Submitter : Miss. JOANNE HOFFMAN BEECHKO **Date:** 02/20/2007

Organization : PSSNY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

We are a strong independent community pharmacy in East Northport, New York. We take our responsiblity to the community very seriously and do everything we can to help our clients. AMP Regulation CMS 2238-P RIN 0938-AO20 threatens our very existence as proposed AMP payments will be far less than what we actually pay, never mind any additionally revenues for operating expenses. Profit is not allowed, I gather. I support my state society, Pharmacists Society of the State of New York, and all their proposed suggestions includng their stand on " trigger mechanisms ", " claw back " fallacies, and use of the 11 digit NDC for cost calculations.

Please heed the local pharmacies warnings regarding all reimbursment issues. Small business, especially those in the health care industry, serve vital functions in the maintenance of community integrity, vitality and growth. Undercutting our margins threatens our very existence.

Submitter : Ms. David Morton **Date:** 02/20/2007

Organization : Morton Drug Company

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1179-Attach-1.DOC

#1179

MORTON
PHARMACY

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

Morton Pharmacy is writing to provide our view 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 owns and operates twelve pharmacies in Wisconsin. We are a major provider of pharmacy services to the Medicare and Medicaid programs in our community.

This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacies. It will jeopardize our 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 retail pharmacies purchase medications (that serve the public). CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data would 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 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. We ask that the implementation of these FULs be suspended because it is 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,

David J. Morton,
Vice President of Operations
Morton Pharmacy
201 E. Bell Street
Neenah, WI 54956
920-727-8660

Submitter : Mr. Chuck Greco

Date: 02/20/2007

Organization : Focus Respiratory

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1180-Attach-1.DOC

1180

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 at 10167 J Street in Omaha. We are a major provider of respiratory pharmacy services in the community. Your consideration of these comments is essential to maintain small business viability and quality patient care.

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

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

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

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

Sincerely,

Pharmacist name

cc: Senator Chuck Hagel
Senator Ben Nelson
Congressman Lee Terry

Submitter : Dr. Kathleen Jordan Peebles **Date:** 02/20/2007

Organization : Publix Food and Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1181-Attach-1.DOC

#1181

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 at Publix, a community retail pharmacy located at 10638 Concord Road, Brentwood, TN 37027. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Kathleen Jordan Peebles, Pharm.D.
8908 Lyman Lane
Nashville, TN 37211

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Beth Halteman Harwell

Submitter : Mr. Peter Durkin **Date:** 02/20/2007

Organization : Planned Parenthood of Houston and Southeast Texas

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1182-Attach-1.DOC

#1182

Planned Parenthood®
of Houston and Southeast Texas, Inc.
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February 16, 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 Houston & Southeast Texas, Inc., which operates 10 non-profit outpatient health centers in six counties, both urban and rural, in southeast Texas. We provide a wide array of family planning and related services to those unable to afford such services elsewhere. We have been meeting the needs of uninsured and underinsured women and men since 1936. Last year, we served over 50,000 patients. We know that many of these patients would not be able to pay full price for these health services, including oral contraceptives, and would go without if we were not here to help.

For over 70 years, Planned Parenthood of Houston & Southeast Texas has provided basic health care that includes well-woman exams, screening for breast cancer, cervical cancer, sexually transmitted infections, diabetes, hypertension, and anemia. We provide medications, including oral contraceptives, directly to our patients through our Class D pharmacy at prices well below retail. Oral contraceptives are particularly expensive as an out-of-pocket expense at retail pharmacies, ranging from $35 – $55 per month.

We estimate that over half of our patients are below 150% of the federal poverty level. They would not be able to pay for oral contraceptives at the retail pharmacy rates, and likely would go without, resulting in many unintended pregnancies. In Harris County, Texas, 32% of people under age 65 do not have health insurance -- the highest among major cities in the United States. An estimated 800,000 low-income residents (those with family income less than 200% of the federal poverty level) are without public or private health insurance or sufficient personal resources to pay for services.

Planned Parenthood of Houston & Southeast Texas has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. We have been able to serve approximately 25,000 low-income women each year because we were able to provide them with affordable birth control – particularly contraceptives that we were able to purchase at nominal prices. These 25,000 women will no longer be able to purchase contraceptives from us if we cannot provide them at a cost they can afford.

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In January 2007, nominal drug pricing became available to only three kinds of providers: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Although many Planned Parenthood health centers across the country receive Title X funding, and therefore are 340B-covered entities, we operate only one health center that qualifies as a 340B covered entity. Our other health centers are funded by Social Services Block Grant Title XX funds appropriated by the Texas Legislature for family planning, as well as Medicaid. Neither of these funding sources qualifies our health centers for nominal pricing, even though they serve very low-income patients (below 185% of the FPL).

We are clearly considered a safety net provider by our patients and other heath care entities that refer patients to us. Our ability to continue to serve our communities as a safety net provider rests on the availability of low cost contraceptives, purchased at nominal prices. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule.

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

Again, 25,000 women in Houston and southeast Texas may no longer be able to get affordable birth control if we are not able to provide contraceptive drugs at low prices.

Respectfully submitted by,

Peter J. Durkin
President and CEO
Planned Parenthood of Houston & Southeast Texas, Inc.

Submitter : Mr. Peters willson **Date:** 02/20/2007

Organization : National Association of Children's Hospitals

Category : Health Care Provider/Association

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

On behalf of the National Association of Children s Hospitals (N.A.C.H.), I am submitting comments on proposed regulations to implement the Deficit Reduction Act of 2005 (DRA), which were published in the Federal Register on December 22, 2006.

In responding to the proposed rules, we bring to your attention three main concerns, which I describe in more detail below. First, the proposed requirements for reporting NDC information would be administratively burdensome, especially for children s hospitals. Second, the rules could effectively preclude children s hospitals from meaningful benefit from participation in the 340B program, contrary to the intent of Congress in enacting Sec. 6004 just last year. Third, the rules ignore implementation of Sec. 6004, which amends Medicaid statute to permit children s hospitals to apply for 340B program participation.

The Rules Are Administratively Burdensome. The proposed regulations would create enormous administrative and financial burdens for children s hospitals by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. At a time when all hospitals are seeking to revamp their electronic information systems, children s hospitals experience even greater costs and burdens, since they always have to retrofit any new information technology system to reflect the unique characteristics of pediatric health care. Their information management costs therefore exceed even the already high costs of the rest of the industry.

The Rules Could Jeopardize the Benefit of 340B Participation for Children s Hospitals, Contrary to Congressional Intent. CMS s proposed policies would significantly decrease the savings a children s hospital could achieve through participation in the 340B program, since the new rules could result in any state imposing manufacturer rebate obligations on hospital outpatient clinic drugs, which should be treated as exempt from rebate requirements. This would be especially harmful to children s hospitals, since on average, nearly 50 percent of outpatient visits in a children s hospitals involve patients covered by Medicaid alone, often a very poor payer of hospital care.

In addition, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP) could drive up the prices a children s 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.

The Proposed Rules Ignore Sec. 6004 of the DRA. Children s hospitals are deeply concerned about the continued failure of the Department of Health and Human Services to address, through Federal Register Notice, its responsibility under Sec. 6004 of the DRA to permit children s hospitals to apply to participate in the 340B program. Although it is a year since the DRA was signed into law and nearly a year since Sec. 6004 took effect, neither the Health Resources and Services Administration (HRSA), which administers the 340B program, nor CMS, which administers Title XIX, has provided the guidance required for children s hospital to apply and be approved for 340B participation.

The effect of such failure is to deny congressional intent, which was to remove an arbitrary barrier to children s hospitals participation as disproportionate share hospitals the fact that children s hospitals are exempt from the Medicare prospective payment system and therefore, based on that alone, cannot be designated as Medicare disproportionate share hospitals. Medicare disproportionate share hospitals are the only hospitals eligible to apply for 340B.

GENERAL

GENERAL

See attachment

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

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

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

Submitter : Mr. Peter Durkin **Date:** 02/20/2007

Organization : Planned Parenthood of LA & the MS Delta, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1184-Attach-1.DOC

#1184

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February 19, 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 Louisiana and the Mississippi Delta, which operates two non-profit outpatient health centers in Baton Rouge and New Orleans. Since 1984, we have provided a wide array of family planning and related services to those unable to afford such services elsewhere. These basic health care services include well-woman exams, screening for breast cancer, cervical cancer and sexually transmitted infections. Last year, we served over 5,000 patients. We know that many of these patients would not be able to afford these health services, including oral contraceptives, and would go without if we were not here to help.

515,960 Louisiana women are in need of contraceptive services and supplies. Of these, 304,270 need publicly supported contraceptive services because they have incomes below 250% of the federal poverty level (FPL) (210,650) or are sexually active teenagers (93,620). Recently, these needs were compounded by the devastating effects of Hurricane Katrina, which halted many reproductive health care services in New Orleans, caused an influx of evacuees to the Baton Rouge area, and overwhelmed state health units. As a result, women, now more than ever, rely on Planned Parenthood's affordable health care.

Planned Parenthood of Louisiana and the Mississippi Delta has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Each year, we have provided affordable birth control—particularly contraceptives that we purchased at nominal prices—to approximately 5,000 low-income women. Unfortunately, these women will no longer be able to purchase contraceptives from us if we cannot provide them at an affordable cost. Oral contraceptives are particularly expensive as an out-of-pocket expense at retail pharmacies, ranging from $35 – $55 per month.

In January 2007, nominal drug pricing became available to only three kinds of providers: 340B covered entities, intermediate care facilities for the mentally retarded, and state owned or operated nursing homes. Although many Planned Parenthood health centers across the country

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receive Title X funding, and therefore are 340B-covered entities, our health centers in Louisiana do not. In 2005, in an attempt to keep state run health units afloat, the Louisiana department of

Health and Hospitals pulled Planned Parenthood's Title X funding, forcing our patients either to pay out of pocket for their services or to go without reproductive health care. An increase in contraceptive and drug pricing will drastically affect these same self pay-patients. While our health centers do receive Medicaid funds, this funding source does not qualify our health centers for nominal pricing, even though they serve very low-income patients.

We are clearly considered a safety net provider by our patients and other heath care entities that refer patients to us. When faced with a health care crisis during Hurricane Katrina, Planned Parenthood helped address the health care needs of evacuees and also eased the patient load of the state health units that were suffering from an influx of new patients. However, our ability to continue to serve our communities as a safety net provider rests on the availability of low cost contraceptives purchased at nominal prices. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule.

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

Again, 5,000 women in Louisiana may no longer be able to get affordable birth control if we are not able to provide contraceptive drugs at low prices.

Respectfully submitted by,

Peter J. Durkin
President and CEO
Planned Parenthood of Louisiana and the Mississippi Delta

Submitter : Mr. James Roderick **Date:** 02/20/2007

Organization : Planned Parenthood of North Texas, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1185-Attach-1.DOC

CMS-2238-P-1185-Attach-2.DOC

#1185

Planned Parenthood of North Texas, Inc.

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:

As President/CEO of Planned Parenthood of North Texas (PPNT), I am writing to address my concerns regarding the Deficit Reduction Act of 2005 and nominal drug pricing. PPNT is a non-profit organization that operates 28 reproductive health care clinics and provides services to more than 90,000 low-income patients a year, most of whom are uninsured and could not otherwise afford health care. We are proud to have been providing high-quality, affordable care in North Texas for more than 70 years.

PPNT provides comprehensive family planning services, including Pap smears; breast and pelvic exams; contraception; diagnosis of and referral for diabetes, breast and cervical cancer, hypertension, and HIV; testing and treatment for gynecological and sexually transmitted infections; colposcopy, cryotherapy and LEEP for the diagnosis and treatment of abnormal cervical cells; vasectomies; and medical and social services referrals as needed. Each PPNT clinic also contains an on-site pharmacy, where patients can purchase needed medicines at a fraction of the cost charged by retail pharmacies. The services we provide help our patients to avoid unintended pregnancies and help increase the chance that manageable conditions and infections will be discovered before they become more advanced, dangerous, and expensive to treat.

Most of our patients (64%) are between 18-29 years old, 27% are over the age of 30, and 9% are 17 and younger. Not surprising given our patient demographics, affordable contraception is a priority for our patients, including the 44% who receive their birth control pills from us. The vast majority of our patients are at or below 200% of the federal poverty level (FPL), including 62% who are at or below 150% of FPL. Our clinics operate on a sliding fee scale based on family size and income. Due to nominal pricing for oral contraceptives, we have been able to offer gynecological exams and other services at very affordable rates.

Vickery Park Office Building • 7424 Greenville Ave., Ste. 206 • Dallas, Texas 75231
Phone (214) 363-2004 • Fax (214) 696-2091

Without nominal pricing, PPNT would be forced to downsize its operations by reducing staff, decreasing hours of operations, and even possibly closing some clinic locations. We would also have to increase prices not only on contraceptives but also on all other drugs and services. With 30% of our clients reporting an income of $50 or less a week, the increase in pricing would prohibit many of them from receiving the health care they need to live a healthy life. Closing clinics would be devastating for some communities because PPNT's clinics are located on bus routes, which are not extensive. In some North Texas counties, PPNT is the only clinic or one of only two providers. If we had to close clinics, many of our patients would not be able to get to another provider without great difficulty.

As a result of the Deficit Reduction Act, only four kinds of providers are now allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded, state owned or operated nursing homes, and "other safety net providers" as defined by the Centers for Medicare and Medicaid Services (CMS). While 13 of our 28 health centers are operated with the help of funding from Title X and are, therefore, 340B covered entities, the remainder of our health centers are not. Thus, PPNT's ability to purchase low-cost contraceptives for patients at the remainder of our clinics is in jeopardy unless PPNT is defined as a safety net provider. Unfortunately, CMS' proposed regulation on nominal drug pricing does not provide such a definition.

PPNT should be classified as a safety net provider. All our clinics provide basic health services to a population that would otherwise fall through the cracks. Our ability to continue to help those who live on the edge is contingent upon our ability to purchase contraceptives at a nominal price. I urge CMS to clarify the definition of "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. I believe that any such definition should include non-profit, outpatient clinics such as PPNT's.

Sincerely,

James T. Roderick
President/CEO
Planned Parenthood of North Texas

Vickery Park Office Building • 7424 Greenville Ave., Ste. 206 • Dallas, Texas 75231
Phone (214) 363-2004 • Fax (214) 696-2091

Submitter : Mr. TRUSHAR SHETH **Date:** 02/20/2007

Organization : GIANNOTTO'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED.

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

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

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

Submitter : Mr. Carl Tubbesing **Date:** 02/20/2007

Organization : National Conference of State Legislatures

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1187-Attach-1.PDF

1187

NATIONAL CONFERENCE *of* STATE LEGISLATURES

The Forum for America's Ideas

Leticia R. Van de Putte, R. Ph.
State Senator
Texas
President, NCSL

Stephen R. Miller
Chief, Legislative Reference Bureau
Wisconsin
Staff Chair, NCSL

William T. Pound
Executive Director

February 20, 2007

Centers for Medicare and Medicaid Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-2238-P

NCSL was pleased with the Deficit Reduction Act provision that calls for monthly reporting to states and for making the prices available to the public. NCSL has called for transparency regarding the prices of prescription drugs in the Medicaid program for a number of years and looks forward to working with you on implementing that provision. On behalf of the National Conference of State Legislatures (NCSL) I submit the following additional comments on the NPRM, implementing provisions of the Deficit Reduction Act of 2005 (DRA) regarding the Medicaid prescription drug program, for your consideration.

Determination of Average Manufacturer Price – Section 447.504

NCSL supports excluding the prices of sales to long term care pharmacies from the calculation of AMP. While the proposed rule makes a strong case for the inclusion of prices of sales to mail order pharmacies and Pharmacy Benefit Managers (PBMs), the rule remains extremely vague on operational issues. Because the inclusion of these prices will have a significant impact on the AMP, the operational details are extremely important. We urge great care and consideration. With regard to "future clarifications of AMP," the proposed rule notes that CMS plans to address future clarifications through the issuance of program releases and by posting clarifications on the CMS Web site. We urge you to reconsider this strategy and to publish a NPRM for public comment.

Determination of Best Price – Section 447.505

Over the years the statutory exceptions to the Medicaid "Best Price" calculation have grown. It is essential that "Best Price" be calculated to include all sales, discounts, or other price concessions provided by the manufacturer for covered outpatient drugs unless the entity is specifically excluded from the best price calculation by statute. NCSL supports the exclusion of Medicaid rebates and supplemental rebates to states from the best price calculation. If significant changes are under consideration for the calculation of best price, we urge you to publish a NPRM for public comment instead of the issuance of program releases and the posting of clarifications on the CMS Web site as proposed in this rule.

Regulatory Impact Analysis – Effects on Retail Pharmacies

NCSL recognizes the reform of the Medicaid prescription drug program is needed. We remain concerned about access issues for Medicaid beneficiaries in rural, inner-city and other underserved areas with large numbers of Medicaid beneficiaries due to the disproportionate impact the lower Federal Upper Limits (FULs)

will have on some small retail pharmacies. Because all the details of the program have not been determined, it is difficult to know which pharmacies will have the most trouble and we appreciate your efforts to get feedback. NCSL supports efforts to encourage states to review the adequacy of their dispensing fees, but we do not believe that increasing state dispensing fees will address the problems facing these small retail pharmacies.

I thank you for your consideration and urge you to call me or Joy Johnson Wilson our Health Policy Director at 202-624-5400, if you have any questions or if we can be of additional assistance to you.

Sincerely,

Carl Tubbesing
Deputy Executive Director
National Conference of State Legislatures

Submitter : Mike Chamberlain **Date:** 02/20/2007

Organization : Edgemont Healthmart Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed rule does not address adequate reimbursement under AMP based reimbursement formula and doesn't provide adequate dispensing fees for pharmacist services.

GENERAL

GENERAL

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies and hospital pharmacies that have access to rebates and price concessions that are not accessible to independent community pharmacies. If the current definitions are approved then mail order pharmacies & hospital pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access their medications. Also, the current dispensing fee for Utah medicaid is $3.90 and the average cost to dispense a medication in the state of Utah is $12.39. We are already severly underpaid on our reimbursements and the new proposal will be even worse. If the current definitions are not changed then I will not be able to accept Medicaid patients at my pharmacy. That will cause an undo burden to many of my patients and will likely increase the costs to Medicaid. The rules need to be fair to all pharmacies including the independent pharmacies who have been shown to give more personalized healthcare and information to their patients.

Submitter : Dr. Seth Matthew Dye **Date:** 02/20/2007

Organization : Wal-Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1189-Attach-1.DOC

#1189

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 at Wal-Mart, a community retail pharmacy located at 911 Hwy 321 N, Lenoir City, TN 37771. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Seth Matthew Dye, Pharm.D.
880 Glenfield Drive
Lenoir City, TN 37771

cc: Senator Lamar Alexander
Senator Bob Corker
Representative John J. Duncan

Submitter : **Joseph Chammas** **Date: 02/20/2007**

Organization : **Sudbury Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Ms. Heather Hulscher **Date:** 02/20/2007

Organization : Iowa Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1191-Attach-1.DOC

#1191

IOWA HOSPITAL ASSOCIATION

June 12, 2006

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

Ref: CMS—2238-P Medicaid Program; Prescription Drugs, Proposed Rule (71 *Federal Register* 77174), December 22, 2006.

Dear Ms. Norwalk,

On behalf of Iowa's 117 hospitals, the Iowa Hospital Association (IHA) is pleased to take this opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding prescription drugs in the Medicaid program, published in the December 22, 2006 *Federal Register*. This proposed rule would implement three sections of the Deficit Reduction Act of 2005 (DRA), including sections 6001(a)-(d), 6002, and 6003. The comments contained in this letter are specific to the proposals to implement section 6002 of the DRA.

IHA opposes any attempt by CMS apply section 6002 to hospitals for the specific reasons outlined below. Any attempt to enhance Medicaid funding to the states should not be done on the backs of Iowa hospitals. In 2006, Iowa hospitals lost $118 million due to inadequate Medicaid reimbursement rates, and cannot sustain further administrative and financial burdens to increase the state's portion of Medicaid funding, without any return for the acquisition, storage and administration of the drugs for Medicaid recipients. The following are IHA's comments:

FFP: Conditions Relating to Physician-Administered Drugs (§ 447.520)
When Congress passed the DRA, it did not intend for section 6002 to apply to hospitals. Rather, this section was only intended to apply to outpatient drugs administered in the physician clinic setting. In its 2004 report to CMS titled *Medicaid Rebates for Physician-Administered Drugs*, the Office of Inspector General (OIG) stated the following: **"Physician-administered drugs (drugs that a medical professional administers to a patient in a physician's office) are covered under this program."**

In the proposed rule, CMS acknowledges the relationship between this OIG report and the enactment of Section 6002. The preamble makes numerous references to the "physician-administered drugs" covered by the OIG report, including a statement that current estimates of Medicaid savings from implementing Section 6002 are based on the 2004 OIG report. CMS'

100 EAST GRAND | DES MOINES, IOWA 50309-1835 515.288.1955 FAX 515.283.9366
www.ihaonline.org

discussion appears to directly equate the physician-administered drugs that were the subject of the OIG report with those that are subject to Section 6002 and its proposed regulation.

The DRA requires the Secretary to clearly define outpatient drugs that are physician-administered, yet the proposed rule fails to do so. Rather, inferences are made in the preamble and the Collection of Information Requirement section that estimate the financial burden on hospital outpatient departments. CMS' intent to apply Section 6002 so hospital outpatient departments is inappropriate and outside the parameters established in statute.

Regulatory Impact Analysis
CMS has grossly underestimated the cost to hospitals to be able to capture and report the National Drug Code (NDC). Presently, hospital chargemasters do not include NDC codes for the primary reason that the NDC code set has never been and still is not a HIPAA compliant code set for hospital outpatient services. Hospitals would incur substantial costs to have their claims software vendors allow for the NDC to be reported on the claim where there is presently no place to report this code set. CMS estimates the annual national cost to implement this provision on the 700 small rural hospitals is $344,000, or $491 per small rural hospital. The 2004 OIG report estimated the potential return for Iowa at a little over $1 million for 40 multiple source drugs, and all single source drugs. The DRA is only requiring states to collect rebates on 20 multiple source drugs and all single source drugs. One million dollars is less than what Iowa hospitals in aggregate would have to spend to add the NDC codes to the chargemaster, and then to pay claims processing vendors to redesign the format to report the correct NDC code on the claim.

HIPAA Administrative Simplification
In the February 20, 2003 final rule implementing modifications to HIPAA, CMS repealed the NDC as the standard medical data code set for reporting drugs and biologicals in all non-retail pharmacy transactions. In fact, CMS made it very clear in its frequently asked question response identifying the proper code sets for hospital outpatient claims by stating: "**when conducting standard transactions, hospitals must use HCPCS codes to report outpatient services at the service line level and the claim level, if the situation applies.**"

Because the NDC is not a named code set for transmitting HIPAA compliant claims for hospital outpatient services, there is no place on either the electronic claim (HIPAA 837) or on the paper claim, (the Uniform Bill) to report the NDC. Hospitals have not collected the NDC in the chargemaster for this very reason. If CMS finalizes this rule as proposed, it will nullify any potential returns from the drug rebates by adding great administrative and financial burdens on hospitals, not to mention state Medicaid programs, who like hospitals, will be required to make significant investments to reprogram their systems to capture the NDC on hospital outpatient claims.

Iowa hospitals presently lose $118 million due to inadequate reimbursement rates from Medicaid program. To impose additional administrative and financial burden on hospitals, for a limited return on investment to the state, is unacceptable policy. Further, the application of the Medicare drug rebate program for physician-administered drugs was never intended to apply to hospital outpatient services.

Thank you for your review and consideration of these comments. If you have questions, please contact me at the Iowa Hospital Association at 515/288-1955.

Sincerely,

Heather J. Hilscher

Director, Finance Policy

cc: Iowa Congressional Delegation
Iowa Hospitals
Iowa Hospital Association Board of Trustees
CMS Kansas City Regional Office

Submitter : **Mr. Ron Grothe** **Date: 02/20/2007**

Organization : **Corner Drug of Le Sueur**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subject: Medicaid Program:Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-Ao20

I am submitting these comments to the Centers for Medicare and Medicaid Services regardng CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy owner located in Le Sueur, MN. We are the only pharmacy provider in the community and your consideration of these comments is essential.

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

2) Implement a Trigger Mechanism
   (i) Addressed severe price fluctuations
   (ii) Mitigated Risk of Pricing Lag

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

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

Sincerely,

Ron Grothe

cc. Members of Congress

Submitter : Mr. Jeffrey Luke **Date:** 02/20/2007

Organization : Basin Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

My name is Jeffrey Luke. I own an independent pharmacy in a small rural town called Roosevelt, Utah. It has come to my attention that you as an enmity, are looking into adjusting the rate of reimbursement on generic drugs. Your formula for doing this would dramatically impact the viability of my business.

If your proposal is put into effect as currently outlined, many pharmacies such as my own will be forced out of business. This will lead to many people being forced to go to mail order or large outlets where possible. What is lost is the counseling and intervention that actually save lives and hospitalizations. You are aware of the statistics concerning the number of hospital stays that are related to medication issues. This number will rise considerably if your plan is implemented . It is a given fact that any money you save by decreasing reimbursement will be lost in the increased number of hospital stays that would be prevented if you allow us a fair reimbursement. A reimbursement that makes it possible for me or any pharmacist the opportunity to counsel, advise, and intervene. That is what we went to school to do and want to do. I do not want to work in an environment where speed and short cuts are the only way to survive.

You people are literally playing with the lives and well being of people over saving money.

May I suggest that you look at the PBM s such as Caremark, Medco, Express Scripts etc&.Make what they pay to us transparent. Make it known exactly what is paid to us, then give them a nominal fee for the transaction. Don t allow them to collect the difference between what we receive and what they bill. They are ones who arc garnishing the profits.

I would exhort you to make it possible for me to stay in business. There are many people who are patients as well as friends who depend on the service which I provide. I believe that at least once a week, we, myself and the other pharmacist make an intervention which impacts the life of an individual. That process is in jeopardy. It is in your hands. Make the right decision!!! Thank you for your time and interest.

Sincerely,
Jeffrey Luke, RPh

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Response to Comments

Response to Comments

Submitter : Dr. William Johnson

Date: 02/20/2007

Organization : Uniontown Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1194-Attach-1.DOC

#1194

February 6, 2007

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

To Whom It May Concern:

On behalf of Uniontown Hospital, 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. Uniontown Hospital is a 225 bed hospital located in Uniontown Pennsylvania 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 proposed rules underestimate the administrative burden and expense involved.
- The proposed rules would divert precious time and attention from patient care.
- Collection of rebates for outpatient drugs used would diminish the benefit of the 340b Program.

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. This would increase drug costs to Uniontown Hospital by $350,000 or more per year.

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.

Uniontown Hospital patient population includes a high percentage of Medicare/Medicaid patients. Limited reimbursement for services to this population creates definite hardships on the ability of the institution to attract competent and adequate staff and allow for the improvement of services. These proposed rule changes would have a dramatic impact on the potential savings that could be achieve through participation in the 340b program. This resulting increase in costs will affect the ability of our hospital to continue to provide and improve upon the services provided.

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,

William F. Johnson PharmD, RPh
Director of Pharmacy Services
Uniontown Hospital
500 West Berkeley Street
Uniontown, Pa 15401

Submitter : JoAnn Stubbings **Date:** 02/20/2007

Organization : University of Illinois at Chicago Ambulatory Care

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1195-Attach-1.TXT

#1195

UNIVERSITY OF ILLINOIS AT CHICAGO

Ambulatory Care Pharmacy Department (MC 884)
College of Pharmacy
840 South Wood Street
Chicago, Illinois 60612-7230

Date: February 20, 2007

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

From: JoAnn Stubbings, RPh, MHCA
Manager, Research and Public Policy

Sandra F. Durley, Pharm.D.
Associate Director

Ambulatory Care Pharmacy Department
University of Illinois at Chicago College of Pharmacy

Re: Medicaid Program: Prescription Drugs; AMP Regulation CMS 2238-P

The Ambulatory Care Pharmacy Department at the University of Illinois at Chicago (UIC) is 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.

This proposed rule is likely to have a significant impact on our pharmacies because we are located in a low-income area, and we serve a high percentage of Medicaid beneficiaries. The UIC Ambulatory Care Pharmacy Department operates six pharmacies that serve UIC students, employees, and patients of the University of Illinois Medical Center at Chicago. We are located in a culturally diverse, inner-city Chicago community. Our outpatient medical clinics have approximately 480,000 patient visits per year, with 47.5% of visits by African-Americans and 24.2% of visits by Hispanics. Our pharmacies dispense over 1200 prescriptions per day. A significant proportion of our patient volume and revenue comes from Medicaid. For example:

- In 2006, we dispensed a total of 205,891 prescriptions, and 44% of our prescriptions were dispensed to Medicaid beneficiaries.
- Approximately half of all Medicaid prescriptions dispensed at UIC were for generic equivalents.
- We served 20,047 patients, and 45% of our patients were Medicaid beneficiaries.
- In 2006, 57% of our pharmacy revenue came from the Medicaid program.

Pharmacies such as ours will be affected by this proposed regulation as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. According to an analysis by the National Association of Chain Drug Stores (NACDS), the effect of this proposed rule would be to reduce retail prescription drug revenues by less than 1 percent, on average. Using this national average, our pharmacy revenues would be reduced by $189,325 per year. That is equivalent to the salaries of two pharmacists per year. Due to our high proportion of Medicaid patients, our actual revenue loss could be much higher. If the reduction in prescription drug revenues goes as high as 5 percent in our pharmacies, this would amount to a loss of $946,625 per year. That is equivalent to the salaries of ten pharmacists per year.

CMS has stated that actual revenue losses to pharmacies might be much lower since pharmacies generate revenue from goods other than prescription drugs. In our pharmacies, less than 1% of our revenue comes from over-the-counter medications and goods other than prescription drugs. Thus, any change in prescription drug reimbursement, however small, will have a significant impact on total pharmacy revenue. Ours is a non-profit, academic medical center. We provide service to the inner-city residents who do not have easy access to community pharmacies due to issues of transportation or the need for specialty services or medications. We offer specialty services in our pharmacies including multiple medication therapy management (MTM), medication assistance programs (MAPs), coordinated medication dispensing, bilingual services, discharge medications, and mail order services.[1] Our pharmacies regularly dispense compounded medications that are not readily available at community pharmacies.

In conclusion, we hope that you will seriously consider the impact of the proposed regulations on pharmacies that serve a large proportion of Medicaid beneficiaries. A total of 57% of our pharmacy revenue comes from the Medicaid program. Pharmacies with a high Medicaid population stand to lose the most with these regulations. If the FUL program for generic drugs is implemented, we believe there should be an exception or recourse for pharmacies, especially non-profit pharmacies, that serve a large proportion of Medicaid beneficiaries to be able to maintain access to pharmacy services and medications. We appreciate your understanding and consideration of our situation.

[1] Stubbings JA, Durley SF, Sin SJ, Kliethermes M, Aruru MD, Evangelista C, and Byun M. Implementing the Medicare drug benefit in a diverse inner-city community. Am J Health-Syst Pharm 64; Jan 15, 2007:193-199

Submitter : **Mr. Donald Sherman** **Date: 02/20/2007**

Organization : **Royer Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment 'CMS-2238-P Donald Sherman - General Comments.pdf' for Adobe file with signature.

Response to Comments

Response to Comments

Please see details discussed in attachment.

CMS-2238-P-1196-Attach-1.PDF

1196

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332 717-859-4911
335 West Main Street, Leola, Pa. 17540-2107 717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702 717-299-4737

02/19/2007

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

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

Acting Director Leslie Norwalk,

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

I will give an overview of my comments and observations and then examine specific requests for comments. General topics are underlined.

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

> "The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower 2 than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006." -GAO-07-239R p.4

This finding validates my and community pharmacy's contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies

that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

There is a definite conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates.

AMP is now proposed to serve two distinct and contrary purposes:
1) as a baseline for pharmacy reimbursement, and
2) as an index for manufacturer rebates paid to states.

AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP.

An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

Following in bold are specific CMS requests for comments with their page number. I address specific request immediately after the bold type. My comments are in agreement with NCPA.

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.—pg. 29

Public Access Defines Retail Pharmacy Class of Trade

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

NCPA recommends and I strongly endorse a "retail pharmacy class of trade" that includes independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.—pg. 31-33

Inclusion in Best Price of PBM rebates, discounts and other price concessions— pg. 53

Treatment of Manufacturer coupons with regard to Best Price—pg. 55

Inclusion of Direct-to-Patient Sales with regard to AMP—pg. 41

AMP Must Differ From Best Price

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

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

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

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

How PBM price concessions should be reported to CMS.—pg. 33

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70

AMP Must Be Reported Weekly

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

Use of the 11-digit NDC to calculate AMP—pg 80

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

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

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

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

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses the impact on pharmacy:

- On independents: potential "significant impact on small, independent pharmacies."— pg. 101
- On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108
- "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

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

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

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

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

CMS Must Employ a Complete Definition on Cost to Dispense

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

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

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

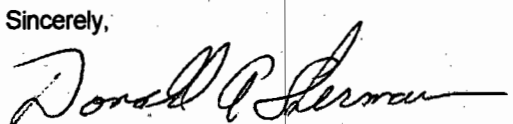
The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Summary of Key Points:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
    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 price from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*
    3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Sincerely,



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Submitter : Mrs. Stephanie Gilson **Date:** 02/20/2007

Organization : Johnson & Johnson

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : Mr. Doug Heidbreder **Date:** 02/20/2007

Organization : Hi-5 Inc.dba Addison Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Hi-5 Inc. is writing to provide input on CMS' proposed regulation that would provide a definition of AMP and implement a new FUL program for generic drugs. Our corporation operates Addison Pharmacy in Addison, Michigan and roughly 30% of our prescription business is from Medicaid customers.
The proposed regulation as it stands would be severely detrimental to my pharmacy and impair my ability to serve Medicaid beneficiaries and the general public. Revisions must be made that would provide an incentive for pharmacists to dispense generic products rather than an incentive to switch to higher-cost brand name drugs. Please do the following:
1. Redefine AMP to reflect what retail pharmacies pay for medications. This must not include any prices that mail order and/or nursing homes pay for medication, nor any rebates, discounts or any other kickbacks that mail order and nursing homes receive. Retail pharmacies like ours do not have access to these or the lower prices that those types of businesses do. Until AMP is properly redefined CMS needs to delay any public release of this data.
2. We ask that the FULs for generic drugs, which would be calculated at 250% of the lowest average AMP for all versions of a generic drug, be scrapped or suspended. Recent reports indicate that pharmacies like ours would be reimbursed, on average, 36% less than OUR ACQUISITION COST if the present proposal is adopted. No business can operate successfully under this format. As professsionals, we expect and must receive adequate reimbursement for the goods AND SERVICES we provide. Clearly this proposal fails in this respect.
3. We ask that CMS REQUIRE states to increase dispensing fees to pharmacies. Dispensing fees have not kept up with inflation for decades. Recent studies show that the average cost to dispense a prescription is now above $10. This is what dispensing fees are supposed to be used for -- to cover the cost to dispense medication. Reimbursement to pharmacies to cover these costs are a necessary part of business and must be accounted for.

We appreciate your consideration of these comments and ask that you contact us with any questions. Thank you.

Sincerely,

Doug and Karol Heidbreder
Hi-5, Inc. dba Addison Pharmacy

517-547-6543 or 517-467-7120

Submitter : Dr. Shabir Somani **Date:** 02/20/2007

Organization : University of Washington Medicine

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1199-Attach-1.DOC

#1199

UNIVERSITY OF WASHINGTON
MEDICAL CENTER
UW Medicine

2/12/2007

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:

I am writing on behalf of the University of Washington Medical Center (UWMC) and Harborview Medical Center (HMC) to ask for your reconsideration of the proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Located in Seattle, Washington, UWMC and HMC, with a total of 863 licensed beds, are disproportionate share hospitals under the Medicare program and are enrolled as covered entities under the federal 340B drug discount program. We have two major concerns about the Proposed Rule.

First, the proposed regulations implementing Section 6002 of the DRA, under Section 447.520, would require our hospitals to greatly increase our operational and administrative workload by mandating that we report National Drug Code (NDC) information on drugs administered in hospital outpatient settings. We note that in Section 447.520, the Centers for Medicare & Medicaid Services (CMS) states that the impact on hospitals will be very limited, adding an estimated fifteen seconds, or nine cents per claim, in order to include NDC numbers in our Medicaid claims. However, we submit that the actual burden for UWMC and HMC would increase substantially more. For example, a significant amount of outpatient drugs administered in our hospitals are compounded or mixed and would carry different NDC numbers. The per claim estimate doesn't appear to take into account manual submission of NDC information on a single Medicaid claim that requires identifying and reporting multiple NDCs – a task that would take much more than 15 seconds. Overall, manual steps would need to be added to an already challenging medication ordering, dispensing and administration process. This is contrary to our broad-based administrative simplification initiatives and would substantially increase the cost of providing outpatient injections and infusions at our hospitals.

Secondly, we contend that expansion of the Medicaid rebate program to drugs administered in hospitals would violate federal law. As per Section 1927(j)(2) of Title XIX of the Social Security Act a hospital that "dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject" to the NDC collection requirements of Section 6002. And yet the express purpose of the NDC collection rule for "physician administered drugs" is to facilitate rebate collections by the States.

Department of Pharmacy Services
Harborview Medical Center, Seattle Cancer Care Alliance, UW Medical Center, &UW Physicians
1959 NE Pacific Street, Room EA-127 Box 356015 Seattle, WA 98195-6015 206-598-6060 Fax 206-598-6075

CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program. Should the new regulations result in Washington State Medicaid requiring manufacturer rebate obligations, UWMC and HMC would necessarily need to forego the benefit of 340B discounts on hospital outpatient clinic drugs. The 340b program was originally designed to reduce the cost of outpatient drugs for disproportionate share hospitals such as ours. Without this savings, UWMC and HMC would incur a 20-25 percent increase in costs for drugs administered to the at-risk patient population we serve. In sum, we believe the CMS-proposed rule to implement Section 6002 of the DRA should take this pre-existing statutory exemption from rebates into account, and similarly except hospital outpatient clinic drugs from the new NDC collection rule.

The 340b program has been and continues to be extremely important to UWMC and HMC, as it allows us to better serve the at-risk patient population. We therefore ask that you give consideration to the issues addressed in this letter, and that the proposed regulations published on December 22 be clarified and revised as a result.

Sincerely,

Shabir Somani, Director of Pharmacy Services
University of Washington Medical Center
Harborview Medical Center

Department of Pharmacy Services
Harborview Medical Center, Seattle Cancer Care Alliance, UW Medical Center, &UW Physicians
1959 NE Pacific Street, Room EA-127 Box 356015 Seattle, WA 98195-6015 206-598-6060 Fax 206-598-6075

Submitter : **Ms. Rachel Chanes** **Date: 02/20/2007**

Organization : **Planned Parenthood of Southern Arizona**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1200-Attach-1.DOC

#1200

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 Vice President of Medical Services of Planned Parenthood of Southern Arizona. We operate three non-profit outpatient clinics in Tucson that provide critical health services to uninsured and underinsured women. Planned Parenthood of Southern Arizona serves more than 11,000 patients annually, many of whom could not afford the health services -- particularly oral contraceptives -- that our health care centers provide.

For more than 73 years, Planned Parenthood of Southern Arizona has served a vulnerable population of women who cannot normally afford contraception by providing them access to oral contraceptive pills at prices far lower than what is available in the retail market. Planned Parenthood of Southern Arizona has been able to serve this underprivileged community because it could purchase oral contraceptive drugs from drug manufacturers willing to provide them at nominal prices. The very existence and fiscal viability of Planned Parenthood of Southern Arizona turns on its ability to purchase oral contraceptives at less than 10% of the average retail price. Without these steeply discounted drugs, we will no longer be able to provide the low-cost outlet for poor and working uninsured women that they so desperately need, and that we very much want to continue to provide.

As you know, the proposed rule -- published by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, to implement section 6001(d) of the Deficit Reduction Act of 2005 ("DRA") -- preserves the ability of three kinds of providers ((I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated nursing homes) to purchase drugs at best price ineligible nominal prices. Many of our Planned Parenthood sister health centers across the country – and one of our three centers – are Title X clinics, and therefore 340B covered entities. The ability of these Title X-funded health care centers to purchase oral contraceptives at very low prices is assured. Our other two health care centers, however, are not federally funded; these centers operate entirely on revenue for services paid for by patients and insurance providers, and donations from the community. Our Sanger Center and Hoffman Center are not 340B-covered entities eligible under the terms of the proposed rule for nominal prices.

Planned Parenthood of Southern Arizona, along with many other non-340B providers of medical services to the poor, must rely on section 6001(d)(IV) of the DRA to permit its continued access to steeply discounted drugs. As you know, that section authorized the Secretary of the Department of Health and Human Services ("HHS") to define "other safety net providers" that would be eligible for the nominal pricing exception. We were deeply disappointed when, in the proposed rule, CMS did not define or apply this fourth statutory exception. We very much hope that HHS will exercise the authority granted it by Congress to define "other safety net providers" in the final rule.

The plight of Planned Parenthood of Southern Arizona and other similarly situated non-profit outpatient clinics across the nation should provide ample evidence to CMS that the other three categories of health services providers are not "sufficiently inclusive" and do not "capture the appropriate safety net providers." It is simply not the case that deserving, non-profit outpatient clinics like Planned Parenthood of Southern Arizona's Sanger and Hoffman Centers are covered by the entities listed in 6001(d), subsections I, II and III. We and many others like us are left on the outside, looking in. Eliminating Planned Parenthood of Southern Arizona's non Title-X facilities and entities like them from the nominal price exception will not effect best price at all -- the only consequence of this policy will be to preclude manufacturers from charitably helping safety net providers like Planned Parenthood of Southern Arizona to serve our patients.

In conclusion, Planned Parenthood of Southern Arizona is a non-profit outpatient health care facility that serves a critical function in the health and well being of more than 11,000 uninsured and underinsured women in southern Arizona each year. Planned Parenthood of Southern Arizona is able to provide these services and deeply discounted oral contraceptive medications to these women only because it can purchase oral contraceptives from drug manufacturers at nominal prices.

Carving safety net providers like Planned Parenthood of Southern Arizona out of the nominal pricing exception would be devastating to our mission, our clients and to our operations -- without nominally priced drugs, our ability to serve low-income and uninsured women would plummet dramatically. Planned Parenthood of Southern Arizona urges CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

Respectfully submitted by,

Rachel Chánes, MBA/HCM
Vice President of Medical Services
Planned Parenthood of Southern Arizona
Tucson, AZ