90

Charleston Area Medical Center

David L. Ramsey
President & CEO

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February 14, 2007

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

To Whom It May Concern:

On behalf of Charleston Area Medical Center ("CAMC"), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005, published in the Federal Register on December 22, 2006. CAMC is the tertiary care safety net hospital for all of Southern and Central West Virginia with the only level I trauma center and one of two level III neonatal intensive care units. We are essentially the "public hospital" for the region without the benefit of public funding. The 340B program is extremely important to us as we struggle to provide highly specialized care to the poor and uninsured. We provide 22 percent of all charity care provided by private (both profit and non profit) acute care hospitals in West Virginia. We are also the largest provider of Medicaid services, losing $25 million below cost on providing care to Medicaid recipients.

The proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of National Drug Code ("NDC") information on drugs administered in hospital outpatient settings. We currently do not track the NDC administered to outpatients at CAMC. These drugs are stocked in Automated Unit Based Cabinets (AUBC), which allow nurses and physicians to remove a specified drug for a specific patient at the time of treatment. However, because many drugs are available from a variety of manufacturers and the software within the AUBC tracks this dispensing based upon a generic nomenclature versus an NDC, the effective and efficient capture of this information is impossible. In addition, our current billing system is not configured in a manner that would allow for the reporting of the requested information. It would be very expensive to modify our billing system to meet this one requirement.

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 could have a significant negative impact on our ability to care for the poor, the uninsured and the Medicaid population.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22, 2006 will be clarified and revised as a result.

Sincerely,

David L Ramsey

David L. Ramsey
President and CEO

91

Planned Parenthood®
of Amarillo and the Texas Panhandle

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Chief Executive

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Ms. Norwalk:

I am the CEO of Planned Parenthood of Amarillo and the Texas Panhandle, which operates one non-profit, non-Title X outpatient clinic in Amarillo, dba ***Women's Wellness Center***. We sincerely hope that the ***Centers for Medicare and Medicaid Services*** (CMS) will reconsider and exercise its authority to name "other safety net providers" such as ours, to purchase drugs at nominal prices without affecting the best price calculation. The ***Women's Wellness Center*** is clearly a safety net provider and we strongly urge CMS to include in its definition of safety net providers that are nonprofit, outpatient clinics like ours that serve the working poor.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Our ***Women's Wellness Center***, however, is not federally funded. It operates as a fee-for-service clinic with steeply discounted rates and meds for the working poor. But, now it does not qualify as a 340B covered entity and these poor women, who are not poor enough, will be driven further into poverty with unintended pregnancies. What a horrible commentary on a government that it drives the poor to be poorer!

The Women's Wellness Center provides a full array of family planning and gynecological services to working poor women who are either uninsured or underinsured. As you know, many poor women work in the service industry, or for small businesses that do not provide health insurance. And, for the few working poor who have health insurance, their insurance does NOT cover contraceptives. This in itself is a national SHAME that must be addressed.

The ***Women's Wellness Center*** serves over 1,000 patients each year, many of whom could not otherwise afford these health care services—particularly oral contraceptives, which they need to control their family size. We opened this non-Title X entity to provide low cost reproductive health services to women who work and cannot qualify for Titles, V, X/XX or the new Women's Health Program (Medicaid Waiver). These women cannot afford to pay regular prices for services from a private physician, clinic or pharmacy; and, aren't otherwise eligible for subsidized services. **They are truly the working middle classes.**

1501 South Taylor Amarillo, TX 79101-4307 Phone (806) 372-8731 Fax (806) 372-8746 www.ppatp.org

We have operated the ***Women's Wellness Center*** for five years. We established it because of decreases in state and federal family planning funding, especially Title X/XX and the growing number of working women with little or no insurance. We have large numbers of women working in beef and pork slaughtering and packing operations. While they have insurance, it does NOT pay for well-woman exams or for contraceptives.

Most of the incomes of patients seen at the ***Women's Wellness Center*** are at 200%- 250% of the poverty level. There is no other low fee family planning clinics in our area, so we charge these patients based on the Title X sliding fee scale for incomes up to 250%.

Our ***Women's Wellness Center*** has been able to serve women in need of low-cost reproductive health care services because we purchase oral contraceptive drugs from manufacturers willing to provide them at nominal or public health prices for our Title X clinic.

At the same time, the ***Women's Wellness Center*** serves as a key safety net provider to our community. Our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we are at a loss to understand WHY CMS did not define "safety net provider," or apply the ability to purchase nominally priced drugs to other safety net providers. Unfortunately, like many other small safety net providers, the ***Women's Wellness Center*** does not qualify as one of the three categories listed above.

Respectfully submitted by,

Claudia Stravato

Claudia D. Stravato CEO
Planned Parenthood of Amarillo and the Texas Panhandle
dba Women's Wellness Center.

Family Tree Clinic
HEALTH CARE WITHIN YOUR REACH
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92

February 14, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Executive Director of Family Tree Clinic in St. Paul, Minnesota. For thirty-five years, Family Tree Clinic has provided high-quality health care to women, regardless of their ability to pay. Family Tree Clinic serves many uninsured and underinsured women living in, or near, the city of St. Paul. The clinic is a key safety-net provider in Minnesota.

One of the most important elements of the high-quality, family planning health care that Family Tree historically has been able to offer its patients is access to low-cost oral contraceptives. The majority of our patients are unable to pay market price for their birth control supplies. Family Tree Clinic has always been able offer access to low cost products because we've been able to purchase contraceptive drugs at a nominal price. However, as you are well aware, on December 22, 2006, CMS limited nominal drug pricing purchases to only three kinds of providers: 340B covered entities, intermediate care facilities for the mentally retarded, and state-owned or operated nursing homes. We at Family Tree are extremely disappointed that CMS choose not define "safety net provider" or apply the ability to purchase nominally priced drugs to safety net providers as provided for by the Deficit Reduction Act of 2006.

Family Tree does not receive Title X funds and therefore does not qualify as a 340B covered entity; however, we are confident that our clinic would qualify for nominal pricing under a 'safety-net provider' definition. We strongly urge CMS to include in its definition of safety-net providers nonprofit, outpatient clinics like ours.

Profile of Family Tree Clinic in St. Paul:

1) Serving low-income and underserved women since 1972;
2) Provides family planning services to over 3,800 patients each year, for a total of more then 8,000 family planning office visits a year;
3) Patients are mainly low-income, uninsured or underinsured women; in fact, 73% of Family Tree Clinic's patients are at or below 200% of poverty, 61% are below 150% of poverty, and 44% are below 100% of poverty;
4) Operates with a seven-level sliding fee scale that is based on the federal poverty level definitions
5) Operates under a community board of directors.

To reiterate, Family Tree has been able to serve low-income, uninsured women in need of low-cost reproductive health care services because we have been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Due to CMS's decision not to define safety net providers, the majority of our patients no longer have access to affordable oral contraceptives. This seriously affects our ability to provide comprehensive reproductive health care services and it limits access to methods that our patients need to prevent unintended pregnancies.

Please reconsider the decision not to define 'safety net providers' and help us in our effort to continue serving the health and family planning needs of uninsured, low-income women in St. Paul.

Most Sincerely,

Peg LaBore
Family Tree Clinic
1619 Dayton Ave # 205
St. Paul Minnesota 55104

Cc: Senator Norm Coleman
And Senator Amy Klobuchar

LARWOOD PHARMACY, INC.

Phone 716/652-1360 / Fax 716/655-0132 / 597 Oakwood Avenue / East Aurora, N.Y. 14052

Independently owned & operated since 1834

Re:CMS-2238-P

Dear Centers for Medicare + Medicaid Services,

I am writing you to express my sincere concerns with the Centers for Medicaid and Medicare Services (CMS) proposed changes in the payment for prescription drugs in the Medicaid program. These proposed changes, announced in December of 2006, would implement provisions of the Deficit Reduction Act of 2005 (DRA).

On July 1st 2007, CMS plans to begin reimbursing for generics with a Federal Upper Limit (FUL) based on a new definition of Average Manufacturers Price (AMP), which it proposed in a regulation released December 15, 2006. As required by the DRA, the FUL will be a ceiling of 250% of the AMP.

The proposed definition of retail pharmacy, which will be used to calculate AMP **includes mail-order pharmacies, hospital outpatient pharmacies, and outpatient clinics. These pharmacies may have access to rebates and price concessions that may not be accessible to community pharmacy.** Therefore, AMP will be set at a rate lower than what community pharmacy can purchase generic drug products.

Community pharmacies will lose money on virtually every one of those transactions, the report by the Government Accountability Office (GAO), the Investigative arm of Congress, confirmed. The GAO examined the AMPs of 27 high expenditure generics, 27 frequently used ones, and 23 that overlapped both categories.
For the high expenditure drugs, GAO calculated the new FULs were **65% lower** on average than community pharmacies' actual acquisition costs. For the frequently used drugs, acquisition costs were 15% lower. In the overlap category, acquisition costs were 28% lower. **For all 77 drugs examined, the average acquisition costs were 36% lower.**
Essentially if this passes we will be asked to sell our generics on an average of 36% below cost.

As Bruce Roberts RPh. Executive Vice President & CEO of the National Community Pharmacists Association stated, "No small business can be expected to operate at a loss, and pharmacies are no exception. In essence, CMS is forcing a pharmacy to accept payment that is 36% below its cost or stop participating in a program that provides prescriptions to our nation's poor."

And, I for one agree!
I am asking you not to allow this to become a reality.

Sincerely,

Linda Noden Andrews, RPh

Fields of Opportunities

STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
PATTY JUDGE, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
KEVIN W. CONCANNON, DIRECTOR

February 16, 2007

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

The Iowa Department of Human Services Medicaid program respectfully submits comments on the Medicaid prescription drug benefit. Iowa Medicaid is commenting on the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS).

II. Provisions of the Proposed Regulation
Reference: Definitions-Section 447.502, Dispensing Fee
(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies."
Comment: The definition of dispensing fee does not address the administrative costs incurred by the pharmacy in the operation of the covered outpatient drug benefit, including systems costs for interfacing with the State. It is not clear whether the definition of dispensing fee is meant to exclude the administrative systems costs incurred by the pharmacy, instead of the State, since the administrative cost incurred by the State is not typically included in the "pharmacy" dispensing fee. If so, then total pharmacy reimbursement will also not be able to cover costs, provoking pharmacies to discontinue their participation in Medicaid.

Reference: Determination of Average Manufacturer Price—Section 447.504, Definition of Retail Pharmacy Class of Trade and Determination of AMP
The specific terms we propose to clarify and the proposed clarifications follow.
Retail Pharmacy Class of Trade: We propose to include in the definition of retail pharmacy class of trade any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public (e.g., retail, independent, chain and mail order pharmacies), except as otherwise specified by the statute or regulation (such as, HMOs, hospitals).
PBM Price Concessions: We proposed to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade.
Comment: Drug acquisition costs available to mail order pharmacies may not be available to smaller retail pharmacies. Inclusion of mail-order pharmacies will serve to drive down pharmacy ingredient costs even further below average retail acquisition cost. The only option that the State will have to assure continued pharmacy access for its Medicaid beneficiaries will be to increase the dispensing fee. This "offset" will subsequently decrease the potential additional savings listed in the Proposed Rule, and may even end up costing the Medicaid Program more money than if the FULs were not changed.

Reference: Aggregate Upper Limits of Payment Section 447.512, Upper Limits for Multiple Source Drugs—Section 447.514
Calculating the AMP at the 11-digit NDC level permits greater transparency, and may increase accuracy and reduce errors for the 340B covered entities where prices are established for a package-size product rather than a per unit cost using the product's weighted average AMP.

However, the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that the Congress intended that AMP should be restructured to collect it by 11-digit NDCs. We are proposing to use the currently reported 9-digit AMP for calculating the FUL. Changing the current method of calculating the AMP would require manufacturers to make significant changes to their reporting systems and have an unknown effect on the calculation of rebates in the existing Medicaid Drug Rebate Program. In State Medicaid payment systems that consider a number of different factors in deriving payment rates, we also believe it would offer minimal advantages. Furthermore, we expect that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to buy the most the economical package size.
Comment: The statement above assumes that any pharmacy adversely impacted by this change should offset the loss by buying the most the economical package size. This appears to limit the definition of "economical" to acquisition cost only. This is, however, not a viable option for pharmacies when the most economical package is more than the pharmacy can utilize. In other words, if the customer demand for a drug is much smaller than the supply, then the pharmacy will have additional carrying costs and waste of the drug, and this package size will no longer be the most economical.

Reference: FFP: Conditions Relating to Physician-Administered Drugs—Section 447.520
If States collect HCPCS codes for single source drugs, they can crosswalk these codes to NDC numbers because most HCPCS codes for single source drugs include only one NDC in order to collect rebates.
Comment: The State compares J codes using an established crosswalk to identify those single-source drugs for which there is a 1:1 relationship (one J code to one NDC only). Our experience has been that "most" HCPCS codes for single source drugs do not include only one NDC. For example, listed below are a few examples of single source drugs for which there is one J code but numerous NDCs.
J2794, Risperidone, longacting, single source, three NDCs
J0215, Alefacept, single source, four NDCs
J0881, Darbepoetin alfa, single source, fifty-three NDCs
J1260, Dolasetron mesylate, single source, six NDCs
J1438, Etanercept injection, single source, four NDCs
J1440, Filgrastim 300 mcg injection, single source, ten NDCs

Reference: FFP: Conditions Relating to Physician-Administered Drugs—Section 447.520
We propose, for the purpose of this section, that the term "physician administered drugs" be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered

by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting.

Comment: Based on the definition, physician administered drugs would have to be rebatable, non-DESI, and in a non-excluded category of drugs. This is the expectation for pharmacies that submit claims on a real-time system. It is not, however, practical with respect to CMS 1500 forms submitted for physician-administered drugs, since there is not an immediate response and since the claims are usually submitted after administration. This definition will, as a result, create a huge administrative burden for the provider's office as well as for the state agency, since they will have to change the existing process and provide timely access to this type of information prior to the administration of the drug. Moreover, the office may not have in stock the correct rebatable product, and therefore the member would have to be charged, and the provider would have to obtain the correct rebatable product. The outcome would be a delay in receiving the needed medication, or the member may opt to go without the medication altogether. Obviously, both circumstances impair a member's access to needed medication.

III. Collection of Information Requirements

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

Assuming all States impose this requirement, the burden associated with this requirement is the time and effort it would take for a physician's office, hospital outpatient department or other entity (e.g., non-profit facilities) to include the NDC on claims submitted to the State. We estimate this requirement would affect an excess of 20,000 physicians, hospitals with outpatient departments and other entities that would submit approximately 3,910,000 claims annually. We believe this would take approximately 15 seconds per claim. We estimated the cost based on the average annual wage and benefits paid for office and administrative support services in 2006 of $21.14 per hour (http://www.bls.gov/news.release/pdf/ecec.pdf). The per claim cost would be under 9 cents.

Comment: While the time of 15 seconds may be the actual amount of time required to record the NDC on the claim submitted to the State, this does not include the research that must be done prior to administration of the drug and prior to claim submission in order to determine whether the drug is rebatable, non-DESI, and in a non-excluded category of drugs. Each provider office will also have to establish a new procedure to record the NDC during the administration of the drug in the patient examination room, while the billing submission occurs at the front desk. Therefore the NDC will actually be recorded twice, thus doubling the time estimate of 15 seconds. The burden associated with this requirement of the provider is not all inclusive of the administrative costs and could be a time-consuming process.

V. Regulatory Impact Analysis

Reference: We believe this rule will have an economically significant effect. We believe the rule would save $8.4 billion over the next five years ($4.93 billion Federal savings and $3.52 billion State savings as shown in the table below). This figure represents a 5.6 percent reduction in total Medicaid drug expenditures in Federal fiscal years 2007–2011.

Comment: Section 6001—Federal Upper Payment Limits and Other Provisions.

It would seem that the savings estimate is overstated if it did not take into account the already reduced reimbursement in those States that have State Maximum Allowable Cost (SMAC)

programs in place. In those instances, the drugs for which lower FULs will be calculated, have been and will continue to be reimbursed at the lower SMAC rate. This would negate some or most of the additional savings projected in the Proposed Rule. In addition, analysis of the December 2006 AMP rates predicts that many FULs would reimburse pharmacies below their actual cost for drugs. States would need to increase their dispensing fees to compensate for deficiencies on the ingredient cost reimbursement, which would significantly diminish the projected savings or possibly end up costing the program more in the long term.

Reference: None of the estimates include Federal or State administrative costs. We believe these costs would be small as they involve changes in work processes rather than new activities. The resulting program savings would be many times these costs.
Comment: The Proposed Rule does not estimate what administrative costs to the State would be. The projected savings do not account for the savings already being received through the State MAC program. In some cases, the State MAC rate is lower than the projected FUL, negating the extra savings stated by CMS. In many other cases, the projected FUL would reimburse below the average acquisition cost of the drug group. Medicaid would need to increase its dispensing fee to compensate for an insufficient ingredient cost, which is something that the dispensing fee is not intended to do, and which would significantly diminish intended savings to the Medicaid Program.

VI. General Comment

Reference: § 447.512 Drugs: Aggregate upper limits of payment.
(a) Multiple source drugs. Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for ''other drugs'' set forth in paragraph (b) applies.
Comment: It is not clear from the regulations that the FUL applies to the payment to the pharmacy (pre-rebate) or the net price after rebate (post-rebate). The regulations refer to the FUL as a limit on "the [state Medicaid] agency payment" or "its Medicaid expenditures" for drugs. 42 C.F.R. §§ 447.331-333. In this case, the focus is on the State's "payment" or "expenditures", and not on the amount received by pharmacies. The real issue, however, is whether the FUL must be compared to the State's initial, gross payments or expenditure, or whether it can be compared to the State's net payments or expenditure after rebates, which is not specifically addressed in the regulations. The focus on the State's payments or expenditure, rather than the amount received by pharmacies, suggests that the limit should be compared to the net payment or expenditure after rebates. Clearly, the intent is to limit what the State can pay or expend for drugs, and not what pharmacies can receive. Since what the State actually pays or expends is reduced by any rebates, it makes sense that the FUL should be compared to net payments or expenditures after rebates, since comparing the FUL to the net expenditure after rebates allows the State to take advantage of the higher rebates on brand-name drugs, is certainly consistent with efficiency and economy, and has no impact on quality of care.

Reference: § 447.514(2)(c) Ensuring a drug is for sale nationally.
Comment: CMS wishes to ensure that a drug is available for sale nationally. However, the Projected FULs that are based upon December 2006 AMPs show many instances where the reimbursement rate would be less than the average acquisition cost of the drugs. This undermines the goal of national availability, since underpayment of ingredient costs will either cause providers to cease participation in the Medicaid program or force States to increase the Medicaid dispensing fee to offset the loss. This outcome will then serve to compromise the integrity of the dispensing fee, which is a fee specifically intended to cover dispensing fee costs and not to over-compensate for insufficient ingredient cost reimbursement. An increase in the dispensing fee also decreases the additional savings estimated in the Proposed Rule.

Thank you for the opportunity to share our comments.

Sincerely,

Susan Parker, PharmD, RPh

Susan L. Parker, Pharm.D., RPh
Pharmacy Consultant

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

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

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

Treatment of Manufacturer coupons with regard to Best Price.

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

AMP Must Differ From Best Price

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

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

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

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

PBM price concessions reporting to CMS.

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

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

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, 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 rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

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

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

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

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-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.

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

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

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

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

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.

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- 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 prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*

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

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Sincerely,

Dominick J. Vizzoni, Pharm.D.
Managing Pharmacist, Siegel's Pharmacy

Dinsmore&Shohl LLP
ATTORNEYS

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February 20, 2007

Leslie V. Norwalk, Administrator (Acting)
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

SENT BY EMAIL: www.cms.hhs.gov/eRulemaking

Re: Comments on Proposed Rule
42 C.F.R. Part 447
File Code CMS-2238-P

Dear Ms. Norwalk:

I am writing to comment on the rule proposed by the Centers for Medicare & Medicaid Services ("CMS") implementing certain provisions of the Deficit Reduction Act of 2005 ("DRA"), published in the Federal Register on December 22, 2006 ("Proposed Rule"). Specifically, my comments relate to:

(1) Proposed Reg. §447.504 "Determination of AMP" and §447.505 "Determination of Best Price" as such provisions relate to manufacturer coupons and other point-of-sale discounts;

(2) The effect of Proposed Reg. §§447.504 and 447.505 (and the statutory provisions of the Deficit Reduction Act of 2005 ("DRA") upon which such proposed regulations are based) on drug manufacturers' obligations under §1927(a)(5) of the Social Security Act (42 USC § 1396r-8(a)(5)) to provide discount prices to "covered entities" under §340B of the Public Health Service Act (42 USC §256b) and certain children's hospitals in light of the position of the Office of Pharmacy Affairs ("OPA") that the 340B discount price is based upon the definition of AMP determined under the Medicaid rebate statute **prior to the changes under DRA** (and, presumably, without regard to guidance under the Final Rule)[1] and

[1] As expressed in the "Dear Pharmaceutical Manufacturer" letter issued by the Director of Office of Pharmacy Affairs on January 30, 2007, available at: http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm.

(3) The absence in the Collection of Information Requirements under the Paperwork Reduction Act and Impact Analysis required under the Regulatory Flexibility Act of an analysis of the impact of the Proposed Rule upon manufacturer information collection requirements under the 340B Discount Pricing Program.

First, CMS should be commended for attempting to set forth clearly in regulatory form agency interpretations of the statute involving inclusions and exclusions from AMP and best price. Introducing elements of certainty into the application of highly ambiguous statutory language that for years has been the subject of limited formal guidance can be expected to have the salutary effect of both leveling the competitive playing field and introducing greater price reporting consistency among manufacturers. Our comments follow in Sections I - IV.

I. Provisions of the Proposed Regulations
Determination of Best Price – Proposed Reg. §447.505(c) and (d)
Determination of AMP -- Proposed Reg. §447.504(g) and (h)
Manufacturer Coupons

The Final Rule should clarify that manufacturer coupons redeemed by consumers, either directly to the manufacturer or at point of sale though pharmacies, are excludable from the computation of AMP and from best price consideration as long as (1) manufacturer payments to pharmacies are limited to administrative fees, charged at fair market rates, to compensate the pharmacies for their services and (2) the prices paid by such pharmacies for the drugs are not affected by the coupon. No distinction should be made between manufacturer coupons and other manufacturer-sponsored point-of-sale discounts.

Proposed Reg. §447.505(d) states, in pertinent part:

> "Best price excludes ... [p]rices negotiated under a manufacturer's sponsored Drug Discount Card Program ...[and]... [m]anufacturer coupons redeemed by a consumer."

CMS has enunciated in the commentary accompanying the Proposed Rule the informal position CMS staff members have previously expressed -- *i.e.*, that manufacturer coupons not affecting the drug prices paid by a pharmacy should not be included in the manufacturer's determination of the drug's best price.[2] But, consistent with this policy, redemption by the consumer "directly" to the manufacturer also may be achieved by means of a point-of-sale redemption, with the pharmacy acting on the consumer's behalf in administering his or her redemption to the

[2] In the preamble to the Proposed Rule, CMS states:

> "In this proposed rule, we propose to clarify how manufacturer coupons should be treated for the purpose of establishing best price. We believe that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy). In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of best price. We believe that the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose sales are included in best price. In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price. CMS invites comments from the public on this proposed policy."

manufacturer, as long as payment to the pharmacy is limited to "bona fide service fees" as defined in the Proposed Rule. In this way, consumers may realize the benefit of manufacturer discounts by the preferred method of redemption -- at point-of-sale. Because the reasonable compensation paid by a manufacturer to a pharmacy for administrative services does not affect the prices of drugs paid by the pharmacy, this interpretation of the Medicaid rebate statute is consistent with CMS' traditional position, as alluded to in the preamble.

Under the alternative "rebate" redemption method, the discount buyer is far less likely to follow through to completion the steps necessary to receive the rebate than is the case for the point-of-sale discount. Further, under a rebate system, the consumer must effectively advance the retailer the amount of the discount for an indeterminate amount of time -- a fact that may discourage the more needy consumers from making the purchase at all. It is unlikely that Congress, in enacting the Medicaid rebate statute, intended to penalize drug manufacturers for discounting their products to consumers or to force drug consumers, already confused by the complexities of the drug distribution and reimbursement system, to deal directly with distant manufacturers in order to obtain discounts on drugs purchased at their neighborhood pharmacies.

Proposed Reg. §§447.504(g)(11) and (h)(9) also should be revised to provide similar AMP treatment of manufacturer coupons and other point-of-sale discounts. A point-of-sale discount as described above does not affect the price received by the manufacturer for drugs distributed in the retail pharmacy class of trade. If a discount is excluded from best price consideration, it should also be excluded in the calculation of AMP unless there is a statutory basis for different treatment.

II. Provisions of the Proposed Regulations
Determination of Best Price – Proposed Reg. §447.505(d)
Determination of AMP -- Proposed Reg. §447.504(h)
Drug Discount Card Programs

The drug discount card program exclusion from best price (Proposed Reg. §447.50(d)(7)) should be clarified or eliminated in favor of an expansion of the manufacturer coupon exclusion in subparagraph (d)(8).

The language of Proposed Reg. §447.505(d)(7), which excludes from best price "[p]rices negotiated under a manufacturer's sponsored Drug Discount Card Program," is confusing and overly narrow. The only definition of "drug discount card program" in existing regulations refers to the Medicare-endorsed discount card program, which was discontinued when Medicare Part D took effect on January 1, 2006. The form a consumer drug discount takes (*e.g.*, discount card, voucher, coupon, etc.), and whether the "sponsorship" resides in the retailer or manufacturer, should not dictate whether it is includable or excludable for purposes of determining best price. The relevant inquiry under the statute is whether the price concession affects the pharmacy price from the manufacturer. A consumer drug discount card program would not affect the pharmacy price if the discount is passed through 100% to the consumer. Accordingly, the best price exclusion under Proposed Reg. §447.505(d)(7) should include prices under any manufacturer-sponsored discount program where 100% of the manufacturer's discount is passed through to the consumer. Alternatively, CMS should consider eliminating this

exclusion and expanding the coupon exclusion in subparagraph (d)(8) to include all point-of-sale discounts.

If the drug discount card program exclusion from best price is retained in the Final Rule, the Final Rule should also provide a similar exclusion from AMP. A drug discount card program involving the pass-through of a manufacturer discount 100% to the consumer does not affect the price received by the manufacturer for drugs distributed in the retail pharmacy class of trade.

III. Provisions of the Proposed Regulations
Determination of AMP -- Proposed Reg. §447.504
Additional Guidance on AMP for Determination of 340B Discount Program Prices

The Final Rule, or a separate regulatory provision, should clarify that the inclusions and exclusions from AMP enumerated in Proposed Reg. §447.504 and the statutory changes enacted in the DRA and other legislation since the enactment of the Veterans Health Care Act of 1992 that affect the determination of Medicaid rebates and the covered outpatient drugs with respect to which such rebates are payable apply with equal force in the manufacturer's computation of the 340B "ceiling prices" and the Federal ceiling prices for such drugs.

Background -- Need for Guidance

On January 30, 2007, the Director of the Office of Pharmacy Affairs ("OPA"), the office within the Health Care Resources Administration ("HCRA") that administers the 340B Discount Pricing Program, issued a "Dear Pharmaceutical Manufacturer" letter setting forth OPA's position on the determination of 340B ceiling prices in light of the changes to the definition of AMP under the DRA. According to the OPA, the following provision in Section 340B(1)(c) of the Public Health Service Act mandates that manufacturers use **the definition of AMP in effect on the date of enactment of legislation that established the 340B Discount Pricing Program** ("340B Enactment Date") in calculating the 340B ceiling price:

> "Any reference in [Section 340B] to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of enactment of this section [enacted Nov. 4, 1992]."

A virtually identical provision can be found in Section 603 of the Veterans Health Care Act of 1992 (38 U.S.C. §8126(g)(1)), which applies to the determination of Federal ceiling prices available to or through other federal agencies.[3]

Section 340B(b) of the Public Health Service Act defines AMP as follows:

> "In this section, the terms 'average manufacturer price', 'covered outpatient drug', and 'manufacturer' have the meaning given such terms in section 1927(k) of the Social Security Act."

[3] This section applies to the Department of Veterans Affairs, the Department of Defense, the Coast Guard and the Public Health Service with respect to drugs purchased under a depot contracting system or the Federal Supply Schedule.

Since inception, the 340B Discount Pricing Program and the Medicaid Rebate Program have been linked.[4] All of the components of the 340B pricing formula are taken from pricing and rebate information reported by manufacturers under the Medicaid Rebate Program and collected by CMS.[5] Under the AMP formula in effect at the enactment of Section 340B, the 340B ceiling price and net price to Medicaid would be exactly the same, although the 340B ceiling price lags the Medicaid rebate by a quarter. Indeed, as recently as August 5, 2005, in an audioconference overview of the 340B Discount Pricing Program, a Powerpoint presentation by a staff member of the HRSA Pharmacy Services Support Center explained how the 340B price is determined as follows:

> "Brand name drugs: 340B price for each unit of the drug cannot exceed AMP (***as reported to CMS under Medicaid rebate program***) minus 'rebate percentage.'"[6]

Similarly, the standard 340B Pharmaceutical Pricing Agreement executed by manufacturers states that it is the manufacturer's responsibility to charge covered entities a drug price not to exceed:

> "the **AMP** for the covered outpatient drug **reported** (or which would have been reported had the [m]anufacturer participated in the Medicaid rebate program) **to the Secretary in accordance with the [m]anufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage**."

In 2005 testimony before the Congress on the 340B program, a Deputy Inspector General of HHS told Representatives that "[b]oth the Government and the manufacturers calculate 340B ceiling prices using **the same statutorily-defined formula and the drug pricing data** that manufacturers report to [CMS] for the purposes of the Medicaid drug rebate program."[7] Within weeks thereafter, DRA was enacted. Among the amendments to the Medicaid rebate statute included in DRA are:

- a new definition of AMP that ends the deduction of customary prompt pay discounts from gross sales and requires manufacturers to combine sales and price data for brand drugs and their authorized generics into a single AMP;
- a new definition of best price that includes prices for authorized generic drugs approved under the same NDA as a brand drug in the determination of the brand drug's best price;
- a limitation on which sales at nominal prices may be excluded in the determination of best price and

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[4] Exchange among Senators Bentsen, Cranston, Kennedy and Rockefeller on joint committee responsibility for legislative matters pertaining to the 340B Discount Pricing Program and Medicaid Rebate Program, *Congressional Record*. 102nd Cong., 2nd Sess., 1992, 138, no. 144, daily edition (8 October, 1992): S17903.

[5] The use by OPA of CMS Medicaid Rebate Program pricing data is explained by the Inspector General of the U.S. Department of Health and Human Services in *Review of 340B Prices, July, 2006*, OIE-05-02-0073 on page 3.

[6] NGA/NCSL Web-assisted Audioconference, August 5, 2005, available at http://www.nga.org/Files/ppt/0508340BGOYETTE.PPT.

[7] Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, December 15, 2005.

- the addition of certain children's hospitals to 340B covered entities in the section requiring manufacturers to extend 340B discounts to safety-net providers.

The effect of the definition of AMP amended by DRA is that the same dollar discount extended by manufacturers results is a higher 340B ceiling price than Medicaid best price for a given drug. Nothing found in the legislative history of DRA indicates that Congress focused on the effect of the AMP definition amendment on 340B ceiling prices or the Federal ceiling price under §603 of the Veterans Health Care Act of 1992 (38 U.S.C. §8126). However, the commentary accompanying the Proposed Rule indicates that CMS believed the amendments to the Medicaid rebate provisions and the Final Rule would apply to 340B pricing.[8]

Support for a Single AMP for Medicaid and 340B Programs

There are two possible interpretations of **paragraph (c) of §340B** of the Public Health Service Act (the "340B Statute) as it relates to the **paragraph (b)** definition of AMP:

> (1) AMP is computed as provided under the Medicaid rebate statute that is current on the date of calculation, but to find what section that is in, you refer to Section 1927(c) of the Social Security Act (42 USC 1396r-8(c)) in 340B Enactment Date form, even if later legislative changes mean that the formula is in a different section of the Social Security Act currently.
>
> (2) Some, but not all, elements of the 340B Enactment Date substantive provisions of the Medicaid rebate pricing scheme are frozen in time for purposes of 340B pricing, so, even though the Medicaid and 340B prices were the same in 1992, any future change in the AMP formula under the Medicaid rebate statute has the effect of creating two different pricing schemes, **without any Congressional expression of an intent to do so**.

We believe that under the coordinated Medicaid/340B pricing scheme as intended by Congress, where prices and rebates reported under the Medicaid rebate statute are used to calculate 340B discounts, the only logical and expedient interpretation of the statutory interpretation provision in the 340B Statute is the first one. The following are some, but by no means all, of the issues and problems engendered if the second interpretation is applied, as the OPA Director has proposed in the "Dear Pharmaceutical Manufacturer" letter:

- Manufacturers who have overhauled their Medicaid price reporting systems to accommodate the new AMP definition and CMS's new DDR software system must retrieve their discarded pre-existing price reporting systems for use under 340B and make additional changes to disregard amendments to the Medicaid rebate statute since the 340B Enactment Date.
- The pricing provisions of existing 340B Pharmaceutical Pricing Agreements will be inconsistent with 340B program requirements.

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[8] CMS states that it believed that a change in the reporting of a drug's NDC number under the Medicaid rebate statute reporting provisions to require eleven digits rather than nine would assist 340B entities in the pricing of different package sizes (Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77186 (December 22, 2006)).

- OPA and HRSA will be unable to calculate the 340B ceiling prices by using publicly-available AMP data and, as a result, must either forgo the calculation or institute a whole new data collection program, file Paperwork Reduction Act forms that estimate the burden upon manufacturers of the new data collection and obtain approval from the Office of Management and Budget.
- The 340B pricing scheme, unlinked from the AMP reported to Medicaid, will be based upon one of the following two formulas, depending upon the interpretation given to the phrase "average total rebate required under section 1927(c) of the Social Security Act ... during the preceding calendar quarter"[9]:

  Alternative Formula 1:

  340B price <= AMP calculated as defined on the 340B Enactment Date - (Medicaid rebate actually paid / AMP calculated as defined on the 340B Enactment Date)

  Alternative Formula 2:

  340B price <= AMP calculated as defined on the 340B Enactment Date - (rebate that would have been required under pre-340B Enactment Date Medicaid rebate provisions / AMP on the 340B Enactment Date)

  (a) Alternative Formula 1 uses the following:

  - the AMP definition in effect on the 340B Enactment Date;
  - the DRA best price definition, which, unlike the definition on the 340B Enactment Date, excludes inpatient prices charged to disproportionate share hospitals, prices negotiated with Medicare Part D plans and retiree drug plans receiving the retiree drug subsidy and only those nominal prices charged to enumerated safety-net entities; and
  - a revised baseline AMP derived from historic AMP data "grossed up" to include customary prompt pay discounts previously deducted.

  The AMP in effect on the 340B Enactment Date, which may or may not need to be adjusted by manufacturers to incorporate regulatory guidance included in the Final Rule (for inclusions and exclusions like manufacturer coupon discounts, mail order pharmacy prices, PBM prices and LTC pharmacy prices), differs from the current Medicaid AMP in that it:

  - includes customary prompt pay discounts;
  - includes returned goods;
  - does not include, for brand drugs, data on sales of authorized generic drugs approved under the same NDA; and
  - does not exclude discounts to Medicare Part D enrollees and employee plans receiving the retiree drug subsidy.

[9] One interpretation is that the average total rebate is the rebate required as provided in the Medicaid statute at the 340B Enactment Date but as actually calculated and reported to Medicaid the previous quarter (Alternative Formula 1). The other interpretation is that it is the rebate that would have been paid during the preceding quarter if the Medicaid rebate statute had been unchanged since the 340B Enactment Date (Alternative Formula 2).

(b) Alternative Formula 2 would, in addition to using the AMP in effect on the 340B Enactment Date (as described above), force manufacturers to compute the Medicaid rebate as if no changes had been made to the Medicaid rebate statute since November 4, 1992. The complexities of such an undertaking would be great.

- Certain drugs used for the treatment of sexual or erectile dysfunction will be covered under the Medicaid Rebate Program but not the 340B Discount Pricing Program. Drug manufacturers will have to assure that future changes to the Medicaid rebate statute involving definitions of "covered outpatient drug," "manufacturer" and "AMP" do not enter into 340B ceiling price computations.
- Any future changes to the definitions of "AMP," "manufacturer" or "covered outpatient drug" that Congress desires to incorporate into pricing under both the Medicaid Rebate Program and the 340B Discount Pricing Program must be coordinated with both CMS and OPA and incorporated into amendments to both the Social Security Act and the Public Health Service Act. If the agencies having responsibility for administering the Federal ceiling price program take the same position as OPA, similar amendments to the Federal ceiling price program statute may require coordination with additional agencies and amendments to additional statutes.
- If agencies that administer the Federal ceiling price program do not agree with OPA's position, an irreconcilable conflict will exist in the construction of two virtually identical provisions adopted as part of the same legislation (*i.e.*, the Veterans Health Care Act of 1992).
- Post-340B Enactment Date changes to the definition of "federally qualified health care center" and to the requirements for disproportionate share hospitals to qualify as 340B "covered entities" will not be given effect under the 340B Discount Pricing Program unless Section 340B of the Public Health Service Act is amended.

For the reasons outlined above, to the extent that it is not possible to discern the original Congressional intent in adopting the 340B Statute provision at issue, CMS and OPA should issue guidance on an emergency basis that gives effect to the integrity of the joint statutory scheme, requires as few changes as possible to newly-established Medicaid price reporting systems and avoids needless systemic complexity that could have the unintended effect of exposing manufacturers to sanctions for inadvertent errors. Consultation with agencies having responsibility for the Federal ceiling price program also may be appropriate.

IV. Collection of Information Requirements
Paperwork Reduction Act Notice
Requirements for Manufacturers (§447.510)
Regulatory Impact Analysis
Anticipated Effects
Effects on Manufacturers

The Paperwork Reduction Act Notice and Regulatory Impact Analysis accompanying the Proposed Rule should incorporate the additional burden on manufacturers in making the

calculations necessary to compute both the Medicaid AMP, best price and rebate and the 340B ceiling price if the OPA's interpretation of the 340B statute is given effect.

Since the 340B Discount Drug Program in the past has used information collected under the Medicaid Rebate Program, if the OPA interpretation of §340B(c) of the Public Health Service Act is given effect, any change to the information collection requirements under the Medicaid rebate statute, including any change in formulas for computing the reported data, after the 340B Enactment Date will require manufacturers to duplicate their efforts in providing price information, because they will have to make separate computations for use by CMS and OPA. We question the accuracy of the additional manufacturer data collection burden of 31 hours per quarter for additional data gathering and pricing and $50,000 (208 hours annually) for systems upgrades in light of the initial and ongoing investment that would be required for manufacturers to establish and maintain two price reporting systems, one for Medicaid rebates and another for 340B ceiling prices.

* * * * * * *

Please accept my thanks in advance to your anticipated consideration of these comments. If you wish to discuss them further, please do not hesitate to contact me at 513-977-8344 or lydon@dinslaw.com.

Sincerely,

Deborah R. Lydon

cc: Centers for Medicare & Medicaid Services,
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development,
Attn: Melissa Musotto, [CMS-2238-P], 93
Room C4-26-05, 7500 Security Boulevard,
Baltimore, MD 21244-1850
Melissa.Musotto@cms.hhs.gov

Office of Information and Regulatory Affairs,
Office of Management and Budget,
Room 10235, New Executive Office Building,
Washington, DC 20503,
Attn: Katherine Astrich, CMS Desk Officer, CMS-2238-P,
katherine_astrich@omb.eop.gov. Fax (202) 395-6974.

Hemophilia Federation of America

97

Advocacy For Persons With Clotting Disorders

February 19, 2007

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

Sent by Federal Express and via electronic transmission

To Whom it May Concern:

The Hemophilia Federation of America is a non-profit organization that advocates for persons with bleeding disorders and especially hemophilia and von Willenbrand Disease. Access to care is vitally important to members of the bleeding disorders community, particularly in regards to anti-hemophilic clotting factor products.

In regards to the Administrative and Service Fees section, we are very concerned about the reimbursement formula for individuals affected by a bleeding disorder who are on Medicaid. Primarily, there is no specific definition for a separate furnishing fee for anti-hemophilic clotting factors. The furnishing fee is a separate payment added into the payment rates which allows patients to maintain access to care, and access to anti-hemophilic clotting factor medications. The Hemophilia Federation of America believes that if Medicaid would reference the Medicare provision in the final rule it would provide clear guidance for a state Medicaid program using the AMP figures to determine Medicaid reimbursement rates.

A similar furnishing fee is referenced in the Medicare law and providing a similar reference in CMS 2238-P would assist state Medicaid programs in providing appropriate resources to cover the unique attributes associated with the administration and utilization of anti-hemophilic clotting factor medications.

The Medicare provision can be found at Section 303 (e)(1) of the Medicare Modernization Act (PL.108-173) that created a furnishing fee for blood clotting factor reimbursement under the Medicare program.

Services required for a patient who receives Medicare are also required for a patient who receives Medicaid. If Medicaid chooses not to add the furnishing fee, they are preventing the patient from having total access to care. The furnishing fee provision under Medicare has served to prevent such issues and has helped maintain access to care and appropriate quality of care as recognized by national accreditation organizations.

Please consider referencing the formula for a furnishing fee as seen in Medicare that some states have already introduced as part of Medicaid.
We appreciate the opportunity to provide comments regarding the proposed rule of the Deficit Reduction Act of 2005.

Sincerely,

Jan Hamilton

Jan Hamilton
Advocacy Director
Hemophilia Federation of America

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98

Regions Hospital®

640 Jackson Street
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February 8, 2007

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

To Whom It May Concern:

On behalf of Regions Hospital in St. Paul, Minnesota, I am responding to the proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. If the proposed 340B pharmacy purchasing changes are enacted, I believe that this could significantly increase our cost of doing business and negatively impact our ability to provide low cost care to the uninsured.

Regions Hospital is a 427-bed Disproportionate Share Hospital (DSH) that purchases outpatient medications under the federal 340B drug discount program. We are the second largest provider of uncompensated care in the state of Minnesota, with 2006 uncompensated care write-offs totaling approximately $34.5 million. Since 2003, our uncompensated care write-offs have nearly doubled.

As a safety net provider, we have significant concerns about the potential changes to the current 340B program. If we were to lose 340B savings for clinic-administered outpatient medications for Medicaid beneficiaries, the increased medication costs would be significant and could jeopardize our ability to provide low cost care to all patients. Purchasing drugs under the 340B discount program has allowed us to continue providing quality care and medications to the uninsured in our community for many years.

We hope that you will give serious consideration to rejecting the changes as proposed since they will have a negative impact on safety net hospitals and in the end, could increase the cost of providing health care to the population we serve.

Sincerely,

Brock Nelson

Brock Nelson
President and Chief Executive Officer

JOSEPH L. CUNNINGHAM

608 FIFTH AVENUE, S.W.
WAUKON, IA 52172
PHONE 563-568-4267

February 15, 2007

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

To Whom It May Concern:

I am writing as a pharmacist to urge you to oppose any additional cuts to pharmacy reimbursement in the Medicaid program, such as those proposed in the President's budget. I am extremely concerned about the potential impact that such a proposal may have on my patients and community.

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

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

On the contrary, I urge you to work with to increase our dispensing fees. While multiple studies have demonstrated that the average cost to dispense a medication is approximately $10, the typical reimbursement for pharmacist services provided by Medicaid is $4. Previously higher margins for product reimbursement helped to make up for the inadequate reimbursement of pharmacist services. But now, what do we do? How do we continue to meet the needs of those in our community who need our help the most while keeping our pharmacy doors open?

As a result, I urge you to oppose any further cuts to pharmacy reimbursement, encouraging you to instead work with Congress to ensure that we receive appropriate reimbursement for our services. Thank you in advance for your consideration. I look forward to hearing from you on this issue.

This change is going to hit rural pharmacists very hard. Iowa citizens and pharmacists really need your help on this issue.

Sincerely,

Joseph L. Cunningham, R.Ph.

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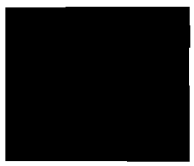

PHARMACY
SOCIETY OF
WISCONSIN

"Leading Our Profession in a Changing Health Care Environment"

February 13, 2007

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

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

The Pharmacy Society of Wisconsin is very concerned about the ability of its members to continue to serve Medicaid recipients if the proposed rule that provides the regulatory definition of AMP as conceived by CMS is implemented for generic drugs.

Summary

PSW supports state and federal efforts designed to positively influence the affordability of and access to prescription drugs and the services provided by healthcare professionals, including pharmacists.

While supportive of such efforts, we are compelled to offer the following comments on the 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.

Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510.

Defining "Retail Pharmacy" Class of Trade

§447.504 address the methodology CMS would employ to determine AMP when the final regulation goes into effect.

Establishing Average Manufacturer's Price

AMP should not and can not mix prices offered to different classes of trade as defined by a manufacturer. If a manufacturer will not avail certain discounts or rebates to one group of customers that is made available to another of its customers due to a class of trade distinction, then CMS can not mix the different class of trade sales prices in the determination of an average.

For example, if a certain sales price for a medication from a manufacturer is available to a mail order pharmacy customer but a higher price is charged to a community pharmacy customer and nothing can be done by the customer to achieve the lower price because of the class of trade distinction made by the manufacturer, than those two prices must not be averaged in order to establish a reimbursement level for the product by the federal government. However, if the average manufacturer's price were to be calculated for each unique class of trade, a reimbursement policy could be established using AMP for each trade class.

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There are further distinctions between pharmacy types that reveal why mail order and PBM pharmacies should be treated differently than community or clinic pharmacies when using purchase price information to determine a reimbursement level for a specific drug product. For example, PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public" as the statute requires when determining AMP for the Medicaid. In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. PSW is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs) from the calculation of AMP for the "retail" pharmacy FUL.

Mail order pharmacies are structurally similar to pharmacies that service nursing homes, which have been excluded in the proposed rule from the retail class of trade. Both types of operations are "closed door" in that they sell only to facilities or plans with which a contractual relationship exists. As with nursing home pharmacies, discounts and rebates that are available to mail order pharmacies are not available to traditional pharmacies.

Section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade. Excluding mail order and PBM pharmacies from the definition of the retail trade of pharmacy would offer numerous benefits to pricing data and regulatory oversight, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens.

Discounts, Rebates and Price Concessions

PSW also contends that certain discounts, rebates and price concessions found in §447.504(g)(6) and (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBM and mail order pharmacies in the form of rebates, chargebacks or other contractual arrangements which, by their very relationship are not available to out-of-pocket customers or third party private sector parties. The proposed regulation concedes that the benefits of these rebates, price concessions, chargebacks and other contractual arrangements may not be - and are not – shared with the community pharmacy networks, consumers, or third party payors, and, thus, they are not available to the "general public."

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and they do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties.

On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP.

On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP below the actual acquisition price to the retail pharmacy.

This concern is highlighted in a recent GAO study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."

§447.510 Requirements for Manufacturers.
This section of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed to set forth the above tasks creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'clawback' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself presents an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome.

Market Manipulation
Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period". The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due. A manufacturer with a vertically integrated market position could use the 'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP. Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions.

'Claw-back'
Given that the proposed regulation allows substantial flexibility, with regard to financial restatement, we would recommend that CMS clearly state its intent on the ability or in-ability to recoup erroneous payments or for a provider to claim shortages based on incorrect AMPs. Since removing the manufacturer's ability too restate AMP would be too restrictive, guidance from CMS on this issue is paramount.

Pricing Lag

Under the proposed regulation, the AMP first reported to CMS could be as many as 30 days old. As such, the data will be out of date prior to dissemination to the states and the general public, a process potentially taking another 30 to 60 days. Additionally, the flexibility given the manufacturer to report discounts employed and the restatement figures will add significant variability to this lag. Material lag in AMP degrades transparency and places an undue burden upon the retail pharmacy class of trade. The technical difficulties and associated overhead burdens of limiting or eliminating this structural lag may prove to be insurmountable. Therefore, CMS should provide guidance to the states and other users of AMP on the proper method to address any issues resulting from the structural lag.

Severe Price Shifts

The inherent market volatility, associated with pharmaceutical manufacturing, occasionally results in dramatic shifts in price structure. The proposed regulation is noticeably silent in offering any mechanism to account for this fact. Severe price shifts and the significant issues associated with pricing lag can be effectively addressed with the implementation of trigger mechanisms. CMS should identify a reasonable and appropriate percentage shift in real time price that would trigger a review and recommendation by the Office of the Inspector General (IG).

The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag.

The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic drug's AMP.

Additional Comments

Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9- digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11- digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

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.

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

Thank you.

Sincerely,

Christopher J. Decker
Executive Vice President & CEO

cc. Wisconsin Members of Congress