

CMS-2238-P-1231

Submitter : Dr. Michael Karpf
Organization : University of Kentucky Hospital
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See attached.

**Provisions of the Proposed
Regulations**

Provisions of the Proposed Regulations

See Attached.

CMS-2238-P-1231-Attach-1.PDF

UK HealthCare

February 19, 2007

**Office of the Executive
Vice President for
Health Affairs**

University of Kentucky
317. Wethington Building
900 South Limestone
Lexington, KY 40536-0200
Phone: (859) 323-5126
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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

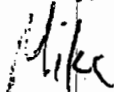
To Whom It May Concern:

On behalf of the University of Kentucky Hospital, I am responding to the request for comments on proposed regulations to implement components of the Deficit Reduction Act of 2005 (the "DRA"), published in the *Federal Register* on December 22, 2006. The University of Kentucky is a 473 bed hospital located in Lexington, Kentucky that 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. We are one of the largest Medicaid providers in the Commonwealth of Kentucky. Our principal concerns about the proposed regulations are twofold:

1. The proposed regulation would create an administrative and financial burden for our hospital by requiring the NDC information on billings of drugs administered in the hospital outpatient setting. At the University of Kentucky this would create significant operational issues as all hospital services are billed on the UB-92 form. Currently there is not an electronic method to include the NDC number on the form. Substantial reprogramming of the billing operations would be required. As a result, these billings would require manual intervention, which would create billing delays for the vast number of outpatient billings submitted to our payers. Further this change would require Kentucky Medicaid and other payers to reprogram their systems in order pay claims appropriately as well.
2. If the new billing procedure is excessively burdensome, the hospital may be forced to choose to withdraw from participation in the 340B program resulting in greater pharmaceutical costs. Our facility alone would see an increase of over \$760,000 in pharmaceutical costs annually for its Medicaid and Medicare patients. This cost would then be passed on to the other payers and individual citizens of the Commonwealth who now enjoy the savings of the 340B pricing in the cost of the drugs sold.

We ask that you exempt hospital outpatient departments from the requirement of reporting NDC numbers on the billing form and clarify the proposed regulations published on December 22, 2007 to allow the University of Kentucky Hospital to continue participating in the Federal 340B drug discount program. The Kentucky Medicaid program has an established program to recognize drug rebates from providers with the exception of those providers who receive the 340B discount. Any change even as seemingly simple as requiring NDC numbers to be placed on a hospital billing form will create administrative problems that ultimately may cost our patients and citizens of the community more than the value of the discounts.

Sincerely,



Michael Karpf M.D.
Executive Vice President for Health Affairs

CMS-2238-P-1232

Submitter : Mr. Stan Rosenstein
Organization : California Medicaid - Medi-Cal
Category : State Government

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT - SIGNED COPY WILL BE SENT VIA OVERNIGHT.

CMS-2238-P-1232-Attach-1.PDF

1232



California
Department of
Health Services

SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

February 20, 2007

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

Attention: CMS-2238-P

Dear Sir or Madam:

SUBMITTAL OF FORMAL COMMENTS REGARDING THE PROPOSED FEDERAL RULE IMPLEMENTING THE MEDICAID PRESCRIPTION DRUG PROVISIONS OF THE DEFICIT REDUCTION ACT OF 2005 – NPRM ISSUED IN THE FEDERAL REGISTER (VOLUME 71, NUMBER 246) ON DECEMBER 22, 2006

This responds to the Centers for Medicare & Medicaid Services (CMS) request for comments on the Notice of Proposed Rule Making dated December 22, 2006, regarding the implementation of Medicaid prescription drug provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to the calculation of Average Manufacturer Price (AMP) and the Federal Upper Limit (FUL) of drugs provided in the Medicaid program.

The proposed rule attempts to clarify how AMP and FUL are to be calculated. More specifically the rule provides definitions, calculations, timeframes and other related aspects that have, to date, been generally provided through policy letters issued by CMS. Though CMS has done an admirable job on a very difficult task, there are problems in the proposed rule that could harm the state Medicaid programs, pharmacy providers and more critically, Medicaid beneficiary access to medically necessary care. The following are comments and recommended solution for these issues.

Bundled Sale Definition

The definition of a bundled sale includes that "the discounts are allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle."

This language should be clarified so there is not room for interpretive error regarding the intent. The phrase "allocated proportionally to the dollar value of the units" should be slightly modified to state "allocated proportionally to the total dollar value of the units" and the word "should" in the last sentence amended to "shall."

Dispensing Fee Definition

The definition of dispensing fee includes "...pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient" and that the fee includes, "measurement or mixing of the covered outpatient drug" and "special packaging." This definition is inclusive of many different types of drugs dispensed by pharmacies. Of special concern are compounded drugs that are more complex and may include non-drug products (diluent, surfactants, suspending agents, special containers, etc.) whose cost cannot be accurately captured within a dispensing fee structure. These products are necessary to provide the "appropriate covered outpatient drug" to the Medicaid recipient.

Therefore this definition should include language that recognizes these additional cost elements as not included in the dispensing fee but as costs that can be paid by the Medicaid agency in addition to the dispensing fee and the cost of the covered outpatient drugs.

Estimated Acquisition Cost Definition

The definition of Estimated Acquisition Cost includes the qualifier of the "package size of drug most frequently purchased by providers." In California Medicaid (Medi-Cal), estimated acquisition cost is spread pursuant to package sizes listed in regulations. As an example, for solid oral dosage forms (i.e. tablets and capsules), the per unit price from the 100s size container is used to price all package sizes (e.g. 30s, 50s, 500s, or 1000s). The requirement that the most frequently purchased package size could change from time to time.

The final rule should provide more specific guidance and a source from which to draw this information from. For example, the language could be altered to read, "package size of drug most frequently purchased by providers within the previous 12 months as provided to state Medicaid agencies by the Centers for Medicare and Medicaid Services."

Retail Pharmacy Class of Trade Definition

The definition of Retail Pharmacy Class of Trade is a key in the calculation of the Average Manufacturer Price (AMP) in that federal statute specifically states that AMP is "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." The proposed rule defines retail pharmacy class of trade to include traditional independent and chain

retail pharmacies, mail order pharmacies, pharmacy benefit managers (PBM) and "other outlets that purchases, or arranges for the purchase of drugs.....and subsequently sells or provides the drugs to the general public." Health Maintenance Organizations (HMO) and long term care pharmacies are not included in the definition.

The inclusion or exclusion of various entities in this definition creates several issues:

- The Centers for Medicare & Medicaid Services (CMS) indicate they decided to include discounts provided by manufacturers to PBMs that affect the net price recognized by the manufacturer. This appears contrary to CMS' own admission that manufacturers cannot accurately determine if discounts provided to a PBM actually affects the price. This decision also appears to be contrary to statute which indicates the AMP reflects prices paid by wholesalers and not rebates provided to entities that neither distribute nor receive shipment of drugs.
- The inclusion of "other outlets" provides for a number of entities that are typically not considered retail pharmacies. For example, physician offices and outpatient clinics are outlets the purchase drugs and provide these drugs to the general public; however, they are not retail pharmacies. The calculation would have to include these entities since they are not expressly excluded in subsequent paragraphs of the rule.
- Also not clear in the proposed rule is how HMO owned PBMs, and the mail order pharmacies of the HMO/PBM should be included or excluded in the calculation of AMP.
- The definition excludes long term care pharmacies because, according to CMS, these pharmacies do not dispense to the general public. Based on this description, dispensing drugs to the general public is an important feature of a retail pharmacy. PBMs and many non-pharmacy entities do not dispense drugs to the "general public" therefore the inclusion of these various entities appears contrary to this CMS established attribute.
- It is clear from the discussion in the proposed rule that the decision to include non-pharmacy entities in the definition of AMP was made primarily as a means to decrease pharmacy reimbursement and also decrease manufacturer rebate liabilities. Though the attempt to adjust pharmacy reimbursement to acquisition cost is in line with federal requirements for states to pay at estimated acquisition cost, the inclusion of PBMs and other non-pharmacy groups would likely depress AMP below a level at which most independent and some chain pharmacies can purchase. In many instances this would put many rural or ethnically sensitive pharmacies with high Medicaid volumes at risk and could cause access

problems. To avoid these access problems, states would have to increase the dispensing fee or provide additional payments as a means to maintain an adequate provider network.

Additionally, the reduction in manufacturer rebate obligation is contrary to the intent of the federal Medicare drug rebate program to obtain the best price (i.e. largest discount) as evidenced by inclusion of best price language in federal Medicaid statutes.

The proposed rule should define retail pharmacy class of trade to more accurately reflect the wholesaler to pharmacy relationship and provide Medicaid the best price by:

- The definition should add PBMs to the list of entities excluded from the definition.
- The definition should not use general, undefined descriptions such as "independent" or "mail-order" pharmacy or "other outlet."
- The definition should be amended to mean any entity in the United States that is licensed as a pharmacy which provides drugs to the general public.
- Though mail order pharmacies have a tendency to decrease AMP they should be included because they are licensed pharmacies and provide drugs to the general public.

It is clear from the final rule discussion that CMS has struggled to balance AMP-based rebate collection and AMP-based reimbursement through the inclusion of non-pharmacy entities. Should CMS believe it important to maintain these entities in AMP for the purposes of reducing manufacturer rebates, then an alternative would be to have monthly and quarterly rebates calculated differently. Monthly and quarterly AMP affords CMS the opportunity to use the monthly AMP to establish the Federal Upper Limit (FUL) in a way that would provide a more accurate reflection of traditional retail pharmacy purchasing (i.e. including only licensed pharmacies and excluding other entities such as PBMs) and maintain the CMS decision to reduce manufacturer rebate liabilities by the inclusion of the various non-pharmacy entities in the quarterly AMP reporting.

Reporting of AMP and FUL – Units of Measure

Manufacturers must report AMP information to CMS and CMS must relay this information to state Medicaid agencies monthly and quarterly. The value reported is a specific dollar amount per unit. States continue to encounter problems with the units used by manufacturers to report AMP information as they are not always in compliance with the National Council of Prescription Drug Programs (NCPDP) claiming standard. Medicaid agencies, like all other third party payers, are required to use the NCPDP standard units to pay claims and use these same units for Medicaid rebate invoicing. With changes to and AMP based FUL, it is important that the AMP match the NCPDP claiming standard.

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The proposed rule should be amended to require manufacturers to report AMP and best price information and CMS to report the FUL using NCPDP standard units.

Reporting of FUL – Timeframe

CMS is required to “establish and issue listings that identify and set upper limits for multiple source drugs.” In issuing FUL prices to state Medicaid agencies, CMS has traditionally made the FUL changes effective 30 days from the date on the notification letter from CMS. This timeframe typically makes it difficult for the state Medicaid agency to adequately notice pharmacy providers of the change. Additionally, pharmacy providers have to alter their inventory to make it economically feasible to dispense drugs under the FUL and the short notification period makes it difficult for them to do so.

The proposed rule should be amended to require CMS to provide a 60-day implementation timeframe for any changes to the FUL list of drugs.

FUL and Capitation Arrangements

The proposed rule indicates that the FUL also applies to payment for drugs “under prepaid capitation arrangements.” This requirement appears to include capitation arrangements that state Medicaid agencies have with managed care organizations. Because the FUL can change frequently and managed care capitation arrangements are negotiated for longer periods of time, it will be difficult for state Medicaid agencies to comply with this provision.

The proposed rule should be amended to exclude capitation arrangements with health maintenance organizations, including managed care organizations, that contract under section 1903(m) of the Social Security Act. This is same as the exclusionary language used for the federal Medicaid rebate.

We appreciate the opportunity to provide input. If you have any questions, please do not hesitate to contact me at (916) 440-7800.

Sincerely,

Stan Rosenstein
Deputy Director
Medical Care Services

CMS-2238-P-1233

Submitter : Mr. Don Faulk

Date: 02/20/2007

Organization : Medical Center of Central Georgia

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1233-Attach-1.DOC

#1233

The Medical Center Of Central Georgia

February 15, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

On behalf of the Medical Center of Central Georgia, 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. The Medical Center of Central Georgia is a 634 bed hospital located in Macon, Georgia, that 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. The design of our pharmacy clinical system does not support provision of the drug NDC information with the data sent to the financial system for billing. We are only able to make the financial system provide this information by using a miscellaneous field to key in the NDC number. This limits us to having only one NDC associated with each drug product. For multi-source items we many times have multiple manufacturers' products on the shelf at any one time. This is due to the quarterly price changes for 340B drugs as well as back orders and other out of stock situations. There is not an automated method to update the NDC numbers when a different product is brought into the hospital. Employees in the pharmacy and the financial systems departments have spent hundreds of hours just to bring our systems into compliance with the Georgia Department of Community Health's recent requirement to add the NDC number on the Georgia Physician Administered Drug List. This list has only about 300 drugs. To add the NDC to the entire catalog of over 3000 pharmacy items will be an enormous burden. Maintaining the information will be very difficult.

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. Our hospital is better able to serve our patients by taking advantage of 340B priced drugs. For our most commonly used drugs, the savings is over 40%. To lose the discount on these drugs will compromise our ability to provide care to the patients who most need it.

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 and by not expanding the list of safety net providers eligible for nominal pricing.

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,

Don Faulk
CEO, President
Medical Center of Central Georgia

777 Hemlock Street

P.O. Box 6000

Macon, Georgia 31208

Submitter : Mr. Paul Pisarzewicz

Date: 02/20/2007

Organization : Columbia St. Marys

Category : Pharmacist

Issue Areas/Comments

Background

Background

On behalf of Columbia St. Marys (CSM), Inc. I am submitting comments of concern regarding the proposed rule to implement certain provisions in the Deficit Reduction Act of 2005. CSM is an integrated health system comprised of 3 acute care hospitals totaling approximately 650 beds, and 30 external clinics. Two of the hospitals, St. Mary's-Milwaukee, and Columbia Hospital qualify as disproportionate share hospitals under the Medicare program, and is enrolled as a covered entity under the federal 340B drug discount program.

Collection of Information Requirements

Collection of Information Requirements

My principal concerns about the proposed regulations are threefold:

First, the proposed regulations would create enormous administrative and financial burdens for our participating hospitals by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. We do have NDC's in our pharmacy system. However, the hospitals do not use the pharmacy system for billing. They have a separate financial system that is used throughout our health system and many others nationally. The NDC's would have to reside in this financial system for this proposal to work. To further complicate things, this financial system would need to be as current as the pharmacy system. In our current environment, this would require dual entry and maintenance of the NDC process. This would be an enormous on-going task. At this point, there isn't a field available to enter the NDC. Our inability to include NDC information on the financial system would not allow us to participate in this program. This would cost our system over \$1M annually. My other concern is the actual tracking of a specific NDC to a specific dispensing occurrence. For example, we utilize a specific anti-nausea agent in Day Surgery. We switch manufacturers due to a contract change. During the switchover, this drug will be available from two different manufacturers with two correspondingly different NDC numbers. There is no way to connect a specific drug dispense for a patient to a specific drug product when generics are involved. We would be either over or under reporting specific NDC usage based on this scenario. Medicare and commercial insurers do not require NDC's for clinic administered medications. Changing a hospital computer system to allow for the submission of the NDC number of medications administered in our institutions would be a substantial cost for our system, and not justified by the interest of only Medicaid. Converting the information billing system to accommodate this change would cost an enormous amount of money, during a time when most hospital systems are heavily engaged in the development of electronic health record systems.

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 hospitals pay for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

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

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The costs of these requirements should be weighed against the potential savings associated with such a mandate. Further, if CMS decides to require this change, it should provide ample lead time and a one-time payment to hospitals and clinics that would have to re-tool their information systems to undertake the system changes that are proposed. Not providing these allowances would ignore the practical and financial consequences associated with our hospitals and clinics in uniquely serving the Medicaid population.

CMS-2238-P-1235

Submitter : - Mr. Barry Christensen

Date: 02/20/2007

Organization : Island Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1235-Attach-1.DOC

CMS-2238-P-1235-Attach-2.DOC

Island Pharmacy
3526 Tongass Avenue
Ketchikan, AK 99901
907-225-6186
e-mail: island.pharm@juno.com

March 3, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in Ketchikan, Alaska and we are only pharmacy in our area to service medicaid patients with specialized services such as compounding and mediset filling. If the proposed regulations regarding AMP are established it will effect our and other Alaskan community pharmacies ability to serve our medicaid patients. Below are my comments.

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 the Alaska 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, Alaska Pharmacists Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

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

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

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

Sincerely,

Barry Christensen, Pharmacist

CC: Senator Lisa Murkowski

Submitter : Ms. sam mittal
Organization : seeley pharmacy inc
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

We will go out of business.

Our poor neighborhood will be deprived of Rx services.

PBM are ripping our viability.

Poor patients wont be able to get face to face RPh consultation.

- the formula for AMP based FULs in the proposed rule will not cover pharmacy acquisition costs for muple source generics medications.

- AMP was never intended to serve as a basis for reimbursements.

- To be an appropriate benchmark, AMP must be defined to reflect the actual cos paid by retail pharmacy. This will be accomplished by

- *excluding all rebates & price concessions made by mfg which are not available to retail pharmacy.

- *excluding all mail order facilities & PBM pricing from AMP calculation. Mail order facilities & PBMs are extended special prices from MFG & they are not publicly accessible in the way that our brick mortar Rx's are publicly accessible.

- Reporting AMP at the 11 digit NDC level to ensure accuracy

Submitter : **Randall Young**
 Organization : **Prescription Shop**
 Category : **Pharmacist**

Date: 02/20/2007

Issue Areas/Comments**Background****Background**

My name is Randall T. Young. I am a pharmacist and own a small rural pharmacy in south central Kentucky (Prescription Shop in Brownsville, KY). I am also a Vietnam Veteran. I employ myself, another pharmacist, 3 full-time pharmacy technicians, 3 part-time employees. 98% of our business is prescriptions.

Collection of Information Requirements**Collection of Information Requirements**

CMS-2238-P, is the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program.

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.

AMP was never intended to serve as a basis for re-imburement.

To be an appropriate benchmark, AMP must be defined to reflect to actual cost paid by retail pharmacy. This will be accomplished by:

- 1) Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
- 2) 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 brick and mortar pharmacies are.
- 3) Reporting AMP at the 11-digit NDC level to ensure accuracy.

Provisions of the Proposed Regulations**Provisions of the Proposed Regulations**

The recent GAO report on Medicaid Federal Upper Limits (GAO-07-239R) finds that AMP-based FULs were lower than average pharmacy acquisition costs. On Average, they were 36% lower than average retail pharmacy acquisition cost. These findings validate community pharmacies claim that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

Regulatory Impact Analysis**Regulatory Impact Analysis**

CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "public accessible." Mail order facilities are operated almost exclusively by PBM's, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. SALES TO MAIL ORDER FACILITIES SHOULD NOT BE INCLUDED IN AMP.

It is recommended that "retail pharmacy class of trade" include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies-will encompasses some 55,000 retail pharmacy locations.

AMP must be reported weekly. Invoice prices to pharmacies change daily.

AMP must be reported as the 11-digit NDC to ensure accuracy.

Response to Comments**Response to Comments**

In thousands of communities across the nation, the local pharmacy is a vital, indispensable community health resource. Pharmacies will be forced to operate below our costs.

Whole communities are at risk of losing their only pharmacy. Medicaid cuts, combined with low and slow reimbursement under Medicare Part D, could force many pharmacies to close so that ALL patients lose access.

Cuts to Medicaid, disproportionately affect independent pharmacies since, on average, 92 percent of their business comes from prescription drugs, and they cannot make up the losses in front-end sales.

Protecting patient access to community pharmacies is an issue that rises to the level of public health policy. Government policies that drive independent community pharmacies out of Medicaid, or even out of business, will result in increased costs to the taxpayers in terms of increased emergency room visits, hospitalizations, and other unintended health consequences. The local community pharmacy is a crucial health care resource that's taken for granted-until it's gone, as we saw in the aftermath of Hurricane Katrina in the Gulf Coast region.

Submitter : Dr. Shirley Jones

Date: 02/20/2007

Organization : Planned Parenthood of Louisville

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1238-Attach-1.DOC



Planned Parenthood of Louisville, Inc.
1025 South Second Street
Louisville, KY, 40203

February 20, 2007
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the CEO of Planned Parenthood of Louisville¹ (PPL), a non-profit outpatient health center with locations in downtown Louisville and the suburban community of Okolona. Both facilities provide gynecologic health care services including cervical and breast cancer screening, STI and HIV testing, treatment of urinary tract and vaginal infections, pregnancy tests with counseling and referrals, sexuality and wellness education, and access to prescription contraceptive services. These services are provided to uninsured and underinsured women in the community. Annually, PPL serves over 6,000 unique patients; many of whom would not otherwise be able to access affordable reproductive health services—especially oral contraceptives.

PPL has been serving the greater metropolitan Louisville community for nearly 75 years. We are committed to the promotion and assurance of a confidential environment in which women are able to access affordable quality reproductive health care.

- Annual surveys identify that patients choose PPL for their reproductive health services as they are able to obtain contraceptive supplies at fees well below retail.
- Clients state that they would otherwise not be able to purchase contraceptives if they were required to pay retail prices as they either have no healthcare insurance or are underinsured. More than half of these women have no insurance or are underinsured as their health plan does not cover prescription medications or the gynecologic exam necessary to receive the contraceptive supplies.
- These same women are also not income eligible for Federally funded services at a Title X facility.
- All services provided to these women are based on a sliding scale fee structure.
- For the women who seek services at the Okolona facility, the nearest Title X facility is located in the heart of the city and this presents a significant barrier to access for those women living outside the city.

The opportunity to purchase oral contraceptives from manufacturers willing to provide them at nominal prices has been the foundation of PPL's ability to serve women in need of low-cost reproductive health care services. Without this mechanism for purchase of affordable

contraceptive supplies, PPL will not be able to continue to provide services at the Okolona Health Center as we have in the past. As a result, most of the women seen at this site will be left without alternative reproductive health services as there is no other private or public reproductive healthcare provider in that area.

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. The PPL facility in Louisville is a Title X facility and will continue to provide services to women who otherwise would not be able to receive reproductive health services and contraceptive supplies. However, the Okolona facility is not a Title X site and therefore, does not qualify as a 340B covered entity. It is the population of women receiving care at Okolona for whom travel into the city of Louisville will become a significant barrier to access. And as noted, there is no other local private or public alternative for them.

Further, with the reduced funding of current Title X facilities, there is no opportunity for PPL's Louisville health center to support the work of the Okolona health center.

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. PPL is a clearly safety net provider and we strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient clinics like the Okolona Health Center.

Do not let the failure to recognize other safety net providers lead to the closure of reproductive health centers committed to the provision of low cost reproductive health services. Prevention through contraceptive access and equity creates healthy families.

Respectfully submitted by,

Shirley L. Jones, PhD, RNC
CEO
Planned Parenthood of Louisville
1025 South Second Street
Louisville, KY, 40203
(502) 584-1981

CMS-2238-P-1239

Submitter : Mr. Scott Melville

Date: 02/20/2007

Organization : HDMA

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1239-Attach-1.DOC



1239

February 20, 2007

VIA ELECTRONIC SUBMISSION

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 21244-1850

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Dear Ms. Norwalk:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on Proposed Rule CMS-2238-P, "Medicaid Program; Prescription Drugs; Proposed Rule (the "Proposed Rule") published in the *Federal Register* on December 22, 2006.¹

HDMA and its members are committed to patient safety by delivering life-saving health products and services through a secure and efficient healthcare distribution system. These primary, full-service healthcare distributors are responsible for ensuring that billions of units of medication are safely delivered each year to tens of thousands of retail pharmacies, nursing homes, clinics and providers, in all 50 states. HDMA and its members are the vital link in a healthcare system that assures medicine safety, quality, integrity and availability in the marketplace. HDMA and its members focus on providing value, removing costs and developing innovative solutions to deliver care safely and effectively.

HDMA and its members are key stakeholders in the prescription drug market in the United States. We recognize that, in an effort to reduce federal and state spending, the Deficit Reduction Act of 2005 (DRA)² provides for some of the most sweeping changes in the Medicaid program in more than a decade. We expect our members' customers and vendors to be profoundly affected by the Medicaid reimbursement and price reporting changes detailed in the Proposed Rule. We envision the already competitive marketplace for prescription drugs becoming even more so in the wake of the enhanced pricing transparency that the Proposed Rule promises. As a result, we anticipate significant changes in the market that will reverberate throughout the healthcare distribution system and impact our members' businesses. We welcome the opportunity to provide CMS with input on the Proposed Rule from the wholesaler perspective.

¹ 71 *Fed. Reg.* 77173 (Dec. 22, 2006).

² Pub. L. 109-171 (Feb. 8, 2006).

EXECUTIVE SUMMARY

HDMA has limited its comments on the Proposed Rule to issues of primary importance to wholesalers. We have endorsed aspects of the proposal with which we agree. We also have pointed out areas of disagreement. Because we intend our comments to be constructive, we have provided explanations for our positions and recommendations for revisions that address our main concerns. A brief summary of the principle suggestions we have made for fine-tuning the Proposed Rule follows:

- **Bona Fide Service Fees:** The Final Rule should reference the discussion of *bona fide* service fees in the preamble to the 2007 Physician Fee Schedule Final Rule,³ and stipulate that CMS intends to apply the *bona fide* service fee definition in the same way in both the ASP and the AMP context. The Final Rule also should clarify whether administrative fees, GPO fees, distribution fees, promotional fees, etc. can qualify as *bona fide* service fees provided that all of the elements of the definition are satisfied.
- **Customary Prompt Pay Discounts:** To avoid confusion, when the Final Rule instructs manufacturers to deduct cash discounts in the AMP and Best Price calculations, the term “cash discounts” should be qualified by the addition of a parenthetical excepting customary prompt pay discounts. In addition, customary prompt pay discounts should be excluded not only from AMP, but also from Best Price.
- **Retail Pharmacy Class of Trade:** The *sine qua non* of the retail pharmacy class of trade is public access. That said, the Final Rule should take a different tack than the Proposed Rule and exclude from AMP the following sales, rebates and other concessions:
 - Sales to mail-order pharmacies
 - Rebates paid to PBMs on retail network sales
 - Sales to hospitals (regardless of whether a drug is used in an inpatient setting or in one of the hospital’s outpatient departments)
- **Lagged Methodology:** To minimize period-to-period variability in AMP, the Final Rule should require manufacturers to implement a 12-month rolling percentage methodology for netting out price concessions and determining lagged unit amounts needed to calculate AMP. The methodology should rely upon data from the four full calendar quarters prior to the reporting period so that the rolling percentage may be used to determine both monthly and quarterly AMPs.
- **Postpone Public Posting of AMPs:** To avoid misleading consumers and commercial payers and to protect pharmacies from misguided reimbursement cuts, CMS should postpone posting AMP data on its Web site until it receives the first AMP reports after the Final Rule has been implemented.
- **Postpone Setting AMP-Based FULs:** To ensure that pharmacies are adequately reimbursed by state Medicaid programs, CMS also should postpone setting FULs based on AMPs until the Final Rule has been implemented.
- **AMPs and FULs Set at the 11-Digit NDC Level:** The Final Rule should require manufacturers to calculate AMPs at the 11-digit NDC level, and report those AMPs along with utilization data to CMS monthly and quarterly. Such reports would permit CMS to continue using AMPs weighted across all package sizes for rebate purposes, but permit FULs to be set at the 11-digit NDC level so that these payment caps for multiple source products may be tied to the most commonly used package size.

³ 71 Fed. Reg. 69623 (Dec. 1, 2006).

- **FUL Outlier Methodology:** In lieu of an outlier methodology, the Final Rule should set FULs based on the weighted average AMP of the therapeutically equivalent products available in the market, not the AMP of the least costly product. If CMS is unwilling to adopt this approach, the Final Rule should include a FUL outlier methodology that examines AMPs on a cumulative market share basis, starting with the lowest AMP, then the next highest and so on, rejecting AMPs until a cumulative market share of 50% has been reached. This approach would allow CMS to set FULs based on a criterion that distinguishes between low-priced NDCs available only on a limited basis and NDCs priced at true market levels and available in quantities sufficient to satisfy retail pharmacy demand. If CMS prefers, as it proposed, to adopt an outlier methodology that uses price as an indirect proxy for availability, the screening percentage used should be set at 50% or less, not 70% or less, of the next lowest AMP and the price comparison test should be applied iteratively until the lowest AMP that is within 50% of the next lowest AMP has been identified.
- **Definition of Wholesaler:** The Final Rule should conform the definition of “wholesaler” to the definitions of “wholesale distributor,” “wholesale distribution” and “distribute” in the FDA regulations at 21 CFR § 203.
- **RSP:** To ensure that RSP data will be – as the statute requires – representative of average “consumer purchase prices” at retail, CMS should engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures to be used to collect, aggregate and disseminate RSP data.

DETAILED COMMENTS

We have keyed most of our detailed comments to the section headings in the Proposed Rule. We also have included a discussion at the end of our comments keyed to an issue identifier in the Proposed Rule that addresses overarching concern we have with the scope of the proposal.

Definitions – Proposed 42 C.F.R. § 447.502

Bona Fide Service Fee

HDMA applauds CMS’ decision to include a definition of “*bona fide* service fee” in the Medicaid regulations codifying the methodology for calculating AMP and determining Best Price that is identical to the definition included at 42 C.F.R. § 414.802 in the Medicare regulations codifying the methodology for calculating ASP. It would be operationally difficult for a pharmaceutical manufacturer to implement Medicare and Medicaid price reporting regulations mandating different handling of the same fees paid to a wholesaler under a distribution service agreement.

In our view, logic also demands similar treatment of *bona fide* service fees in all price reporting calculations, regardless of whether those calculations support Medicare or Medicaid. Accordingly, we also applaud the instruction in proposed 42 C.F.R. § 447.504(h)(11) establishing that *bona fide* service fees should not be deducted when AMP is calculated and the parallel instruction in the Best Price context in proposed 42 C.F.R. § 447.505(d)(12). These instructions are consistent with the regulation at 42 C.F.R. § 414.804(a)(2)(E)(ii) excluding such fees from the ASP calculation.

We were particularly pleased CMS provided extensive commentary about its interpretation of the *bona fide* service fee definition in the preamble to the 2007 Physician Fee Schedule Final Rule (the “2007 PFS Final Rule”)⁴, where the definition was originally adopted in the Medicare ASP context. That commentary explained that *bona fide* services “encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs.”⁵ They include services “the manufacturer has the capacity to perform, and those that can only be performed by another entity.”⁶ Moreover, the definition of *bona fide* service fee itself makes it clear that such services may be performed either by entities that take title to and possession of drugs from a manufacturer or entities that do not. We are in complete agreement and believe the same analysis should apply for AMP and Best Price purposes as well.

The commentary in the 2007 PFS Final Rule on *bona fide* service fees also stated that fair market value (FMV) fees involve payments at rates generally available in the market from other similarly-situated entities, may be calculated for “a set of itemized *bona fide* services, rather than . . . for each individual itemized service, when the nature of the itemized services warrants such treatment,” and may be set in terms of percentage of goods purchased.⁷ We note the Proposed Rule requests comments on an appropriate definition for FMV in the section of the preamble that discusses the treatment of administrative and services fees in the AMP calculation. HDMA provided extensive input on this topic in its comments on the 2007 Physician Fee Schedule Proposed Rule⁸. The discussion of FMV in the context of service fees that CMS presented in the preamble to the 2007 PFS Final Rule is consistent with the views we expressed in our comments. The same approach seems appropriate in the AMP and Best Price context.

In the commentary to the 2007 PFS Final Rule on *bona fide* service fees, CMS acknowledged that manufacturers often have no effective way of knowing whether a *bona fide* service fee is passed on to the fee recipient’s customer, and advised that manufacturers may “presume, in the absence of evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.”⁹ It also clarified that the “treatment of service fees for ASP purposes and financial accounting purposes may be different, and that if a fee meets our definition of a *bona fide* service fee it can be excluded from the ASP regardless of its treatment for financial accounting purposes.”¹⁰ The same problem exists with respect to the treatment of Medicaid rebates. Under Social Security Act § 1927 and the Medicaid Rebate Agreement, rebates may not be deducted when AMP and Best Price are determined. In contrast, the treatment of Medicaid rebates in accordance with GAAP for financial accounting purposes requires the rebates to be handled as a deduction from revenues (e.g., like a price concessions).¹¹

CMS should stipulate that the commentary explanations applicable to the definition of *bona fide* service fees when manufacturers are calculating ASP also apply when they are determining AMP and Best Price as well. Many pharmaceutical manufacturers do not make products subject to ASP reporting. As a result, some manufacturers may not be familiar with the discussion of service fees in the preamble to the 2007 PFS Final

⁴ 71 Fed. Reg. at 69666-70.

⁵ 71 Fed. Reg. at 69668.

⁶ *Id.*

⁷ 71 Fed. Reg. at 69669.

⁸ 71 Fed. Reg. 48981 (Aug. 22, 2006).

⁹ 71 Fed. Reg. at 69669.

¹⁰ *Id.*

¹¹ Revenue Ruling 2005-28, published in Internal Revenue Bulletin 2005-19 (May 9, 2005).

Rule. Further, given recent enforcement actions facing drug manufacturers, and the proliferation of multi-million dollar settlements involving Medicaid price reporting issues, we suspect those manufacturers aware of the 2007 PFS Final Rule would prefer to have CMS reiterate its view of the various elements of the *bona fide* service fee definition in conjunction with the Medicaid regulations on AMP and Best Price. In the name of efficiency, we ask that CMS expressly reference the discussion of *bona fide* service fees in the preamble to the 2007 PFS Final Rule when it prepares the preamble for the Final Rule implementing the Medicaid prescription drug provisions of the DRA. We also encourage CMS to make it clear it is adopting the principles and positions applicable to *bona fide* service fees outlined in the 2007 PFS Final Rule in the ASP context for purposes of AMP and Best Price determinations under Medicaid.

Dispensing Fee

HDMA is pleased CMS took a relatively expansive approach to the definition of dispensing fee in the Proposed Rule. We also applaud CMS' decision to recommend that state Medicaid programs "reexamine and reevaluate the reasonableness of the dispensing fees paid as part of a pharmacy claim"¹² if they elect to adopt AMP-driven pharmacy reimbursement formulas.

We urge CMS to consider the results of a recently-completed national survey of dispensing costs when it reviews proposed State Plan Amendments revising Medicaid pharmacy reimbursement formulas. Grant Thornton LLP obtained cost data from nearly half the retail pharmacy outlets in the United States for the six-month period from March through August 2006 and determined that the mean cost of dispensing per prescription was \$10.50 and the mean cost of dispensing per pharmacy was \$12.10.¹³ For the 65 million Medicaid prescriptions included in the sample, the mean cost per prescription was \$10.51 and the mean cost per pharmacy was \$12.81. Given these cost data, it will no longer be acceptable for states to reduce payments for dispensing services to Medicaid recipients once they take steps to trim the margins on ingredient costs that have been subsidizing Medicaid dispensing.

We also recommend including a few additional elements in the list of services detailed in proposed 42 CFR § 447.502 that must be considered when a dispensing fee representative of fully loaded costs is developed. We are hesitant to rely on the "[p]harmacy costs include, but are not limited to" language currently used to preface the list because of the inadequacy of dispensing fees paid by state Medicaid programs over the years. The revised definition also needs to include the time pharmacists spend entering billing information into their computer systems and communicating by telephone, fax and e-mail with state Medicaid agencies and PBMs about coverage and billing questions. More importantly, the Proposed Rule must include as an element of pharmacy costs the important health, safety and counseling services community pharmacists routinely provide – typically based on an individualized understanding of the customers' medical needs and personal preferences – to ensure that each physician's prescription leads to the best drug regimen for the patient.

Innovator Multiple Source, Multiple Source and Single Source Drugs

¹² Medicaid Drug Rebate Program Release for State Medicaid Directors No. 144 (December 2006).

¹³ *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared for The Coalition for Community Pharmacy Action by Grant Thornton, LLP (January 2007), available at http://www.rxaction.org/publications/COD_Study.cfm. The cost of dispensing per pharmacy treats every pharmacy equally, regardless of prescription volume. It is higher than the cost of dispensing per prescription because high-volume, lower-cost stores are weighted more heavily in this statistic.

The proposed definitions of an innovator multiple source drug and a multiple source drug require there to be two or more drug products that are therapeutically, pharmaceutically and bio-equivalent on the market in the United States. Furthermore, although the definition of a single source drug recognizes products approved by the FDA under a new drug application (NDA), a biologics license application (BLA) or an antibiotic approval, the definition of an innovator multiple source drug only reaches products initially marketed under an original NDA. None of these definitions reaches the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the United States happens to be a version of the product that was originally approved by the FDA under an abbreviated new drug application (ANDA). CMS should revise the definitions to correct this oversight.

The Proposed Rule also does not define "covered outpatient drug" but rather lets stand without elaboration the definition of covered outpatient drug in the Medicaid Drug Rebate Statute at Social Security Act § 1927(k)(2). That statutory definition reaches beyond drugs approved by the FDA under NDAs, BLAs, antibiotic approvals or ANDAs to over-the-counter (OTC) products that have been prescribed by a physician. To capture the full breadth of the Medicaid drug benefit, we recommend including a definition of covered outpatient drug in the Final Rule that addresses both OTC and prescription drug products. The statutory definition of covered outpatient drug also incorporates grandfathered products and drugs still undergoing the DESI review process. The Proposed Rule's definitions of single source, innovator multiple source and multiple source drugs do not, however, reach all of the products that came to market before 1962, and remain commercially available today. To avoid any ambiguities, HDMA suggests CMS revise the definitions of multiple source, innovator multiple source and single source drugs to address these gaps.

National Drug Code

The Proposed Rule defines NDC at 42 C.F.R. § 447.502 to mean "the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size." We would like to point out that the FDA maintains 10-digit NDCs configured in three segments (i.e., 5-4-1, 5-3-2, or 4-4-2 formats), not 11-digit NDCs, to identify drugs.¹⁴ Manufacturers create the 11-digit NDCs that are used by Medicaid by inserting a placeholder zero in the official 10-digit numerical codes maintained by the FDA to permit proper computer manipulation of product NDCs.

HDMA recognizes CMS has administered the Medicaid drug rebate program since 1991 using 11-digit NDC codes. We also realize federal and state systems for processing manufacturer price reports, pharmacy claims

¹⁴ 21 CFR § 207.35(b)(2)(i) and (ii) state:

(i) The first 5 numeric characters of the **10-character code** identify the manufacturer or distributor and are known as the Labeler Code...

(ii) The last 5 numeric characters of the **10-character code** identify the drug and the trade package size and type... [emphasis added].

Further, FDA has recently proposed changes in its regulations regarding the NDC system, including assignment and use of the NDC number (*Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs*. Docket No. 2005N-0403, 71 Fed. Reg. 51276, (August 29, 2006)). To define the code number, FDA proposed the following language in 21 CFR § 207.33(a):

What is the NDC number? The NDC number is a unique **10 digit number** with 3 segments. The three segments are the labeler code, the product code, and the package code... [emphasis added].

and rebate invoices all run off 11-digit NDCs. We are not proposing that CMS or the states move away from the 11-digit NDC format in their Medicaid systems. We know, for technical reasons, the 11-digit format has become the standard for all commercial and industrial purposes. Our members also use NDCs formatted as 11-digit numbers for the same reason Medicaid does – because computers cannot read spaces or hyphens and cannot adequately distinguish between drugs coded using a segmented 10-digit system. Nonetheless, we recommend that, for the sake of clarity, CMS revise the definition of NDC in the Proposed Rule to more accurately reflect the current regulatory landscape. A better approach would be to define NDC as “the segmented, 10-digit numerical code maintained by the FDA that indicates the labeler, product and package size, and that for commercial and technical reasons, must be converted to an unsegmented 11-digit number by inserting a place-holding zero”.

More importantly, we also wish to draw to CMS’ attention to a recently published FDA proposed rule¹⁵, which contemplates changes in the NDC system maintained by the FDA. Specifically, FDA noted it may consider switching from the 10-digit code to an 11- or 12-digit code because the FDA is concerned it may “run out” of numbers. In its public comments to FDA, HDMA pointed out that any changes to the current 10-digit FDA configuration will have enormous repercussions throughout the supply chain, including, but not limited to, compliance with international standards and existing regulations that govern the bar coding of pharmaceutical products. Additionally, we pointed out that the discrepancy between the FDA and CMS NDC definitions suggests any change by FDA to an 11- or 12-digit code could, at a minimum, result in confusion as to the appropriate code to use to meet Medicaid reporting requirements. We would like to make CMS aware of this concern and recommend to CMS, as we have to FDA, that the agencies consult with one another prior to finalizing their rules so that, to the extent possible, they determine how best to harmonize their use and definition of the national drug codes.

Determination of AMP – 42 C.F.R. § 447.504

Customary Prompt Pay Discounts

Express Exclusion from AMP.—The DRA changed the statutory definition of AMP at Social Security Act § 1927(k)(1) by deleting a phrase in the original definition stipulating that customary prompt pay discounts (CPPDs) paid to wholesalers were to be deducted. We were concerned that CMS might take a similar tack and remain silent about the handling of CPPDs in the Proposed Rule, implying, because they were not discussed, that the discounts should not be considered as part of the AMP calculation. We, therefore, applaud the decision to include language in the Proposed Rule expressly instructing manufacturers not to deduct CPPDs given to wholesalers when they determine AMP.

Definition of CPPDs.—We endorse the definition CMS has crafted for the term “customary prompt pay discount.” We are particularly pleased the agency resisted the temptation to integrate specific payment amounts or time terms in the definition. We suspect that some manufacturers may ask CMS to further define what is “routine” (e.g., how frequently and consistently does a discount have to be offered to be routine? Can prompt pay terms be routine if they are regularly used with one customer only, or must the same terms apply to multiple customers? Most customers? All customers?), what is “prompt?” (e.g., 30 v. 60 v. 90 days?) and possibly even whether what is prompt may vary depending on the circumstances (e.g., product launch v. ongoing sales), etc.

¹⁵ 71 Fed. Reg. 51276 (August 29, 2006).

Although we would welcome discussion of such issues in the preamble, we encourage CMS to maintain the proposed definition in the Final Rule. This approach allows manufacturers and wholesalers enough flexibility to negotiate payment terms, including CPPDs, appropriate to their particular situations and to changing commercial conditions, such as interest rate fluctuations. Flexibility also will foster continued competition in the healthcare distribution business – competition that has promoted consistent gains in productivity and driven down the cost of distribution significantly over the last decade.

Cash Discounts v. CPPDs—We recognize the Proposed Rule explicitly instructs manufacturers to exclude customary prompt pay discounts extended to wholesalers when they calculate AMP. We note, however, that many in the industry have historically referred to “prompt pay discounts” as “cash discounts.” We are concerned that some could inadvertently read certain provisions of the Proposed Rule instructing the deduction of cash discounts too broadly. We ask that you guard against this contingency by adding a parenthetical reading “(except customary prompt pay discounts extended to wholesalers)” after the term “cash discount” in proposed 42 C.F.R. § 447.504(d) and 447.504(i). Further, if you accept our recommendation, discussed below, to completely exclude CPPDs extended to wholesalers from the determination of Best Price, similar clarifying language would be needed in 42 C.F.R. § 447.505 (e)(1).

Definitions of Wholesaler and Retail Pharmacy Class of Trade

Wholesaler Definition. – Proposed 42 C.F.R. § 447.504(f) defines “wholesaler” in an overly expansive fashion, including within the reach of the definition not only traditional full-service wholesalers and specialty distributors but also pharmacy chains, pharmacies and PBMs. This definition is inconsistent with the provisions of the Food Drug and Cosmetic Act incorporating the Prescription Drug Marketing Act (PDMA)¹⁶, and with the definitions of “wholesale distributor,”¹⁷ “wholesale distribution”¹⁸ and “distribute”¹⁹ in the FDA regulations that govern prescription drug marketing. Read together, the FDA regulatory definitions – although in their own right, quite broad – limit wholesalers to entities engaged in selling, offering to sell, delivering, or offering to deliver drugs to persons other than a consumer or patient.

We agree that warehousing pharmacy chains and warehousing mass merchant and supermarket pharmacy operations should be treated as wholesalers. They, like traditional wholesalers and specialty distributors, buy drugs directly from manufacturers and/or other wholesalers, consolidate orders for products from a variety of sources, and distribute the drugs, often by the single bottle or vial, to pharmacies within their chain that, in turn, resell the drugs at retail to consumers who present a prescription. Warehousing chains and warehousing mass merchants and supermarkets are licensed as wholesalers under state laws implementing the requirements of the PDMA.

We object to identifying individual pharmacies, including mail-order pharmacies operated by PBMs, as wholesalers. Simply put, these entities sell drugs to consumers and patients, and they rarely function as or are licensed as wholesalers. Their inclusion in the proposed definition of wholesaler is antithetical to the concept of wholesale distribution, as that term has been defined by Congress and the FDA.

¹⁶ P.L. 100-293.

¹⁷ 21 CFR § 203.2(dd).

¹⁸ 21 CFR § 203.2(cc).

¹⁹ 21 CFR § 203.2(h).

We recognize the Medicaid Drug Rebate Agreement has characterized pharmacies as wholesalers since 1991, but, in our view, that definition was added to the Agreement to clarify that manufacturers should include direct sales, as well as indirect sales to pharmacies, in the calculation of AMP in light of a statute that defines AMP as the “average price paid to the manufacturer . . . by wholesalers for drugs distributed to the retail pharmacy class of trade. . . .”²⁰ The way CMS chose to structure the definition of “wholesaler” in the Rebate Agreement demonstrates CMS’ belief it has the statutory authority to capture both direct and indirect pharmacy sales in AMP, despite the words of the statutory definition, because such an approach reflects Congressional intent.

We agree with CMS’ interpretation of Congressional intent. We also recognize the logic of requiring the inclusion of both direct and indirect retail pharmacy sales in AMP. After all, beginning this spring, AMP likely will be the pharmacy reimbursement metric for most multiple source drugs. Moreover, depending on the actions of state Medicaid programs, AMP could become the pharmacy reimbursement metric of choice over the next few years in many, if not most, jurisdictions for single source drugs as well.

We note the CBO recently reported that independent pharmacies purchase 98% of their drugs through wholesalers.²¹ We ask that CMS incorporate direct retail pharmacy sales in AMP without adopting a strained, overly broad definition of wholesaler. It should be sufficient to include a provision in the Final Rule expressly stating that net sales to retail pharmacies are to be included when AMP is calculated, but CMS could avoid all ambiguity about the requirement to include direct pharmacy sales in AMP by adding the parenthetical “(direct and indirect)” after the word “Sales” at the beginning of proposed 42 C.F.R. § 447.504(g)(5).

We are particularly troubled by the inclusion of PBMs in the definition of wholesaler. We view the mail-order pharmacies that are operated by many PBMs as an ancillary PBM line of business, and we have already explained above why individual pharmacies, including PBM mail-order operations, should not be classified as wholesalers. That said, at their core, we consider PBMs to be health plan contractors tasked with: (1) developing and administering prescription drug formularies, (2) organizing networks of retail pharmacies that will accept plan enrollees’ drug cards and dispense drugs to them under coverage and co-pay terms dictated by the plan and (3) adjudicating and processing claims for drugs submitted by those network pharmacies. Because the use of formularies permits health plans and the PBMs with which they contract to drive market share, PBMs are able to negotiate concessions from manufacturers of single source drugs in competitive therapeutic categories in exchange for formulary position and enhanced market volume. Those concessions are paid to the PBMs on sales of formulary drugs made through their retail pharmacy networks in the form of rebates because the plans and their PBMs do not buy, take title to, deliver, or otherwise distribute drugs.²²

PBMs are only involved with paying network pharmacies for the drugs they dispense to enrollees in the health plans the PBMs serve. PBMs play no role in the arrangements manufacturers, wholesalers and group purchasing organizations make with brick-and-mortar pharmacies for the sale of drugs used to stock in-store inventories. PBMs neither purchase nor take possession of drugs dispensed by the pharmacies in their retail pharmacy networks. Given that PBMs are not part of the supply chain, it is a perversion of the concept of

²⁰ Social Security Act § 1927(k)(1).

²¹ *Prescription Drug Pricing in the Private Sector*, Congressional Budget Office (January 2007), p 5, available at <http://www.cbo.gov/ftpdocs/77xx/doc7715/01-03-PrescriptionDrug.pdf>.

²² *Id.* at p 2.

wholesale distribution, as the term has been defined by the FDA – and as the term is generally understood in virtually all other industries aside from pharmaceuticals – to characterize PBMs as wholesalers.

We urge CMS to rethink the definition of wholesaler at proposed 41 C.F.R. § 447.504(f). We advocate aligning that definition with the definitions of wholesale distributor, wholesale distribution and distribute in the FDA regulations implementing the PDMA. We also suggest including a statement in the preamble to the Final Rule saying CMS has conformed its definition to the approach taken by the FDA in the PDMA regulations. Our recommended approach would require CMS to eliminate pharmacies, including mail-order pharmacies and PBMs, from the parenthetical expounding upon the meaning of the term “entity” in the definition of wholesaler. It would be appropriate, instead, to clarify the meaning of entity in an explanatory parenthetical listing full-service wholesalers, specialty distributors, warehousing chain, and warehousing mass merchants and supermarkets that operate in-store pharmacies in some or all of their outlets. Depending upon whether CMS has made clear the connection between its definition for wholesaler and the FDA definitions in the PDMA regulations, CMS also could include the other types of entities detailed in 21 C.F.R. § 203.2(dd) in the explanatory parenthetical. As discussed above, CMS could then expressly capture direct sales to retail pharmacies in the calculation of AMP simply by modifying 42 CFR § 447.50(g)(5).

Retail Pharmacy Class of Trade. – We agree with CMS that the *sine qua non* of the retail pharmacy class of trade is public access. For that reason, as we will explain in more detail below, we disagree with including sales to mail-order pharmacies (or the PBMs that own them) in the list of entities in 42 CFR § 447.504(e) that define the retail pharmacy class of trade.

We also object to the inclusion of PBMs in that list. PBMs contract with retail pharmacies to offer pharmacy services at prearranged prices to enrollees in the health plans they represent. Negotiating insurance payment terms is not the same thing as arranging for the purchases of drugs that pharmacies make from their manufacturer and wholesaler vendors. Retail pharmacies hold two sets of contacts – one with vendors for the purchase of drugs and another with payers setting reimbursement terms. These two sets of contracts are negotiated independently. Reimbursement terms in pharmacies’ payer contracts do not affect the prices they pay manufacturers and wholesalers for the drugs they dispense. Similarly, the contract terms manufacturers negotiate with PBMs and, indirectly, with the health plans they represent, are independent of the chargeback contracts the manufacturers hold with pharmacies. They simply do not affect the net prices manufacturers are paid by wholesalers and retail pharmacies for drugs dispensed to the general public. Accordingly, under the controlling statutory definition of AMP, the contract terms between manufacturers and PBMs should not be factored into the determination of AMP. The statutory definition of AMP does not permit CMS to focus on the amount realized by a manufacturer on a drug sale net of all expenses, including PBM rebates, associated with the sale. Rather, the statute requires CMS to look to the amount actually paid to the manufacturer by customers in the retail pharmacy class of trade to define AMP. Those customers are, in our view, independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Long-Term Care Facilities, Including Nursing Home Pharmacies

HDMA agrees long-term care (LTC) facilities and the pharmacies that serve them do not sell prescription drugs to the general public and should not be considered entities involved in the retail pharmacy class of trade under the definition CMS has put forward for that concept in proposed 42 C.F.R. § 447.504(e). We, therefore, strongly support CMS' decision to reverse the position taken in Manufacturer Release No. 29 and to exclude sales to LTC entities from the calculation of AMP.

Mail-Order Pharmacies

We are opposed to the inclusion of sales to mail-order pharmacies in the calculation of AMP. The definition CMS has suggested for retail pharmacy class of trade at proposed 42 C.F.R. § 447.504(e) turns on drugs being sold or provided to the general public. Indeed, the reason CMS gave for excluding sales to LTC pharmacies from the calculation of AMP was that those pharmacies are closed operations that serve only the residents of specific LTC facilities, not pharmacies that are open to the general public. The same is true for mail-order pharmacies, the vast majority of which are affiliated with PBMs or with health plans that administer pharmacy benefits internally. These mail-order pharmacies are not open to the general public. Access to any particular mail-order pharmacy is limited to individuals enrolled in a health plan with a mail-order option that is sponsored by the organization that operates the pharmacy or that contracts with the PBM that operates the pharmacy. In other words, mail-order pharmacies are closed operations in the same way that LTC pharmacies are closed operations. CMS can verify the closed nature of mail-order pharmacies by assessing the operations of PDPs and MA-PDs under contract with Medicare Part D, or by checking with OPM staff responsible for contracting for and overseeing the pharmacy benefits available to enrollees in Federal Employee Health Benefits Plans.

Mail-order pharmacies fail the public accessibility test in another important way. Because of the turn-around time on order processing and delivery, mail-order operations cannot adequately meet the acute pharmacy care needs of the limited population of individuals permitted to use them. Even those health plan enrollees with mail-order access need to turn to a conventional brick-and-mortar pharmacy for antibiotics and other drugs when treatment needs to begin immediately or when the expected treatment regimen involves only a single course of therapy lasting a matter of days to a few weeks.

If access available to the general public is the *sine qua non* for the retail pharmacy class of trade, mail-order pharmacies simply do not fit the class because they are closed operations. It seems illogical to us to include mail-order sales in AMP when sales to HMOs and managed care organizations (MCOs) are excluded. After all, most of the health plans that offer a mail option, either through an internal pharmacy operation or under contract with a PBM, are MCOs. Furthermore, even for those health plan enrollees eligible to use them, mail-order pharmacies are incapable of providing the full range of their pharmacy care needs. We believe these operational facts give CMS little choice but to reverse the position it took in Manufacturer Release No. 29 and in the Proposed Rule and, instead, add sales to mail-order pharmacies to the list of sales that must be excluded from the AMP calculation. Of course, doing so would also eliminate the need for manufacturers to net out rebates paid to PBMs and health plans on sales of drugs to their mail-order operations when they determine AMP.

We understand most manufacturers currently code mail-order pharmacy sales and brick-and-mortar pharmacy sales as sales to different classes of trade because mail-order pharmacies buy in pallet quantities, not the bottle and vial quantities that conventional pharmacy outlets need to stock their shelves. As a result, a decision to exclude mail-order pharmacies from the AMP calculation should not present operational difficulties for manufacturers.

PBM Rebates

CMS acknowledges in the preamble to the Proposed Rule that it has been criticized by both the GAO and the OIG for failing to provide clear instructions to manufacturers about the proper handling of rebates paid to PBMs in the calculation of AMP. It declares, however, that its historic position has always been that "PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement."²³ Since the Rebate Agreement defines wholesaler as "any entity . . . to which the labeler *sells* the Covered Outpatient Drug . . . (emphasis added)"²⁴ and since PBMs do not purchase drugs to support the retail pharmacy side of their operations, we must conclude that historically CMS did not intend for manufacturers to include in AMP rebates paid to PBMs on sales made through their network pharmacies.

The Proposed Rule reverses the position CMS claims to have taken in the past. In addition to the proposed definition of wholesaler that expressly, but inappropriately, includes PBMs (discussed above), the Proposed Rule contains a provision at 42 C.F.R. § 447.504(g)(6) mandating that the AMP for a covered outpatient drug "shall include . . . discounts, rebates, or other price concessions to PBMs associated with sales for drugs provided to the retail class of trade." The preamble explains CMS' reversal of position by saying the agency is concerned that its previous position "exclude[s] from AMP certain PBM prices and discounts which have an impact on prices paid to the manufacturer. We believe that AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer."²⁵

CMS' explanation for its proposed handling of PBM rebates focuses on the total costs that manufacturers incur to market their single source drugs. It combines discounts on drug sales to the retail pharmacies that actually buy branded products to dispense to their customers with payments manufacturers elect to make to PBMs for formulary placement and market share - even though the CBO concluded "[p]harmacies do not benefit from the rebates that manufacturers give to PBMs."²⁶ Rather, the PBM rebates are shared with the PBM's health plan customers.²⁷

²³ 71 *Fed. Reg.* at 77179.

²⁴ Medicaid Drug Rebate Agreement at Art. I(ee).

²⁵ 71 *Fed. Reg.* at 77179.

²⁶ *Prescription Drug Pricing in the Private Sector* at p 12 (footnote 22).

²⁷ *Id.* at p 2 stating "Retail pharmacies . . . negotiate drug prices with wholesalers or pharmaceutical manufacturers. In the retail pharmacy market, there are two additional negotiations: one between health plans or self-insured employers and the manufacturers and the other between health plans or self-insured employers and retail pharmacies. The health plans or self-insured employers often contract out those two additional negotiations to pharmacy benefit managers (PBMs). PBMs that organize a large number of patient under a formulary . . . obtain discounted prices on many brand-name drugs in the form of rebates from manufacturers, which are in turn shared with health plans or self-insured employers (emphasis added)."

CMS' focus on the net revenues realized by manufacturers is misplaced. The Proposed Rule implements the DRA, a statute that was intended, in large part, to reduce Medicaid reimbursement to retail pharmacies, directly by revamping the formula for setting the FULs that cap payments on multiple source drugs and indirectly by providing states with data that will permit them to integrate AMPs into reimbursement formulas for both brand and multiple source drugs. The intended objective of the DRA is to reform Medicaid drug reimbursement in a way that reflects the actual acquisition costs of the pharmacies that serve Medicaid recipients. In most instances, these are chain or independent pharmacies with stores in communities where Medicaid beneficiaries live. Including rebates paid to PBMs on pharmacy networks sales in the AMP calculation defeats the purpose for the single source drugs subject to such rebates.

CMS' proposal for deducting PBM rebates when AMP is calculated also is contrary to the statutory definition of AMP at Social Security Act § 1927(k)(1) (as amended by the DRA), and to the definition of AMP in the Rebate Agreement. Both definitions say AMP is "the average price *paid to* the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (emphasis added)." Rebates *paid by* the manufacturer to a PBM that does not buy or take possession of drugs simply do not qualify. They are not part of the price paid to the manufacturer by the pharmacies in the PBM's retail pharmacy network because those pharmacies do not share in the PBM rebates. CMS does not have the statutory authority to reinterpret the definition of AMP to focus on the net revenues realized by manufacturers instead of the net costs incurred by retail pharmacies for the drugs they dispense.

CMS ignores the change it made in instructions for handling PBM rebates completely in the Proposed Rule's impact analysis. Rather, it estimates only the reductions in reimbursement for multiple source drugs that retail pharmacies will experience because of the changes in the way FULs are set. The impact of the Proposed Rule's handling of PBM rebates on pharmacies likely would be significant, however. AMPs for single source drugs probably would be lower, on average, by more than \$6.00 per prescription.²⁸ Moreover, even though about half the prescriptions paid for by Medicaid are for multiple source products,²⁹ those prescriptions only constitute about 15% of the program's total drug spend.³⁰ Pharmacy revenues are largely attributable to single source drugs even though pharmacy margins may be higher on generics.

Finally, although PBMs only collect rebates on single source drugs,³¹ CMS' position on the handling of these rebates will have a negative impact on state Medicaid budgets. The OIG found that some manufacturers do not currently view transactions with PBMs as sales and, therefore, do not net PBM rebates out when they calculate AMP.³² It observed, too, that other manufacturers only include a portion of their PBM rebates in AMP.³³ As a result, the Proposed Rule's treatment of PBM rebates will lead to lower AMPs and lower rebate payments on some single source products. We do not have access to the data needed to estimate the total revenue reduction, but we are confident the losses will be significant, since the CBO recently reported state Medicaid programs

²⁸ *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, FTC (August 2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

²⁹ *Generic Drug Utilization in State Medicaid Programs*, OIG (OEI-05-05-00360 (July 2006), p 9.

³⁰ *Payments for Prescription Drugs under Medicaid*, CBO Testimony of Douglas Holtz-Eakin, Director, before the Special Committee on Aging, United States Senate (July 20, 2005), available at <http://www.cbo.gov/showdoc.cfm?index=6564&sequence=0>.

³¹ *Prescription Drug Pricing in the Private Sector* at p 12; *Pharmacy Benefit Managers* at 50-55.

³² *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005*, OIG (A-06-06-00063) (May 30, 2006).

³³ *Id.*

received rebates in 2003 on single source drugs that were, on average, equal to 31.4% of AMP.³⁴ Further, the CBO observed that the percentage of state Medicaid revenues tied to rebates on single source drugs has been trending upward.

Outpatient Hospital Sales

Those hospitals that operate pharmacies open normal commercial hours for walk-up business from the general public typically contract separately for drugs used in these retail pharmacy operations. We agree sales to such pharmacies – which in our experience are more the exception than the rule – should be aggregated with sales to more conventional brick-and-mortar retail pharmacy outlets and treated as sales to the retail pharmacy class of trade for purposes of the AMP calculation.

That said, we disagree with categorizing other prescription drug sales to hospitals as sales to the retail pharmacy class of trade unless the drugs are used in the inpatient setting. The Proposed Rule makes access to the general public the *sine qua non* of the definition of the retail pharmacy class of trade. Hospital outpatient departments simply do not fit that definition because they are not publicly accessible. Rather, they are served by institutional pharmacies that only dispense drugs furnished to patients who have been admitted to the hospital for either inpatient or outpatient services. The Medicare Hospital Conditions of Participation, which apply to the vast majority of acute care hospitals in the United States, support treating inpatient and outpatient drug sales to hospitals in a uniform fashion for purposes of the AMP calculation in that they require hospital outpatient services to be “appropriately organized and integrated with inpatient services.”³⁵

Aside from being inconsistent with the definition of the retail pharmacy class of trade, the proposed distinction in the treatment of hospital sales based on where in the facility a drug is furnished is highly impractical and cost-inefficient. The pharmacy management practices of 340B disproportionate share (DSH) hospitals should not influence CMS’ thinking about the reasonableness of treating outpatient hospital sales as retail sales for AMP purposes because all outpatient and inpatient sales at 340B prices are excluded from the AMP calculation for other reasons. In our experience, however, unless hospitals are 340B Covered Entities, they do not buy or contract separately with pharmaceutical manufacturers or with GPOs for drugs intended for patients admitted for inpatient care and those admitted for outpatient care. They do not order separately from our members for inpatient and outpatient uses and they do not inventory drugs separately for such uses. As a result, we suspect that most manufacturers do not currently operate granular enough contract administration systems to distinguish hospital sales used in the inpatient setting from hospital sales used in the outpatient setting. Our member companies certainly anticipate a Final Rule that distinguishes between inpatient and outpatient hospital sales will result in additional work for wholesalers. Wholesalers would need to set up separate accounts; maintain more contracts; submit and track more chargebacks; and pick, pack and ship more deliveries. Such work would inevitably reduce efficiency and increase the cost of distributing drugs to our hospital customers. We suspect our hospital customers have similar concerns about the potential impact on their operating costs.

Before CMS moves forward with a Final Rule that treats hospital sales differently depending upon where in the hospital a particular unit of drug is administered, it should assess the impact on the hospital industry. Any increase in costs attributable to hospitals having to negotiate twice as many drug purchase agreements, process

³⁴ Payment for Prescription Drugs under Medicaid at Table 2.

³⁵ 42 CFR § 482.54.

twice as many drug purchase orders and maintain two different drug inventories merely to support the price-reporting needs of their pharmaceutical vendors will flow, in significant measure, to the Medicare and Medicaid programs.

CMS also needs to consider another practical implication of treating inpatient and outpatient hospital sales differently for AMP purposes. Because many hospital contracts for the purchase of prescription drugs would have to be renegotiated and because data on sales under new contracts would take time to work through the chargeback system, we doubt most manufacturers would be in a position to reliably report on hospital sales in accordance with the provisions of the Proposed Rule for six months to a year. This reality could necessitate a delay in the implementation of the AMP rule that we suspect CMS and Congress would find unacceptable.

Administrative, Service and Distribution Fees

The Proposed Rule includes a provision at 42 C.F.R. § 447.504(i)(1) that purports to further clarify elements of the AMP calculation. That provision states:

AMP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, PBM price concessions, chargebacks, incentives, administrative fees, service fees, [sic] (except bona-fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

We are troubled by three aspects of this instruction. We encourage CMS to address all three concerns when it publishes the Final Rule.

First, this provision again combines fees, discounts and other concessions offered to purchasers of drug products with payments made to third parties like PBMs and GPOs that do not purchase or take possession of drugs and that, in the case of GPOs, are not even a payer for drugs. The provision suggests all concessions to non-purchasers should be deducted when AMP is calculated. As we discussed earlier in our comments on the Proposed Rule's inclusion of PBMs in the definitions of wholesaler and retail pharmacy class of trade and its handling of PBM rebates, payments that manufacturers make to entities that are not purchasers of their products are outside the bounds of the statutory and Rebate Agreement definitions of AMP, and should not be deducted when AMP is calculation. For that reason, we find this provision overly broad in its reach. We hope CMS will limit the provision to price reductions and other payments that flow to purchasers, and expressly exclude payments that flow to third parties not involved in the purchase transaction.

Second, the provision clouds the issue of the proper handling of *bona fide* service fees and appears to create distinctions between administrative fees, service fees and distribution fees that do not always exist. Although it is a minor point, the placement of the comma between "service fees" and the parenthetical that excludes *bona fide* service fees from the AMP calculation leaves the reader wondering what the parenthetical modifies. In most instances, *bona fide* service fees paid to wholesalers and distributors include compensation for distribution services. Furthermore, administrative fees – a term typically used to describe fees manufacturers pay to GPOs and PBMs to support the contracting functions those entities perform on behalf of numerous buyers or health plans – meet the definition of a *bona fide* service fee under a variety of circumstances. Other fees paid to PBMs

for administering fill compliance and other programs also may comport with all the elements of the *bona fide* service fee definition. We recommend that CMS clarify, either in § 447.504(i)(1) itself or by adding a new paragraph to the subsection, that all fees that manufacturers pay to customers or third parties meeting the definition of a *bona fide* service fee are to be excluded from the calculation of AMP.

Third, as we discussed earlier in our comments on customary prompt pay discounts extended to wholesalers, the Final Rule needs to clarify, by the inclusion of a parenthetical after the term “cash discounts”, that only those cash discounts that fail to qualify as wholesaler customary prompt pay discounts are to be deducted when AMP is calculated.

Returns

HDMA commends CMS’ decision to exclude returns from the calculation of AMP. We agree that doing so will help smooth out period-to-period variations in AMP that are incompatible with the use of the statistic as a reimbursement metric.

Nominal Sales

We agree with the Proposed Rule provision directing manufacturers to exclude nominal sales from the AMP calculation. It would be unfair to allow deeply discounted prices offered only to safety-net providers, and not available in commercial transactions, to put downward pressure on AMPs and, in turn, depress Medicaid reimbursement available to retail pharmacies.

Determination of Best Price – 42 C.F.R. § 447.505

Customary Prompt Pay Discounts

We were surprised by CMS’ decision to require manufacturers to consider CPPDs extended to wholesalers when they determine the Best Price of single source or innovator multiple source drugs. CMS justified its decision by saying it “can find no evidence in the legislative history of the DRA that Congress intended to change the definition of best price to exclude customary prompt pay discounts.”

We acknowledge the DRA did not change the definition of Best Price at Social Security Act § 1927(c)(1)(C). We also recognize the statute says Best Price is “the lowest price available from the manufacturer . . . to any wholesaler, . . .” However, we are of the view that CPPDs extended to wholesalers are not price concessions and, therefore, should not have to be deducted under the statutory definition of Best Price. Rather, wholesaler CPPDs are payments to the wholesaler that recognize the time value of money to the manufacturer. In addition, CPPDs compensate wholesalers for assuming the credit risks associated with the sale of the manufacturer’s drugs to customers that dispense the products at retail, or use them in their healthcare operations. In essence, CPPDs are more akin to *bona fide* service fees than they are to price concessions. Thus, in our view, the lowest price available to a wholesaler is not a price net of CPPDs, but rather the stated contract price, which is typically WAC.

HDMA was very involved in the legislative debate over the DRA, and it was particularly focused on the CPPD issue. We understood Congress ultimately decided to amend the Medicaid Drug Rebate Statute to exclude CPPDs extended to wholesalers from the calculation of AMP because it recognized the discounts were retained by wholesalers and not passed on to end-consumers as price concessions. Simply put, Congress wanted AMP to be a transactional price that reflects the prices available to end-customers in the market. Congress recognized that including CPPDs in AMP would distort AMP as a measure of average end-customer costs. This same logic suggests that manufacturers should not be required to include wholesaler CPPDs in Best Price either.

If CMS cannot see its way clear to completely excluded wholesaler CPPDs from the determination of Best Price, it should expressly indicate that manufacturers should not aggregate CPPDs paid to wholesalers with contract discounts offered to end-customers but administered through the wholesaler's chargeback system when they determine Best Price. Rather, they should look only to the contract prices in their chargeback contracts when they assess whether the Best Price for the rebate period was set by a particular contract sale. If CMS elects this approach, we would prefer to see such a clarification incorporated into proposed 42 C.F.R. § 447.505(e) as a separate numbered paragraph reading:

When Best Price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third-party buying group.

Requirements for Manufacturers – Proposed 42 C.F.R. § 447.510

Monthly AMP Calculation Methodology

The Proposed Rule provides scant guidance on how manufacturers should determine monthly AMP values. This lack of specificity is problematic from the perspective of pharmacies, since monthly AMPs will determine the FULs that will cap their payments for multiple source drugs dispensed to Medicaid recipients beginning sometime this spring. It also is problematic, in our view, to instruct manufacturers to devise their own procedures for estimating end-of-quarter rebates and allocating them to each month in a quarter. Such an approach puts manufacturers at risk of enforcement actions for estimation and allocation methodologies deemed inappropriate by government authorities after years of consistent good faith use. Moreover, the approach in the Proposed Rule fosters the very type of methodological variability from company to company that Congress intended to eliminate when it mandated the promulgation of an AMP regulation in the DRA. We offer as a reasonable solution the 12-month rolling percentage methodology discussed in our comments immediately below about a methodology for the handling of lagged data in the AMP calculation.

Methodology for Handling Lagged Data

The Proposed Rule does not set forth a methodology for dealing with lagged unit data or lagged discounts when monthly or quarterly AMPs are calculated. This deficiency is particularly troubling given that the Proposed Rule, in a reversal from prior instructions, directs manufacturers to consider sales and associated price concessions extended to SCHIPs and SPAPs when they determine AMP. Manufacturers have no way of knowing how many units of drug were dispensed to enrollees in these programs, or what their program rebate

liabilities will be until they receive quarterly rebate invoices from the states. Unfortunately, these invoices never arrive until long after the deadline for filing quarterly AMP reports under the Proposed Rule. Depending on the plan, Part D rebate demands also may arrive too late to be properly included in quarterly calculations. The same could be true about PBM rebate demands if CMS decides to continue requiring their inclusion in AMP under the Final Rule. It seems to us the only practical way to address the inevitable delays in the receipt of data critical to AMP calculations is to build instructions for processing lagged data into the Final Rule. We strongly recommend using a 12-month rolling percentage methodology, similar to that required in the ASP rule.

The current instructions for calculating AMP (and ASP) are silent on whether chargebacks, rebates and other lagged discounts should be accounted for on an as-paid or an as-earned basis. As a result, different manufacturers have adopted different approaches. Some use the as-paid methodology for both chargebacks and rebates. Others use as-paid for chargebacks because the amount of chargebacks paid during a period is readily available within a few days after the period closes, but use an accrual approach for rebates. Still others accrue for both chargebacks and rebates. Even if the Final Rule adds a methodology for handling lagged discounts, it will fail to eliminate all the variability in different manufacturers' AMP calculations unless the methodology expressly stipulates whether chargebacks, rebates or both are to be considered lagged data and whether discounts are to be accounted for on an as-paid or an as-earned basis.

Many large purchasers often buy pharmaceuticals – particularly multiple source drugs – in bulk and then sell from inventory for many months. This buying pattern can result in periods when a manufacturer's sales outstrip price concessions accounted for on an as-paid basis, leading to an artificially high AMP, followed by one or more periods when discounts outstrip sales, leading to an artificially low AMP. Monthly reporting of AMP could exacerbate this problem. If a manufacturer elects to address the problem by accounting for lagged discounts on an accrual basis, it must periodically true-up AMP and Best Price reports to address accrual errors. The instructions in the Proposed Rule for handling bundled sales also will necessitate true-ups in some instances. Such true-ups likely will tax the capabilities of the rebate processing teams at the state Medicaid programs. They definitely will tax the price reporting teams at the manufacturers now that they will be called upon to make at least 16 price-report filings a year, instead of the four that had been due for Medicaid.

More importantly, the true-up approach, while it does allow for the eventual payment of the correct amount of Medicaid rebates, is inconsistent with the use of AMPs prospectively as the reimbursement metric that will set FULs for multiple source drugs. True-ups also will complicate the use of AMPs by state Medicaid programs as a reimbursement metric in the formulas that determine payment amounts to retail pharmacies for single source and multiple source drugs dispensed to Medicaid patients. The need for true-ups becomes particularly troubling in the face of a Proposed Rule that stipulates manufacturers may not – barring extraordinary circumstances and only with permission from CMS – restate monthly AMPs, but notes, in the preamble, that CMS intends to use those monthly AMPs to set and update FULs.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time also can distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, HDMA encourages CMS to build a well-defined smoothing methodology for handling all price concessions – not just lagged concessions – and for handling lagged unit data that must be considered when AMP is determined. Ideally, that methodology would operate much like the 12-month rolling percentage methodology specified for quantifying lagged discounts under the ASP rule. However, for AMP

may not accurately reflect prices available in the market to retail pharmacies. Similar disclaimers should be sent to the states with their download tapes or new electronically-transmitted price report files. These disclaimers also should be reiterated in a State Medicaid Director Letter.

HDMA is pleased the Proposed Rule requires states to amend their state plans before changing their Medicaid pharmacy reimbursement formulas. We also applaud the caveats about the AMP data currently being downloaded to the states that CMS included in State Medicaid Director Letter No. 144 released in mid-December. We were pleased the letter recommended that states revise their dispensing fees when they implement changes in their formulas for reimbursing pharmacies for ingredient costs. We remain concerned, however, about states prematurely using AMP data for reimbursement purposes and inappropriately cutting pharmacy payments to levels that could reduce access to pharmacy services for Medicaid beneficiaries. We strongly urge CMS to use its authority to review and approve State Plan Amendments to prevent states from making precipitous changes before the Final Rule has been implemented and the "new" AMP data assessed.

Upper Limits for Multiple Source Drugs – 42 C.F.R. § 447.514

Monthly FULs

HDMA appreciates CMS' decision to wait until AMPs have been calculated without prompt pay deductions before it begins distribution of revised FULs. Ideally, however, for reasons similar to those discussed earlier concerning why CMS should delay posting AMPs on the Web, we encourage CMS to extend the delay in setting new FULs until the regulations defining AMP have been finalized and pricing statistics calculated under them submitted.

We are particularly concerned about the potential for underpayments to pharmacies if FULs are set prematurely based on AMPs that may be lower than the "new" AMPs reported under the Final Rule. Even if CMS makes no changes to the Proposed Rule, we would expect the exclusion of sales to long-term care pharmacies from AMP to increase the AMP for those products used heavily by residents in those facilities. AMP likely would be further increased if CMS accepts our recommendations to exclude mail-order pharmacy sales and PBM rebates as well.

Schedule for Establishment and Dissemination of Monthly FULs

The Proposed Rule does not discuss CMS' plans for using AMP data to set FULs beyond saying it intends to revise FULs monthly based on monthly AMP reports. Because FULs will be determinative of the maximum reimbursement amounts available on multiple source drugs to pharmacies in many states, we view the establishment of a predictable update schedule as critical. We recommend explaining what that schedule will be in the Final Rule. We also suggest coordinating the posting of AMP data on the CMS Web site with the effective date of updated monthly FULs based on the posted monthly AMPs.

FULs Representative of the Most Commonly Purchased Package Size

We understand the Proposed Rule would require FULs to be set at 250% of the lowest AMP (calculated without regard to customary prompt pay discounts) whenever two or more suppliers have A-rated therapeutic

The example in the following table illustrates the outlier methodology we endorse.

Table 1 - Scenario:

Product at 11-Digit NDC Level	Price	Units	Cuml. Units	Cuml. Share
A	\$ 0.30	100	100	0.1%
B	\$ 1.50	400	500	4.76%
C	\$ 4.50	6000	6500	62.2%
D	\$ 5.00	3500	10000	95.24%
E	\$ 5.50	500	10500	100%

Market Share Sensitive AMP = \$4.50 (lowest price @50% market share (5250 units))
FUL per Proposed Regulation = \$3.75 (250% x \$1.50)

The table illustrates a reporting period for which manufacturers submitted monthly AMPs for five NDCs of a given drug/strength/dosage form of a multiple-source product of \$0.30, \$1.50, \$4.50, \$5, and \$5.50, with corresponding sales volumes of 100 units, 400 units, 6,000 units, 3,500 units, and 500 units. Under our recommended outlier methodology, the first two AMPs would be classified as outliers because collectively these NDCs represent less than 5% of the cumulative market demand. The FUL would be set based on the \$4.50 price because the 6,000 units available at that price, added to the previous 500 units (100 + 400) sold at lower AMPs would cross the 50% market share threshold. In other words, \$4.50 is the lowest AMP for product that is available for sale nationally. This contrasts with a FUL of \$3.75 (250% x \$1.50) under the price-based outlier methodology described in the Proposed Rule – a FUL that, in this example, would not be representative of prices for more than 95% of the market, and would likely result in actual losses on most Medicaid sales.

If CMS prefers to rely on an outlier methodology that uses price as a proxy for national availability rather than a methodology that relies directly on market share data, it would be more appropriate, in our view, to reject as an outlier any AMP that is 50% or less of the next highest AMP. As the Proposed Rule now stands, if the lowest AMP for a product were \$0.31 and the next lowest AMP were \$1.00, the outlier procedure would not be triggered despite the fact that the product's FUL would be only \$0.78 – an amount less than the next lowest AMP. Under the revision to the price-based approach that we have suggested, when an AMP of \$0.51 is accepted as the basis for setting FUL in the face of a next lowest AMP of \$1.00, the FUL of \$1.28 may or may not be enough to permit a pharmacy to sell product to Medicaid recipients without losing money. Further, any price outlier test should be applied iteratively until the lowest AMP that is not more than the specified percentage below the next lowest AMP is selected, even if satisfying that criteria requires rejecting a number of lower AMPs.

Even with these suggested modifications, we are convinced that a price-based approach to outlier identification will be inadequate. Suppose for example the AMPs on a particular multiple source product were \$0.30, \$0.50, \$0.90, \$3.00, \$3.25, and \$3.50 in one reporting period. Even with the modifications we have suggested for improving the price-based outlier methodology, this product's FUL would be set at \$0.75 (250% x \$0.30) simply because the most deeply discounted prices is less than 50% below the next lowest AMP. While it is

likely that most of the product on the market would cost at least \$3.00, pharmacies would be left facing a cost cap that covers a quarter or less of their acquisition costs for the product.

Background – Retail Survey Price

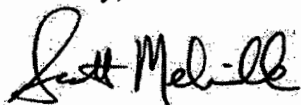
We had hoped CMS would address implementation issues related to DRA § 6001(e) in the Proposed Rule. We were looking forward to the opportunity to comment on how and from what sources data underlying RSP should be collected and how the data should be used to determine “a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)”³⁹ since the DRA defines RSP but provides little other substantive guidance on RSP-related issues. For example, because RSP is supposed to be representative of “consumer purchase prices” at retail, we wanted to talk about how CMS and its vendor would ensure only pharmacies within the retail class of trade are surveyed. We wanted to speak to how CMS would ensure valid results by structuring surveys to include an appropriate sample size and geographic distribution. We also wanted to discuss other steps that could be taken to ensure that RSP data is true to the statutory requirement to capture the out-the-door prices pharmacies charge consumers.

We note Medicaid Drug Rebate Program Release No. 144 for State Medicaid Directors dated Dec. 15, 2006 – a week before the Proposed Rule was published in the *Federal Register* – advises states that CMS will begin disseminating a monthly national survey of retail prices beginning in January 2007. We take that promise to mean CMS is moving forward with plans to implement DRA § 6001(e). That said, we strongly urge CMS to engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures the RSP contractor will be tasked with using when it collects, aggregates and disseminates RSP data. Including stakeholders in the regulatory and sub-regulatory processes relating to the implementation of DRA § 6001(e) likely will allow the development of RSP policies and procedures that anticipate issues associated with data availability and adequacy, reflect a more nuanced approach to data collection and analysis, and, in the end, result in the dissemination of RSP data that is – as the DRA mandates – representative of consumer purchase prices at retail for outpatient prescription drugs.

* * * * *

In closing and on behalf of HDMA and our member companies, thank you for this opportunity to provide our comments on Proposed Rule CMS-2238-P. As you know, we are grateful for the opportunity to engage in substantive discussions with CMS officials about supply chain issues, and we continue to stand ready to address any questions you may have about the issues, concerns, and suggestions discussed above.

Sincerely,



Scott M. Melville
Sr. Vice President
Government Affairs

³⁹ DRA § 6001(e) adding Social Security Act § 1927(f)(1)(A).

Submitter : John Grubbs
Organization : UC Davis Health System
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1240-Attach-1.DOC

February 20, 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

Re: Comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006.

To Whom It May Concern:

The University of California Davis Health System opposes the imposition of the new data submission requirement to drugs administered by medical professionals to patients in hospital outpatient clinics or departments for the following reasons:

1. This new administrative burden would fall initially on clinicians (as opposed to billing personnel) while they are otherwise engaged in patient care. There is often no way to record the exact source of drugs administered, except by the person administering them. This is because a common drug provided at one clinic may come in several different generic versions, and be packaged in several different size containers. It just won't work to impose this kind of additionally painstakingly detailed 9 or 11 digit data entry duty on a physician or nurse while they are in the process of administering the drugs. This isn't something that can be easily reduced to a check-off form, because 600 milligrams of a particular drug might be filled with various generics kept in stock (lowest cost at the time of purchase), and it might be filled one time from a 500 mg vial, plus a 100 mg vial, and another time from a 1000 mg vial, each with different NDC numbers. In addition, preparation of drugs for infusion will require fine-tuning the amounts to bodyweight or other indicators. If the clinicians cannot just check it off, it's not reasonable or practical to impose this kind of meticulous recordkeeping burden on them. It won't work, and if tried it will cause more providers to simply refuse to deal with Medicaid patients.

2. In the emergency room setting, this type of problem will be magnified tremendously, by the much wider variety of possible drug combinations administered, by the often urgent nature of the clinical care requirements that will, of course, take precedence. Moreover, the clinicians really shouldn't be worrying about whether or not the patient is covered by Medicaid or not. Another problem is that, in the emergency room, clinicians often don't know if the patient will end up as an inpatient (not subject to the new requirement), or being discharged to home or outpatient setting (subject to the new requirement), until after stabilization has occurred, or test results returned and read. By that time, the particular vials used should have long since been cleaned up or returned to inventory. So the emergency room should be exempted from this excessive burden, if it is unwisely imposed at all.

3. The purpose of the proposed data submission is to enable State Medicaid agencies to collect rebates on drugs that are "physician administered" within the meaning of Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA. However, disproportionate share hospitals like ours are able to buy drugs at below "best price" cost under the 340B program, and Medicaid agencies are prohibited from claiming rebates for such drugs, since they may have already gotten a bigger discount on the drug through 340B. So, 340B covered entities that sell rebate-ineligible drugs to Medicaid patients should also be exempted from this excessive burden, if it is unwisely imposed at all.

4. Finally, inclusion of hospital outpatient-departments in the requirement of reporting NDC codes is inconsistent with the Social Security Act, Section 1927(j)(2), 42 U.S.C. 1396r-8(j)(2). That section requires that State Plans exempt from the rebate requirement: "a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan)." In those hospital outpatient department settings, the actual cost of the drugs is reported on the hospital cost report, and the actual payment is as determined under the state plan. Accordingly, the effort in the preamble to expand the definition of "physician-administered drugs" to include drugs dispensed within hospital outpatient departments, is inconsistent with statute, and therefore is likely to be reversed by a reviewing court.

Thank you for your consideration of these views in connection with the recently published proposed regulations to implement the Deficit Reduction Act of 2005.

Sincerely,

John H. Grubbs, MS, MBA, RPh
Director of Pharmacy
UC Davis Health System

CMS-2238-P-1241

Submitter : Mr. James Stewart
Organization : Planned Parenthood of Wisconsin, Inc.
Category : Other Health Care Provider

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1241-Attach-1.DOC



February 20, 2007

VIA ELECTRONIC MAIL

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 writing on behalf of Planned Parenthood of Wisconsin, Inc. (PPWI), a non-profit health care organization, in response to your request for comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule seeking to implement provisions of the Deficit Reduction Act of 2005 (DRA). PPWI strongly recommends that the Secretary and CMS define "other safety net providers" as Congress provided in the DRA.

PPWI operates 28 non-profit outpatient family planning health centers throughout the state of Wisconsin. We provide annual exams, breast and cervical cancer screenings, testing and treatment for sexually transmitted infections, pregnancy testing and birth control to more than 70,000 individuals each year in our health centers. Most of these patients would not be able to afford this basic but vital health care, and in particular, access to oral contraceptives, if PPWI were not able to continue to provide low cost reproductive health care services to individuals most in need.

Since its inception in 1935, PPWI has been a leader in providing reproductive health care and birth control in Wisconsin. Our agency has grown to include 28 family planning health centers that have been able to provide oral contraceptive pills at prices far below retail prices to our patients in need. In 2006, 62% of our patients were at or below the federal poverty level (FPL), 76% were at or below 150% of the FPL, and 84% were at or below 200% of the FPL. In 2006, 61,769 of our 73,456 patients were at or below 200% of the FPL. PPWI uses a sliding fee scale for fees charged to our patients. For example, no fee is charged for our Title X patients at or below the FPL, 25% of the

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

full fee is charged for patients at or below 150% of the FPL, and 50% of the full fee is charged for patients at or below 200% of the FPL.

According to the Guttmacher Institute, the nation's recognized authority on reproductive health statistics, close to 300,000 women in Wisconsin were in need of publicly supported family planning services in 2005, and only 93,000 of them received services. PPWI served about 75% of those women in need in 2005. These data underscore the significant need in Wisconsin for low cost reproductive health care services, and PPWI is committed to providing this care.

Access to this prevention-based health care not only benefits individual and community health, but it is cost-effective. Without access to this affordable care for poor and low-income patients, the cost would fall more heavily on taxpayers and the fiscal benefit entities like PPWI provide to the community as a whole would be greatly reduced.

We are deeply concerned that CMS's December 2006 proposed rule to implement § 6001(d) of the DRA only preserves the ability of three kinds of providers to purchase drugs at nominal prices: 1) 340B covered entities; 2) intermediate care facilities for the mentally retarded; and 3) state owned or operated nursing homes. However, the three categories in the proposed rule are not sufficiently inclusive because they do not include other safety net providers.

At present, PPWI is fortunate that the majority of its family planning health centers qualify as 340B covered entities. Because of the fragility of funding that qualifies current safety net providers as 340B-eligible, PPWI urges CMS to further define "safety net providers" as Congress has provided in the final rule. If PPWI's 340B eligibility were ever jeopardized for some or all of our health centers, we would no longer be able to purchase drugs at nominal prices, and this would likely result in our having to greatly reduce our services and/or close many of our health centers. PPWI would not be able to provide access to critical prevention based health care and oral contraceptives to the vast majority of the low-income, uninsured and underinsured women we currently serve. Such a loss of service would seriously impact both the health and financial well-being of our patients and the community.

PPWI truly serves as a "safety net provider" for communities where we have health centers throughout Wisconsin. It is critical that CMS reconsider its authority granted to it by Congress to designate "other safety net providers" in its final rule that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. Further, we urge CMS to consider adopting a definition of "safety net provider" that would apply to an entire organization (rather than just to stand alone nonprofit outpatient clinics) like PPWI that allows tens of thousands of poor and low-income women to afford critical reproductive healthcare services and oral contraceptives in a cost-effective manner.

Leslie V. Norwalk, Esq.
February 20, 2007
Page 3

PPWI is committed to continuing to serve our largely poor and low-income patient population, including the provision of affordable oral contraceptives. If our 340B eligibility for nominal pricing were put at risk or lost, our ability to serve the vast majority of our patients would be drastically diminished. As a charitable organization serving as a safety net health care provider, we urge CMS to include a definition of safety net provider that includes organizations like PPWI.

Sincerely,

A handwritten signature in black ink, appearing to read "James M. Stewart". The signature is fluid and cursive, with a large loop at the end.

James M. Stewart
President and CEO
Planned Parenthood of Wisconsin, Inc.

Submitter : Mr. Gaston Redondo

Date: 02/20/2007

Organization : Malecon Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Retail pharmacy in low to low middle income area servicing many elderly patients for 30 years.

GENERAL

GENERAL

Regarding CMS-2238-P it is completely unrealistic to think that a small independent pharmacy can purchase an AMP level. We do not buy at mail order or VA prices. Besides that our dispensing fees have been slashed from around 4.00 fees to .50 cents to 1.50. There is no way we can stay in business to service our elderly and sick patients at those prices. These reductions are being put on the shoulders of community pharmacies instead of negotiating prices with manufacturers and PBM's. Our pharmacy cost are increasing everyday and we will not be able to stay in business.

If these laws are enacted and a fair dispensing fee is not enacted you are going to see a majority of small business (pharmacies) go out of business and jeopardizing the lives of millions of Americans that we provide service for. Sick and elderly patients that we take the time and explain, consult and deliver medication to. If you think the large chains have the or deliver the patient care we do, you are going to be sadly mistaken.

These rule's are going to bring down the backbone of this country the small business owners. Not to mention the most important thing the lives of the patient's we help everyday!

Submitter : Dr. shukri saliba

Date: 02/20/2007

Organization : ST.LUKE PHARMACY INC.

Category : Pharmacist

Issue Areas/Comments

Background

Background

THE PROPOSED RULE CMS2238P WILL HAVE A HUGE IMPACT ON COMMUNITY PHARMACIES THROUGHOUT THE COUNTRY. WE HAVE SEEN A HUGE REDUCTION IN REIMBURSEMENTS SINCE PART D IMPLEMENTATION AND THE COST OF OPERATION HAS INCREASED.

Collection of Information Requirements

Collection of Information Requirements

THIS NEW PROPOSED REGULATION WILL PUT A LOT OF COMMUNITY PHARMACIES OUT OF BUSINESS AND LOSS OF JOBS.

Submitter : Mr. Larry Fligor
Organization : Ritzman Pharmacies, Inc
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. MARK TARQUINIO
Organization : HARTER'S DRUG STORE
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

AMP IS NOT A FAIR AND ACCURATE TOOL IN REIMBURSING RETAIL PHARMACY. RETAIL PHARMACIES BUY THROUGH WHOLESALERS, NOT DIRECT FROM THE MANUFACTURE. UNDER THE CURRENT REIMBURSEMENT FORMULA MY PHARMACY IS NOT MAKING EXORBITANT SUMS OF MONEY. I REVIEWED THE LAST 10 GENERIC PRESCRIPTIONS I HAVE FILLED TODAY AND DETERMINED THAT THE MOST I GROSSED ON A PRESCRIPTION WAS \$7.51 AND THE LEAST WAS 75 CENTS. CONSIDERING THAT A NATIONAL "COST OF DISPENSING" STUDY, BY GRANT THORNTON, REVEALED THE COST OF DISPENSING IN PENNSYLVANIA IS \$9.90, THE PROFIT ON MY SCRIPT SAMPLING ISN'T ENOUGH TO MEET MY OVERHEAD. TODAY INDEPENDENTLY OWNED RETAIL PHARMACY IS FIGHTING FOR IT'S OWN EXISTENCE ON EVERY FRONT. WE OUR LOSING MARKET SHARE TO MAIL-ORDER, PBM'S ARE CONTINUALLY REDUCING OUR RERIMBURSEMENT, MEDICARE PART D PLANS FORCE US TO ACCEPT NEGATIVE REIMBURSEMENTS(HUMANA PART D 90 DAY SUPPLIES GENERATE A LOSS)AND THERE IS A RELENTLESS PURSUIT BY THE GOVERNMENT TO REDUCE INADEQUATE REIMBURSEMENT TO THE POINT OF DESTROYING SMALL RETAIL PHARMACIES. WHILE ALL THIS IS GOING ON THE MINIMUM WAGE IS BEING RAISED, OUR STATE'S GOVENOR WANTS UNIVERSAL HEALTH COVERAGE WITH A PORTION OF IT TO BE FUNDED BY THE BUSINESS COMMUNITY, AND OVERHEAD KEEPS RISING WITH NO WAY TO PASS ON THESE INCREASED COSTS BECAUSE RETAIL PHARMACIES OWE MOST OF THEIR BUSINESS TO 3RD PARTY PLANS AND GOVERNMENT PLANS THAT HAVE CONTINUALLY SOUGHT TO PAY LESS AND DEMAND MORE SERVICES. IN CLOSING, I ASKED THAT YOU TAKE A CLOSER LOOK AT HOW PHARMACY IS TO BE REIMBURSED AND NOT SOME CONCOCTED FORMULA THAT DOES NOT TRULY REFLECT OUR COSTS.

CMS-2238-P-1246

Submitter : Dr. Lori Heninger

Date: 02/20/2007

Organization : HiTOPS

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1246-Attach-1.DOC

CMS-2238-P-1246-Attach-2.DOC

20 Years
& still growing...

HiTOPS

Promoting Adolescent Health & Well-being

Join us and be a part of our legacy.

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Executive Director of HiTOPS, a non-profit ambulatory clinic in Princeton, New Jersey; for the past 20 years, we have provide health and education services to uninsured and underinsured young women, ages 13-26. HiTOPS currently serves over 1,800 patients annually, many of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide. HiTOPS serves young women regardless of their ability to pay; we are committed to ensuring that all youth who want low-cost reproductive health care have access to services.

HiTOPS provides health and wellness services to both young women and young men. Our clients come from Mercer County, and also from Pennsylvania and New York because of our model of care; we take a great deal of time with youth to ensure that their needs are fully met. HiTOPS provides physical exams, STI testing and treatment, smoking cessation, stress management, nutritional counseling, gynecological exams, and birth control. We do not do medical procedures. Young women come to HiTOPS because they know they will receive confidential, dramatically reduced-cost or free health care and birth control (including oral contraceptives, injectibles, patches and hormonal rings)—girls who would otherwise not have access to, or be able to afford birth control.

According to our most recent data, only 30 percent of the young women who come to HiTOPS are covered by any type of health insurance. Visits from Latina clients, most of whom are indigent, have risen by 41 percent this past year. Given their ages, confidentiality issues and lack of personal income, low-cost or free birth control is the only option for most of our clients.

HiTOPS 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, injectibles, patches and hormonal rings from manufacturers willing to provide them at nominal prices. We have projected that our birth control costs would increase from our 2006 level of about \$12,000 to over \$130,000; this is an exponential

increase that will absolutely prohibit almost 800 of our young women from being able to access birth control through HiTOPS, leaving them without protection from pregnancy. It will also mean that HiTOPS will need to close its Health Center because, not being a 340B provider, we do not qualify as a "safety net provider" and are no longer eligible for reduced-cost birth control.

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. HiTOPS, however, is not federally funded; Title X moneys have been flat for many years, and there is no competitive process to secure Title X funding in New Jersey. We do not qualify as a 340B covered entity; however, we serve as a key safety net provider in our community by providing family planning services to low-income women, and our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. HiTOPS was 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 listed 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. HiTOPS 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.

The cost-benefit analysis of this lack of definition is faulty at best. HiTOPS currently serves almost 800 young women who will no longer have access to birth control that they manage themselves; reliance on a boyfriend to use a condom every time takes reproductive control away from the young woman and leaves her more vulnerable to unintended pregnancy. It is not difficult to imagine that a number of these young women will become pregnant and will opt for abortion or will carry the child to term, both being extremely expensive alternatives to the woman, the child, and our society in contrast to the provision of low-cost birth control. Low-cost birth control is a primary method of ensuring that young women in financial need can afford, in all confidentiality, a product that allows them to postpone pregnancy so that they can continue their education and healthy development, and reach their full potential.

Respectfully submitted by,

Lori Heninger, PhD
HiTOPS
21 Wiggins St.
Princeton, NJ 08540
1.609.683.5155 ext. 215

Submitter : Mr. Emmett McVey

Date: 02/20/2007

Organization : Milly's Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background
see attachment.

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

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

CMS-2238-P-1248

Submitter : Traci Gleason

Date: 02/20/2007

Organization : Planned Parenthood of Kansas and Mid-Missouri

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-2238-P-1248-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 am the Director of Public Affairs at Planned Parenthood of Kansas and Mid-Missouri (PPKM). PPKM operates 11 non-profit clinics throughout the state of Kansas and Western-Central Missouri and provides a broad range of reproductive health care services to uninsured and underinsured women. PPKM serves nearly 33,000 patients each year, many of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide. PPKM is committed to providing confidential, affordable reproductive health care to all individuals, regardless of their ability to pay. Without access to these services, many of our patients would fall through the cracks of our health care system and be unable to obtain potentially lifesaving health care.

For over 72 years, PPKM has worked to ensure that every individual has the knowledge, opportunity, and freedom to make informed private decisions about reproductive health care. We provide a broad array of services to the community, including family planning and contraception, vasectomy, pregnancy testing, HIV testing, testing and treatment of sexually transmitted infections (STI), detection of cervical, breast, and testicular cancers, and detection of sickle cell anemia.

Because of our commitment to providing services to those in need, sixty-eight percent of our patients receive some subsidy for their care. We provide oral contraceptive pills at prices far below retail for women who otherwise would be unable to afford these contraceptives. No family planning patient is ever turned away because of an inability to pay.

Seventy-five percent of our patients are below 200% of the federal poverty level, and 63% are below 150% of the federal poverty level. We use a sliding fee scale based on a client's family size and income to ensure that the inability to pay is never a barrier to service. We may be the only low-fee family planning option for many of our clients – Kansas health departments no longer provide family planning services, and we are the largest provider of these services in Missouri.

PPKM 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. Unfortunately, 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. Eight of PPKM's clinics are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured.

However, three of our clinics do not receive Title X funds. These clinics are largely dependent on sales of oral contraceptives purchased through the nominal pricing structure. If those clinics were unable to purchase contraceptives at nominal prices, we would likely have to close those three health care clinics. As a result, at least 10,000 patients at those clinics would be unable to purchase their contraceptives. Moreover, the surrounding communities would lose access to our limited primary care, colposcopy, and STI testing and education services.

PPKM's ability to continue to serve as a key safety net provider to those communities 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 eligibility categories previously listed.

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. All PPKM clinics are clearly safety net providers, and we strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient clinics like ours.

Respectfully submitted by,

Traci Gleason
Director of Public Affairs
Planned Parenthood of Kansas and Mid-Missouri
Overland Park, Kansas

Submitter : Joseph Fuselli
Organization : Aston Pharmacy Inc
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1249-Attach-1.DOC

#1249

The Home Health Center Aston Pharmacy Inc.

10 Scheivert Avenue Ph. 610.494.1445
Aston, PA 191014 Fax 610.494.7697
www.Thehomehealthcenter.org

February 19, 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

Dear Sirs,

I want to thank you for this opportunity to comment on the proposed changes regarding CMS proposed rule on AMP as well as the FUL program for generic drugs. Our pharmacy is located in Aston, Pennsylvania where we have provided pharmacy services to the surrounding community for 52 years. The proposed changes in reimbursement will have catastrophic effects on our ability to continue servicing the Medicare and Medicaid population in our communities. We ask that you reconsider the proposed changes.

Before the proposed changes become law I would ask that a re-evaluation take place and include the input of pharmacy organizations whose interest is in serving the general population and considers the interests of all patients and providers.

Listed below are some key areas of concern:

1. Inclusion of mail order pricing to calculate federal upper limit (FUL) levels.

AMP calculation for "Retail Pharmacy Class of Trade" should only include organizations that dispense to the "general public" or the majority of Medicaid clients. In other words, this means they should exclude hospital, nursing home as well as mail-order pharmacies. The reason being is that manufacturers have a different pricing system that is NOT available for the independent pharmacies, independent chains, traditional chains and mass merchants. *Because including mail order in FUL calculations will render inaccurate values we request the calculation be made without its inclusion.*

2. Inclusion of rebates to PBMs and mail order pharmacies in calculating AMP.

AMP should reflect the actual prices paid by retail pharmacies. *Rebates offered to mail order and PBMs are NOT available to the retail pharmacy class of trade so therefore; it should be excluded from the AMP calculation.*

3. Inclusion of administration fees and service fees in calculation of AMP.

Since administration fees, service fees and nominal pricing are not available to the Retail Pharmacy Trade, they should all be excluded from the calculation.

In conclusion, I want to thank you for this opportunity to express my concerns. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Respectfully,

Joseph Fuselli R.Ph.

President

The Home Health Center

Aston Pharmacy, Inc.