amount will not and should not exceed the State's payment amount.⁸⁴ These authorities together lead to the single conclusion that Congress did not intend or provide for the payment of rebates that exceed a State's expense and CMS should implement the statute accordingly.

CMS' position also is inconsistent with the purpose of the Medicaid rebate statute. The legislative history repeatedly demonstrate that Congress enacted the statute to enable States to access the same discounts for covered drugs that manufacturers were offering other purchasers.⁸⁵ At the time of enactment Medicaid was paying *more* than other purchasers for the same drugs.⁸⁶ The Medicaid rebate program was thus enacted to ensure that Medicaid paid the *same* prices as the other purchasers.⁸⁷ When States are able to obtain full rebates for the drug utilization that they submit, regardless of their actual expenditures, they are not getting the same discounts as other providers; they are getting an unjustified windfall.

Senator Grassley, former Chairman of the Senate Finance Committee has confirmed that Congress intended Medicaid rebates to be proportional to Medicaid expenditures, in a letter sent to former CMS Administrator Mark McClellan.⁸⁸ In that letter, Senator Grassley clarified that “[f]ederal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program.”⁸⁹ He explained that the DRA language amended the Medicaid rebate statute so to provide that States must seek rebates “for drugs administered *for which payment is made under this title*,” with this language clarifying that “the Medicaid rebate is only available for the Medicaid portion of the payment.”⁹⁰ BIO strongly urges CMS to adopt guidance implementing this statutory language as Senator Grassley suggested.

BIO also believes that CMS' current position is procedurally invalid. Under the Administrative Procedures Act (APA), only rules promulgated through formal notice-and-comment rulemaking can be binding.⁹¹ CMS has indicated that it intends its

⁸⁴ Id. at § 1927(b)(1)(B).

⁸⁵ See 136 Cong. Rec. S12954-01 (1990), as reprinted in 1990 U.S.C.A.N.N. 2017, 2108.

⁸⁶ See H-Rep. 101-88, at 96 (1990).

⁸⁷ In fact, Senator Pryor, one of the sponsors of the Medicaid rebate statute opposed the drug manufacturers' proposed plan that would have provided a \$1.36 rebate for each Medicaid prescription. As Senator Pryor explained, a 1000-pill bottle of a drug could be purchased for \$3.00. If that bottle was used to fill 10 prescriptions of 100 pills each, the State could claim a rebate of \$13.60, realizing a gain of \$10.60. Senator Pryor, rightly, found it grossly unfair that manufacturers could be forced to pay \$4.00 for every \$1.00 of sales. 136 Cong. Rec. S12954-01, S12960.

⁸⁸ Letter from Chairman Charles E. Grassley to Administrator Mark B. McClellan (Aug. 14, 2006).

⁸⁹ Id.

⁹⁰ Id.

⁹¹ 5 U.S.C. § 533(c); Chrysler Corp. v. Brown, 441 U.S. 281, 313 (1979). To the extent that CMS would argue that the rule is merely an interpretative rule not subject to notice-and-comment rulemaking, it would not have the power to bind. Heckler v. Ringler, 466 U.S. 602 (1984).

interpretation with regard to proportionality to be binding on drug manufacturers.⁹² However, CMS has never issued this guidance pursuant to APA's formal rulemaking procedures. CMS' interpretation is thus invalid because it purports to bind manufacturers but has never been subject to notice-and-comment rulemaking.

Even if the provision were valid, it would not be entitled to a court's deference.⁹³ Only guidance issued through formal notice-and-comment rulemaking is accorded deference,⁹⁴ and that is not the case here. Although informal guidance may be given "respect" if it is persuasive,⁹⁵ BIO asserts that CMS' position is not persuasive because it contravenes the statutory text and, rather than ensuring that Medicaid receives the best price available for a drug, creates a windfall for the States and an unjustified financial burden on manufacturers.

The capability to calculate pro-rated rebates exists. The State invoice form, Form R-144, has a column for States to report the amount reimbursed by Medicaid and a column for States to report the amount reimbursed by another payor. With this information, manufacturers can calculate the ratio of Medicaid's payment to the total amount reimbursed and apply that ratio to the full rebate amount to determine what portion of the rebate should be paid to the State. Pro-ration is not only feasible, but, in BIO's estimation, required. BIO strongly encourages CMS to take the opportunity to revise its position in the Final Rule.

2. CMS Should Implement the Statutory Time Limit on State Submission of Rebate Claims.

The Medicaid rebate statute requires States to submit drug utilization data to manufacturers "not later than 60 days after the end of each rebate period."⁹⁶ This statutory language is explicit and without exception. CMS nevertheless has stated previously that it does not believe that this statutory provision relieves manufacturers of liability for rebate claims submitted beyond the 60 day limit.⁹⁷ CMS has never provided any rationale for this interpretation or explained how it can be reconciled with the statute's explicit direction to the contrary. BIO urges CMS to implement this statutory requirement immediately through the Final Rule.

CMS previously has recognized a need to impose a time limit on State rebate claims.⁹⁸ At the same time that CMS stated this prior position, in the 1995 proposed rule, CMS proposed to establish a "maximum time limit of 1 year from the end of a rebate

⁹² See Medicaid Rebate Program Release #27 for Participating Drug Manufacturers (1997) ("[W]e believe it is inappropriate for manufacturers to routinely, quarter after quarter, dispute rebates" when Medicaid is a secondary payor.)

⁹³ See United States v. Mead Corp., 533 U.S. 218 (2001).

⁹⁴ Id.

⁹⁵ Christen v. Harris County, 529 U.S. 576, 587 (2000).

⁹⁶ SSA § 1927(b)(2)(A).

⁹⁷ 60 Fed. Reg. at 48,460.

⁹⁸ Id.

period for States to bill a manufacturer for a rebate.”⁹⁹ CMS never finalized this requirement, and BIO urges CMS to implement a limitation on the period of manufacturer liability, as mandated by statute, as soon as possible.

CMS’ previous consideration of this issue evaluated a number of important factors and determined that a one-year statute of limitations was a reasonable limit on State claims.¹⁰⁰ CMS found that a one-year time limit is consistent with the timeframe for pharmacies to bill States and for States to reimburse pharmacies. CMS also determined that a one-year limit accounts for circumstances that might prevent States from being able to generate Medicaid utilization data within 60 days while at the same time allowing manufacturers to close their books within a reasonable amount of time. BIO believes that the Medicaid rebate statute requires CMS to implement a limitations period, and urges CMS to do so immediately. As the 60 day time limit has always existed in statute, CMS should implement this time limit effective with the Final Rule and as of that date prohibit States from submitting rebate claims for periods that precede the specified time limit.

3. CMS Should Take the Change to AMP into Consideration When Setting the ASP Threshold Percentage.

The changes to AMP provided in the DRA and Proposed Rule are likely to affect the AMP calculation for many covered drugs. These changes in AMP may have unintended consequences for Medicare reimbursement rates, which are normally calculated using a formula based on the ASP for a drug. The Social Security Act requires the Secretary to substitute the lesser of the widely available market price (WAMP) or 103% of AMP when the ASP for a drug or biological exceeds WAMP or AMP by the “applicable threshold percentage.”¹⁰¹ The applicable threshold percentage is currently 5% but is subject to adjustment by the Secretary each year.¹⁰²

BIO is concerned that the revisions to the calculation of AMP included in the Proposed Rule could cause AMP to decrease for certain drugs and biologicals and thus increase the likelihood that the applicable threshold percentage will be triggered, forcing the substitution of AMP for ASP. The substitution of AMP is inappropriate where the triggering of the threshold results solely from the revision to the AMP definition. In such circumstances, which could occur as soon as with the submission of AMP for the first quarter 2007, CMS should refrain from substituting AMP for ASP. BIO asks CMS to closely monitor this issue in 2007 and refrain from substituting AMP for ASP where the threshold is triggered due to the revised definition of AMP and consider the revised definition of AMP when setting the ASP threshold percentage for future years.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ SSA § 1847A(d)(3).

¹⁰² SSA § 1847A(d)(3)(B); 71 Fed. Reg. at 69,680, 69,788 (codifying 42 C.F.R. § 414.904(d)(3)).

4. CMS Should Reference the Separate Additional Payment for Blood Clotting Factors Under Medicare Within the Final Rule

BIO believes that the final rule should reference the blood clotting factor separate additional payment under Medicare as required by the Medicare Modernization Act.¹⁰³ This reference will provide valuable knowledge to state Medicaid Pharmacy Directors, should they use AMP as a basis to determine Medicaid reimbursement rates. This separate additional payment, which under Medicare is added onto the statutory reimbursement of ASP plus 6% was determined to be \$0.152 per unit of blood clotting factor for 2007.¹⁰⁴ Under Medicare, this separate additional payment has served to enhance patient access by recognizing the costly and unique attributes and services associated with providing blood clotting factors and reimbursing more appropriately. BIO has concern that without such a reference in this final rule, Medicaid Pharmacy Directors will be unaware of the need for this separate additional payment and not consider its value should they look at AMP based payment rates. BIO believes that a separate additional payment would also serve to improve patient access under Medicaid, should an AMP based reimbursement model be pursued in a particular state. At the very least, BIO believes that reference to the precedent of the separate additional payment for blood clotting factors should be incorporated into the final rule in order to provide such knowledge to state Medicaid departments as they determine reimbursement rates moving forward.

5. CMS Should Issue Additional Guidance Through Notice-and-Comment Rulemaking Whenever Feasible and Apply Guidance Issued Through Program Releases Prospectively Only.

The preamble to the Proposed Rule includes a discussion of future clarifications of AMP. In that discussion, CMS stated that it believes that it needs “to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace of the sale of drug. We plan to address further clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed.”¹⁰⁵ BIO encourages CMS consider providing continuing guidance on other elements of the rebate program as well, and not just the definition of AMP.

In the past, CMS has provided guidance to manufacturers and States exclusively through informal means such as program releases and the Operational Guide. BIO recognizes that formal rulemaking will not always be possible, and that certain issues do not merit such a process. BIO nevertheless urges CMS to issue guidance through notice-and-comment rulemaking whenever possible to ensure that policy changes and new developments are evaluated and addressed by all interested parties. CMS also should confirm that any guidance it issues that is not subject to formal rulemaking, including

¹⁰³ SSA § 1842(o).

¹⁰⁴ CMS 1321-FC. Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.

¹⁰⁵ 71 Fed. Reg. at 77,181.

guidance issued through Releases, Frequently Asked Questions posted on the CMS website, and Policy Guides, will comply with the OMB Final Bulletin for Agency Good Guidance Practices.¹⁰⁶ BIO urges CMS to specify that its guidance, in whatever form, is to be applied prospectively only. Where that is not CMS' position, CMS should clearly articulate the administrative basis for retrospective application and subject the proposal to full notice-and-comment rulemaking.

6. CMS Should Clarify that the Final Rule Is Prospective in Application Only and Permit Additional Time For Manufacturer Implementation.

CMS notes in the preamble to the Proposed Rule that the Rule's provisions represent changes and clarifications to CMS' prior informal guidance and in some cases represent CMS' first pronouncements on an issue. For this reason, CMS should clarify that the Final Rule necessarily is applicable on a prospective basis only. Given the magnitude of the changes required by the Proposed Rule, BIO also requests that CMS mandate compliance with the Final Rule no earlier than four full quarters following its publication. Implementation will require manufacturers to train and even hire new personnel, create new government pricing methodologies, and then validate those procedures. In light of CMS' proposed certification requirement, it is critical that manufacturers have sufficient time to ensure a compliant implementation effort. BIO therefore urges CMS to provide participating manufacturers with the time they need to ensure this result.

* * *

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to working with CMS to ensure that Medicaid beneficiaries continue to have access to critical drug and biological therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions into its Final Rule. Please feel free to contact me at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement & Economic Policy
Biotechnology Industry Organization

¹⁰⁶ OMB Final Bulletin for Agency Good Guidance Practices, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.

Submitter : Mrs. Elizabeth Schinina
Organization : Adventist Health
Category : Health Care Provider/Association
Issue Areas/Comments

Date: 02/20/2007

GENERAL

GENERAL

California's safety-net hospitals are concerned about the potential impact on the '340B Program.' Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to provide discounts on covered outpatient drugs purchased by specified entities, including safety-net hospitals. Hospitals participating in the 340B Program are entitled to receive 340B discounts on all covered outpatient drugs. One condition of participation is that a drug purchased under Section 340B shall not be subject to both a 340B discount and a Medicaid rebate. To avoid these duplicate discounts, 340B hospitals bill Medi-Cal at acquisition cost (plus dispensing fee) for 340B drugs, and Medi-Cal, in turn does not collect manufacturer rebates on the drugs acquired at the discounted 340B prices.

If Medi-Cal collected rebates on drugs administered to Medi-Cal patients in hospital outpatient settings, this would result in manufacturers providing duplicate discounts on many of those drugs because manufacturers already will have provided the 340B discounts to participating hospitals.

If Medi-Cal were to pursue rebates as planned, which ultimately would entail the 340B hospitals essentially passing their 340B savings on to California instead of using them to stretch their own indigent-care resources, it likely would drive many 340B providers out of the program. Ultimately this would increase Medi-Cal net drug costs by depriving Medi-Cal of the savings it now derives from these hospitals' participation in the 340B Program. The fiscal impact on these facilities would be significant and coming at a time when more than half of the state's hospitals are operating in the red and facing burdensome unfunded mandates, such as seismic retrofitting.

Response to Comments

Response to Comments

Hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer's NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS) to report a particular drug or biologic rendered to a patient.

It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must 'provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered.' The DRA further states that the 'reporting would include J-codes and NDCs.' As such, CHA believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information. California estimates rebates will net the state Medicaid program approximately \$50 million. Hospitals will clearly be required to invest this much and more to ensure compliance with this onerous rule.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take roughly 500 to 1,500 work hours to design, build and test a short-term work around. Early estimates are that California hospitals could be required to spend \$1 million and more to make the necessary system and staffing changes to put these reporting requirements in place. It is worth noting that California's Medicaid expenditures per beneficiary are either the lowest in the nation or among the lowest (depending on which data source cited). Requiring such an expensive, onerous requirement with no hope of recovering any of the associated costs will force hospitals to cut costs in other areas. This could result in reduced hospital services and compromised access to care for all Californians.

When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital's need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. Therefore, the hospital pharmacy record keeping systems will need the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

During the past several years many hospitals have introduced new automated drug-dispensing systems in an effort to reduce medication errors. Many of these systems also would require costly modifications. For example, these drug-dispensing systems have bins for each specific drug based on ingredient and dosage, not on manufacturer NDC. There also is a human cost since hospitals that are interested in acquiring such systems to reduce medication errors would have to postpone their acquisition until the vendors make all of the system modifications. And, patient safety could be compromised in other ways as hospitals transition to using and reporting NDCs.

This proposed rule applies to Medicaid only. This eliminates efficiencies and administrative simplification, and increases costs, that comes with submitting standard claims using standard coding systems. The bottom line is this proposed requirement requires a costly upgrade without tangible benefit for Medi-Cal patients.

Submitter : Mr. Marc Claussen

Date: 02/20/2007

Organization : Alharma Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1321-Attach-1.DOC

Submitter : Mr. George Chelland

Date: 02/20/2007

Organization : Costa Drugs, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare Services(CMS)regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper limit(FUL) program for generic drugs. Costa Drugs, Inc. is an independent pharmacy with 3 stores, located in Scranton, PA., Dickson City, PA., and Clarks Summit, PA. We are a major provider of pharmacy services in the community, with special services such as free pick-up and delivery of prescriptions, blood pressure monitoring, bubble packing, and many other services not provided by chains and certainly not provided by mail order. Many of our patients are elderly or disabled. We truly believe that if we are forced out of business by the low reimbursements from medicaid and PBM's, including Medicare D, it will be a great loss to these patients. They will not find the personal assistance and special services we provide if our doors are closed. We are already losing money with the current medicaid pricing. Some drugs are paid at far below our actual cost. The new proposed rule on AMP will, without a doubt, put us out of business. Your consideration of these comments is essential.

Our comments are as follows:

1. Definition of "Retail Class of Trade- Removal of PBMs and Mail Order Pharmacies

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These Organizations do not dispense to the "general public." The more extensive comments submitted by Pennsylvania Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2.Calculation of AMP-Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent.

3.Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

4. Manufacturer Data Reporting for Price Determination-Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulations could create an avenue for market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, Pennsylvania Pharmacists Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, we ask that you consider the independent retail pharmacy when making your decision on the proposed AMP regulation.

We support the more extensive comments that are being filed by Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

George J. Chelland, R.Ph.
Corporate Secretary
Costa Drugs, Inc
Corporate Secretary

Submitter : Ms. Mary Jo Carden
Organization : Transplant Pharmacy Coalition
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background
See attached

Collection of Information Requirements

Collection of Information Requirements
See attached

GENERAL

GENERAL
See attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations
See attached

CMS-2238-P-1323-Attach-1.DOC

CMS-2238-P-1324

Submitter : Ms. Michelle Butler
Organization : Hyman, Phelps & McNamara, P.C.
Category : Drug Industry

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1324-Attach-1.PDF

1324

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February 20, 2007

Via Electronic Submission

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
750 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on CMS-2238-P, Medicaid Rebate Program; Prescription Drugs (Proposed Rule) – Upsher Smith Laboratories, Inc.

Dear Sir or Madam:

On behalf of Upsher Smith Laboratories, Inc. (“Upsher Smith”), we are pleased to submit the following comments on the rule proposed by the Centers for Medicare & Medicaid Services (“CMS”) regarding the Medicaid Drug Rebate Program on December 22, 2006.¹

I. Calculation and Reporting of Average Manufacturer Price (“AMP”), Best Price (“BP”), and Customary Prompt Pay Discount

A. Authorized Generics

Upsher Smith seeks clarification from CMS regarding the calculation of AMP and BP for branded products for which there are authorized generic products. Under the proposed rule, a manufacturer holding title to a new drug application (“NDA”) would be

¹ CMS, Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77,174 (Dec. 22, 2006).

required to include in its AMP calculations its "direct" and "indirect" sales of the authorized generic and would also be required to include in its BP prices to certain specified types of purchasers.² The preamble elaborates that the NDA holder would include in AMP and BP sales of the authorized generic marketed by the secondary manufacturer or by the NDA holder's subsidiary.³ Upsher Smith seeks guidance from CMS in three areas.

First, Upsher Smith asks CMS to clarify whether an NDA holder's sales of an authorized generic to a secondary manufacturer are to be included in the NDA holder's AMP. On one hand, the term "direct" sales would appear to encompass such sales. However, this interpretation would lead to the double-counting in AMP of every authorized generic unit – once when the unit is sold by the NDA holder to the secondary manufacturer, and again when the unit is sold by the secondary manufacturer to its customers – an obvious distortion of AMP. Because manufacturer-to-manufacturer sales should be excludable as non-retail,⁴ Upsher Smith urges CMS to clarify that such sales are excluded from AMP in the authorized generic context.

Second, Upsher Smith asks CMS to clarify whether an NDA holder's sales of an authorized generic to a secondary manufacturer are to be included in BP. The proposed rule specifies types of purchasers the prices to which are to be included in the computation of BP.⁵ This list includes "any manufacturer," which could include the secondary manufacturer. As noted above, the preamble makes it clear that the NDA holder is required to include in its BP all sales of authorized generic drugs by the secondary manufacturer to the specified types of purchasers.⁶ However, the preamble does not address the sales of the authorized generic by the NDA holder to the secondary manufacturer. Because sales to a manufacturer that repackages/relabels under the purchaser's NDC number are only included in BP if the entity is a health maintenance organization or other non-excluded entity,⁷ sales to the secondary manufacturer in the authorized generic context should be

² Id. at 77,198 (proposed 42 C.F.R. § 447.506(b), (c)).

³ Id. at 77,184.

⁴ Id. at 77,196-97 (proposed 42 C.F.R. § 447.504(g)(2)).

⁵ Id. at 77,198 (proposed 42 C.F.R. § 447.506(c)).

⁶ Id. at 77,184.

excluded from BP. Therefore, Upsher Smith urges CMS to clarify that such sales are excluded from BP.

Third, Upsher Smith seeks clarification regarding how an NDA holder is to take into account the AMP and BP of the secondary manufacturer in its own calculations of AMP and BP. This is of particular concern given potential anti-trust concerns pertaining to the sharing of AMP and BP information among manufacturers. One alternative would be to require the NDA holder to obtain the secondary manufacturer's raw sales, chargeback, and rebate data and perform its own calculations of AMP and BP. However, this would be unduly burdensome, and would, in many cases, be hampered by differences in automated data systems and data fields. For example, the secondary manufacturer's classes of trade might be incompatible with those of the NDA holder (e.g., the secondary manufacturer might sell to chain pharmacies whereas the NDA holder does not). Furthermore, every automated price calculation system has certain data formatting requirements. Raw data from the secondary manufacturer's systems may not be formatted in the correct way for the NDA holder's systems. To modify the latter's systems so that they can accommodate differently formatted data will often be an enormous IT project.

Upsher Smith believes these problems could be avoided by permitting the NDA holder to obtain the AMP, total number of units sold, and BP for each authorized generic from the secondary manufacturer and to feed those numbers into its own calculations.⁸ In doing so, the NDA holder should be permitted to rely on the secondary manufacturer's certification of the accuracy of its information and calculations and of its compliance with CMS regulations and policy.

B. Bona Fide Service Fees

Upsher Smith urges CMS to clarify the proposed definition of "bona fide service fees."⁹ Specifically, Upsher Smith asks that CMS provide guidance regarding how a

⁷ Id. at 77,197 (proposed 42 C.F.R. § 447.505(c)(11)).

⁸ For AMP, the product of the secondary manufacturer's AMP times the total units sold would be added to the NDA holder's net retail sales dollars to arrive at total net retail sales dollars, and the total units sold by the secondary manufacturer would be added to the NDA holder's AMP-eligible units to arrive at total AMP-eligible units.

⁹ 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. § 447.502).

company should determine the fair market value for a service. CMS has provided guidance regarding fair market value in the Medicare Part B average sales price ("ASP") context.¹⁰ For ASP, CMS stated that fair market value "means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities."¹¹ CMS also clarified that, depending on the nature of the drug distribution services, it may be appropriate to calculate fair market value for a set of itemized services rather than for each individual itemized service. While CMS did not mandate any specific method for determining fair market value, it acknowledged a manufacturers' ability to determine the most appropriate, industry accepted method. Upsher Smith requests that similar guidance be provided for purposes of the Medicaid Drug Rebate Program.

C. Combination Facilities

Upsher Smith seeks clarification from CMS regarding the treatment of sales to facilities that may operate both a closed-door long-term care pharmacy (excludable from AMP in the proposal)¹² and a retail pharmacy (includible in AMP).¹³ For such a facility, it is impossible for the manufacturer to identify which units were sold through the long-term care pharmacy and which units were sold through the retail pharmacy, since their orders do not distinguish between the two. It might be possible (though we are not certain) to separate the purchases by means of data purchased from IMS Health. However, this would be costly and would involve substantial manual data manipulation. Small and midsize manufacturers have limited resources to purchase such additional data. Upsher Smith therefore seeks clarification from CMS regarding whether all sales to such a combination facility should be included in or excluded from AMP.

¹⁰ CMS, Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; Final Rule, 71 Fed. Reg. 69,624, 69,669 (Dec. 1, 2006).

¹¹ Id.

¹² 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. § 447.504(h)(6)).

¹³ Id. (proposed 42 C.F.R. § 447.504(g)(5)).

D. TriCare Rebates

Upsher Smith seeks clarification from CMS regarding the proposed treatment of prices to TriCare in the calculation of AMP and BP. The proposed regulations state that “depot prices (including TriCare)” are excluded from the determination of AMP and BP.¹⁴ In accordance with the recent decision by the U.S. Court of Appeals for the Federal Circuit in The Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs,¹⁵ the TriCare retail pharmacy refund program was suspended and voluntary manufacturer refunds that had been paid are being returned by the government. The court invalidated on procedural grounds a determination by the Department of Veterans Affairs that retail drug sales reimbursed by the TriCare Retail Pharmacy Program constitute a depot contracting system. Accordingly, it is our understanding that, at the current time, there is no authority for considering the TriCare retail pharmacy network prices to be depot prices. If that is the case, Upsher Smith requests clarification regarding which TriCare prices, if any, are considered depot prices and are thus excludable from AMP and BP.

E. Customary Prompt Pay Discount

Upsher Smith seeks clarification from CMS with regard to the proposed definition of “customary prompt pay discount.”¹⁶ Upsher Smith requests that CMS clarify that “prompt” is defined by the manufacturer regardless of the length of time in which the purchaser can receive the discount. Upsher Smith also proposes that CMS clarify that, in accordance with current industry practice, it is appropriate for manufacturers to calculate prompt pay discounts reportable under 42 C.F.R. § 447.510(a)(3) by applying the available prompt pay discount percentage (e.g., two percent) to total direct sales. This procedure, which is based on the valid assumption that virtually all customers qualify for the prompt pay discount, is currently prevalent among manufacturers in the calculation of AMP. The alternative, which is to track down the prompt pay discount actually paid on each order, would be very burdensome. For example, Upsher Smith does not process the prompt pay discount at an NDC number level, but rather at an order or invoice level, and would find it difficult, if not impossible, to reconcile the prompt pay discount to the NDC number level.

¹⁴ Id. (proposed 42 C.F.R. §§ 447.504(h)(3), 447.505(d)(4)).

¹⁵ 464 F.3d 1306 (Fed. Cir. 2006).

¹⁶ 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.504(c)).

Upsher Smith also notes that the customary prompt pay discount will receive inconsistent treatment in different price calculations – *i.e.*, not deducted from AMP; deducted in determining BP; deducted from AMP in determining 340B ceiling price. This inconsistent treatment would result in complex system requirements that would be difficult to implement for small manufacturers, such as Upsher Smith. We recognize that prompt pay discounts must be excluded from AMP under the statute. However, Upsher Smith urges CMS to consider and implement an approach to the prompt pay discount that is consistent between AMP and BP, and also to coordinate with the Health Resources and Services Administration to implement a consistent treatment of prompt pay discounts under the 340B Drug Pricing Program.

F. Smoothing of Monthly and Quarterly AMP

With regard to the monthly AMP calculation, CMS has proposed a 3-month smoothing methodology to estimate the impact of end-of-quarter discounts.¹⁷ While this would help to reduce wide month-to-month variations caused by lagged discounts, we believe that a 12-month smoothing methodology, similar to the methodology implemented by CMS in the ASP context,¹⁸ would be preferable. Twelve-month smoothing would result in AMPs that have even less month-to-month fluctuation, and would thus help maintain stable federal upper limits.¹⁹ Accordingly, Upsher Smith requests that CMS permit manufacturers to use a 12-month rolling average ratio methodology for the monthly AMP.

Twelve-month averaging of price reductions should be permitted for quarterly AMP also. This would minimize short-term variations in AMP. Moreover, under Medicare Part B, the Office of Inspector General of the Department of Health and Human Services is authorized to conduct surveys to compare ASP with AMP and to implement a rate substitution if the ASP exceeds AMP plus five percent.²⁰ Unless AMP uses the same smoothing methodology as ASP, the two prices may not be comparable in any given quarter. Without 12-month smoothing for AMP, there are almost certain to be many quarters when chargebacks or rebates cause AMP to be far lower than ASP, even though

¹⁷ Id. at 77,198 (proposed 42 C.F.R. § 447.510(d)(2)).

¹⁸ 42 C.F.R. § 414.804(a)(3).

¹⁹ 71 Fed. Reg. at 77,187.

²⁰ 42 U.S.C. § 1395w-3a(d)(2).

the two are similar when averaged over a 12-month period. This could result in unwarranted rate substitutions for drugs that are covered under both Medicare Part B and the Medicaid Drug Rebate Program.

II. Reimbursement – Coordination of Benefits

Upsher Smith seeks clarification of how CMS intends to implement section 6002 of the Deficit Reduction Act of 2005, which requires state Medicaid programs to collect Medicaid rebates for physician-administered drugs. Given that federal law does not authorize states to collect rebates for the proportion of the payment for a drug made by the Medicare program, Upsher Smith calls CMS's attention to the special case that arises for dual-eligibles and Qualified Medicare Beneficiaries where Medicare is the primary payor for drugs provided in the physician-administered setting. Accordingly, Upsher Smith urges CMS to issue specific guidance stating that the rebate due for physician-administered drugs furnished to dual-eligibles and Qualified Medicare Beneficiaries is pro-rated for the portion of the Medicaid allowable payment that the state actually pays as a copayment or deductible on the claim paid by Medicare as the primary payor. In making this recommendation, Upsher Smith supports the position taken in letters from Charles E. Grassley, then Chairman, Committee on Finance, United States Senate, to Mark B. McClellan, then Administrator, CMS (Aug. 14, 2006) and from Jayson Slotnik, Director, Medicare Reimbursement and Economic Policy, BIO, to Deirdre Duzor, Director, Pharmacy Division, CMS (July 3, 2006).

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We appreciate the opportunity to comment on this important proposed rule on behalf of Upsher Smith. If you have any questions about these comments, please do not hesitate to contact me at 202/737-7551.

Respectfully submitted,



Michelle L. Butler

MLB/dcp