

CMS-2238-P-1216

Submitter : Derek Holyfield
Organization : Duncan's Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1216-Attach-1.RTF

February 20, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and co-owner of Duncan's Pharmacy, a community retail pharmacy located at 137 South Main Street in Dyer, Tennessee. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

In my opinion, the proposed changes will have an incredibly detrimental effect to our health care system. In this day and age where large retail chains and PBMs attempt to cheapen patients' lives in order to make a quick profit, community pharmacists carry out prescription orders from doctors, dentists, and other health care professionals with the intention of ensuring the patients' health and well being. If the changes continue without further modification, it is inevitable that many community pharmacies will be forced to close because reimbursement for medication would not cover the acquisition cost that pharmacies like mine are paying.

Before I became co-owner of a community pharmacy, I worked at a large chain where the basic rule was "make them wait for their prescriptions so they will go buy something else." I quickly learned that I did not want to be a part of this organization for the rest of my career. These large chains are able to purchase larger quantities at a lower price, yet still charge prices that are often more than most community pharmacies. The chains and PBMs only have one thing in mind and that is profit.

The lives of thousands of my patients, as well as millions of other patients at community pharmacies across the nation, will be directly impacted if these changes proceed as written.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy where over 90% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Derek Holyfield, Pharm. D
126 Nancewood Drive
Alamo, Tennessee 38001
731-696-3288
731-692-3578 Duncan's Pharmacy

cc: Senator Lamar Alexander
Senator Bob Corker
Representative John Tanner

Submitter : Mr. Michael Farmer
Organization : Farmer's Prescription Shop
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

My family owns 3 pharmacies in Barrow and Oconee counties in Georgia. I steadfastly disagree with the new definition of AMP that is scheduled to be implemented later this year. I echo 100% the sentiments expressed by NCPA and the possible extinction of the independent community pharmacy due to fiscal damage from the proposed reimbursement cuts. These changes in payment methodology make no sense, because a pharmacist is paid more for brand pharmaceuticals than less expensive generic medications. Pharmacists have the ability to manage costs if given the chance. The health care infrastructure of Medicaid patients throughout the country does need an overhaul, but there are other ways to achieve this. This new definition of AMP will cause many pharmacies, including mine, to seriously consider disenrolling in Medicaid pharmacy programs. If massive losses in community pharmacy providers occur, you will spend twice these proposed savings in ER and hospital costs. Thank you for your consideration.

Sincerely,
Michael Farmer
Farmer's Prescription Shop
232 E. Broad St.
Winder, Ga. 30680
770-867-9072

Submitter : Dr. Jennifer Hagen
Organization : Wolff's Mushel Health Mart Drug
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

Seriously, does the service community pharmacy has to offer mean nothing? In the past two weeks I have referred two people to the clinic one of which needed to be admitted and one which needed medication right away. I helped a person with the flu seek out Tamiflu and start appropriate OTC medication. I helped people with stomach flu, people who couldn't go to the bathroom and referred someone with ringworm. I did two MTM cases and made therapeutic changes which will save insurance several hundred dollars. I picked up a new patient who needed a pharmacy enrolled in a Tikosyn program because Walmart was too busy to enroll and help this person out. These are just some of the extra things I have done in the past few weeks. I fear that if the government does not recognize the service that community pharmacists provide that someone will have to pick up these costs and services, probably at the expense of loss of quality of life or increase in doctors visits and finally medicare dollars.

I work in Little Falls, MN and the effect of lower reimbursement will put Wolff's Mushel Drug out of business, we just can't compete with mail order and large corporations. The owner has taken out a line of credit just to stay in business and get past this first phase of poor Part D reimbursement. I fear he may need to close if things don't get better.

Even though I don't get paid as much as other pharmacists at big corporations I choose to work in community pharmacy because of what I can do for people. I am the last stop in the health care team and I take the time to answer questions that the physician may not have had time for. I like helping people and putting my six year degree to work.

In a few months there will be a super Walmart in Little Falls and Walgreen's has already purchased land and is projected to be completed within two years. If our pharmacy closes it will be hard on the elderly population some of whom have expressed that they don't want to have to go to a store where they have to walk a mile from the parking lot to the pharmacy only to wait for an hour to get their medicine.

Please reconsider the definition of retail pharmacy which will be used in the calculation of AMP and please consider a fair dispensing fee that reflects the actual cost of providing a full range of professional services.

Submitter : Carole Ray
Organization : Carole Ray
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

Please explain how a pharmacy is suppose to survive and stay in business at 36% below acquisition cost.....The amp reimbursement will put all the independent pharmacies out of business.....the rural areas of Georgia would have nowhere to go without the independent pharmacy...they open account and hold tickets until they have money but no one can do this at 36% below the cost of the medication...

Submitter : Ms. Judith Cahill
Organization : Academy of Managed Care Pharmacy
Category : Health Care Professional or Association

Date: 02/20/2007

Issue Areas/Comments

Background

Background

The Academy of Managed Care Pharmacy (AMCP) is pleased to have the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicaid Program; Prescription Drugs; Proposed Rule.

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

GENERAL

GENERAL

The Academy's comments on specific items within the proposed rule appear on the attachment.

CMS-2238-P-1220-Attach-1.DOC

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

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

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

CMS-2238-P-1221

Submitter : Mr. mike latif

Date: 02/20/2007

Organization : Benuellie bros

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1221-Attach-1.DOC

ATTACHMENT A

MODEL COMMENTS TO CMS

SUBMIT COMMENTS TO:

[HTTP://WWW.CMS.HHS.GOV/ERULEMAKING](http://www.cms.hhs.gov/erulemaking)

COMMENTS DUE FEBRUARY 20th

February 20, 2007

Centers for Medicare and Medicaid Services

Attention CMS 2238-P Mail Stop C4-26-05

7500 Security Blvd

Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation

CMS 2238-P RIN 0938-AO20

The Benuelli Bros Corporation is writing to provide our views on CMS' December 20th 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.

Our Corporation operates ___1___ pharmacies in Hawaii states. We are a major provider of pharmacy services in the communities in which our stores are located.

This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacies. It could jeopardize my ability to provide pharmacy services to Medicaid beneficiaries and the general public. This regulation should not move forward unless substantial revisions are made. Incentives need to be retained for pharmacies to dispense low-cost generic medications. I ask that CMS please do the following:

- **Delay Public Release of AMP Data:** The Centers for Medicare and Medicaid Services (CMS) should not make Average Manufacturers Price (AMP) data public until a final regulatory definition of AMP is released. This definition should reflect the prices at which traditional retail pharmacies purchase medications. CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data could adversely affect community retail pharmacies if used for reimbursement purposes. CMS has already delayed release of these data, and we urge that release of these data be delayed again.
- **Define AMP to Reflect Retail Pharmacy Purchasing Costs:** CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires.

Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade.

In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.
- **Require that States Increase Pharmacy Dispensing Fees:** CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Mike latif

CMS-2238-P-1222

Submitter : Mr. Frank Barnes

Date: 02/20/2007

Organization : University of North Carolina Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment in letter format

CMS-2238-P-1222-Attach-1.DOC

February 20th, 2007

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

To Whom it May Concern:

We are responding on behalf of the University of North Carolina Hospitals to the request for comments on regulations proposed to implement the Deficit Reduction Act of 2005 ("DRA"), published in the December 22, 2006 Federal Register. The University of North Carolina Hospitals is a 700 bed teaching hospital located in Chapel Hill, North Carolina, 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 have a number of concerns about the proposed regulations. As a general comment, the proposed guidelines do not recognize the widely-established realities of U.S. hospital care, especially the fact that hospital services are integrated into wider health care systems incorporating a mixture of hospital and clinic services and utilizing different organizational structures with common ownership at the healthcare system level. Recognition of this fact of healthcare organizations would probably remove most problems associated with the proposed regulations. Three specific concerns about the regulations are discussed below.

First, the proposed regulations would create extremely onerous financial and administrative burdens for our hospital by requiring the reporting of NDC information for drugs administered in hospital outpatient settings ("clinics"), for the following reasons:

- a. The requirement appears pointless since 340B hospital clinic-administered drugs are exempt from rebates (section 1927(j)(2) of the Medicare statute applies). If no rebates will be obtained, what is the point of all the expense and disruption which will occur in order to achieve no end?
- b. Hospital electronic billing systems do not presently have the capability to include NDC numbers identifying clinic-administered drugs. It would require a very substantial investment to change the institution's electronic financial systems to allow inclusion of the NDC number and to perpetuate it throughout all the pathways required to achieve the CMS objective.
- c. The clinics where the drugs are administered are located some distance from the offices where the UB-92 billings actually take place. There is no simple way to communicate the NDC number of the drugs being administered by the clinic staff, to the billing office.

- d. Frequently, a multi-drug cocktail is administered and this has but one entry on the UB-92. Which NDC should be used?
- e. The UB-92 billing document, mandated by the Federal Government, has no place on it where an NDC can be entered.
- f. The NDC cannot reliably be entered by the billing staff since they have no idea which NDC was used. Any given drug might have several NDC's corresponding to several brands on the shelf at one time so it is not possible for a remote staff member to know which was used.
- g. The system, as proposed, is rife with the potential for error, placing hospitals at risk of audit penalties for attempting to comply with a system that is burdensome, poorly conceived and which defies the best effort of the staff to comply with it.
- h. Finally, we consider it highly speculative that the 15-second CMS estimate will suffice to allow all the above factors to be considered, and the drug's NDC to be determined and entered onto the billing document.

Second, the proposed policies would substantially decrease the savings this hospital receives through use of 340B-priced drugs in the clinic, since if the State insists on filing for rebates from the manufacturer, we would have no alternative but to cease using the 340B program. This would cost the hospital approximately two million dollars in increased drug expense which would in turn limit our ability to expand services to the poor and indigent, which is precisely what the 340B program was enacted to accomplish. Again, it is our interpretation that section 1927(j)(2) of the Medicare Statute intends to exempt hospital-based clinics from rebates.

Third, the proposed changes to the rules related to the treatment of prompt pay discounts used in computing Average Manufacturer Price ("AMP") could raise 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 (e.g., Children's Hospitals) eligible for nominal pricing. We estimate that inclusion of the prompt pay discounts in the AMP calculation would cost us an additional \$110,000 in drug expense and this can have no other effect than to make it more difficult to provide care to indigent patients and disadvantaged children.

We hope that the problems mentioned above will cause serious consideration to be given to the proposed regulations and that they will be revised in such a manner as to not harm DSH hospitals and to not invalidate the intention to assist indigent patients Congress demonstrated when it passed the Veteran's Health Care Act of 1992 which established the 340B program.

Sincerely,

Gary L. Park
President

John P. Lewis
Senior Vice President
Chief Financial Officer

James C. Mcallister, III
Director of Pharmacy

Frank Barnes
Pharmacy Business
Manager

Submitter : Mr. Tom Myers
Organization : AIDS Healthcare Foundation
Category : Other Health Care Provider

Date: 02/20/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

DS HEALTHCARE FOUNDATION COMMENTS FOR DOCKET CMS-2238-P PRESCRIPTION DRUGS February 20, 2007 To Acting Administrator Leslie Norwalk: Please see attachment Tom Myers General Counsel AIDS Healthcare Foundation 6255 W. Sunset Blvd., 21st FL Los Angeles, CA 90028 323-860-5259 tomm@aidshhealth.org

GENERAL

GENERAL

see attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

AIDS HEALTHCARE FOUNDATION

COMMENTS FOR

DOCKET CMS-2238-P

PRESCRIPTION DRUGS

February 20, 2007

To Acting Administrator Leslie Norwalk:

Please see attachment

Tom Myers
General Counsel
AIDS Healthcare Foundation
6255 W. Sunset Blvd., 21st FL
Los Angeles, CA 90028
323-860-5259
tomm@aidshhealth.org

CMS-2238-P-1223-Attach-1.DOC

CMS-2238-P-1223-Attach-2.DOC

AIDS HEALTHCARE FOUNDATION**COMMENTS FOR****DOCKET CMS-2238-P****PRESCRIPTION DRUGS**

February 20, 2007

To Acting Administrator Leslie Norwalk:

AIDS ("AHF") is exactly the kind of organization, treating exactly the kind of Medicaid patients, which the proposed Medicaid pharmacy reimbursement levels will most hurt. AIDS Healthcare Foundation operates precisely the kind of small pharmacies, in low-income areas with high concentration of Medicaid beneficiaries, upon whom CMS states it cannot quantitatively estimate the effects of the proposed regulations. Pursuant to CMS' request for "any information that may help us better assess the effects before we make final decisions," AHF submits these comments:

AHF is a non-profit organization that provides medical care and advocacy to Americans with HIV/AIDS regardless of ability to pay. It is the largest private provider of such care in the United States, treating over 17,000 people with HIV/AIDS annually in 12 outpatient clinics in California and Florida. Consistent with its mission and nonprofit status, the vast majority of AHF's patients are low income, and are insured either through Medicaid or the Ryan White CARE Act, or have no insurance or means of payment.

In order to better coordinate and improve the care of these patients, AHF has established pharmacies many of its clinics. In this way, doctors can better communicate with the pharmacists, patients can more easily obtain their medications, and the pharmacists have unique, specialized training in AIDS pharmacy issues. Many of AHF's clinics and pharmacies are in low income and/or underserved geographic areas. Many of AHF's pharmacies participate in the 340B drug price program for eligible patients, a program designed to provide relief and access to pharmaceutical therapy to underserved populations receiving primary health care from safety net primary care providers.

Because AHF's pharmacies are located within clinics, and are geared solely to serve the health needs of people with HIV/AIDS, the sole source of revenue for the clinics is the sale of drugs. There are no food sales, no cosmetics, magazines, etc. Moreover, these pharmacies are by and large within AHF's outpatient clinics, and are not storefront establishments accessible by the general public. AHF's client base is necessarily and deliberately limited to promote patient adherence to medication regimens, and HIV/AIDS confidentiality for the very targeted population. In addition, any excess revenue generated by the pharmacies is put back into fulfilling AHF's nonprofit mission.

In 2005, AHF's pharmacies had approximately \$56 million in revenue; nearly half of that came from Medicaid patients. AHF's margin on this revenue is approximately 7%.

In short, AHF's pharmacies are set up to serve those most in need of Medicaid covered services – low income people living in underserved areas, who suffer from a highly complex disease that is fatal if not treated properly. The existence of AHF's pharmacies, with their expertise in serving this population, frankly is the epitome of Medicaid's goals of eliminating financial barriers to medical care, and guaranteeing that Medicaid recipients receive equal or even better care than people with private insurance.

Ironically and unfortunately, the proposed regulations regarding pharmacy reimbursement will completely undermine this care, as the impact on pharmacies like AHF's, which do the bulk of the very difficult, complex care that many Medicaid recipients require, will be enormous.

It is unclear what study CMS did regarding the effects of these regulations on the Medicaid populations served by these pharmacies, in terms of numbers, acuity, complexity of health conditions and pharmacy needs. In fact, it appears that CMS has done very little study of the impact of these regulations on the pharmacies themselves, stating in the rulemaking guidance that it is

Unable to quantitatively estimate effects [of the rules] on small retail pharmacies, particularly in low-income areas.

While CMS may be unable to estimate this, the General Accounting Office has recently issued a report finding that the proposed rules could cut pharmacy reimbursement by an average of 36% for multiple source drugs. While AHF understands that CMS disputes the GAO's findings, it is clear that the impact of these rules will be large.

This impact will be particularly hard on pharmacies like AHF's. As CMS has noted, the impact of these regulations on chain, supermarket, and other pharmacies will be small, because these entities do not rely on drug sales as their primary source of revenue, and have large and diverse payors, meaning Medicaid revenue is one small part not only of drug sales, but of entire store revenues.

This is not the case for pharmacies like AHF's, where almost 50% of total revenue is generated by Medicaid. Even a 10% cut in Medicaid reimbursement will decimate AHF's margin, and render it pharmacies non-viable. Low-income populations throughout California and Florida will lose this valuable resource, and the quality of healthcare available in these areas of high Medicaid beneficiary populations will suffer. It need hardly be mentioned that even a slight decrease in the health of someone with a potentially fatal disease such as HIV/AIDS will cause a disproportionate increase in the

use of health care services, which will wipe out a great deal of the anticipated savings emanating from these regulations.

The regulations need to recognize the unique status and role of pharmacies like AHF's. A "one size fits all" approach clearly will not work. AHF proposes two solutions.

First, more State flexibility is required to address the unique, local situations of pharmacies like AHF's. One way to do this is to allow a greater degree of autonomy on state fill fee reimbursement. The impact on pharmacies like AHF's cannot be mitigated by an increase in state-set dispensing fees as envisioned by the regulations. If state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average \$10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states.

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

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists like AHF's regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient. This is especially true, and especially vital, when dealing with a complex disease like HIV.

Second, the language of the proposed regulations need to be changed to clarify that States still set reimbursement and fill fee rates for single source drugs. As most AIDS drugs are single source drugs still under patent, and as the cost of these drugs is by far the single largest cost of treating AIDS, this clarification is extremely important.

The proposed 42 CFR Section 447.512(b) does not make clear which "agency" will determine the price and fill fee for "other drugs," including single source drugs. In contrast, proposed 42 CFR Section 447.514(b) specifically states that CMS will determine the AMP, and the "State agency" still determine the fill fee for multiple source drugs. The ambiguity in Section 447.512(b) should be eliminated.

Sincerely,

Tom Myers
General Counsel
AIDS Healthcare Foundation
6255 West Sunset Blvd., 21st FL
Los Angeles, CA 90028
323-860-5259
tomm@aidshhealth.org

Submitter : Mr. Fred Brown
Organization : Miller's Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

I am a retail Pharmacist working in a independant pharmacy serving a small rural farming&manufacturing community.

Collection of Information Requirements

Collection of Information Requirements

Average Manufactures Drug Prices

GENERAL

GENERAL

Please see response to comments above

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Government's own studies

Regulatory Impact Analysis

Regulatory Impact Analysis

The average price for retail purchased drugs should be determined by the average price "retail pharmacies" have to pay for them. The average price should not include discounts that are available to hospital-nursing homes-mail order pharmacies- and the government as they are not working at the retail level and con not recieve those discounts and rebates.

Submitter : Ms. Tina Welsh
Organization : Women's Health Center
Category : Other Health Care Professional

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-2238-P

Dear Administrator Norwalk:

I am the Executive Director of Women's Health Center, a reproductive health care clinic headquartered in downtown Duluth, Minnesota. My non-profit organization provides a wide range of reproductive health services, including annual exams, affordable birth control, sexually transmitted disease testing and treatment, pregnancy tests and breast and cervical cancer screening.

Women's Health Center has been open for 26 years. We operate family planning clinics in Duluth and five northern Minnesota counties. Last year, Women's Health Center provided care 1,524 patients, one third of who live below 200% of the federal poverty level. Women's Health Center operates a sliding-fee scale for services and supplies which is based on cost and on the individual's ability to pay as determined by their family size and income. We do not charge for family planning patients that are below 200% of the federal poverty level.

Essential to Women's Health Center's ability to serve low-income women has been the ability to purchase contraceptive drugs from manufacturers willing to provide them at nominal prices. If we are no longer able to do this, Women's Health Center will face significant financial difficulties and may be faced with deciding whether or not to continue to serve low-income patients. An additional challenge to our patients in Cook County Minnesota is that there is only one pharmacy in the entire area, therefore their access to contraceptives is extremely limited.

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. Women's Health Center is not federally funded and therefore does not qualify as a 340B covered entity. Nonetheless, we are an essential safety net provider in our community.

I strongly urge the Centers for Medicare and Medicaid Services (CMS) to 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. It is vitally important to northern Minnesota women and families that 'safety net providers' be defined by CMS and that the definition includes clinics like Women's Health Center. It is essential that clinics like ours be able to provide low-cost birth control pills to patients who are financially unable to purchase them at market prices.

Thank you for your time and assistance in this urgent matter.

Respectfully submitted by,

Tina Welsh
Women's Health Center
32 East 1st Street
Suite 300
Duluth, MN 55802

Submitter : Mr. Andrew Peterson
Organization : Peterson Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

CMS is considering revising formula for determining generic drug payment to pharmacies.

**Collection of Information
Requirements**

Collection of Information Requirements

The new Payment formula is based on "AMP".

GENERAL

GENERAL

The new basis for generic drug payment is not adequately defined to insure that small pharmacies like mine will be reimbursed adequately to remain in business. There is no assurance that medications can be purchased by pharmacies at the low payment levels proposed by CMS.

This payment scheme needs to be re assessed and implementation delayed until a mechanism is established to allow profitability by small community pharmacies.

CMS-2238-P-1227

Submitter : Mr. Barry Christensen
Organization : Alaska Pharmacists Association
Category : Health Care Provider/Association

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1227-A\atch-1.DOC



Alaska Pharmacists Association

VIA Electronic Submission

March 3, 2007

Leslie Norwalk
Acting Administrator
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 Ms. Norwalk,

The Alaska Pharmacists Association(AKPhA) represents over 200 licensed pharmacists, pharmacy technicians, and pharmacies in the State of Alaska. On behalf of our membership we are writing to express our deep concerns with the Center for Medicare and Medicaid Services'(CMS) proposed payments for prescription drugs in the Medicaid program. Our comments will likely mirror those expressed by other pharmacy associations but will also include specific details of how we feel the changes will impact smaller pharmacies in our State.

Definition of "Retail Class of Trade"-Removal of PBMs and Mail Order Pharmacies and calculation of AMP

Mail order pharmacies should not be included in the definition of retail pharmacy class of trade for the purposes of determining AMP. Although mail order pharmacies serve consumers on a retail level their dispensing rate, per day (purchases), are many hundreds-times larger than a community based retail pharmacy allowing them to buy at a lower cost; a cost not available to a community based retail pharmacy. Therefore, inclusion of mail order pharmacy drug purchase pricing in the calculation of AMP will lower the reimbursement to community pharmacies below their cost of the drug.

PBM rebates, discounts or other price concessions should not be recognized in the calculation of AMP. PBMs are not distributors of drugs to retail pharmacies; they do not buy, warehouse nor do they deliver pharmaceuticals to retail pharmacies; they do not act as wholesalers. Retail pharmacies do not share in rebates, discounts or other price concessions that PBMs have negotiated.

E-mail: akphrmcy@alaska.net

It is incorrectly assumed that retail pharmacies share in the cash discounts and other price reductions from a manufacturer for drugs purchased by wholesalers and eventually distributed to retail pharmacy, and therefore inappropriate to include such cash discounts and price reductions in the calculation of AMP.

Rebates paid by the manufacturer to the PDP or MA-PD should not be included in the calculation of AMP. Rebates paid to health plans are, generally, incentives to include the manufacturer's drug on a plan formulary. Manufacturer rebates paid to PDPs or MA-PDs are not considered by a wholesaler when determining the purchase price to a retail community pharmacy and, therefore, should not be included in any calculation to reimburse the pharmacy.

Sales and rebates associated with the sales to patients through direct programs should not be included in the calculation of AMP for pharmacy reimbursement. Manufacturers' patient assistance programs bypass wholesalers and pharmacies and are often greatly discounted for patients who meet the manufacturer's low income criteria for the discount or rebate programs.

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.

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.

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.

E-mail: akphrmcy@alaska.net

Effects on Small Retail Pharmacies

Nearly one-third of all community retail pharmacies in Alaska are considered small retail pharmacies by SBA standards. The proposed rule recognizes that these pharmacies would be directly impacted by the proposed AMP regulations but concludes that "we are unable to specifically estimate quantitative effects on small retail pharmacies". Many of our small Alaskan retail pharmacies are located in rural low income areas that serve high concentrations of Medicaid patients. The proposed rule dictates the Federal Upper Limit(FUL) for a generic drug will be based upon 250% of the lowest AMP for all versions of that generic medication. However, a December 22, 2006 report by the GAO indicated that retail pharmacies will be reimbursed on average 36 percent lower than their COST to purchase the medications. This change would clearly put pharmacies at risk of staying in business and would also create a disincentive to dispense generic medications.

In conclusion, the proposed payment formula will be devastating to many community Alaskan retail pharmacies, Alaska Medicaid patients, and the financing of the Medicaid program itself. The Alaska Pharmacists Association asks you to carefully consider all comments received on this matter and please contact us with any questions.

Sincerely,

Barry D. Christensen, Pharmacist
Co-Chair Legislative Committee
Alaska Pharmacists Association

CC: Senator Lisa Murkowski

E-mail: akphrmcy@alaska.net

4107 Laurel Street, Suite 101 • Anchorage, Alaska 99508 • (907) 563-8880 • (907) 563-7880

Submitter : Dr. Laura Tyson
Organization : Dogwood Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

I am honored to fill prescriptions for many Medicaid recipients in South Georgia on a daily basis. However, if new regulations go in to effect, it is my understanding that in order to serve these patients, I will have to lose money on every prescription. I have only been open for business for 7 months and am working hard at providing excellent care for anyone that needs it. Unfortunately, health care costs continue to rise and I have to be concerned about "breaking even". A cut in profit is not the primary concern. The ability to keep the doors open is. The Chain Pharmacies do a great job at filling prescriptions at cut rate prices, but the care is also cut rate. I do more than just fill a prescription and the Medicaid recipients of South Georgia will have to suffer if the new provision goes into effect.

Submitter : Mr. Alan Shepley
 Organization : Shepley Pharmacy
 Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

I am writing to provide my views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

I operate a small pharmacy in Mount Vernon, Iowa. We are the only pharmacy in our town and thus the only provider of pharmacy services in our community. This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy. It could jeopardize my ability to provide pharmacy services to Medicaid beneficiaries and the general public. This regulation should not move forward unless substantial revisions are made. Incentives need to be retained for pharmacies to dispense low-cost generic medications. I ask that CMS please do the following:

1) Delay Public Release of AMP Data: The Centers for Medicare and Medicaid Services (CMS) should not make Average Manufacturers Price (AMP) data public until a final regulatory definition of AMP is released. This definition should reflect the prices at which traditional retail pharmacies purchase medications. CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data could adversely affect community retail pharmacies if used for reimbursement purposes. CMS has already delayed release of these data, and we urge that release of these data be delayed again.

2) Define AMP to Reflect Retail Pharmacy Purchasing Costs: CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires. Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade. In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

3) Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system. With this in mind we would be forced to stop serving the Medicaid population in our area.

4) Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) and others regarding this proposed regulation.

Thank you.

Sincerely,

Alan M. Shepley R.Ph.

Submitter : Dr. Terry Forshee
 Organization : Cherokee Pharmacy
 Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Cherokee Pharmacy a community retail pharmacy located at 2850 Westside Dr NW, Cleveland, TN 37312. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy, where over 85% of our business comes from prescription drugs. What the other sales in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

GENERAL

GENERAL

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions. The future of independent pharmacy in this country depends upon your strong consideration of this issue. We as independent pharmacists provide a valuable service that saves our health care system billions of

dollars each year by being the final checkpoint before patients receive their medications. We have always fought very hard to implement positive changes in our profession as witnessed by our commitment to Medicare Part D. Please allow us the opportunity to continue to compete and practice in our communities. We have held off the major chains, discount stores, mail order (in spite of regulations that give them unfair purchasing advantages), PBM's (who have been proven to provide no price savings or any other advantage to the health care system other than to siphon money into their coffers) and even Medicare Part D which in its design benefits PBMs and drug manufacturers more than patients. Now, it is up to CMS to make sure fairness is built into this new reimbursement model. Please let us help you!

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Use of 11-Digit NDC versus 9-Digit NDC

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

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**

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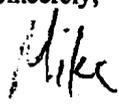
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

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

Date: 02/20/2007

Organization : California Medicaid - Medi-Cal

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT - SIGNED COPY WILL BE SENT VIA OVERNIGHT

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

1232

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



California
Department of
Health Services

SANDRA SHEWRY
Director



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 (diluents, 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.

Centers for Medicare & Medicaid Services
CMS-2238-P
Page 5
February 20, 2007

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

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

Submitter : Mr. Paul Piszczewicz
Organization : Columbia St. Marys
Category : Pharmacist

Date: 02/20/2007

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.

GENERAL

GENERAL

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.

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 mulple 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 Rxs 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.

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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.



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 Louisville (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



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

CMS File Code: CMS-2238-P

Federal Register
Publication Date: December 22, 2006

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 place-holding 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 distributions, 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/pharmbenefit05/050906pharmbenefittrpt.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

purposes, we suggest instructing manufacturers to look to the four full calendar quarters before the reporting period to calculate the rolling 12-month percentage. A similar rolling percentage approach should be used to deal with lagged unit data needed to calculate AMP. The price and unit percentages could then be used to determine all three monthly AMPs and the quarterly AMP.

If CMS is not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates because chargebacks often relate back to sales several periods prior. Because of the complexities involved, CMS should provide examples showing how the methodology should be applied in both the monthly and the quarterly context. Those examples also should take into account the proper treatment of the various types of bundled sales.

Posting of AMP Data

HDMA suspects that making AMP values publicly available on the CMS Web site before all the regulatory changes have been finalized and manufacturers given sufficient time to update their systems could mislead consumers about the appropriateness of the prices they are charged for drugs at retail pharmacies. It also could mislead commercial carriers about the drug costs experienced by network pharmacies. The simplest way to avoid possible confusion and data misuse would be to delay Web site postings until the new AMP rule becomes effective. We strongly encourage CMS to take this step.

We understand CMS believes it does not have the statutory authority to delay posting AMP data beyond the point when it has January AMPs in hand. Nonetheless, HDMA knows that executive branch agencies occasionally miss statutory deadlines without suffering legal repercussions, particularly when there is a valid reason for delay and the delay is reasonably short. We note, too, that CMS failed to meet the statutory deadline included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2005 for implementing the competitive acquisition program (CAP) for drugs covered under Medicare Part B because it needed to work out problems with its initial program design, and attract a CAP vendor.

We realize the DRA sets an effective date of January 1, 2007, for the posting of AMP data. We appreciate the decision to read the law as applying to data related to sales occurring on or after January 1st and CMS' commitment not to post AMP data until it can process January monthly AMPs due to be filed by March 2, 2007. This timing ensures that posted AMPs will at least reflect the DRA's removal of customary prompt pay discounts extended to wholesalers from the calculation. That said, it does not fully resolve the potential problems associated with AMP postings that do not fully reflect the impact of the regulatory changes that will be implemented once the Proposed Rule is finalized.

If CMS decides to go forward with AMP postings this Spring, we hope that, at a minimum, the agency will review the January monthly reports carefully before placing the data on its Web site or downloading it to the states. Moreover, we hope any posting will be prefaced by a warning indicating that limited instructions were provided to guide manufacturers' January AMP calculations. Many manufacturers may have been unable to update or complete updating their government price reporting systems prior to reporting. Moreover, methodologies for calculating AMP are likely to change again mid-year when CMS promulgates a Final Rule codifying the AMP calculation methodology. Accordingly, posted data should be viewed as preliminary and

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

equivalents listed in national pricing compendia. AMPs calculated at the nine digit NDC level will be used even though this approach will preclude tying FULs to the package sizes most frequently purchased by pharmacies.

We are strongly opposed to using nine digit AMPs to set FULs because applying a nine digit price likely will lead to reimbursement rates too low to fairly reimburse pharmacies for some products. CMS' collection and use of only of nine digit weighted average AMPs will become problematic when the weighted average is controlled by a high volume of sales of a larger-sized package with a lower per-unit cost, compared with smaller package sizes of the same drug, strength and dosage form. For example, the weighting could result in an AMP based largely upon pricing for a 500-tablet bottle even though retail pharmacies typically stock 100-tablet bottles to deal with shelf-space limitations and to control inventory costs. The problem with nine digit AMPs likely will become particularly acute with topicals and other products commonly distributed in unit-of- use packages (such as eye drops). The per-unit cost of an ointment in a larger 60-gram tube may be substantially less than the unit cost of the same product in 15-gram tube. Nonetheless, pharmacies have no choice about dispensing the small tube, regardless of the cap the product's FUL places on reimbursement if, as is frequently the case, the physician writes a prescription that specifies the unit-of-use package size.

To address this problem, we urge CMS to modify the Proposed Rule to require manufacturers to calculate and report AMPs routinely at the 11-digit level. Such reports would permit FULs to be set based on the most commonly purchased package sizes, as has been the practice in the past. If manufacturers also were required to report the number of units of each package size sold, as they do now when they report ASP values to Medicare, then CMS could calculate weighted nine digit AMPs that the states could continue to use for rebate purposes. CMS also would be in a position to permit states interested in reworking their pharmacy reimbursement formulas to select whether they want to receive 11-digit AMP data in addition to or in lieu of the nine digit AMPs that CMS has historically used to calculate Unit Rebate Amounts. We are of the view that pharmacy payments based on 11-digit data would more appropriately match reimbursement to per-store ingredient costs, since it is not always reasonable or appropriate for every retail outlet to buy drugs in the size container that promises the lowest per-unit price.

Reporting of 11-digit AMPs could also improve the utility to some consumers and commercial payers of the AMP data CMS will make publicly available through web postings. Finally, having 11-digit AMP data and accompanying unit sales information would permit CMS to set FULs based on weighted-average AMPs, instead of the lowest AMP, should Congress change the law in this regard. As we will discuss below, requiring manufacturers to report 11-digit AMPs and unit sales would permit CMS to address the problem of AMP outliers effectively when it determines FULs by using an approach that takes price and market share information into account simultaneously.

Eliminating Outliers From FUL Calculations

HDMA applauds the decision to carry out the FUL determinations without considering the AMPs reported for drugs once manufacturers have terminated a product. We understand current sub-regulatory guidance, which we presume will remain in effect after the Final Rule is issued, requires manufacturers to continue reporting the AMP calculated for the last quarter a product was marketed until one year after the last-batch expiration date of

the freshest product the manufacturer distributed. Obviously, since such AMPs could be several years old and no longer reflective of market pricing, using them could inappropriately skew FULs.

HDMA also commends CMS for adding a procedure to its methodology for setting FULs intended to ensure that caps on multiple source drug reimbursement are based on pricing keyed to that for a product available in quantities sufficient to meet national distribution demands. Eliminating the sale of product that is extremely short-dated or otherwise distressed avoids setting an artificially low FUL based upon AMP prices that do not reflect true market conditions.

We would prefer to see FULs calculated using the weighted average AMP of the therapeutically equivalent products available in the market, not the AMP of the least costly product. The DRA does not specify that FULs must be set at 250% of the lowest AMP for a product family, as the Proposed Rule would require. Rather, the DRA merely directs CMS to change the regulation at 42 C.F.R. § 447.332(b) to substitute “250 percent of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)” for “150% percent of the published price.”³⁶ Since Congress never expressly mandated tying FULs to a multiple of the lowest AMP for a product family, we are of the view that CMS still retains the discretionary authority first granted it under Social Security Act § 1927(e)(4) to change other aspects of the FUL regulation. We urge CMS to use that authority to base the FUL on 250% of the weighted average AMP. Otherwise, we fear that pharmacies will be underpaid for many of the multiple source drugs they dispense to Medicaid beneficiaries perhaps leading many pharmacy owners to withdraw from providing prescription drug services to Medicaid beneficiaries, thereby reducing access to the most needy Americans.

If CMS is unwilling to amend the existing regulatory language setting FULs based on the least costly therapeutic equivalent, we encourage it to adopt, by regulation, an outlier methodology that uses market-share as the fundamental criteria for determining whether a low AMP should be rejected as non-representative in lieu of the price-based outlier approach detailed in the Proposed Rule.

We support requiring manufacturers to report, along with monthly AMPs, data at the 11-digit level (as discussed above) on the volume of product sold during each reporting period. CMS could then classify monthly AMPs associated with low market shares as outliers that do not represent widely available prices in the market. Specifically, we recommend examining AMPs on a cumulative market share basis, starting with the lowest reported AMP, then the next highest AMP and so on, rejecting AMPs until a cumulative market share of at least 50% has been reached. In contrast to the indirect price-based approach described in the Proposed Rule, this approach will allow CMS to focus directly on whether a low-priced NDC is available only on a “limited basis.”³⁷ Doing so should “ensure that a drug is nationally available at the FUL price”³⁸ because the market-share-based outlier methodology will disregard AMPs that, despite the low price, were only able, collectively, to satisfy less than 50% of market demand during the reporting period. Simply put, such AMPs are not indicative of true market conditions because product priced at such levels is in limited supply and cannot be said to be available for sale nationally.

³⁶ DRA § 6001(a)(5).

³⁷ 71 *Fed. Reg.* at 77188; *see also* proposed 42 CFR § 447.514(c).

³⁸ *Id.*

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

Table 1 - Scenario:

Product at NDC Level	Price	Units	Cumulative Units	Cumulative Market 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

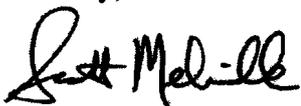
We had hoped CMS would address implementation issues related to DRA § 6001(e) in the Proposed Rule. We were looking forward to the opportunity to comment on how and from what sources data underlying RSP should be collected and how the data should be used to determine “a nationwide average of consumer 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.

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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).