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Sent: Friday, March 09, 2007 3:28 PM
To: Bryson, Stacey L. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA)
Cc: Cooper, Cheryl C. (CMS/CMSO); Reed, Larry L. (CMS/CMSO); Duzor, Deirdre D. (CMS/CMSO)
Subject: CMS-2238-P Another Letter

Hi there,

We received another letter electronically. Please add this to the public comment log for the AMP rule.

Thanks,
Marge
x64361

Giannotto's Pharmacy
195 First Avenue
Newark, NJ 07107
973-482-8220
FAX:973-482-0615
Trushar A. Sheth, RPh
President

VIA ELECTRONIC SUBMISSION

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 toθ 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.
θ 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.

Respectfully,

Trushar Sheth, R.Ph., CCP,
PRESIDENT,
GIANNOTTO'S PHARMACY
973-482-8220

Angela B. Taube
Operations Specialist
Disabled & Elderly Health Programs Group
Center for Medicaid and State Operations
Ph: (410) 786-2638
Fax: (410) 786-9004

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VIRGIL H. GOODE, JR.
5TH DISTRICT, VIRGINIA

Congress of the United States
House of Representatives
Washington, DC 20515–4605

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08 MAR 2007
9:36 am

February 9, 2007

Mr. Kevin Berna, Congressional Affairs Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW, Room 341 H
Washington, DC 20201

Dear Mr. Berna:

I write with concerns that have been expressed to me by several pharmacists in my District who own independent pharmacies. The concern expressed relates to the decision the Centers for Medicare and Medicaid Services has made to base federal reimbursement for pharmaceuticals on the use of the Average Manufacturing Price (AMP). Concerns have been raised that for an independent pharmacy to compete with the very large pharmacies, such as WalMart is hard enough; to compete with mail order houses, which can purchase for up to 25% less, is impossible.

Pharmacists in my District are concerned that the policy enacted by CMS will lead to similar policy by the private insurance companies. A suggested possible option, which has been suggested to my office, would include CMS considering the category, such as Mail Order, Nursing Home or Retail, when basing the reimbursement and not just the Average Manufacturing Price.

I appreciate your consideration of the independent pharmacists and look forward to hearing from your office. With kind regards, I am

Sincerely,

Virgil Goode, Jr.

Virgil Goode, Jr.

Post Office Box 366
Farmville, VA 23901
Telephone 434-392-8331
FAX 434-392-6448

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515–4605

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02/27/2007 08:1[illegible] AM

Virgil Goode, Jr.
M.C.

Mr. Kevin Berna, Congressional Affairs Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW, Room 341 H
Washington, DC 20201

24013+1907 C052 [redacted]

>Stop C4-26-05 7500 Security Blvd.
>Baltimore, Maryland 21244-1850
>
>
>I appreciate the opportunity to submit comments to the Center for
>Medicare and Medicaid Services (CMS), regarding the December 20, 2006
>proposed legislation to provide a regulatory definition of AMP and
>implement the Medicaid Federal Upper Limit (FUL) program for generic
>drugs. I am a pharmacist and owner of Kimsey Pharmacy, a community
>retail pharmacy, located at 125 Five Points Dr., Ducktown, TN 37326.
>My store is not only a major provider of pharmacy services in this
>community, it is also the only pharmacy in this very small rural town.
>
>I. REMOVE PBMs and MAIL ORDER PHARMACIES from the Definition of
> "Retail Class of Trade"
>
> CMS proposes a broad and all inclusive definition of "retail class of
>trade" in order to determine the AMP used to calculate FULs. This
>proposal will NOT reflect prices at which retail pharmacies can
>purchase prescription medication. The only sale that should be
>included in the AMP definition is that from manufacturer to wholesaler.
>This is where the purchase occurs from the manufacturer. In addition,
>mail order pharmacies are NOT "open to the public" because they require
>a unique contractual relationship to be able to provide patient
>services. PBMs do NOT purchase drugs from a manufacturer or a
>wholesaler, nor do they dispense drugs to the general public upon a
>physician's prescription order. Because of their place in the system,
>and their definition, as such, they should be EXCLUDED from any
>information used in calculation of AMP to be used to determine FUL.
>
>II. REMOVE REBATES AND CONCESSIONS TO PBMs and MAIL ORDER
> PHARMACIES to calculate AMP
>
> AMP should reflect prices paid by "retail pharmacies". To include the
>elements defined in the proposed regulation 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 therefore, DO NOT REDUCE PRICES that
>pharmacies pay for prescription drugs, nor are these reductions
>available to "the general public". In no way, should these rebates and
>concessions be included in calculating AMP used to determine FULs.
>GAO has conducted an analysis of the relationship between the proposed
>AMP- based FULs and the prices that retail pharmacies actually pay to
>acquire drugs. GAO used the highest expenditure and the highest use
>drugs for Medicaid in the analysis. They reported that retail
>pharmacies will be reimbursed, on average 36% less than their costs to
>purchase the drugs. A business cannot be sustained or continue to
>operate if it is forced to continuously sell its products below actual acquisition costs.
>CMS claims that "almost" all stores sell goods other than prescription
>drugs and overall store sales average more than twice as much as
>prescription drug sales. In my pharmacy, over 96% of our business
>comes from prescription drugs. "Other sales" in the store are
>irrelevant, in any case, but are negligible in our case as in many community pharmacies.
>These "other sales" have nothing to do with the decisions regarding
>determination of FULs and should NOT be used as a factor in making
>these decisions. FUL pricing should be based solely on prices that
>retail pharmacies pay for drugs!
>
>III. REMOVE MEDICAID DATA
> Since Medicaid pricing is heavily regulated by state AND federal
>government, it should be treated consistently with other federal payor
>programs, and should also be EXCLUDED from AMP in the proposed regulations.
>
>IV. MANUFACTURER DATA REPORTS WITH MARKET LAG GIVE RISE TO THE
> POTENTIAL FOR MANIPULATION.
> The AMP regulations could create an opportunity for market
>manipulation. Due to the fact that manufacturer reporting is not

>always timely and there is an extended ability to revise the reported
>data, the risks of both price fluctuations and market manipulation are
>amplified tremendously under these proposals. The Tennessee
>Pharmacists Association
>(TPA) proposes a "trigger mechanism", whereby, severe price
>fluctuations must be promptly addressed by CMS. Also, TPA makes
>comments on the lack of clarify on "claw back" from manufacturer reporting error.
>
>V. USE OF THE 11-DIGIT NDC IS NECESSARY
>
> The 11-digit NDC value, must be used by CMS. The most commonly
>dispensed package sizes purchased by retail pharmacies should be used
>to calculate FULs, and this makes using the 11-digit NDC imperative, as
>the 11-digit code designates package size. It is not practical, nor is
>it affordable or good business, to purchase drug products in package
>sizes of 5000, 10,000, 25,000, or even 40,000 tablets or capsules, in
>the typical retail pharmacy. This would create an extra cost burden on
>the pharmacy, tying up dollars on the shelf, when most of the drug
>would go out of date before it could be dispensed, causing even greater loss to the
business.
>Prices used to set the limits should be based on the most common
>package size dispensed by retail pharmacies, and this can only be
>captured if the 11-digit package size if used.
>
>In conclusion, it is important to note that community retail pharmacies
>do not just sell a product. We provide a service to our patients/customers.
>The community retail pharmacist is the most accessible healthcare
>provider, and there is no fee for our services, other than what is
>attached to the cost of the prescription drug. There are no charges
>for overhead, for counseling patients, for technical help, or even the
>label and vial that contains the dispensed product. In spite of not
>charging a fee for service, we are available to answer questions and
>concerns, research drug information for patients and physicians,
>perform quality assurance with dispensing, maintain legal documentation
>on all prescription orders, detect drug-drug interactions and intervene
>when necessary---communicating with physicians on behalf of patients,
>and providing quality pharmaceutical care to help patients obtain the maximum
>benefit from their prescription medication. As a matter-of-fact,
>pharmacists are required by law to counsel on all patient's
>prescriptions, and there is no fee for this service provided. The
>pharmacist is often one of the first to detect medication related problems and/or side
effects.
>All of these efforts take time, and due diligence to ensure the best
>possible outcomes for our patients. All of this is performed, on top
>of maintaining control over the drugs for which we are responsible.
>
>I would like to be able to continue to provide this level of
>pharmaceutical care to the community that I serve. I support the more
>extensive comments being filed by the TPA regarding these proposals. I
>appreciate your consideration of these comments and ask that you please
>contact me with any questions you may have.
>
>Sincerely,
>
>
>Linda Campbell, D.Ph.
>1830 Scenic Drive
>Maryville, Tennessee 37803
>cc: Senator Lamar Alexander
> Senator Bob Corker
> Rep. Zach Wamp (3rd District)
> Rep. John Duncan, Jr. (2nd District)
>
>Auto-Response - 02/20/2007 09:51 AM
>Title: Which DESI drugs do not satisfy the definition of a Part D drug?
>Link: http://questions.cms.hhs.gov/cgi-
>bin/cmshhs.cfg/php/enduser/popup_adp.php?p_faqid=8053&p_created=1165343