

CMS-2238-P-1156

Date: 02/20/2007

Submitter : Matthew Klefer
Organization : Watson's City Drug
Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1156-Attach-1.TXT

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.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments. Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing. *All calculations must be independently verifiable with a substantial level of transparency to have accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.*

Final Comments:

The rule, as currently written, would amount to gross negligence on the part of CMS if it ignores the GAO findings and input from all retail pharmacy organizations. By choosing to listen to the highly erroneous and self-serving input from PBM's, (which is readily apparent in the rule as submitted), CMS would be ignoring the one group (Independent Pharmacy) that truly makes the Medicaid plan work on the patient level. For example: Most independent pharmacies deliver, chains and discount pharmacies do not. Many independent pharmacies are at the clinics near where patients live.

Independent pharmacies were the most responsive and helpful entities for CMS in signing up patients for Medicare part "D" plans, only to find the reimbursements were pitifully low and payments from PBM's were slow in coming.

As a new independent pharmacy owner I am quickly learning that CMS audits, reimbursement turnaround times, payments for generics, and support make Medicare part "D" claims an unhealthy part of my business.

And now the proposed definition of AMP will make another government plan more trouble than it is worth. In this case I have a choice! If the Final Rule on CMS-2238-P is not more accurately defined to reflect *my true cost and include a reasonable fee for service* I will not be taking Medicaid prescriptions after July 1st.

#1157

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VIA ELECTRONIC SUBMISSION

February 20, 2007

Leslie Norwalk
 Acting Administrator
 Centers for Medicare and 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

Ms. Norwalk:

American Pharmacy Services Corporation (APSC) is a cooperative buying group headquartered in Frankfort, Kentucky. It represents 380 independent pharmacies throughout Kentucky, Ohio and West Virginia. Many of these independent pharmacies are located in areas where the population is heavily dependent on Medicaid for health care services. It is on behalf of these pharmacies that I submit these comments to CMS today.

- The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail order pharmacies, hospital outpatient pharmacies and outpatient clinics. These pharmacies have access to rebates and price concessions that are not available to independent pharmacies. Despite this distinction, the acquisition costs for these entities are to be included in the calculation of AMP. As such, APSC is concerned AMP may be set at a rate lower than what independent pharmacies can purchase.
- The proposed change in reimbursement for multi-source prescription drugs is going to have a significant negative impact on independent pharmacies and, most importantly, the patients they serve. Using existing AMP data, GAO has estimated the new Federal Upper Limit (FUL) formula will cause retail pharmacies to be reimbursed, on average, 36% lower than actual cost for a large number of the most frequently prescribed multi-

Leslie Norwalk
Re: CMS-2238
February 20, 2007
Page 2

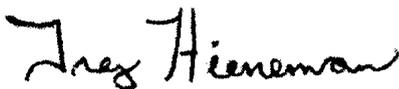
source medications. Independent pharmacies derive the bulk of their revenues from prescription drug sales, and 60% of these sales are for multi-source drugs. If the current formula is not revised, they will no longer be in a position to continue to care for patients if doing so forces them to accept a loss on a significant number of the prescriptions they provide.

- The proposed rule does not address dispensing fees to be paid to pharmacy providers. CMS has asked states to amend their dispensing fees to counter this loss. However, as federal payment reductions to state Medicaid programs continue, the likelihood of this happening is small.

- Data and Market Delays
 - The proposed rule directs manufacturers to consider sales and associated price concessions extended to SCHIPs and SPAPs. Manufacturers do not have access to this information until they receive quarterly invoices from the states. The same is true for some Part D information. Instructions for addressing lagged data should be included in the final rule.
 - The current instructions for calculating AMP are silent as to whether chargebacks, rebates and other discounts to be paid at a later date should be treated as-paid or as-earned. The final rules should state with specificity which methodology should be used.
 - Upfront discounts on large purchases to be sold over an extended period of time can distort pricing available to retail pharmacies in the market. The final rule should adopt smoothing methodologies to handling price concessions of this nature.

- The proposed rule directs that AMP be calculated using a 9-digit NDC verses an 11-digit NDC. If pharmacies purchase the most economical size, the return on investment decreases and the chance of outdated increases. Current regulations specify that FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. The final should continue using the 11-digit methodology to support market efficiencies and eliminate waste.

Sincerely,



Trey Hieneman, Director of Government Affairs

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541
 113 South Seventh Street, Akron, Pa. 17501-1332 717-858-4911
 335 West Main Street, Leola, Pa. 17540-2107 717-856-3784
 1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215
 508 Hershey Avenue, Lancaster, Pa. 17803-5702 717-298-4737

02/15/2007

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 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.

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

I 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 me with any questions.

Sincerely,



Margret A. Sanbower, R.Ph.
Pharmacist Manager
Royer Pharmacy
335 W. Main St.
Leola, Pa. 17540
717-656-3784

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

CMS-2238-P-1159

Submitter : Dr. Sandra Lawson
Organization : Family Prescription Center
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1159-Attach-1.TXT

██████████ 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 pharmacist of Family Prescription Center, a community retail pharmacy located at 129 Main St., Mountain City, 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 my 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,

Sandra K. Lawson
3418 Campbell Road
Mountain City, TN 37683

cc: Senator Lamar Alexander
Senator Bob Corker
Representative David Davis

CMS-2238-P-1160

Submitter : Mr. Craig Harvey
Organization : Regions Outpatient Pharmacy
Category : Pharmacist
Issue Areas/Comments

Date: 02/20/2007

GENERAL

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See Attachment

CMS-2238-P-1160-Attach-1.DOC

 **Regions Hospital**

February 19, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

To Whom It May Concern:

On behalf of Regions Hospital Pharmacy, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Regions Hospital is a 427 bed hospital located in St. Paul, Minnesota. **Regions Hospital is the 2nd largest provider of uncompensated care in the state of Minnesota. Regions 2006 uncompensated care write-offs will total approximately \$34.5 million.** Since 2003, our write-offs have nearly doubled. Regions Hospital qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. In order to comply with these requirements if passed, Regions would need to create an electronic management system to report NDC data. At this time the NDC data requested does not currently exist in an accessible format. To comply using a manual process would be cumbersome and would consume people resources that currently provide direct patient care. The expense of creating an electronic process could easily exceed several hundred thousand dollars for Regions Hospital.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices. The projected impact on Regions could exceed \$200,000 per year for this rule.

If the proposed rules changes are implemented as written, Regions Hospital Outpatient Pharmacy will need to evaluate participation in the 340B program as the cost to comply with the rules could easily exceed the annual savings currently realized and used to fund uncompensated care for the hospital as a whole. The ability of Regions Hospital to provide quality care at affordable prices for the underserved population we serve could be in jeopardy.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Craig Harvey
Outpatient Pharmacy Manager
Regions Hospital
640 Jackson Street
St. Paul, MN 55101

651-254-9560

Submitter : Mr. MAHENDRA PATEL
Organization : FAMILY FARMACIA INC/AIPHA
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

We are Medicaid provider in state of Illinois. Almost 80 % of our business is Medicaid. We would like to submit comments about proposed AMP base reimbursement for Medicaid to go into effect on July 01, 2007.

Collection of Information Requirements

Collection of Information Requirements

A study done by Grand Thornton LLP on behalf of NCPA and NACS determine the cost of dispensing at \$10.50 per prescription on average. This study was conducted on August 2006 that included data from 24,400 pharmacies. The cost of doing business is increase every single day.

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If AMP base reimbursement goes into effect, many independent pharmacies are forced out of Medicaid business, the quality of care will suffer in urban & rural area. This will increase the medical expenses of state as many Medicaid recipients will end up with bigger health problem requiring hospitalization. If AMP base reimbursement should go into effect, it should reflect the actual acquisition cost of pharmacy with dispensing fee should be increase at least \$ 13.50 to reflect the increase cost for filling prescriptions.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed ruling make AMP as basis for FUL (Federal Upper Limit) is in Medicaid program. According to the GAO (Government Accountability) these FULs will be 36 % below average acquisition cost of most pharmacies.

Regulatory Impact Analysis

Regulatory Impact Analysis

The average dispensing fee being so low. If this AMP based reimbursement goes into effect many independent pharmacies will stop filling Medicaid prescriptions and some who do, much of their business with Medicaid will be forced out of business.

CMS-2238-P-1163

Submitter :

Date: 02/20/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1163-Attach-1.RTF

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 pharmacist and owner of Down Home Pharmacy, a community retail pharmacy located at 1034 Main Street Bean Station, TN 37708. 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.

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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 my pharmacy [OR the pharmacy in which I work], where over ____% [OR 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.

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

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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,

Jimmy Collins
420 Derbyshire Court
Morristown, TN 37814

cc: Senator Lamar Alexander
Senator Bob Corker
U.S. Representative David Davis

CMS-2238-P-1164

Submitter : Virginia Toblason

Date: 02/20/2007

Organization : Abbott

Category : Drug Industry

Issue Areas/Comments

GENERAL

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See Attachment

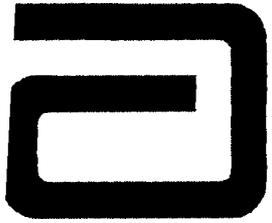
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#1164

Virginia Tobiason

100 Abbott Park Rd.
0391, Bldg. AP6D-2
Abbott Park, IL 60064-6008

t 847-937-8438
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February 20, 2007

VIA ELECTRONIC SUBMISSION AND HAND-DELIVERED
(<http://www.cms.hhs.gov/eRulemaking>)

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

Re: Comments on Proposed Rule Related to the Medicaid Drug
Rebate Program, (CMS-2238-P)

Dear Administrator Norwalk:

Abbott is pleased to submit comments regarding several specific provisions of the Centers for Medicare & Medicaid Services' (CMS) proposed rule to implement the Medicaid prescription drug provisions of the Deficit Reduction Act of 2005 (DRA). Abbott is a broad-based health care company that discovers, develops, manufactures and markets products that span the continuum of care – from prevention to treatment and cure. Our product portfolio includes pharmaceuticals and medical devices as well as nutritional products for children and adults. Abbott is headquartered in north suburban Chicago, Illinois and employs 65,000 people worldwide.

We commend CMS for the thoughtful approach taken in the proposed rule. Abbott understands the difficulties faced by CMS in drafting a regulation that addresses the complexities and realities of today's pharmaceutical marketplace.



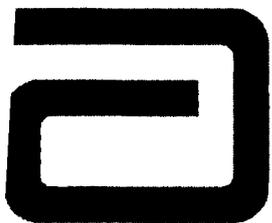
Our specific comments follow.

Determination of AMP (Section 447.504)

CMS has advanced a proposed rule that provides the much-needed clarity that has been recommended and requested by Congress, the GAO, OIG and stakeholders. In defining AMP with respect to the “retail pharmacy class of trade” we agree with CMS’ interpretation that Congress intended to include multiple entities beyond the traditional walk-in retail pharmacy. Therefore, to reflect the reality of today’s retail pharmaceutical marketplace, it is appropriate that CMS defines “retail class of trade” to include entities such as independent pharmacies, chain pharmacies, mail order pharmacies, and other arrangements that utilize retail class of trade for the dispensing of pharmaceuticals such as PBMs. Abbott also supports the inclusion of SCHIP, Medicare Part D, and SPAP sales, units and rebates in the calculation of AMP.

- **PBM Payments** – Abbott commends CMS’ recognition that PBMs have assumed a significant role in retail drug distribution since the enactment of the --- Medicaid rebate law. We fully support CMS’ proposal that AMP should be calculated to reflect the net price realized by the manufacturer inclusive of any “discounts, rebates, or other price concessions to PBMs associated with sales for drugs to the retail pharmacy class of trade.” Abbott agrees that other arrangements with third party intermediaries, such as PBMs, which impact the amount realized by the manufacturer on drugs distributed to the retail class of trade should be included in the calculation of AMP.

In the proposed rule, CMS seeks comment as to whether the inclusion of PBM rebates, discounts, and other price concessions in the AMP calculation is operationally feasible. As a manufacturer, Abbott would not have difficulty tracking rebates, discounts and other price concessions, as we are knowledgeable of such payments to the PBMs. Contracts with these entities generally provide that rebates, discounts, and other price concessions are payable to a PBM for prescriptions dispensed at retail and mail order pharmacies. Therefore, Abbott believes that manufacturers should be able to include all such rebates and other price concessions in the AMP calculation.

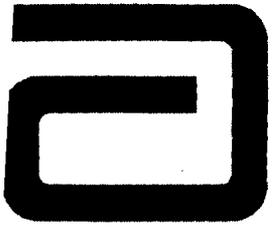


Abbott, however, is concerned about any approach that would impose on manufacturers an obligation to determine whether such price concessions are passed on to others, because we do not have access to that information. We ask that CMS clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning such downstream transactions.

- Coupons - The proposed rule would require manufacturers to include in their AMP and Best Price calculations the value of any patient coupons except those redeemed by a patient directly to the manufacturer. We ask CMS to reconsider this proposal for two reasons. First, patient coupons provide a benefit only to the individual and do not provide a benefit or truly impact any third party. And second, differential treatment of coupons based on method of redemption could have unintended consequences for patients who rely on coupons to help lower their drug prices. For example, patients could experience a delay in receiving the benefit of the coupon at point of purchase or some may never realize the offered benefit due to the additional steps that would be required to redeem the coupon directly with the manufacturer. We ask that CMS reconsider and permit manufacturers to exclude patient coupons from AMP and Best Price calculations.
- Single AMP- CMS should be aware that the Office of Pharmacy Affairs (OPA), within the Healthcare Systems Bureau of the Health Resources and Services Administration issued a letter dated January 30, 2007 advising pharmaceutical manufacturers that the DRA's statutory and regulatory changes to AMP will not impact the AMP used by the 340B program. If OPA's determination stands, pharmaceutical manufacturers will be required to calculate and maintain two separate AMPs.

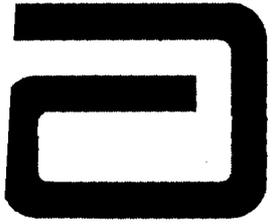
We believe that a single AMP is intended for use by both the Medicaid Rebate Program and the 340B program. We believe that Congress did not intend for two separate AMPs to be used – one for Medicaid rebates and the other for 340B pricing.

We respectfully request that CMS work with OPA to ensure that pharmaceutical manufacturers are required to maintain only one AMP per 11-digit NDC.



Determination of Best Price (Section 447.505)

- **Prompt Pay Discounts** – While the DRA requires pharmaceutical manufacturers to exclude customary prompt pay discounts to wholesalers from AMP calculations, Congress was silent on the treatment of prompt pay discounts on Best Price determinations. A change in treatment of prompt pay discounts to exclude them from the calculation of AMP not only increases the basic rebate (15.1% of a now higher AMP) but also, in fact, establishes a new Best Price. We do not believe that it was Congress' intent to create a new level of Best Price and we urge CMS to reconsider its position. A more equitable treatment is to exclude the prompt pay discount not only from AMP but also from a manufacturer's Best Price determination.
- **Bundled Sales** – We recommend that CMS refrain from expanding the definition of bundled sales and instead adopt in the final rule the current definition contained in the Medicaid Rebate Agreement. The Medicaid Rebate Agreement 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.” We ask CMS to confirm that it is only in arrangements where a discount/rebate is offered on one drug contingent on the actual purchase of a separate drug, that a bundled sale exists. Also, in recognition of the fact that a given contract may describe multiple discounts, only some of which are bundled discounts, we ask CMS to confirm that the allocation required by the proposed rule need only be performed in connection with bundled discounts and the products whose sales create the bundle.



Authorized Generic Drugs (Section 447.506)

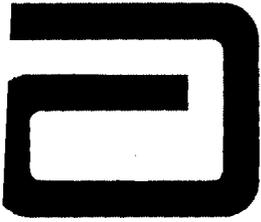
The DRA requires a manufacturer holding title to an original NDA of an authorized generic drug to include in the branded drug's Best Price calculation the sales of the authorized generic drug.

Abbott interprets the statute and proposed rule as imposing a new requirement on an NDA holder to include in its Best Price determination sales of the authorized generic drug by the authorized generic company/secondary manufacturer. The statute and proposed rule do not appear to require the NDA holder to include in its Best Price determination the transfer price from the NDA holder to the authorized generic company/secondary manufacturer. The proposed rule's preamble language reads in pertinent part, "We propose to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and Best Price." This language indicates that it is the downstream sales of the authorized generic company or secondary manufacturer that the statute requires to be included in the brand manufacturer's Best Price determination. This interpretation is consistent with the manner in which CMS has historically treated Best Price, intending to capture in the calculation all downstream sales into the commercial marketplace. Although the proposed rule provides some guidance, Abbott encourages CMS to explicitly confirm in the final rule that the statute does not require an NDA holder to include in its AMP and Best Price calculations the transfer price of the authorized generic drug from the NDA holder to the secondary manufacturer.

Also, CMS should provide assurances that the primary manufacturer is permitted to rely on the accuracy of the pricing information provided by the authorized generic company.

Requirements for Manufacturers (Section 447.510)

- **12-month Rolling Average Methodology** – We appreciate CMS' willingness to entertain comments from manufacturers about applying a 12-month rolling average methodology to the calculation of monthly and quarterly AMPs. This methodology is particularly helpful for the monthly calculation,



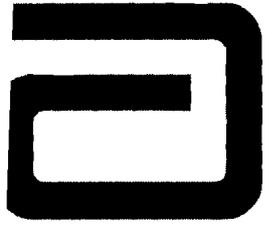
payer for a drug for which the Medicaid program pays only a small co-payment.

We believe this to be the intent of the statutory language, which is bolstered by then Senate Finance Chairman Grassley in his August 14, 2006 letter to CMS in which he advised that it was not Congress' intent to require manufacturers to pay rebates at a level above the percentage paid for the drug by a state Medicaid program. Applicable statutory language further supports this point. As a prerequisite to receiving federal Medicaid matching funds, Section 1927(a)(7)(A) of the Social Security Act, as amended by Section 6002 of the DRA requires states to collect and submit utilization and to secure Medicaid rebates for single source physician-administered drugs. The statutory language reads in pertinent part, "to secure rebates *under this section* for drugs administered for which payment is made *under this title*." This language clearly refers to payments under the Medicaid program. The statutory language does not give states the authority to collect rebates based on expenditures through the Medicare program.

Abbott appreciates the opportunity to comment on the proposed rule, as well as the effort that CMS has put into the development of the proposed rule. We look forward to further dialogue with CMS on the many important topics addressed in this rulemaking and hope our comments are helpful. Please feel free to contact us if we can be of further assistance.

Sincerely,

Virginia Tobiason
Senior Director, Corporate Reimbursement
Government Affairs
Phone: 847-937-8438
virginia.tobiason@abbott.com



because the DRA does not permit manufacturers to restate monthly AMPs. In general, a rolling average methodology benefits virtually all stakeholders by providing stability in pricing and avoiding significant fluctuations in monthly and quarterly AMPs caused by lagged sales and rebate data.

- Recalculation of Base Date AMP - Abbott applauds CMS for recognizing that manufacturers should have the opportunity to adjust base date AMP to account for the changes set forth in the DRA and the final rule. However, we request that pharmaceutical manufacturers be given the opportunity to restate earlier 2007 AMPs to account for the CPI impact caused by implementation of the DRA's Prompt Pay and authorized generic provisions and also be able to re-establish the base date AMP for the new calculation metric created by the CMS final rule. Senator Grassley stated in his May 12, 2006 letter to CMS in pertinent part, "... your recommendations should suggest a means for adjusting rebate computations so that no manufacturer is subject to increased inflation adjustment rebates by function of the changing definition." The Senator's statement is consistent with the two-step approach advocated by Abbott above.
- Certification of Pricing Reports - CMS proposes to adopt the certification requirements established by the Medicare Part B Program for average sales price (ASP). While we applaud the goal of consistency with ASP procedures, we respectfully remind the agency that ASP is calculated on a quarterly basis, not every month. The timeliness of our monthly AMP reports will be undermined if we are required to provide certification as outlined in the proposed rule. The Medicaid Rebate statute contains a civil monetary penalty provision for knowingly submitting false information. As there is no statutory requirement in the DRA for such a certification we ask that CMS eliminate the certification process for the monthly AMP reports.

Physician-Administered Drugs (Section 447.520)

Concerning rebates for physician-administered drugs, we respectfully request that CMS provide clarification in the final rule that the states should collect a Medicaid rebate only for that portion of the payment made by a state Medicaid program. If CMS does not clarify this provision, manufacturers could be required to remit full rebate payments to states where Medicare is the primary

Submitter : Mrs. Colleen Cox
Organization : ClearSpring Pharmacy
Category : Individual

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

- > The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- > Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- > To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
- > Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
- > Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

Submitter : Ms. Nancy Mosher
Organization : Planned Parenthood of Northern New England
Category : Health Care Provider/Association

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1166-Attach-1.DOC

CMS-2238-P-1166-Attach-2.DOC

**COMMENT FROM
PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND HEALTH CENTERS**

February 16th, 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 and CEO of Planned Parenthood of Northern New England (PPNNE), which includes a network of 26 non-profit outpatient health centers in Vermont, New Hampshire, and Vermont that provides critical reproductive health services to uninsured and underinsured women, men and teens. PPNNE serves over 60,000 patients each year. Over 70% of these patients are under 200% of the Federal Poverty Level and can not afford the health services -- particularly oral contraceptives -- that PPNNE provides without discounted prices and our sliding fee scale.

For over 40 years, PPNNE has been committed to ensuring access to quality reproductive health services to women and men in Vermont, New Hampshire and Maine regardless of their ability to pay. In addition to providing deeply discounted oral contraceptive medications to women, we provide pregnancy tests, screening for cervical, breast and testicular cancer; testing and treatment for sexually transmitted infections, and immunizations for women, men and teens. Our ability to provide this range of services to the underprivileged members of our communities rests in large part with our ability to purchase oral contraceptive drugs from drug manufacturers willing to provide them at nominal prices

We are writing with great concern that the Centers for Medicare and Medicaid Services ("CMS") did not define "other safety net providers" as authorized by section 6001(d)(IV) of the Deficit Reduction Act of 2005 ("DRA"). PPNNE is a safety net provider, but it is critical that we are defined as such to ensure access to nominal prices for contraceptives.

At this time all but one of PPNNE's health care centers are considered 340B covered entities (as defined in DRA section 6001(d)(I)) through either Title X federal family planning program or the section 318 STD prevention program. While the 340B program currently keeps our health centers eligible for nominal drug pricing, 340B is simply not our golden ticket to sustained business. Given state and federal financial constraints, we simply cannot rely on the continued

funding from Title X and section 318, thus our eligibility as a 340B program is under constant threat. Thus, It is crucial to the continued operation of PPNNE's health centers that the Department of Health and Human Services (HHS) immediately defines "other safety net providers."

Quite simply, Title X and section 318 provide us with only a thin layer of eligibility for favorable drug pricing, but this protection is easily upset. This tenuous nature of our participation in the TX and 318 programs is real. Therefore, this issue is of great concern to us. The continuation and fiscal viability of PPNNE lies in our ability to purchase oral contraceptives at less than 10% of the average retail price. Should we lose our Title X or section 318 at any of our health centers, our ability to continue to serve our patients would be greatly compromised.

If we lose our Title X or section 318 status, we also lose our 340B status. While losing our 340B status would not change our commitment to providing poor women with affordable contraception, we would have no statutory access to the nominal drug pricing program. For this reason, we strongly urge CMS to include in its definition of safety net providers non profit health care facilities like ours.

If we are not defined as a safety net provider and lose eligibility under 340B, our ability to serve our clients would be crippled – not only in the areas of offering low cost contraception, but in all areas of reproductive health care. In effect we would no longer be able to provide the high quality services for poor women and men that they desperately need. This gap in services would have a particularly devastating impact to over 40,000 clients who are under 200% of the Federal Poverty Level that we serve in Vermont, New Hampshire and Maine each year.

Planned Parenthood of Northern New England urges CMS very strongly to reconsider its position and exercise the authority granted it by Congress to define "other safety net providers" in the final rule.

Respectfully Submitted,

Nancy Mosher
President and CEO
Planned Parenthood of Northern New England
Vermont, New Hampshire and Maine

Submitter : Ms. Michelle Featheringill
Organization : Planned Parenthood of New Mexico
Category : Other Health Care Provider

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1167-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 Administrator Norwalk:

I submit these comments as President and CEO of Planned Parenthood of New Mexico, Inc. – a non-profit organization that has been providing reproductive health care in New Mexico since 1964. Each year we serve over 26,000 individuals in our five outpatient health centers located in Albuquerque, Rio Rancho and Santa Fe. More than 22 percent of New Mexicans lack health insurance so many women in the state count on us for low-cost, high quality health care.

In a recent survey, we determined that more two-thirds of our patients at Planned Parenthood of New Mexico (PPNM) have incomes below 150 percent of the federal poverty level. On the state level, twenty-three percent of women aged 15-44 have incomes below the federal poverty level, and 31 percent of all women in this age group are uninsured (i.e. do not have private health insurance or Medicaid coverage). Fifteen percent of women aged 15-44 are enrolled in Medicaid. However, according to the Guttmacher Institute, public family planning clinics in New Mexico only serve 54 percent of all women in need of publicly supported contraceptive services and 52 percent of the teenagers in need.

Many women and teens choose to come to PPNM because we've been providing services for over 40 years in the state, while other health care organizations have come and gone. They know who we are and where we are. Students and women who work appreciate our convenient walk-in and same-day appointments, and our evening and weekend hours.

Our patients know that Planned Parenthood is committed to keeping costs for services and supplies affordable and accessible. We've developed programs like PILLS NOW, PAY LATER a plan that allows a patient to take home a years worth of contraceptives, which she can pay for via debit card or bank draft each month. This is especially appealing for women who may have to travel some distance every month to reach a pharmacy in a state as large as New Mexico. However, our recent increase in pill prices has caused some patients to reconsider entering the program since they're not certain they'll have enough money in their account each month. Others are struggling to cover the monthly cost of their oral contraceptives now – we've had patients pay with a pile of bills and change.

PPNM has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Like most Planned Parenthood providers, we strive to keep all of our prices for services, as well as contraceptive methods, as low as possible. When we were hit with the direct impact of the "Deficit Reduction Act," we were unable to fully absorb the increased costs that we experienced, and subsequently were forced to pass on the substantial increase to our patients. Without nominal pricing availability, we fear that the negative impact and inability of our patients to pay the necessary increases will make it extremely difficult for us to sustain our clinics financially. If PPNM were forced to close our clinic doors, the negative impact in our very poor State would be immense.

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. Many of our Planned Parenthood sister health centers across the country are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. Planned Parenthood of New Mexico, however, is not federally funded. Therefore, we do not qualify as a 340B covered entity.

At the same time, PPNM serves as a key safety net provider to many women in our state. 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. Unfortunately, like many other small safety net providers, we do not qualify for the three categories above.

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. PPNM is a clearly safety net provider and we strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient clinics like ours.

Over 26,000 women rely on PPNM every year for their family planning and contraceptive needs; we are an integral resource for New Mexicans. It is imperative for us to maintain our ability to purchase contraceptives through a nominal pricing purchasing contract. Please strongly consider our request.

We appreciate your time and the opportunity to present our comments

Respectfully submitted by,

Michelle Lynn Featheringill
President/CEO
Planned Parenthood of New Mexico
Albuquerque, NM

Submitter :

Date: 02/20/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL**GENERAL**

The proposed rule could have a devastating impact on the financial viability of retail pharmacies and pharmacy practice. Community pharmacies cannot purchase multi-source generics at the prices obtained by PBM owned pharmacies and mail order pharmacies. Major mail order pharmacies and PBM's buying power allows them to leverage manufacturers for substantial rebates which are not available to retail pharmacies. This rule will give mail order pharmacies an unfair competitive advantage over retail pharmacy. PBM's are currently already forcing the majority of patients to use their own mail order pharmacies in order to save money on their copays. If you ever speak with those patients forced either financially or otherwise to use mail-order you will find the majority are dissatisfied with the care they receive. They continue to go to their neighborhood retail pharmacy for counseling and other services. If you pass legislation that continually only affects the little guy then where will YOU go to fill your antibiotic prescription or pain pills when all the neighborhood pharmacies are out of business. Who will fill prescriptions in the rural areas? If you want to control the cost of medications, target those ultimately responsible, the drug manufacturers and physicians that are prescribing brand name medications when there are generics that would work just as well 80% of the time. It is not the retail pharmacies that are profiting. If you find that hard to believe then look at the reported profits of the major drug companies and PBM's versus independent retail pharmacies. I guess every legislative effort in this great country of ours is only aimed at helping the rich get richer and the poor get poorer. I'm glad my tax dollars are spent on helping companies like Merck who own the manufacturers, mail order pharmacies and insurance companies get richer. What next? I know let Merck own physicians too. Then they alone can tell patients and CMS what the patient can take, where they can purchase it and what physician they are required to go to. Maybe then companies like Merck can take over CMS or wait maybe in certain ways they already have.

Submitter : Dr. Thad Schumacher

Date: 02/20/2007

Organization : Dr. Thad Schumacher

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I am writing to you to express my concerns with regard to the current proposed medicare prescription drug pricing suggested under CMS 2238 P. It is my opinion and that of the majority of my profession that using the proposed rules to calculate AMP will have a dramatic reduction of Medicare patients access to their pharmacists and disastrous effects on the small businesses of independent retail pharmacies across the nation.

As a manager of a new independent pharmacy in a metropolitan area, I see and experience retail pharmacies struggle to provide personalized patient care such as compliance assistance, patient education, and home delivery while seeing reimbursements continue to be reduced. Everyday, I help Medicare patients choose the right medication to compliment their therapy while simultaneously choosing the most cost-effective therapy for them. It costs about \$9.00 according to the National Association of Chain Drugstores to fill the average prescription. This number at my pharmacy would be higher as I make it a point to spend quality time with each of my patients.

Not only does it more expensive to fill prescriptions for the Medicare population, the profit made per prescription is also less, leading to significantly reduced margins that are not sustainable in a successful business. The average gross profit on a Medicare prescription at my pharmacy currently is \$10. This profit can be compared to my overall gross profit per prescription (Medicare and all other third parties) of \$14.32 showing that Medicare is already failing to provide adequate reimbursement for the services that I provide my Medicare patients. The National Community Pharmacists Association has reported that the current proposed rules will lead to a reimbursement 36% less than pharmacy acquisition costs. These numbers lead me to one conclusion. If AMP in its current form were to be implemented, this pharmacy would be forced to stop accepting Medicare patients prescriptions. In my opinion, this would be the fate of many Medicare recipients with regard to accessing their current pharmacist. This huge decrease in pharmacy providers especially in rural areas will be detrimental to public health.

What can be done to change this detrimental outcome? Do not base Federal Upper Limits (FULs) on AMP because this does not account for the acquisition cost of multisource generic medications. Do not use AMP as a basis for reimbursement, for it was never intended to represent the acquisition costs of medications by pharmacies. For AMP to be considered an appropriate benchmark, it must be redefined to reflect the actual costs to retail pharmacies. This could be attained by excluding all rebates and price concessions made by pharmaceutical manufacturers that are not available to retail pharmacies. You should exclude all mail order facility and PBM pricing formats from AMP calculations as mail order and PBM pharmacies receive special pricing from manufacturers and they are not as accessible to the public as a pharmacy located in a patient s neighborhood. Making these special price compensations and rebated programs transparent to the public would also bring light to the unlevel playing field in acquisition costs of retail pharmacies and mail order and PBM facilities. It would also be important to report AMP at the 11-digit NDC level to ensure accuracy.

Thanks you for your time with regard to this matter. If you have any questions or wish for clarification please do not hesitate to call me 623-221-6630 or email me at thad67@msn.com. This decision effects future access of Medicare patients to their pharmacists. Please do not let them down.

Thad Schumacher, PharmD
Cactus & 35th Ave Family Pharmacy
12450 N 35th Ave #25
Phoenix, AZ 85029
602-298-1460

Submitter : Dr. Connie Bolte
Organization : Moore Compounding Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

The use of AMP as currently defined as the basis for the reimbursement of the cost of generic drugs for Medicaid patients will reduce payment for those drugs to a level where my pharmacy will not be able to provide them to Medicaid patients. The AMP was designed as a way for drug manufacturers to report what they are charging for their product to CMS, and is to their advantage to report the lowest prices they charge (which are NOT available to the retail pharmacy providers), since the lower the cost, the lower the rebates they have to pay. To be accurate for the retail pharmacy sector, the prices charged to classes of trade such as the VA, mail order pharmacy, and direct to the consumer programs by the drug manufacturers must be excluded from the AMP calculation. The drug manufacturers will not give retail pharmacy the same low prices, or the rebates they give to these classes of trade, and any reimbursement from CMS/Medicaid that is based on those prices will be much lower than the net cost of goods available to my retail business. My business has already felt the impact of low dispensing fees and low reimbursement from the Medicare D drug plans (our net profit was down \$40,000 from 2005, which means NO profit for 2006), and as you are well aware, the SSI disability people and senior Medicaid eligible people have been moved into the Medicare D plans. To further reduce the reimbursement for the remaining Medicaid recipients to a level where as a business I can no longer afford to accept the Medicaid contract will limit the availability of pharmacy services to the patients in my area. My pharmacy is the only specialty pharmacy in a 40 mile radius that offers compounded prescriptions to the Medicaid clients in our area. The health needs of those patients will not be served in a timely fashion if their last remaining access to pharmaceutical care is limited by forcing independent (and chain) pharmacies to refuse Medicaid contracts, or go out of business if they accept them. Please take into consideration the report of the GAO and the impact AMP will have on reimbursement to retail pharmacy, as well as the cost of dispensing survey information that places the national average overhead cost (not including ingredients) at \$10.50 per prescription. A fair AMP figure can be arrived at, but ALL of the factors effecting retail pharmacy have to be part of the computation to make it accurate!

CMS-2238-P-1171

Submitter : Mr. Michael J Ruggiero
Organization : Astellas Pharma US
Category : Private Industry

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-1171-Attach-1.PDF

CMS-2238-P-1171-Attach-2.PDF



Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

VIA ELECTRONIC SUBMISSION AND EXPRESS MAIL
(<http://www.cms.hhs.gov/eRulemaking>)

Re: Comments on Proposed Rule related to the Medicaid Rebate Program, CMS-2238-P

Dear Ms. Norwalk:

Astellas Pharma US appreciates this opportunity to comment on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) on December 22, 2006 implementing certain provisions of the Deficit Reduction Act of 2005 (DRA) relating to the Medicaid program.¹ Astellas is a global, research-based pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products that treat unmet medical needs. Our North American product lines focus on the therapeutic areas of immunology, cardiology, infectious disease, dermatology, and urology.

We appreciate the challenges involved in implementing the DRA, and commend CMS on its efforts in this area. We generally agree with the comments being submitted by the Pharmaceutical Research and Manufacturers of America, and we urge CMS to give careful consideration of the recommendations set forth in those comments. In our comments, we wish to focus in particular on the need to ensure adequate access to oral immunosuppressives at the pharmacy level for Medicaid transplant patients.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the average manufacturer price (AMP) for the least costly drug in each multiple-source group.² 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."³ 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.⁴

¹ Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).
² Social Security Act (SSA) § 1927(e)(5).
³ 71 Fed. Reg. 77174, 77187 (Dec. 22, 2006).
⁴ *Id.* at 77188. 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.

We support CMS' proposal to establish these safeguards in the FUL methodology, and we believe an additional safeguard is warranted to ensure adequate access to anti-rejection immunosuppressives for Medicaid beneficiaries who have had organ transplants. Transplant patients must take immunosuppressives to prevent rejection of the transplanted organ, and 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 for these therapies under Part D. CMS did this "because it was necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."⁵ This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.⁶

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives. Specifically, we propose 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 anti-rejection immunosuppressive FULs, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor.

* * *

Astellas appreciates your consideration of these comments, and would be pleased to provide any additional information that might be helpful to CMS as it prepares the final rule. Please contact me at 847-405-1640, or via email Michael.Ruggiero@us.astellas.com, if we can be of any assistance.

Sincerely,



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

⁵ Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines -- Formularies*, at 7.

⁶ GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs* (Dec. 22, 2006).



Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

VIA ELECTRONIC SUBMISSION AND EXPRESS MAIL
(<http://www.cms.hhs.gov/eRulemaking>)

Re: Comments on Proposed Rule related to the Medicaid Rebate Program, CMS-2238-P

Dear Ms. Norwalk:

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We appreciate the challenges involved in implementing the DRA, and commend CMS on its efforts in this area. We generally agree with the comments being submitted by the Pharmaceutical Research and Manufacturers of America, and we urge CMS to give careful consideration of the recommendations set forth in those comments. In our comments, we wish to focus in particular on the need to ensure adequate access to oral immunosuppressives at the pharmacy level for Medicaid transplant patients.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the average manufacturer price (AMP) for the least costly drug in each multiple-source group.² 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."³ 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.⁴

¹ Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

² Social Security Act (SSA) § 1927(e)(5).

³ 71 Fed. Reg. 77174, 77187 (Dec. 22, 2006).

⁴ *Id.* at 77188. 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.

We support CMS' proposal to establish these safeguards in the FUL methodology, and we believe an additional safeguard is warranted to ensure adequate access to anti-rejection immunosuppressives for Medicaid beneficiaries who have had organ transplants. Transplant patients must take immunosuppressives to prevent rejection of the transplanted organ, and 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.

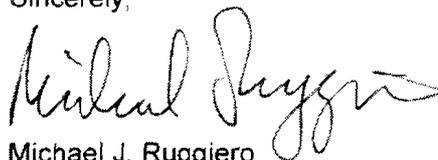
The special importance of access to immunosuppressives has prompted CMS to use its regulatory authority to establish safeguards for these therapies under Part D. CMS did this "because it was necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."⁵ This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.⁶

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives. Specifically, we propose 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 anti-rejection immunosuppressive FULs, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor.

* * *

Astellas appreciates your consideration of these comments, and would be pleased to provide any additional information that might be helpful to CMS as it prepares the final rule. Please contact me at 847-405-1640, or via email Michael.Ruggiero@us.astellas.com, if we can be of any assistance.

Sincerely,



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

⁵ Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines – Formularies*, at 7.

⁶ GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs* (Dec. 22, 2006).

Submitter : Rod Reinhardt
Organization : First Choice Pharmacy of Henderson
Category : Other Health Care Provider

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

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 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 owner located in Henderson and Gaylord, MN. 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) 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 Minnesota Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Rod Reinhardt, Owner

Submitter : Alan Layton

Date: 02/20/2007

Organization : Mountain West Medical Center/Wal-mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

It appears that the proposed rule assumes a level playing field both in purchasing and in patient counselling. This is a huge disadvantage to community pharmacies who will be expected to compete with PBM owned mail order facilities which are able to contract for lower manufacturer pricing and bigger rebates. These types of rules and decisions continue to increase the required number of prescriptions per pharmacist hour needed to maintain viability let alone profitability for community pharmacies. As the workload increases it has a direct negative effect on patient safety. The time available to counsel patients has continually eroded away as the required workload has increased. Mail order facilities continue to dispense prescriptions with "counseling available" allowing them to avoid the costs of pharmacies true benefit, educating and protecting the patient.

Please revisit the differences between mail-order and retail pharmacy, both in the purchasing and the service expectations before passing this rule

Submitter : Dr. Tracy Hart
Organization : Family Prescription Center
Category : Pharmacist
Issue Areas/Comments

Date: 02/20/2007

GENERAL

GENERAL

see attachment

CMS-2238-P-1174-Attach-1.TXT

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 pharmacist of Family Prescription Center, a community retail pharmacy located at 129 Main St., Mountain City, 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 my 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,

Tracy D. Hart
PO Box 105
Mountain City, TN 37683

cc: Senator Lamar Alexander
Senator Bob Corker

Representative David Davis

Submitter : Mr. Jerry Friedman
Organization : American Public Human Services Association
Category : State Government

Date: 02/20/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

See attachment

GENERAL

GENERAL

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1175-Attach-1.DOC



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 American Public Human Services Association (APHSA) and its affiliate, the National Association of State Medicaid Directors (NASMD), respectfully submits this comment letter on the Medicaid prescription drug benefit. APHSA and NASMD are 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). Please be assured that the state Medicaid agencies are fully committed to implementing the prescription drug related provisions of the Deficit Reduction Act of 2005 (DRA) and to their respective initiatives that seek to improve the efficiency of the Medicaid pharmacy benefit.

APHSA and NASMD believe that the DRA included important provisions that could facilitate increased transparency in prescription drug pricing in the Medicaid program and provide states with the tools they need to improve the accuracy of their reimbursement methodologies. States also recognize that these are essential steps in providing quality, affordable care to Medicaid consumers.

Medicaid's fundamental federal-state partnership necessarily means that states have a vested interest in ensuring the policy on drugs ensures ease of implementation. Further, states have an interest in assuring that the Congressional intent with respect to the DRA provisions can be implemented. As CMS continues to evaluate the best course of action to achieve these goals, we are submitting comments in the following areas:

- Ensuring the accuracy of average manufacture price (AMP) data for use in validating states' reimbursement methodologies and establishing AMP-based federal upper limits (FULs);
- Providing states with the flexibility to respond to market forces in a timely fashion; and
- Minimizing procedural challenges and recommending steps to improve the efficiency of collection of rebates on physician administered drugs.

Definitions – Section 447.502

Definition of Dispensing Fee

The proposed dispensing fee definition infers a specific methodology – that is a cost-based calculation not reflective of economies and competition in the marketplace. This is inconsistent with the intent of Congress and the administration to provide states' with the flexibility to set their own dispensing fee levels. In addition, it may result in Medicaid rates that are not representative of a marketplace in which other insurers consistently pay lower rates for ingredient costs and dispensing fees together than most Medicaid programs.

States also have noted that the proposed definition allows payment of a dispensing fee each time a drug is dispensed, regardless of whether such dispensing is consistent with economical practices. States have identified situations where some pharmacies, sometimes colluding with prescribers, fraudulently split maintenance drug prescriptions to obtain additional dispensing fee payments. States request that CMS clarify the proposed definition so that it does not preclude states from preventing such behaviors.

Determination of AMP – Section 447.508

In its proposed rule CMS requested input on its definition of AMP. With regard to mail order pharmacies, states note that 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. Based on this disparity, CMS should consider excluding mail order pharmacies in the AMP calculation.

CMS also requested comments on the new AMP calculation for setting FULs on generic drugs and whether there could be possible impacts on utilization and reimbursement for brand name drugs under Medicaid. States have conducted initial evaluations of the AMP data and will need additional time to conduct more comprehensive assessments and fully evaluate the new AMP-based FULs. Further, states believe it may be premature to evaluate the changes and impact of AMP pricing in the marketplace that may occur over time.

At this time, states note that there could be a challenge in achieving the most accurate reimbursement while not indirectly creating a disincentive to dispense generic prescription drugs. Some states have raised concerns that the proposed AMP-based reimbursement could discourage generic dispensing and have the unintended effect of increasing brand utilization and Medicaid costs. That is, if the aggregate impact of the AMP-based FULs results in a shift to brand name drugs and/or increase in dispensing fees, this could cause inefficiencies in the Medicaid prescription drug benefit. In addition, states recognize that provisions of the proposed rule may directly or indirectly impact their provider network, particularly in communities with small providers and/or those dependent on one provider.

For these reasons, states urge CMS to examine the range of factors – in addition to the ingredient costs – impacting states' reimbursement methodologies and preserve states flexibility to maintain a reasonable, market-based threshold for reimbursement. States ask that CMS consider the variations in prices and availability across states. We wish to offer for CMS' consideration the

possibility of creating an appeals process to allow pharmacies, drug wholesalers, and states to report situations whereby prescription drugs are not available or not available at the prices listed under the AMP-based FUL. For example, rural pharmacies may not have access to the same pricing available to larger markets or mail order pharmacies. Confirmed reports could result in CMS raising or suspending a FUL.

States also offer for your consideration that the appropriate definition of fair market value can only be truly determined by measuring the prices wholesalers charge all pharmacies in the aggregate on a real-time basis. In general, the wholesaler effect needs to be considered an essential component of this equation to accurately and equitably determine "fair market value."

Requirements for Manufacturers – Section 447.510

States believe that the DRA and this proposed rule begin to elaborate on the important steps that will help to increase access to and transparency of AMP data and a more appropriate reimbursement system, including by defining AMP in statute and regulation. However, states have identified several challenges and concerns with the proposed rule related to AMP.

AMP Data

States strongly encourage CMS to ensure that the AMP data is of a level of quality that will permit states to validate their current reimbursement methodology and improve the efficiency of the Medicaid pharmacy benefit. At a minimum, standard AMP data should reflect only those products currently available and be based on a specified supply time period, specifically:

- 1) CMS began providing states with sample or "non-standard" AMP data in July of 2006, and, based on this information, most states have conducted preliminary analysis of the AMP data. States have reported that there are a significant number of terminated products or products that were not available in every state that were included in the manufacturers' lists. The result is that states are presented with new challenges and questions as to why manufacturers would be reporting such data, even if this were a "sample" AMP file.
- 2) Some states have reported that there is significant fluctuation in AMP and that this inconsistency could result in inaccurate estimates of the acquisition costs that providers pay. This also could result in fluctuating FULs, thereby making it difficult for states to make timely and reasonable adjustments to their reimbursement methodologies to reflect such fluctuations. At the onset of implementation of the DRA provisions, states believe that it would be appropriate to provide additional time to allow states to monitor the fluctuations of the complete AMP data before they could make adjustments in reimbursement.
- 3) We encourage CMS to provide additional guidance on FUL pricing for prescription drugs that is not based on a different supply schedule, that is, by the actual package size of the drug. A FUL set on a weighted AMP by package price may not cover the actual acquisition costs of pharmacies purchasing smaller package sizes – while other pharmacies purchasing larger package sizes would be over paid.

Accountability for Accurate Data

We respectfully request that CMS assist in verifying the accuracy of the data by implementing accountability measures for manufacturers. States understand from the CMS call held on January 4, 2007, that the agency believes that the transparency of AMP information should help to reduce the erroneous data problem. However, states remain concerned by the lack of controls and accountability measures for manufacturers. In addition, the historical experience of states indicates that existing CMS processes have been insufficient in monitoring and managing the prescription drug files. The lack of updated data can reasonably be expected to result in inappropriate FUL calculations and impose an unforeseen burden on states to identify and subsequently report any inaccuracies to CMS.

As a result, states urge CMS to implement systems checks and measures to hold manufacturers accountable for the quality of data they provide, including reporting or not reporting accurate data. States request that in developing this system of checks and accountability measures, CMS include representation from state Medicaid agencies in addition to CMS representatives.

Implementation Timeline

States are concerned that the final regulation may not be published until July 1, 2007 and that many questions essential to implementation of the proposed rule will remain unanswered until this time. We understand that this is the date specified in the DRA. However, we urge CMS to consider and account for the steps states' will need to take in order to operationalize the final rule and meet this deadline.

States are unlikely to have the processes and systems in place for a number of reasons, including:

- 1) States must wait for CMS to finalize the provisions of this rule before they can develop the systems and processes to implement it, otherwise, states will have to undertake a second implementation initiative to reflect the changes and additional information CMS is expected to provide in the final rule.
- 2) Although states received AMP data in 2006, this was sample data, so they will have had insufficient time to evaluate the monthly fluctuations in AMP and any impacts on various facets of their Medicaid program. As noted above, the sample data was inaccurate and insufficient to make firm policy decisions. Any changes that states will need to make to their state Medicaid plan or dispensing fees are likely to require state legislation and/or submission of a state plan amendment and this will take considerable time.
- 3) The implementation timeframe is short and some states are unlikely to have the staff and funding resources to meet the deadline.

Transfer of AMP Files

Finally, with regard to AMP, the proposed rule states that CMS will distribute the monthly AMP file to states. States are concerned that the monthly file that CMS intends to send will contain only the drug name. In turn, states will have to translate the drug descriptions in the file that will enable them to easily analyze the impacts of the FUL with their processed claims. In addition, providing the file to states in such a fashion may lead to misinterpretations and lack of identification of applicable products with their National Drug Codes (NDCs) that are necessary to

process claims. In essence, this will require many states to invest new resources to manage this information.

States believe CMS can and should assist in making this process more efficient. We believe there would be a significant strain on states' resources if they were required to manage all of the new AMP data, including pricing updates, manually without some assistance. Therefore states request that CMS consider alternative mechanisms to facilitate states' utilization of workable data in a timely fashion. Specifically, a mechanism is needed that applies the rate to the new NDC that meet those criteria listed in the proposed rule. One possibility is to provide the file on at least a monthly basis to the nationally recognized pricing compendia that, in turn, could provide descriptive drug information, unique identifiers and pricing data, including updated NDC codes, within the file that would be distributed to states.

New FUL Calculation and Impact on Preferred Drug Lists

States also urge CMS to consider the adverse impact that the new AMP-based FUL could have on state prescription drug lists (PDLs) that have otherwise been effective in helping to appropriately contain costs in the Medicaid prescription drug benefit. For example, every month states could be required to consider the new AMP-based FUL for their respective PDLs. States have noted that in addition to procedural difficulties with this process, there may be challenges and unintended consequences on the level of savings expected to accrue from the new FUL if the net cost to the federal government and a particular state is less than the costs of generic. Specifically, this could compromise supplemental rebate agreements that states have in place in situations where the federal rebate and supplemental rebate together produce greater savings than the new FUL.

Access to Data for Territories

APHS and NASMD also respectfully request that CMS provide the U.S. territories with access to the new AMP data so they may leverage the information in their calculations for reimbursement on brand-name and generic drugs, as well as on rebates negotiations with the drug companies. Access to the proposed new AMP data will provide a benchmark in the rebate negotiation process, maximizing the utilization of available Medicaid funds.

Drugs: Aggregate Upper Limits of Payment – Section 447.512

The proposed rule includes an exception to allow providers to indicate when a specific brand drug is medically necessary for a particular recipient. However, CMS has indicated that this exception is permitted only in instances when the physician "certifies in his or her own handwriting" that the drug is necessary. States request that CMS reconsider this requirement as it is contradictory to state and federal efforts to transition to e-prescribing and other health information technology innovations.

Upper Limits for Multiple Source Drugs – Section 447.514

In the proposed rule, CMS notes that Congress did not intend that AMP should be restructured to collect it by 11-digit National Drug Codes (NDCs) and that this would create a new burden for manufacturers. We respectfully disagree with CMS' decision not to restructure the information collection method. Rather, the 11-digit NDC methodology will more accurately reflect the prices

paid by the majority of rural and sole proprietorship pharmacies. Specifically, states note that in some areas there is a lack of availability of all package sizes. This is particularly the case with rural or sole proprietorship pharmacies. Thus, the 9-digit NDC favors large scale purchasers and mail order pharmacies who capitalize on economies of scale by purchasing pharmaceuticals in the largest package size or those available in bulk where this methodology is not financially feasible or available to our rural pharmacies. States also recommend that AMP-based FUL pricing should be calculated on standardized package sizes.

FFP: Conditions Relating to Physician Administered Drugs – Section 447.520

The DRA called for a number of changes to improve the efficiency of billing methodologies for physician administered drugs. States are prepared to work with CMS to develop the appropriate measures and guidance that will be needed to ensure these provisions are implemented effectively.

Provider education

States are 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 with the new physician administered drug billing methodologies. A “standardized rebatable labeler list” would help to avert states having to deny claims several months later. States expect 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.

As such, states respectfully request that CMS inform providers of the Healthcare Common Procedure Coding System (HCPCS) codes will require a National Drug Code (NDC) that they can bill the state. As stated above, without this information, providers may not know who is and is not a rebating labeler.

In addition, 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 for rebatable drugs. States believe that since this is a national issue impacting all states and providers in the same way, it is reasonable to request that CMS develop standardized literature to educate providers rather than requiring each Medicaid agency to develop its own materials.

States also believe that CMS has significantly underestimated the burden of this provision on states if it is implemented as proposed. 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.

Aligning Medicare and Medicaid rules

States also request that CMS provide clarification and guidance on the rule’s impact and interaction with Medicare. There are a significant number of providers that will be impacted because of Medicaid’s role in providing coverage for individuals dually eligible for Medicare and Medicaid. States are concerned that the proposed rule does not address the impact on Medicare carriers and, in turn, this will create obstacles in Medicaid agencies’ ability to efficiently comply with these provisions. In fact, based on previous experience working with Medicare providers, states believe that Medicare carriers are not prepared to provide detailed NDC information that is

necessary to ensure that Medicaid can obtain the rebate, when applicable. Without this information, there could be a significant number of denied claims that may not be able to be resolved. In turn, beneficiaries could receive bills for denied claims or be refused treatment.

States urge CMS to use its authority to ensure that the Medicare and Medicaid rules align so that state Medicaid agencies can comply in a timely, efficient manner. That is, CMS should require Medicare to do a "crosswalk" and address Medicare's responsibility in providing rebate information for certain prescription drugs provided to a dually eligible beneficiary.

Impact on DMERC

Many states currently do not receive an NDC from a DMERC. However, states believe that the standardization of physician administered drugs necessarily should impact DMERCs and that there may be a multitude of requirements for DMERCs. As such, states also request that CMS provide clarification and guidance on the role and responsibilities of DMERCs with regard to the provisions of the proposed rule.

NDC requirement for HCPCS drugs

In addition, states note that 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 in use. The electronic 837 format for both the CMS 1500 and UB04 can accommodate the NDC, including the NDC quantity. However, 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.

States urge 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, states face great challenges in meeting this requirement. Instead, states respectfully request that CMS develop a standard UB04 form that provides for a way to indicate the NDC. This will guarantee uniformity across states and ensure that states are not subject to lose any rebates or revenues.

Hardship waiver

CMS in the proposed rule and in its verbal communication with states indicated that the agency does not expect that states will need a hardship waiver to meet these requirements. For the reasons stated above and other factors impacting state Medicaid programs, such as the concurrent implementation of the National Provider Identification number (NPI) and ongoing systems upgrades that cannot accommodate the change in the specified timeframe, states respectfully request that CMS be amenable to the possibility that a hardship waiver may be needed in some states and be prepared with a hardship waiver process.

Retail Price Survey

Although this proposed rule does not specifically address Section 6001(e) of the DRA which provided for a survey of retail prices and state performance rankings, states wish to offer comments that we believe impact this proposed rule and CMS' related work on the retail price survey. As it finalizes this process, states request that CMS consider various factors and unique state situations that will impact this information. Specifically, pharmacies are required to bill

Leslie V. Norwalk, Esq.
February 20, 2007
Page 8 of 9

Medicaid their usual and customary price that is supposed to reflect what the pharmacy charges a "regular" customer. However, although states are diligent in ensuring that pharmacies are compliant with Medicaid policies, due to misunderstandings associated with this requirement, there may be some pharmacies that increase the rate they charge to Medicaid programs because they do not think they have to charge the same to both types of customers. This could skew the data used in the retail price survey. In addition, in the state reimbursement price ranking, the state supplemental rebates are excluded in the best price determination. However, for gross payments made to pharmacies this does not reflect the true price a state Medicaid agency may be paying. In turn this will skew the ranking and could result in over reporting. As such, states strongly encourage CMS to make note in its report of these and any other factors that clarify the results.

Regulatory Impact

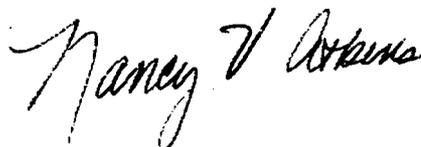
States respectfully request that CMS reconsider or clarify the level of administrative costs associated with this regulation. Specifically, CMS should provide estimates of the federal and state administrative costs. This estimate should reflect the fact that AMP-based FUL pricing is not currently in effect. Although the rule has not yet been finalized, states already have invested significant time and resources assessing the impact of AMP and the proposed rule.

We would be pleased to meet with you at any time or provide any additional information that may helpful to you on these matters. Thank you for considering our comments. If you have any questions, please do not hesitate to contact me or Martha Roherty at (202) 682-0100, ext. 299.

Sincerely,



Jerry W. Friedman
Executive Director



Nancy Atkins
Chair, NASMD Executive Committee

Cc:
Dennis Smith
Director
Center for Medicaid State Operations, CMS

Matt Salo
Director of Health Legislation
National Governors Association

Leslie V. Norwalk, Esq.
February 20, 2007
Page 9 of 9

Joy Wilson
Director, Health Policy
National Conference of State Legislatures

NASMD Executive Committee

Submitter : Ms. Cristal Thomas
Organization : Ohio Medicaid
Category : State Government

Date: 02/20/2007

Issue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1176-Attach-1.PDF

CMS-2238-P-1176-Attach-2.PDF

1176-1

Ted Strickland
Governor



Helen E. Jones-Kelley
Director

30 East Broad Street Columbus, Ohio 43215-3414
jfs.ohio.gov

February 15, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

**Comments on the Proposed Rule Concerning
the Medicaid Program: Prescription Drugs
CMS-2238-P**

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed rules regarding the Medicaid prescription drug program changes outlined in sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA). Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid and the Medicare Premium Assistance Program. These programs cover 1.7 million Ohioans each month.

Preserving access to prescription drugs for Medicaid recipients should be a priority for the Centers for Medicare and Medicaid Services (CMS). The Ohio Medicaid program is concerned that several provisions contained in the Notice of Proposed Rule Making (NPRM) in the December 22, 2006, Federal Register may limit access to prescription drugs, both at the pharmacy and in the physician's office.

Ohio Medicaid has three main concerns. First and foremost, we are concerned that the requirement that physicians bill using National Drug Code (NDC) in addition to Healthcare Common Procedure Coding System (HCPCS) code for physician-administered drugs will create a new billing procedure that is used only for Medicaid, creating an administrative burden that many physicians may not be able to carry. This causes Medicaid patients to be treated differently than other patients in the practice, and as a result physicians may choose to not accept Medicaid patients. We believe that this will create a barrier to access.

Second, we are concerned that CMS has indicated that it does not expect any states to submit a hardship waiver to accommodate a delay in collecting NDCs on claims for physician-

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administered drugs. In addition to the concern that physicians will not be able to accommodate this new billing procedure, we will be unable to make system updates in time to meet the January 1, 2008, deadline.

Third, we are concerned about the variability that will occur in the proposed calculation of Average Manufacturer Price (AMP), leading to wide variations in the Federal Upper Limit (FUL). These variations will create an unfair burden on pharmacies, as they will not be able to predict reimbursement for future months to plan for inventory. This provision will also be administratively burdensome for states to implement if the FUL changes on a monthly basis.

More information about each of these concerns appears below, along with additional comments. Please carefully consider these comments as CMS prepares to publish the final rule.

Section II: Provisions of the Proposed Regulations

Basis and Purpose of Subpart I – Section 447.500

The definition of “dispensing fee” outlined in this section indicates that CMS does not intend to mandate a dispensing fee methodology to which states must adhere. Ohio Medicaid agrees with this point. However, CMS goes on to indicate that states should evaluate the relationship between AMP and pharmacy acquisition cost to determine a dispensing fee that is adequate to cover a pharmacy’s cost. We are concerned that the AMP changes will result in a FUL that is too low for pharmacies to be able to acquire the drugs. In response, many states have already increased the dispensing fee, and other states have this under consideration. In fact, CMS staff have encouraged states to increase dispensing fees. We are concerned that states’ increases in dispensing fee will negate any savings from changes to the FUL.

Recommendation:

- * CMS should examine whether increases in dispensing fees will negate any savings anticipated from the AMP changes proposed in this NPRM.

Determination of Average Manufacturer Price – Section 447.504

Ohio Medicaid agrees with the proposed definition of “retail pharmacy class of trade” as it relates to the calculation of AMP. The exclusion of long-term care (LTC) pharmacies is consistent with a policy that the retail class of trade exclude special populations. We also agree that mail order pharmacies should be included in the retail class of trade due to their availability to most consumers. Pharmacy benefit manager (PBM) discounts should also be included in the calculation of AMP since most Americans, including dual eligibles enrolled in the Medicare prescription drug program, benefit from these discounts.

Recommendations:

- * CMS should use the definition of “retail pharmacy class of trade” that is proposed in the NPRM.
- * CMS should require manufacturers to include PBM discounts in the calculation of AMP.

Requirements for Manufacturers – Section 447.510

Ohio Medicaid believes that it is imperative that AMP pricing must be fairly stable, due to its use in calculating the FUL. If AMP changes substantially from one month to the next, the FUL may also be changed on a monthly basis. This is an administrative infeasibility for Medicaid programs and for pharmacy providers. Pharmacies must be assured that they are able to purchase drugs at or below the FUL, and that any stock previously purchased at a higher price will not be reimbursed in the next month by the state at a new, unfairly low, FUL. States must be assured that the FUL will not change monthly for each drug, due to the administrative time in updating pricing each time a new FUL is released.

Our analysis of the AMP data provided to states by CMS since July 2006 revealed wide variations between the lowest AMP for many drug/strength combinations (FUL group). For example, one FUL group examined in the months July through November 2006 showed that in the five-month period, three different manufacturers provided the lowest AMP in at least one month. The lowest AMP, and resulting FUL, is shown below, along with the percent change from the previous month:

	Lowest Reported AMP	FUL (250% AMP)	Percent Change from Previous Month
July	0.021014	0.052535	
August	0.021014	0.052535	0.00%
September	0.008659	0.021648	-58.79%
October	0.008659	0.021648	0.00%
November	0.011646	0.029115	34.50%

The same FUL group shows one manufacturer’s AMP changing from 0.025796 to 0.108960, and back down to 0.013098 within the same five-month period. If this amount of volatility is seen in a FUL group that has a limited number of generic products available, the FUL could vary wildly.

The Government Accountability Office (GAO) report presented to Rep. Joe Barton on December 22, 2006¹, confirmed the volatility in AMP. GAO found that the majority of FUL groups had a median increase or decrease in AMP of 33 percent from one quarter to the next. While both our analysis and GAO’s used AMPs reported under previous guidelines, the new calculations proposed in this NPRM would not change the variability from month to month. Changes this great are unacceptable for pharmacies and state Medicaid programs.

¹ GAO-07-239R Medicaid Federal Upper Limits, December 22, 2006.

CMS has offered suggestions for reducing the volatility of AMP from month to month. One suggestion is that manufacturers be allowed to rely on estimates of their quarterly price concessions when submitting monthly AMP data. CMS has also requested comments on allowing manufacturers to use a twelve-month rolling average estimate of discounts. We believe that CMS should mandate, not simply allow, manufacturers to use a twelve-month rolling estimate of price discounts in reporting monthly AMP. This will reduce the volatility in the FUL, giving states and pharmacy providers assurance that access will not be denied to Medicaid recipients due to pharmacies being unable to purchase drugs within the FUL. This will also reduce the administrative burden on states of updating FUL pricing for each drug on a monthly basis.

By mandating manufacturers to use a rolling average of price concessions for AMP calculations, CMS will reduce volatility in FUL pricing. However, we believe that best price calculations should be made using only actual price concessions realized by the manufacturer in the quarter. In this way, states will be assured that the rebate per unit amount will be accurate.

Recommendation:

- * CMS should mandate manufacturers to use a rolling twelve-month estimate of price concessions while reporting the monthly AMP, but require actual discounts be used in reporting the quarterly best price.

Upper Limits for Multiple Source Drugs – Section 447.514

As noted in the previous section, Requirements for Manufacturers, Ohio Medicaid is concerned that updating the FUL on a monthly basis based on monthly reported AMP will result in great variation. This situation will cause hardship for both state Medicaid agencies and pharmacies. State Medicaid agencies will be required to spend large amounts of administrative time to comply with the FUL, and pharmacies will not be able to plan inventory levels if the reimbursement can change at any time. Again, Ohio requests that CMS mandate that manufacturers use a rolling twelve-month average discount in reporting AMP. We do agree that CMS should not use the new formula for calculation of AMP until it is apparent that manufacturers are correctly reporting AMP, and that the volatility from month to month has been resolved.

Ohio Medicaid also asks CMS to clarify whether states will be responsible for using the AMP published on the CMS web site to calculate the FUL, or whether CMS will continue to send FUL updates as it has done in the past. We request that CMS continue to calculate the FUL and send periodic updates to the states.

We agree with CMS's proposal to set the FUL based on the lowest AMP that is not less than thirty percent of the next highest AMP, except in the case of the first generic product available. This is a reasonable way to ensure that an outlier is not used as the basis for the FUL, and that pharmacies will be able to purchase the product at a price below the FUL.

Recommendations:

- * CMS should mandate manufacturers to use a rolling twelve-month estimate of price concessions while reporting the monthly AMP.
- * CMS should continue to publish FUL updates.
- * CMS should proceed with its proposal to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP.

FFP: Conditions Relating to Physician-Administered Drugs – Section 447.520

We are concerned about the requirements for physicians to bill multiple-source drugs using NDC in addition to HCPCS code. Ohio Medicaid has five major concerns related to this provision.

First, the requirement that physicians bill using both HCPCS and NDC creates a billing system for Medicaid that is different from other payers, including Medicare, which may result in physicians choosing not to serve Medicaid patients. For most physician offices, Medicaid clients are the exception rather than the rule. We believe that many physicians and other providers affected by this provision will find that recording the NDC for Medicaid patients is administratively burdensome, and not worth the effort. Medicaid reimbursement for many physician services is already below cost, and this will add an additional incentive for providers to limit or even eliminate Medicaid patients from their practice. This will result in a reduction in access to care for our recipients.

It is important to note that the clinical professionals who administer care do not generally look at a patient's insurance plan when treating the patient. Clinicians are more concerned with care than with payment, and let their billing staff worry about reimbursement. However, it will be the clinicians that incur the burden of recording NDCs when drugs are administered in the office. This may result in Medicaid patients being treated differently than privately-insured patients or those covered by Medicare. In addition, Medicaid is a secondary insurance for many patients. As noted in the Regulatory Impact Analysis of this NPRM, CMS believes "most of the Medicaid beneficiaries who receive physician-administered drugs are also in Medicare." While Ohio Medicaid does not agree with this statement about the scope of physician-administered drugs, it illustrates that even if clinicians were to look at the patient's insurer when administering a drug during an office visit, it is Medicare rather than Medicaid that would be noted. Medicare does not require reporting of NDC on claims, so this obligation would be overlooked.

Ohio Medicaid is also concerned that clinicians may not know where to obtain the NDC from a package label, and how to correctly record an eleven-digit code. For billing purposes, an eleven-digit code is required. Many drug packages list a ten-digit NDC, and there are conventions to determine where a zero must be added. It is unlikely that the administering clinician will know how to turn the ten-digit number into an eleven-digit NDC.

Second, we are concerned that the requirement for an NDC to be included on a claim will apply to Medicare Part B crossover claims, and that at this time Medicare does not require NDC to be included on claims for a non-miscellaneous HCPCS code. Without this information, states will

be forced to deny claims that Medicare has already paid. We have communicated with the Medicare Part B carrier that serves our region, and they have indicated that NDC numbers may be included in the electronic documentation record, which is the 2400-NTE, 02 field of the electronic claim. This is a notes field that is difficult to use for claims adjudication because it is a text field that may be used for many purposes. The presence of an eleven-digit number in this field may or may not signify an NDC. Unless and until Medicare requires NDC numbers to be reported in an easily identifiable field on the claim, Medicaid programs will be unable to use an NDC reported on the claim.

A third concern is that CMS staff have indicated that physicians will need to bill for products that are included in the rebate program, or the state will be required to deny the claim. While pharmacy claims are generally billed through a point-of-sale system in real time, physicians often do not bill until several weeks after the service was rendered. Physicians would not know ahead of time which products are part of the rebate program, and which are not. This creates a potential for medically appropriate claims to be denied.

Fourth, HCPCS codes are billed by units that may be different from the unit identified by the rebate program for a particular NDC. CMS has provided a list of the twenty most frequently-billed multiple source drugs². Of the drugs included on this list, the difference between billing and rebate units is an issue for at least two drugs. First is HCPCS J2550, promethazine hydrochloride injection. The billable unit for this HCPCS code is each 50 milligrams. The rebate unit for the NDC is per milliliter, with the product packaged 25 mg/ml. A second example from this list is J7644, ipratropium bromide inhalation solution, unit dose. The billable unit for this HCPCS code is each one milligram. The rebate unit for corresponding NDCs is per milliliter, with the product packaged 0.2mg/ml in 2.5ml units (0.5mg per dose). Unless these drugs are always billed in the correct multiples of units, an unlikely scenario from a clinical standpoint, states will have to bill manufacturers for partial units, and manufacturers will have to respond. These are just two examples from the "top 20" list that has been published by CMS. Another example is J1815, insulin, per 5 units. The rebate unit for insulin under most NDC numbers would be each milliliter. There are 100 units per milliliter of insulin.

Fifth, Ohio's Medicaid Management Information System (MMIS) is outdated, having become operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the current claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. We therefore request that CMS reconsider its position that it will not accept hardship waiver requests from any state. Ohio plans to submit a hardship waiver request.

Recommendations:

- * CMS should examine whether this requirement will result in reduced access to care for Medicaid recipients due to a non-standard billing procedure for these patients versus patients insured under other programs, including Medicare.

² Posted at <http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf>

- * CMS should mandate that Medicare Part B carriers require NDCs on claims that will be crossed to Medicaid, and that the NDC must be included on the crossover claim from the carrier. The NDC must be in an easily identifiable field, not in a "notes" field that may also be used for other purposes.
- * CMS should reconsider the implementation of the provision that states require NDC in addition to HCPCS on provider-administered claims, and that states deny claims for NDCs of products not included in the rebate program.
- * CMS should reconsider its position that all drugs billed by HCPCS codes must be a product from a manufacturer participating in the rebate program.
- * CMS should resolve discrepancies between rebate units and HCPCS billing units before implementing this provision.
- * CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Section III: Collection of Information Requirements *Note: the comments in this section have also been submitted to the Office of Strategic Operations and Regulatory Affairs.*

FFP: Conditions Relating to Physician-Administered Drugs. (447.520)

Ohio Medicaid disagrees with the estimates that CMS has proposed for the time for physician office staff, hospital outpatient departments, and other entities to bill using both NDC and HCPCS. The estimate of 15 seconds, or nine cents per claim, significantly understates the time and funds that will be required for these providers to learn the requirements, train staff, and implement the procedures. In addition to the individual administering the drug, the entire billing staff will need to be trained to include NDC on the claim. While the ongoing effort may be small, the initial training will be intensive for both providers and for Medicaid programs.

We are also concerned with CMS's position that no state will need to apply for a hardship waiver for this provision. As previously stated, Ohio's Medicaid Management Information System (MMIS) became operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the existing claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. Ohio Medicaid asks that CMS reconsider its position that it will not accept hardship waiver requests from any state. We also believe that the estimate for the time that it would take a state agency to apply for a hardship waiver is not accurate. Five hours is not enough time for a state to gather the information, synthesize it into the format required by CMS, and gain approval of the request from all stakeholders that would need to be involved.

Recommendations:

- * CMS should reconsider the financial impact on providers that bill for drugs administered in the provider setting.

- * CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Section V: Regulatory Impact Analysis

A. Overall Impact

The impact statement indicates that the savings estimates do not include federal or state administrative costs, because CMS believes that the costs would be small. Ohio Medicaid strongly disagrees with this statement. Administrative costs include state staff training for new processes, state staff time to perform new tasks, the time and resources needed for training stakeholders, and significant technology updates. Administrative costs related to implementing the FUL changes include planning staff time to analyze and implement the FUL for a much larger number of drugs than have been included in the past, as well as the anticipated increased frequency of FUL updates. Administrative costs related to requiring NDCs on claims for physician-administered drugs will likely outweigh the increased revenue from rebates related to these claims. As previously mentioned, Ohio's MMIS is twenty years old, and in the process of being replaced. Enhancing the system to accept NDCs on claims for physician-administered drugs will be a huge undertaking that will be obsolete in only two years when the new MITS application is installed. In addition to the technology updates, state staff, providers, and billing entities will need to be trained on the new procedures. Due to the high cost of implementing these provisions, CMS should accept and approve hardship waiver requests from states.

Ohio Medicaid also disagrees with CMS's estimate of the impact of compliance on physician practices, hospitals, and non-profit providers. As previously mentioned, each employee in these settings will need to be trained on new billing procedures for physician-administered drugs, and will need to adjust their administrative processes accordingly. While an estimate of less than nine cents per claim may be accurate at some time in the future, the initial costs of implementing this provision will be significantly higher and should be included in the total impact on billing providers.

Recommendations:

- * CMS should include state and federal administrative costs in the impact analysis.
- * CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance.
- * CMS should include the cost of implementing NDC billing on providers that bill for drugs administered in the provider setting.

B. Anticipated Effects

2. Effects on State Medicaid Programs

CMS has underestimated the costs related to implementing the provisions included in this NPRM. As previously noted, states will need to allocate resources to implement FUL pricing for a much larger number of drugs, and likely at more frequent intervals. States will also need to allocate resources to train state staff and providers about the requirement for NDCs to be included on claims for physician-administered drugs. Finally, states will be required to expend resources to update the technology required to process claims that include NDCs. Ohio Medicaid believes that these costs will far outweigh any savings due to increased rebate revenue or decreased reimbursement to pharmacies for FUL drugs. In addition, many states have indicated, and CMS has encouraged, a need to increase dispensing fees for pharmacies. These costs may also negate any proposed savings due to decreased reimbursement.

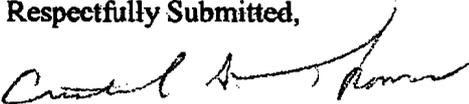
Recommendation:

- * CMS should reduce savings estimates to account for increased administrative burden on state Medicaid agencies.

Conclusions

Ohio Medicaid looks forward to working with CMS on the implementation of the Deficit Reduction Act changes to the Medicaid pharmacy program. Preserving access to prescription drugs for Medicaid consumers is a priority. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,



Cristal A. Thomas
State Medicaid Director

Ted Strickland
Governor



Helen E. Jones-Kelley
Director

30 East Broad Street Columbus, Ohio 43215-3414
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February 15, 2007

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**Comments on the Collection of Information Requirements
For the Proposed Rule Concerning the Medicaid Program: Prescription Drugs
CMS-2238-P**

Dear Ms. Musotto and Ms. Astrich:

Thank you for the opportunity to comment on collection of information requirements reported in the proposed rules regarding the Medicaid prescription drug program changes outlined in sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA). Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid and the Medicare Premium Assistance Program. These programs cover 1.7 million Ohioans each month.

Preserving access to prescription drugs for Medicaid recipients should be a priority for the Centers for Medicare and Medicaid Services (CMS). The Ohio Medicaid program is concerned that the information collection requirements outlined in this Notice of Proposed Rulemaking (NPRM) are understated.

Ohio Medicaid is particularly concerned that the requirement that physicians bill using National Drug Code (NDC) in addition to Healthcare Common Procedure Coding System (HCPCS) code for physician-administered drugs will create a new billing procedure that is used only for Medicaid, creating an administrative burden that many physicians may not be able to carry. This causes Medicaid patients to be treated differently than other patients in the practice, and physicians may choose to not accept Medicaid patients. We believe that this will create a barrier to access.

Section III: Collection of Information Requirements

FFP: Conditions Relating to Physician-Administered Drugs. (447.520)

Ohio Medicaid disagrees with the estimates that CMS has proposed for the time for physician office staff, hospital outpatient departments, and other entities to bill using both NDC and HCPCS. The estimate of 15 seconds, or nine cents per claim, significantly discounts the time and funds that will be required for these providers to learn the requirements, train staff, and implement the procedures. In addition to the individual administering the drug, the entire billing staff will need to be trained to include NDC on the claim. While the ongoing effort may be small, the initial training will be intensive for both providers and for Medicaid programs.

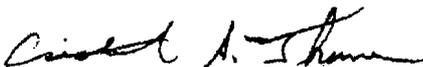
We are also concerned with CMS's position that no state will need to apply for a hardship waiver for this provision. Ohio's Medicaid Management Information System (MMIS) became operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the existing claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. Ohio Medicaid asks that CMS reconsider its position that it will not accept hardship waiver requests from any state. We also believe that the estimate for the time that it would take a state agency to apply for a hardship waiver is not accurate. Five hours is not enough time for a state to gather the information, synthesize it into the format required by CMS, and gain approval of the request from all stakeholders that would need to be involved.

Recommendations:

- * CMS should reconsider the financial impact on providers that bill for drugs administered in the provider setting.
- * CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Ohio Medicaid looks forward to working with CMS on the implementation of the Deficit Reduction Act changes to the Medicaid pharmacy program. Preserving access to prescription drugs for Medicaid consumers is a priority. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,



Cristal A. Thomas
State Medicaid Director

CMS-2238-P-1177

Submitter : Mr. Harry Rieck
Organization : Merck & Co., Inc.
Category : Drug Industry

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See REVISED attachments from Merck & Co., Inc.

CMS-2238-P-1177-Attach-1.PDF

CMS-2238-P-1177-Attach-2.DOC

1177-1

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February 20, 2007

VIA EXPRESS MAIL AND ELECTRONIC SUBMISSION
(<http://www.cms.hhs.gov/eRulemaking>)

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
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Mail Stop C4-26-05
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**Re: Comments on Proposed Rule Related to the Deficit Reduction Act and
the Medicaid Drug Rebate Program, MS-2238-P**

Dear Acting Administrator Norwalk:

Merck & Co, Inc. (Merck) is pleased to submit the following comments regarding the Proposed Rule to implement provisions of the Deficit Reduction Act of 2005 (DRA) that was published by the Centers for Medicare and Medicaid Services (CMS) in the *Federal Register* on December 22, 2006 (Proposed Rule).¹

Merck has long been involved in the Medicaid rebate program, not only through its participation, but also by its recommendation of policies to further the successful implementation of the program. Prior to the enactment of the rebate program, Merck had implemented its own voluntary "Equal Access to Medicines Program," which represented the first initiative by a major pharmaceutical manufacturer to provide voluntary rebates to state Medicaid programs. Subsequently, Merck played a constructive role in both providing technical comments on the statutory language adopted in the Omnibus Budget Reconciliation Act of 1990 that established the Medicaid rebate program and on regulatory guidance adopted by the then-Health Care Financing Administration. More recently, in April and August 2006 respectively, Merck provided input to both the United States Department of Health and Human Services Office of Inspector General (OIG) and

¹ Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

Leslie V. Norwalk, Esq.
February 20, 2007
Page 2

to CMS concerning implementation of the DRA. In September 2006, Merck provided data in response to CMS's request for "Sample AMP" calculations.

Merck appreciates the opportunity to submit the following comments on the Proposed Rule regarding the calculation and reporting of Average Manufacturer Price (AMP) and Best Price. Merck joins in the comments submitted today by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). Merck submits these comments to supplement the PhRMA and BIO comment letters on matters that Merck believes are of particular importance and on which Merck believes modifications from the Proposed Rule are required to achieve greater efficiency, to increase the likelihood of consistency in price reporting, and to reduce the complexity of price calculations. Merck hopes that these comments are helpful to CMS as it formulates its Final Rule and remains willing to assist CMS in any manner that CMS believes would be beneficial to this process.

A. Definitions Section (447.502)

1. Bona Fide Service Fees

The Proposed Rule would exclude "bona fide service fees" from AMP and Best Price, and would define a bona fide service fee as: "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not an entity takes title to the drug."² As the Proposed Rule notes, this is the same definition of bona fide service fee that CMS recently adopted in the context of Average Sales Price (ASP) calculations.

In the ASP context, CMS has announced several important principles relating to the fair market value component of the bona fide service fee definition that Merck believes should apply to AMP and Best Price calculations as well.³ To address concerns expressed by commenters in the ASP context that the fair market value criterion might

² 71 Fed. Reg. 77174 at 77176, 77180.

³ These interpretations were announced in the Medicare final physician fee schedule rule for 2007, published in the Federal Register on December 1, 2006.

not encompass fees for services “that can only be performed by the entity to which the fee is paid,” CMS clarified that bona fide service fees mean expenses that a manufacturer “generally would have . . . paid for . . . at the same rate had these services been performed by other or similarly situated entities.”⁴ CMS further clarified that it was not necessary for manufacturers to calculate a fair market value for each individual service purchased from an entity; instead, “it may be appropriate to calculate fair market value for a set of itemized services, rather than fair market value for each individual itemized service, when the nature of the itemized services warrants such treatment.”⁵ In addition, CMS made clear that the appropriate methods for determining whether a fee represents fair market value “may depend on the specifics of the contracting terms, such as the agreed-upon mechanism for establishing the payment (for example, percentage of goods purchased).” CMS also emphasized that, because “manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value,” CMS was “not mandating the specific method manufacturers must use to determine whether a fee represents fair market value.”⁶ Because a standard methodology for determining fair market value will simplify price reporting calculations, Merck believes that CMS should explicitly confirm that these particular principles also apply to determining whether a fee constitutes fair market value in the Medicaid context.

In addition to the fair market value component, the bona fide service fee definition as proposed also requires that such fees must not be “passed in whole or in part to a client or customer of an entity [that receives the fee].” As CMS is aware, manufacturers such as Merck generally do not know whether certain of their customers, such as PBMs, pass through or retain fees that are paid to them. Accordingly, to address this uncertainty, Merck believes that CMS should establish in the Final Rule that, unless a manufacturer and its customer agree by contract that part or all of a particular fee that would otherwise qualify as a bona fide service fee should be passed on to another party, the manufacturer may presume that the fee is not passed through to a third party and therefore can treat the fee as a bona fide service fee. This approach would be easy to apply and would offer certainty to manufacturers, thus increasing the likelihood of accurate and consistent AMP calculations and Best Price determinations.

⁴ Id.

⁵ Id.

⁶ Id.

The rule that we have proposed for addressing this issue also would be consistent with the suggestion previously made by the Health Industry Group Purchasing Association (the trade association for GPOs) concerning GPO fees, for which, as with fees to PBMs, the ultimate recipient is unknown to the manufacturer. In its letter to CMS, HIGPA recommended that fees to GPOs should not be treated as price concessions "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."⁷ In our view, this would be a sensible, easily-applied standard for distinguishing fees, both to GPOs and to other customers, that are intended as price concessions on the manufacturer's products from those that are not.

With respect to GPO fees in particular, CMS may also want to clarify that such fees do not affect AMP calculations when the GPO negotiates purchase prices for member hospitals for drugs used in the inpatient setting, since the underlying sales to hospitals would be excluded from AMP in this circumstance.

2. *Bundled Sales*

CMS proposes the following new definition of "bundled sale":

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug⁸ or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or, where the resulting discounts or other price concessions are greater than those which would have

⁷ January 2, 2007 Health Industry Group Purchasing Association letter to CMS, at 2.

⁸ Merck's understanding is that the use of the term "drug" in the Proposed Rule refers to the term "covered outpatient drug" as defined in the Medicaid Rebate Act. As noted below, Merck believes that this point should be clarified in the Final Rule.

been available had the bundled drugs been purchased separately or outside the bundled arrangement.⁹

The new definition would replace and expand the definition in the existing Medicaid Rebate Agreement, which provides:

Bundled Sale refers to 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.

The new definition that CMS has proposed significantly changes and expands the existing definition, for example:

- Under the proposed definition, contracts involving the “purchase of the same drug” apparently can result in a “bundled sale,” whereas under the current contractual definition a “bundled sale” requires “the packaging of drugs of different types.”
- Under the proposed definition, “drugs of different types” refers to drugs that have different nine-digit National Drug Codes (NDC-9), whereas previously the definition of “bundled sale” did not refer to “drugs of different types” at the NDC-9 level.
- The proposed definition expands the scope of “bundled sales” to include contracts under which the only condition for a discount or other price concession on a drug is the inclusion of the drug on a formulary, the achievement of market share, or some other unspecified “performance requirement.” Under the current definition, a bundled sale exists only if a price concession on a drug is contingent on a “purchase requirement” for a drug of a different type. The proposed rule’s apparent focus on “performance requirements,” as opposed to “purchase requirements,”

⁹ CMS, “Medicaid Program; Prescription Drugs; Proposed Rule,” 71 Fed. Reg. 77174, 77195 (Dec. 22, 2006) (to be codified at 42 C.F.R. § 447.502); see also id. at 77176.

could mean that a bundled sale would exist even if a particular arrangement does not require a customer to purchase any drugs, much less more than one drug type.

- The phrase "some other performance requirement" as used in the proposed definition is undefined and open-ended, and could raise questions about whether virtually any contract should be treated as a "bundled sale."

The proposed definition of "bundled sale" is overbroad, and the method by which discounts would be allocated appropriately among drugs within the new definition is unclear. The broad scope of the new proposed definition could create both unnecessary disruption to the marketplace and confusion and complexity from a price reporting perspective. The purpose of requiring manufacturers to reallocate discounts among drugs constituting a "bundled sale" is to ensure that the AMP and Best Price reported for each drug within the bundle accurately reflects the value of the discounts offered on each product. The Proposed Rule never explains how (or if) its proposed changes would improve the accuracy of AMP or Best Price calculations in any respect. We are not aware of any improvement in accuracy of either AMP or Best Price calculations that would result from the proposed expansion of the definition of "bundled sale" in the Proposed Rule. CMS should not require manufacturers to reallocate the discounts that customers actually paid unless there is a compelling reason why the reallocation would improve the accuracy of AMP and Best Price.

The consequence of CMS's proposed expansion of the definition of "bundled sale" is that manufacturers would be required to reallocate discounts across products (or even across different dosage forms or strengths of a drug or across sales of the same drug during different months or quarters), for a wider variety of arrangements. Thus, AMP and Best Price calculations would become even more complex, and the risk of error and the burdens imposed on manufacturers would substantially increase. In turn, this complexity could result in inconsistencies among the methodologies that manufacturers use to apportion bundled discounts in their AMP and Best Price calculations.

Now that AMP is potentially a reimbursement metric that will be calculated and reported on a monthly basis (and will have to be certified as accurate), the heightened risks of error and inconsistency among manufacturers are of even greater concern. CMS recognized these risks when addressing "bundled sales" in the context of ASP calculations -- which, unlike AMP, is reported quarterly. There, CMS concluded that: (a)

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it did not have sufficient information concerning the types of arrangements that manufacturers had with various customers and could not predict how those arrangements might evolve over time; (b) it was premature to issue specific guidance on bundled sales; and (c) in the absence of specific guidance, manufacturers could make reasonable assumptions regarding how discounts under bundled sales are allocated, so long as the methodology chosen resulted in an accurate ASP calculation and did not create inappropriate financial incentives.¹⁰

Merck believes that CMS should take a similar approach to bundled sales in the Medicaid program. With AMP as a reimbursement metric, the objective in the Medicaid program should be the same as the objective in the Medicare Part B program -- to ensure accurate calculations and not to create inappropriate financial incentives. Merck does not believe that any facts have changed since the promulgation of the Physician Fee Schedule Rule that warrant a different treatment of bundled sales for AMP and Best Price purposes than for ASP purposes. Indeed, the fact that AMP will be reported monthly and certified by manufacturers amplify the need for simplicity in the calculation process. Moreover, Merck believes that CMS should continue to take caution to avoid changes in a manufacturer's price calculations that increase their complexity and that are not required

¹⁰ Specifically, CMS noted as follows: "Since we do not yet fully understand the variety of bundling arrangements that exist in the marketplace and how they are likely to evolve over time, we believe it is important to be cautious in establishing a specific methodology that all manufacturers must follow for ASP purposes. Consequently, we are not establishing a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, federal regulations, and its customary business practices. Our intent in not being prescriptive in this area at this time is to allow manufacturers the flexibility to adopt a methodology with regard to the treatment of bundled price concessions in the ASP calculations that, based on their particular circumstances, will best ensure the accuracy of the ASP calculation and not create inappropriate financial incentives."

See 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. 69624, 69675 (Dec. 1, 2006) (emphasis added).

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by statute, unless such changes are necessary to improve the accuracy and consistency of AMP and/or Best Price calculations. In this regard, we note that neither the Medicaid Rebate Act nor the DRA directs CMS to make changes via rulemaking to the contractual definition of "bundled sales."

Merck's Recommendations Concerning "Bundled Sale" Arrangements

Based on the foregoing, Merck respectfully requests that CMS take the following actions in the Final Rule:

- CMS should retain the definition of "bundled sale" that is set forth in the Medicaid Rebate Agreement.
- In the alternative, if CMS decides that a definition of "bundled sale" that goes beyond the Medicaid Rebate Agreement's current definition of a "bundled sale" is necessary, CMS should: (1) explain specifically why the expansions in the definition of a "bundled sale" are needed to improve the accuracy and consistency of AMP and/or Best Price calculations, and exactly how the new, broader definition would produce more accurate figures and would warrant the additional burdens imposed on manufacturers; (2) delete the phrase "other performance requirements" from the proposed definition, or provide additional specificity regarding the meaning of that phrase; (3) provide specific examples of each type of arrangement that would be encompassed by the new "bundled sale" definition; and (4) avoid unnecessary marketplace disruption by allowing manufacturers to apply the new definition of "bundled sale" only to agreements entered into subsequent to the effective date of the Final Rule.
- CMS should also confirm that "bundled sale" arrangements are limited to arrangements that involve covered outpatient drugs. That is, the Final Rule should reiterate the guidance now contained in the Medicaid Drug Rebate Operational Training Guide (p. F11d) on arrangements that include products other than covered outpatient drugs: "Valid bundled sales only include drug products that meet the definition of a covered outpatient drug as defined in the drug rebate agreement and statute. If a non-drug product . . . is included in the bundled sale, it is not eligible for inclusion in the Medicaid Drug Rebate Program."

- With respect to the allocation methodology, CMS should adopt the same approach that it took in the ASP context, where CMS decided that it was premature to establish a specific allocation methodology. Instead, CMS concluded that manufacturers “may make reasonable assumptions” in their ASP calculations, “consistent with the general requirements and the intent of the Act, federal regulations, and its customary business practices.” Merck believes that CMS should adopt a similar approach with respect to AMP and Best Price. In the alternative, if CMS does propose an allocation methodology, Merck requests that CMS develop methodologies specific to each type of transaction that CMS identifies as a “bundled sale” and that CMS give manufacturers and other interested parties an opportunity to comment on those methodologies.

B. Retail Pharmacy Class of Trade (447.504)

1. Closed Mail Order Pharmacies

AMP is defined by statute as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade” (excluding prompt pay discounts starting in 2007).¹¹ The Proposed Rule would define the “retail pharmacy class of trade” as “any independent pharmacy, chain pharmacy, mail order pharmacy, [PBM], or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer . . . and subsequently sells or provides the drugs to the general public.”¹² Similarly, the Proposed Rule describes the retail pharmacy class of trade as “that sector of the drug marketplace . . . which dispenses drugs to the general public”¹³

Merck agrees with the approach of identifying entities within the retail pharmacy class of trade as those that dispense drugs to the “general public” and believes that this approach is consistent with Congressional intent. We note, however, that mail order pharmacies will not always fall into this class, because some mail order pharmacies are “closed” pharmacies that only serve individuals covered by certain payors or health

¹¹ 42 U.S.C. 1396r-8(k)(1)(A).

¹² Fed. Reg. at 77196 (proposed) 42 C.F.R. § 447.504(e).

¹³ Id. at 77178.

plans. Consequently, CMS should clarify in the Final Rule that the retail pharmacy class of trade includes those mail order pharmacies that “sell[] or provide[] drugs to the general public,” but not closed mail order pharmacies. Prices to closed mail order pharmacies should thus be excluded from AMP calculations.

2. *Third Party Rebates*

The Proposed Rule provides that “to the extent manufacturers are offering . . . price concessions to [a] PBM that are not bona fide service fees, we propose that these lower prices be included in AMP.”¹⁴ Consistent with this treatment of PBM rebates, the Proposed Rule would also include in AMP rebates paid to third-party payors such as Medicare Part D plans, qualified retiree prescription drug plans, and State Pharmaceutical Assistance Programs.¹⁵

Merck supports the general approach CMS has proposed of including rebates to PBMs and third-party payors in AMP calculations. However, this approach could reduce AMP, which will shortly become a reimbursement metric. Federal upper limits for multiple source drugs will be 250% of AMP starting this year, and some States might decide to use AMP in their Medicaid reimbursement formulas for other drugs once AMPs become public. As noted in our August 2, 2006 letter to CMS, Merck believes it is critically important for pharmacy reimbursement to correlate to pharmacy acquisition cost. Because AMP as defined in the Proposed Rule would include rebates that are not necessarily offered to retail pharmacies, it will be important for CMS to caution the States about the need to evaluate the relationship between AMP and pharmacy acquisition costs carefully before adopting any type of AMP-based reimbursement formula.

To help ensure that AMP-based Medicaid reimbursement formulas have a percentage markup over AMP that preserves Medicaid beneficiaries’ access to medicines, CMS should re-emphasize in the Final Rule that it “encourage[s] States to analyze the

¹⁴ *Id.* at 77179.

¹⁵ *Id.* at 77180. It is unclear whether the Proposed Rule would require manufacturers to include supplemental Medicaid rebates in AMP. CMS should clarify this point in the Final Rule.

relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.”¹⁶

3. *Price Concessions to PBMs*

As noted above, the Proposed Rule provides that “to the extent manufacturers are offering . . . price concessions to [a] PBM that are not bona fide service fees, we propose that these lower prices be included in AMP.”¹⁷ The proposed regulatory text would similarly provide that “[d]iscounts, rebates or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade” are included in AMP.¹⁸ However, the Proposed Rule also includes language that could create confusion about the treatment of price concessions to PBMs in AMP calculations; in particular, the Proposed Rule notes that AMP includes price concessions to PBMs “that affect the net price recognized by the manufacturer” for drugs provided to the retail pharmacy class of trade.¹⁹ To promote greater uniformity in AMP calculations and preclude the possibility of confusion regarding the treatment of PBM price concessions, CMS should state clearly in the Final Rule that any price concessions to PBMs should be included in AMP calculations.²⁰

4. *Non-Purchasing HMOs*

Like the Medicaid Rebate Agreement, the Proposed Rule would expressly exclude sales to health maintenance organizations (HMOs) from AMP calculations.²¹ However, the Proposed Rule does not distinguish between HMOs that actually purchase drugs and distribute them to members through the HMO’s own closed pharmacies, and

¹⁶ *Id.* at 77176.

¹⁷ *Id.* at 77179.

¹⁸ *Id.* at 77196 (proposed 42 C.F.R. § 447.504(g)(3)).

¹⁹ *Id.* at 77179.

²⁰ We agree with CMS that bona fide service fees paid to PBMs (or others) should be excluded from AMP and Best Price. CMS should make clear that these fees are not properly considered price concessions, rather than use language suggesting inaccurately that bona fide service fees are price concessions but nonetheless are excluded from AMP and Best Price.

²¹ 71 Fed. Reg. at 77179.

those HMOs that do not purchase drugs but instead reimburse retail pharmacies for drugs dispensed to HMO members. The latter category of HMOs act as third-party payors. Thus, as with other retail pharmacy sales that are reimbursed by third-party payors,²² sales of drugs that are dispensed by retail pharmacies and reimbursed by those HMOs (and the amount of any concessions associated with those sales) should be included in AMP. To enhance consistency, CMS should clarify in the Final Rule that sales of (and price concessions associated with) drugs dispensed at retail pharmacies that are reimbursed by non-purchasing HMOs also are included in AMP.

C. Coupon Programs (447.504(g)(11) and 447.505(c)(12))

Among the types of programs that Merck utilizes to assist patients are coupon programs and voucher programs. Merck uses the terms “coupons” and “vouchers” to describe two distinct types of programs which may fall under the rubric of “manufacturer coupons” as used by CMS in the Proposed Rule. Although “coupon” and “voucher” programs may appear similar, they are different in purpose and function. Merck believes that an understanding of this distinction is essential for CMS to regulate their impact on AMP and Best Price calculations.

As Merck uses the term, “coupons” are certificates provided to patients that entitle them to discounts on their prescription drug purchases, either at the point-of-sale (through a reduction in the amount the consumer is required to pay the dispensing pharmacy) or subsequent to the purchase (by sending the coupon to the manufacturer or a clearinghouse with proof-of-purchase in order to receive a cash reimbursement from the manufacturer). In either case, the amount of the discount provides a dollar-for-dollar reduction in the amount paid out-of-pocket by the patient. Whether the coupons are redeemed by the dispensing pharmacy or directly by the patient, the entire discount represented by the coupon goes to the patient. In point-of-sale coupons, the dispensing pharmacy receives reimbursement for the discount passed on to the patient plus a small handling fee for administering the transaction. The impact of the handling fee on Merck’s AMP and Best Price should be evaluated under the rules that CMS establishes for determining bona fide service fees. However, with respect to the drugs dispensed subject to the discount conferred by the coupon, the pharmacy receives no part of the

²² The Proposed Rule provides that drugs reimbursed by Medicaid, Medicare Part D plans, and State Pharmaceutical Assistance Programs are included in AMP when the drugs are dispensed by retail pharmacies. *Id.* at 77180.

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discount and is prohibited from charging more than its usual and customary price less the discount. If the patient is a member of a managed care plan, the discount on the product is limited to the amount of the patient's copayment or coinsurance.

"Vouchers," by contrast, are certificates provided to patients that entitle the patient to receive a specified number of units of a drug free-of-charge. In this respect, vouchers function similarly to product samples. The manufacturer in a voucher program contracts with a vendor, which in turn contracts with the pharmacy. The pharmacy dispenses the drug free-of-charge to the patient and is then reimbursed by the vendor according to a formula negotiated between the vendor and the pharmacy, plus a dispensing fee. The vendor bills the manufacturer for this reimbursement expense (which is designed to be revenue neutral to the retail pharmacy), plus a service fee. Again, the service fee to the vendor should be evaluated under the definition of "bona fide service fee" adopted in the final rule. Since the manufacturer indirectly reimburses the dispensing pharmacy through the negotiated formula, the dispensing pharmacy does not submit a reimbursement claim for those units to any public or private insurance program of which the consumer may be a beneficiary. Although vouchers are submitted for redemption through a pharmacy, the discount has no effect on the acquisition price paid by the pharmacy for the prescription drug dispensed upon the presentation of a voucher.²³

CMS proposes to require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP," but "to include coupons redeemed by any entity other than the consumer in the calculation of AMP."²⁴ Similarly, CMS proposes to require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price," but "to include coupons redeemed by any entity other than the consumer in the calculation of best price."²⁵ In the context of Best Price calculations, CMS premises its proposed disparate treatment of manufacturer coupons on its belief that "the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose

²³ The mechanics of how coupons and vouchers are processed and redeemed are outlined in more detail in Exhibit A.

²⁴ 71 Fed. Reg. 77174, 77181 (Dec. 22, 2006); see also *id.* at 77197 (to be codified at 42 C.F.R. §§ 447.504(g)(11) & (h)(9)).

²⁵ *Id.* at 77183; see also *id.* at 77197 (to be codified at 42 C.F.R. §§ 447.505(c)(12) & (d)(8)).

sales are included in best price,” but that “the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy).”²⁶ Although CMS does not state so explicitly, this rationale presumably underlies CMS’s proposed treatment of manufacturer coupons in AMP calculations as well.

Although CMS does not propose a definition of “manufacturer coupon,” we assume that this term encompasses “coupons” as described above. In addition, we are concerned that “vouchers” may also be included in potential interpretations of “manufacturer coupon,” whether or not this was CMS’s intent. We respectfully submit that CMS’s proposed treatment of coupons (and possibly vouchers) in AMP and Best Price calculations is not appropriate. In our view, coupons redeemed directly by patients to the manufacturer should not be treated any differently from coupons redeemed to the manufacturer through other parties. CMS suggests that coupons redeemed “by entities other than consumers” somehow affect the prices those entities pay for drugs dispensed subject to those coupons. CMS thus appears to believe that, by honoring coupons presented by patients, which the entities then submit to manufacturers for redemption, the redeeming entities receive a price concession. This belief is contrary to Merck’s experience, in which coupons (and vouchers) are intended solely for the financial benefit of patients, regardless of the means by which they are redeemed.

When a patient presents a coupon to a pharmacy that dispenses prescription drugs, the pharmacy provides the patient with a discount equal to the coupon’s face value. When a patient presents a voucher, the pharmacy provides the drug to the patient for free. Upon “redeeming” the coupon or voucher to the manufacturer, the pharmacy receives a reimbursement that correlates to the coupon or voucher’s value. Consequently, the value of the coupon or voucher “passes through” the redeeming entity to the patient and has no effect on the acquisition price paid by the redeeming entity to purchase the units of the drug dispensed subject to the coupon or voucher. The transaction that establishes the price the redeeming entity paid to acquire the drug occurs well before the patient ever presents the coupon or voucher to the redeeming entity. Indeed, the transaction in which the drug is acquired often involves only a wholesaler and a retail pharmacy; the

²⁶ Id. at 77183.

manufacturer may not even be a party.²⁷ Because the redeeming entity in the case of both coupons and vouchers does not retain any portion of the discount conferred to the patient, the coupon or voucher has no effect on the price the entity paid for the prescription drugs it dispenses to the patient. The coupon/voucher, accordingly, is not a cost-saving program offered to an entity other than the patient, and the value of the coupon or voucher should not be included in manufacturers' calculations of either AMP or Best Price.

Moreover, CMS's proposed approach could have unintended adverse consequences on both coupon and voucher programs, which offer substantial financial benefits to patients. This is especially true with regard to voucher programs, if CMS considers vouchers under the umbrella of "manufacturer coupons." Although vouchers function similarly to product samples (like samples, vouchers allow a patient to try a drug without cost for a limited time to enable the patient's physician to determine the safety and efficacy of the drug for the particular patient), they have many advantages over product samples. From the physician's standpoint, vouchers are easier to safeguard, store and distribute to patients; indeed, an increasing number of physician practices will not accept samples and will only accept vouchers. Also unlike samples, vouchers offer advantages because they require a prescription before they can be used and a pharmacist must fill the prescription. For the patient, vouchers allow the dispensing pharmacy an additional opportunity to track prescription drug use and thereby monitor for adverse drug interactions. Thus, they provide another opportunity for the patient to ask questions of a healthcare practitioner. Manufacturers should not be penalized from a pricing standpoint for offering vouchers that are redeemable at the point of sale.

²⁷ If coupon or voucher programs were "relevant" to AMP or Best Price, it is not clear how the manufacturer should account for the value of such a program in its price calculations. If the pharmacy buys the drugs from a wholesaler, the manufacturer would not: (a) know the acquisition price for the drug that the pharmacy paid (because it is not a party to the agreement between the distributor and the pharmacy); or (b) have the ability to trace the units dispensed to the patient using a coupon or voucher to a sale from the manufacturer to a wholesaler. Moreover, if the Proposed Rule were to become effective, would the net price for AMP or Best Price purposes require the manufacturer to subtract from the acquisition price: (a) the dispensing fee paid to the redeeming entity, (b) the discount paid to the consumer, (c) the reimbursement amount paid to the redeeming entity; or (d) some combination of these elements?

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With regard to coupon programs, CMS's proposed approach could also result in manufacturers requiring patients to redeem coupons directly to them. This would burden patients by requiring them to put forth the full out-of-pocket cost of the prescription and to wait 6-8 weeks for reimbursement after mailing proof-of-purchase forms to the manufacturer. It also potentially could require manufacturers to pay for additional infrastructure to administer such coupon programs. Merck does not believe that such additional steps are necessary or warranted. Coupons serve the valuable purpose of encouraging patients to obtain the medications their physicians have prescribed by reducing the cost of such medications to the patients, and we are concerned that CMS's proposal could reduce or unduly burden patient participation in those programs.

Based on the foregoing, Merck respectfully requests that CMS take the following actions in the Final Rule:

Coupons

- Adopt a definition of "manufacturer coupon" that encompasses cost-saving programs offered to patients but that recognizes the different means by which coupons may be redeemed. Merck proposes that CMS adopt the following definition:

"Manufacturer coupon" means "any certificate provided to a consumer that provides by its terms that the consumer is entitled to a discount on his or her purchase of drugs, either: (A) at the point-of-purchase, through a reduction equal to the face value of the coupon up to the amount the consumer is required to pay the entity that dispenses the drugs, or (B) subsequent to the purchase, through receipt of a cash reimbursement from the manufacturer (or a vendor under contract to the manufacturer to administer the coupon program) where the reimbursement amount is equal to the lesser of the amount the consumer paid to the dispensing entity or the face value of the coupon."

- Require manufacturers to exclude from their AMP and Best Price calculations:

- Any manufacturer coupon redeemed by a consumer either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the coupon program; and
 - Any manufacturer coupon redeemed by an entity other than a consumer (after being presented to and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program.
- Specify that manufacturers should also exclude from their AMP and Best Price calculations: (A) the reimbursement amount paid to the redeeming entity for the manufacturer coupon; and (B) any fees paid to an entity other than a consumer that redeems a manufacturer coupon where the fee satisfies the definition of “bona fide service fee” adopted by CMS in the Final Rule.

Vouchers

CMS does not expressly address in the Proposed Rule how manufacturers should treat in their AMP and Best Price calculations drugs that are ultimately dispensed to patients upon presentation of vouchers. Merck believes that CMS should confirm that manufacturer vouchers are not subject to CMS’s guidance regarding “manufacturer coupons.” If CMS does decide to treat manufacturer vouchers explicitly in the Final Rule, Merck respectfully requests that CMS take the following actions with regard to vouchers:

- Adopt a definition of “manufacturer voucher” that encompasses cost-saving programs offered to patients but that recognizes the different means by which vouchers may be redeemed. Merck proposes that CMS adopt the following definition:

“Manufacturer voucher” means “any certificate provided to a consumer that provides by its terms that the consumer is entitled to a specified number of units of a drug free-of-charge, without (A) any co-payment from the consumer, or (B) reimbursement to the entity that dispenses the drug from any insurance program of which the consumer may be a beneficiary.”

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- Require manufacturers to exclude from their AMP and Best Price calculations:
 - Any manufacturer voucher redeemed by a consumer either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the voucher program; and
 - Any manufacturer voucher redeemed by an entity other than a consumer (after being presented to and honored by such entity) either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the voucher program.
- Specify that manufacturers should also exclude from their AMP and Best Price calculations: (A) the reimbursement amount paid for any manufacturer vouchers; and (B) any fees paid to an entity other than a consumer that redeems a manufacturer voucher where the fee satisfies the definition of “bona fide service fee” adopted by CMS in the Final Rule.

The approach that we have suggested is the most practical and fair method for all parties because the relevant price of a covered outpatient drug for AMP and Best Price purposes is the price that the manufacturer charges to the wholesaler or retail pharmacy (if the manufacturer sells directly to the retail pharmacy) for the drug, not the reimbursement amount paid to the entity at which a voucher is redeemed or the financial value of a voucher to the patient.

If CMS does not adopt the approach that we have suggested above, Merck respectfully requests clear guidance from CMS as to how manufacturers should account

for coupons and vouchers in their calculations of AMP and Best Price.²⁸

D. Authorized Generic Agreements (447.506)

Section 6003 of the DRA directed innovator manufacturers, effective January 1, 2007, to take sales of authorized generic products into account in the calculation of the innovator manufacturer's AMP and Best Price. With respect to AMP, the DRA required that, "in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [FFDCA],"²⁹ the innovator manufacturer's AMP "shall be inclusive of the average price paid for such drugs by wholesalers for the drugs distributed to the retail pharmacy class of trade."³⁰ With respect to Best Price, the DRA provides that the innovator manufacturer's Best Price "shall be inclusive of the lowest price for such authorized [generic] drug available from

²⁸ The Medicaid Rebate Act defines Best Price as the lowest price charged "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i). Accordingly, Merck is concerned with the Proposed Rule's discussion of Best Price, which provides: "[w]e propose to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as 'other arrangements' . . . that . . . should be included in the calculation of Best Price." 71 Fed. Reg. at 77182. To avoid any confusion, CMS should confirm explicitly in the Final Rule that Best Price is the lowest price realized by the manufacturer net of all price concessions to a specific Best Price-eligible customer. This clarification would recognize the Medicaid Rebate Act's requirement that Best Price must be determined by reference to customer-specific prices, rather than prices derived by aggregating price concessions to different customers.

²⁹ DRA section 6003(a)(2)(B)(iii). Section 505(c) of the FFDCA addresses new drug applications (NDAs) that the FDA must approve as a prerequisite for a company to market drugs and certain biologics (such as human growth hormone and insulin).²⁹ By contrast, FDA approves abbreviated new drug applications (ANDAs) under 505(j) (for certain generic products) and biologics license applications (BLAs) (for certain biologics) under section 351 of the Public Health Service Act (PHSA). Therefore, Section 6003 by its terms, including the reference to Section 505(c) of the FFDCA, applies to authorized versions of products marketed under NDAs, but does not apply to products marketed under ANDAs or BLAs.

³⁰ Id.

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the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, [HMO], nonprofit entity or governmental entity.”³¹

The DRA is silent concerning how manufacturers should blend sales of an authorized generic version of their drugs with their own sales of the drug for purposes of the AMP calculation. It also does not expressly address whether the Best Price determination takes into account the transfer price of the authorized drug from the innovator manufacturer to the authorized generic manufacturer, or the lowest price of the authorized drug from the authorized generic manufacturer to its Best Price-eligible customers, or both.

Section 447.506 of the Proposed Rule suggests a definition of the term “authorized generic” and proposes to require manufacturers to include “the direct and indirect sales of [an authorized generic] drug in its AMP” and “the price of [an authorized generic] drug in the computation of best price for the single source or innovator multiple source drug . . . to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States.” However, like the DRA, the Proposed Rule neither specifies a procedure for blending sales by the authorized generic manufacturer in the innovator company’s AMP nor identifies the prices that must be taken into account in determining Best Price. In the preamble to the Proposed Rule, CMS appears to conclude that the only relevant price for Best Price purposes is the price from the authorized generic manufacturer to its customers:

we would require that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in the sales used to determine the best price for the single source or innovator multiple source drug approved under Section 505(c) of the FDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity or governmental entity within the United States. The primary manufacturer must include in its calculation of best price all sales of the authorized generic drug which have been sold or marketed by a secondary

³¹ DRA section 6003(a)(2)(B)(iii).

manufacturer or by a subsidiary of the brand manufacturer.³²

Merck agrees that, for Best Price purposes, the relevant price for a drug that is the subject of an authorized generic agreement should be the lower of: (a) the lowest price charged by the innovator manufacturer in a Best Price-eligible sale; or (b) the lowest price charged by the authorized generic manufacturer in a Best Price-eligible sale. We also agree that the transfer price -- that is, the price at which the innovator manufacturer sells the drug to the authorized generic manufacturer -- should not be taken into account in Best Price, even if the transfer price would otherwise be the lowest price at which the drug is sold. Transfer prices may involve complex royalty or profit-sharing arrangements that would be difficult for the innovator manufacturer to incorporate into its Best Price and for CMS to evaluate. In such situations, the amount of the royalty or profit share likely will not be known until long after the reporting period has ended. Therefore, Merck supports the approach that CMS has suggested in the preamble to the Proposed Rule. To avoid any confusion, we request that the wording of the regulation be clarified so that the Final Rule will more closely track this approach, making it clear that the transfer price is not a Best Price-eligible sale for the innovator manufacturer.

With respect to both AMP and Best Price, as Merck explained in its August 2, 2006 letter to CMS, we recommend that CMS adopt a specific methodology for blending authorized generic sales with sales by the innovator manufacturer. We believe that there are two potential blending methodologies available to CMS:

1. CMS could require manufacturers of innovator drugs and manufacturers of authorized generic version(s) of those innovator drugs to calculate AMPs and to determine Best Prices for their own products, using only the sales data specific to those products (as identified by their National Drug Code (NDC) numbers), and to include in their AMP reports the number of units sold during the rebate period. CMS could also require innovator drug manufacturers to identify the NDC(s) associated with authorized generic versions of their innovator drugs marketed under their NDAs. CMS would be responsible for using this information to calculate weighted AMPs and to determine Best Prices for the innovator drugs and then for reporting this information to innovator drug manufacturers.

³² 71 Fed. Reg. 77174, 77184 (Dec. 22, 2006).

2. CMS could require manufacturers of innovator drugs to obtain information from manufacturers of authorized generic version(s) of their innovator drugs, either the AMPs or Best Prices themselves or the underlying sales data. Manufacturers of innovator drugs then would use this information, in combination with sales data for their innovator drugs, to calculate AMPs and to determine Best Prices for their innovator drugs. If this approach were taken, CMS should allow the innovator manufacturer to rely on a certification from the authorized generic manufacturer as to the accuracy of the information provided.

Merck recommends that CMS adopt the first option in the Final Rule.³³ Merck's concern with the second option is that the thirty days available to manufacturers to calculate AMP and to determine Best Price would make it difficult for innovator drug manufacturers to obtain information from the manufacturers of authorized generic versions of their innovator drugs, to take any steps they may consider appropriate to verify the accuracy of that information, and then to calculate AMPs and determine Best Prices for their innovator drugs. With a short time period to complete these tasks, innovator drug manufacturers could have reduced confidence in the accuracy of their AMPs and Best Prices.

The first blending option would avoid this concern by making manufacturers responsible only for the accuracy of their own price information, while also enabling CMS to exercise effective oversight with respect to the information being submitted by both the innovator and the authorized generic manufacturer. Additionally, Merck

³³ If CMS does adopt a manufacturer blending procedure, we urge CMS also to specify that the innovator manufacturer need not begin applying the blending procedure until the quarter following the launch of the authorized generic product. If an authorized generic agreement is effective in the middle of a quarter, our view is that, for ease of administration, CMS should permit innovator manufacturers to defer accounting for authorized generic sales in its AMP or Best Price until the quarter following the launch of the authorized generic drug. Additionally, CMS should take steps to avoid the need for disclosure of potentially business sensitive information, such as transaction-level data, from authorized generic manufacturers to innovator manufacturers.

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believes that the first option would avoid risks associated with requiring a private company to obtain pricing and utilization information from a competitor.³⁴

Merck's Recommendations Regarding Authorized Generic Arrangements

- With respect to AMP and Best Price, CMS should include a provision in the Final Rule that would expressly require manufacturers of innovator drugs and manufacturers of authorized generic version(s) of those innovator drugs to calculate AMPs and to determine Best Prices for their own products, using only the sales data specific to those products (as identified by their NDC numbers), and to include in their AMP reports the number of units sold during the rebate period. CMS should also require innovator drug manufacturers to identify the NDC(s) associated with authorized generic versions of their innovator drugs marketed under their NDAs. CMS should be responsible for using the information provided to calculate weighted AMPs and to determine Best Prices for the innovator drugs and then for reporting this information to innovator drug manufacturers. For authorized generic agreements that are effective in the middle of a quarter, CMS should not begin to apply this blending procedure until the following quarter.
- CMS should confirm that the Best Price of a drug that is the subject of an authorized generic agreement is the lower of: (a) the lowest price charged for the drug by the innovator manufacturer in a Best Price-eligible sale; and (b) the lowest price charged for the drug by the authorized generic manufacturer in a Best Price-eligible sale. CMS should also confirm in the language of the Final Rule the principle expressed in the preamble to the Proposed Rule: that Best Price does not include the transfer price at which the innovator manufacturer sells the drug to the authorized generic manufacturer.

³⁴ See Statement 6, "Provider Participation in Exchanges of Price and Cost Information," of the Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, which is available at <http://www.ftc.gov/reports/hlth3s.htm#6>.

E. Rolling Average Methodology (447.510)

CMS proposes to require manufacturers to calculate monthly AMP using the same methodology as for quarterly AMP, except that: (a) the monthly AMP would cover one month instead of one quarter; (b) the monthly AMP would not be subject to revision; and (c) manufacturers would be permitted to estimate end-of-quarter rebates or price concessions in monthly AMP calculations.³⁵ CMS requests comments on whether it should adopt a 12-month rolling average methodology to apply to lagged price concessions in both the monthly and quarterly AMP calculations. Under the approach adopted by CMS, manufacturers would continue to report revisions to AMP that result from information learned after the quarterly reporting date.

As noted in Merck's August 2, 2006 letter, Merck believes that, because of the role that AMP may play in product reimbursement, an important objective of the Medicaid program going forward should be to minimize unnecessary instability and volatility in AMP calculations. To accomplish this goal, Merck continues to believe that CMS should revise the AMP calculation to eliminate the need to adjust AMPs after they have been reported. In this regard, we applaud CMS's decision to preclude routine restatements of monthly AMP.

However, Merck does not believe that the three-month rolling average methodology proposed by CMS covers a sufficient amount of time to ensure accurate and stable reported AMPs. Instead, Merck would urge CMS to adopt a "twelve-month rolling average methodology" for monthly (and quarterly) AMPs similar to the methodology used to estimate the value of lagged discounts when calculating ASP, another reimbursement metric.³⁶ Adoption of the twelve-month rolling average methodology, allowing smoothing of all lagged pricing information (including chargebacks), not only would have the benefit of consistency across the Medicaid and Medicare programs, but also would enable companies to use a sufficient period of time in the rolling average

³⁵ 71 Fed. Reg. 77174, 77185-86 (Dec. 22, 2006).

³⁶ See 42 C.F.R. § 414.804(a)(3). In this regard, Merck applauds CMS's proposal that manufacturers exclude product returns from the AMP calculation. This proposal will align AMP reporting with ASP reporting and also will remove a potential source of volatility from the AMP calculation.

calculation to improve the accuracy of the monthly (or quarterly) AMPs that may be used to determine pharmacy reimbursement.

In the event that CMS implements this change to the AMP calculation, Merck also recommends that CMS describe in the Final Rule the (presumably limited) circumstances in which CMS would either expect or permit manufacturers to recalculate AMPs. In particular, CMS should provide guidance to manufacturers regarding whether, in light of the need to maximize stability in reimbursement metrics, restatements remain an appropriate means for correcting subsequently discovered AMP calculation errors.

F. Effective Date

The DRA requires CMS to promulgate rules concerning AMP by no later than July 1, 2007. Many of the changes that would result from promulgation of the Final Rule will require time for manufacturers to implement. For example, the issues raised concerning coupon and voucher programs could affect millions of coupons and vouchers that are currently on the market. Similarly, the changes to the definition of retail pharmacy class of trade, and to AMP and Best Price generally, will require companies to revise their price reporting processes and to re-program and test their information technology systems. Whatever decisions that CMS ultimately makes in the Final Rule concerning these and other issues, manufacturers will need time to implement them. The reprogramming and testing of systems will take considerable time and effort and cannot be started until manufacturers know what the Final Rule requires.

Accordingly, to allow for reprogramming and testing of systems to occur and for manufacturers otherwise to come into compliance with the requirements of the Final Rule, Merck recommends that CMS give manufacturers a period of not less than four quarters from the date that the Final Rule is issued before the changes made in the Final Rule that are not required by the DRA become effective. This window, through at least July 1, 2008, would afford both manufacturers and CMS time to prepare their processing systems for the changes that the Final Rule will require. If such a "ramp up" period is not granted, not only would there be a heightened risk of error and inconsistency in the periods immediately following the issuance of the Final Rule, but also reimbursement to retail pharmacies could be adversely affected because AMPs are not reported accurately. For these reasons, Merck strongly urges CMS to allow manufacturers a period of time of not less than twelve months to make the necessary system modifications

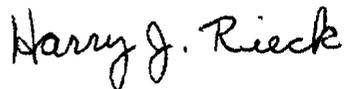
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and to put procedures in place to mitigate the risk that AMP (and Best Price) are not calculated and reported accurately.

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Merck appreciates the opportunity to comment on the Proposed Rule. Merck also recognizes and appreciates the considerable effort that CMS put into the development of the Proposed Rule, and we hope that our comments will be useful to CMS as it develops the Final Rule. Merck would be pleased to provide any additional information upon request.

Sincerely,



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