

Submitter : Ms. Lynda Donegan
Organization : Truman Medical Centers
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

On behalf of Truman Medical Centers, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the DRA), published in the Federal Register on December 22, 2006. Truman Medical Centers (TMC) is a two-hospital not-for-profit health system located in Kansas City, Missouri that qualifies as a disproportionate share hospital (DSH) under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program.

TMC provided 220,051 outpatient prescriptions during 2006. Of those prescriptions, 75,941 were given to the patients at either no-charge or at a nominal fee.

Our principal concerns about the proposed regulations are addressed below.

TMC already complies with many of the proposed changes. TMC requires that all prescriptions filled with 340B purchased medication be dispensed on a TMC prescription, written by a TMC physician, and be for outpatient services provided by one of the hospital s clinics. The new definition would have a large impact on the discharge process at TMC. While the number of discharge prescriptions account for only one percent of the total scripts dispensed, the ability to provide these medications facilitates TMC s bed turnover rate. This directly impacts the number of patients for which we can provide care.

TMC also provides cancer treatment to a large patient population. 340B drug is a tremendous cost saver not only to the institution but to the patients the TMC serves. Currently, TMC can use 340B medication in our outpatient oncology clinic to provide continued treatment that was initiated during an inpatient visit. Under the proposed changes most, if not all, of these patient treatments may be excluded from using 340B purchased medications because the treatment did not result from an outpatient service.

Another issue of concern to TMC is that the proposed regulations would create enormous administrative and financial burdens for TMC by requiring the reporting of National Drug Code (NDC) information on drugs administered in hospital outpatient settings.

Finally, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

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

Submitter : Mr. John Covello

Date: 02/20/2007

Organization : IPA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

CMS-2238-P-1394-Attach-1.DOC

CMS-2238-P-1394-Attach-2.DOC



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February 20, 2007

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

RE: CMS file code: CMS - 2238 - P

Federal Register

Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

On behalf of the Independent Pharmacy Alliance, the professional trade association representing 650 independently-owned, community-based pharmacy store in New Jersey serving a diverse Medicaid patient population for pharmacy care needs, I am submitting formal comments on the above referenced CMS proposed regulation. IPA is very troubled by the CMS proposed regulation to define and establish an average manufacturers' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that New Jersey's independent pharmacies can afford to continue provide Medicaid generic pharmacy prescription services to Medicaid prescription patients without incurring unsustainable financial losses.

Below are IPA's 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.

State Pharmaceutical Assistance Program (SPAP) price concessions

The rulemaking preamble comment states that “these sales [to SPAP] are included in the AMP to the extent they are sales to the retail pharmacy class of trade. Therefore, we propose that SPAP sales should not be backed out of the AMP calculation.” Rebates paid by the manufacturer to the SPAP should not be included in the calculation of AMP as these rebates do not affect the price paid by a community pharmacy nor are the rebates shared with the pharmacy from the SPAP.

It seems inconsistent with legislative intent of the DRA for CMS to include within the calculation of the AMP sales reimbursed by SPAP for non-Medicare Part D covered prescriptions. These reimbursements do not expend any federal dollars and should be beyond the scope of the CMS purview to design a formula for AMP.

Manufacturer Coupons

Coupons redeemed by a pharmacy on behalf of the consumer should not be included in the calculation of AMP. Manufacturer coupons are, essentially, cash discounts from manufacturer to the consumer and in no way affect the price paid by a community pharmacy for the drug.

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 are 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-digit 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.

Posting of AMP Data

While the DRA states that AMP data should be posted as of January 1, 2007, IPA appreciates CMS’ decision that it has the authority to not post AMP data until it can process January monthly AMP’s due to be filed by March 2, 2007. This ensures that posted AMP’s will at least reflect the DRA’s removal of customary prompt pay discounts extended to wholesalers from the calculation.

CMS should review very carefully the January monthly reports before placing the data on its website or submitting it to State Medicaid Program offices. At the outset, CMS should post a disclaimer with this data warning that limited instructions were provided to guide manufacturers’ January AMP calculations. Many manufacturers may have been unable to update or complete updating their government price reporting systems prior to reporting. This is critical given the fact that AMP will change after CMS adopts a Final Rule codifying the AMP calculation methodology. Therefore, posted data should be viewed as preliminary and may not accurately reflect prices available in the market to retail pharmacies. Similar disclaimers should be sent to the States with their download tapes or new electronically transmitted price report files. These disclaimers also should be reiterated in a State Medicaid Director Letter.

Although CMS may not have the statutory authority to delay posting AMP data beyond the point when it has January AMPs in hand, CMS has in the past missed such statutory deadlines (i.e. MMA’s the competitive acquisition program) without suffering legal repercussions, particularly when there is a valid reason for delay and the delay is reasonably short

IPA believe that CMS risks misleading Medicaid pharmacy patients about the prices they are charged for drugs at retail pharmacies by making AMP values publicly available on the CMS website prior to the adoption of a final AMP formula and before manufacturers have time to time to update their data reporting systems. It also could mislead commercial carriers about the drug costs experienced by network pharmacies. The simplest way to avoid possible confusion and data misuse would be to delay website postings until the new AMP rule becomes effective.

Also, any web-postings of AMP values should include in bold face type a disclaimer explaining AMP's limitations as a measure of retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year.

IPA is very concerned that States such as New Jersey that are currently developing their next state budgets will prematurely use preliminary AMP data to design a reimbursement formula that will severely cut pharmacy payments below our acquisition costs to the point that Medicaid patients will see dramatic reductions in their access to pharmacy services. We strongly urge CMS to deny any changes to State Plan Amendments in order to prevent States from making premature changes to their Medicaid generic prescription drug reimbursement before this rule becomes final and the "new" AMP data is available to the states.

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.*
 3. Exclude manufacturers coupons and SPAP non-Medicare Part D price concessions.
- ❑ Reporting AMP at the 11-digit NDC level to ensure accuracy.
- ❑ Use a 12-month rolling average price to accurately reflect the rapid changing nature of generic drug prices.
- ❑ Use care in posting and explaining to the public the methodology, accuracy and validity of AMP data as it relates to a pharmacies actual acquisition cost for generic pharmaceuticals.
- ❑ Avoid premature use of preliminary AMP data in State Medicaid Plans.

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 submitted,

John A. Covello
Director of Government and Public Affairs

Submitter : Dr.
Organization : Dr.
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

I am writing with concerns over the proposed definition for Average Manufacturers Price (AMP), and the formulas used for reimbursements to retail pharmacies.

The CMS is making a big mistake if mail order and PBM pricing is included in those calculations. Most retail pharmacies in the United States would be paid significantly lower than the pharmacy's actual cost for the drug. The end result would basically be the death of independant pharmacies in the United States.

I would hope that the CMS is working with some of our national organizations such as the National Chain Pharmacists Association or the Retail Druggists Association as this plan is developed.

Submitter : dee simons
Organization : biogen idec
Category : Drug Industry

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : Ms. Laurie Clark
Organization : Garden State Pharmacy Owners
Category : Health Care Professional or Association

Date: 02/20/2007

Issue Areas/Comments

Background

Background

On behalf of Garden State Pharmacy Owners, a non-profit professional organization representing over six hundred independent pharmacies in New Jersey, we thank you for the opportunity to present our views on the proposal which appeared in the Federal Register in December of 2006.

Collection of Information Requirements

Collection of Information Requirements

While we understand the difficulty of establishing a new benchmark for the cost of the drug, a methodology must be put in place, which at a minimum approximates retail pharmacy acquisition costs inclusive of inventory costs, and incorporates a dispensing fee, which reflects true retail pharmacy dispensing costs.

In fact, AMP has never been adequately defined by CMS. Therefore, the inherent variable nature of AMP coupled with the fact that CMS proposes to include the prices paid by mail order pharmacies and PBMs in the calculation will not provide for a viable benchmark for the cost of the drug that will allow states to control prescription drug costs while providing pharmaceutical care for the Medicaid population.

Mail order pharmacies and PBMs are not part of a level playing field with community pharmacy. These entities have tremendous advantages over community retail pharmacy due to their preferential treatment by pharmaceutical manufacturers. Their special discounts and pricing is not available to the public. Therefore, adding their pricing into the equation will cause an artificially low number to be reported.

Moreover, a recent Government Accountability Office (GAO) report from December of 2006 indicated that retail pharmacies would be reimbursed on average 36% lower than their costs to purchase generic medications. We believe this payment structure if adopted as proposed will put up barriers to pharmaceutical care for Medicaid recipients as services cannot be provided under these terms.

In terms of reporting, AMP must be reported on a weekly basis to ensure that pricing is reflective of price increases imposed on retail pharmacy on a daily basis. As proposed, reporting requirements will cause a delay in the reimbursement process. In addition, there is the opportunity for market manipulation via the improper use of NDC numbers. A mechanism must be established to counter these unintended effects.

In addition, we have the following suggestions:

1. No where does the proposed rule appear to address the process for NDCs that are terminated or discontinued. We should recommend that a process for timely removal (within a month) be implemented of the NDCs when this occurs.
2. A redetermination process should be implemented for pharmacies and other providers, including state Medicaid programs, that would allow for CMS to either suspend or terminate an AMP if a redetermination is approved.
3. CMS should be required to provide a 1-800 phone number for individuals to obtain information on AMPs and to report discrepancies.

Laurie A. Clark
Director of Governmental Affairs
Garden State Pharmacy Owners

GENERAL

GENERAL

See Attachment

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

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

Submitter : Dr. John Gans
Organization : American Pharmacists Association (APhA)
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1398-Attach-1.DOC



American Pharmacists Association

Improving medication use. Advancing patient care.

February 20, 2007

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention CMS-2238-P
7500 Security Boulevard
Baltimore, Maryland 21244

[Submitted electronically to: <http://www.cms.hhs.gov/eRulemaking>]

Re: CMS-2238-P

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the proposed rule, 42 CFR Part 447 – Payment for Services, that was published in the Federal Register on December 22, 2006 (71 FR 77174.) The proposed rule would implement sections of the Deficit Reduction Act of 2005 (DRA) pertaining to reimbursement for generic medications under the Medicaid program. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

The proposed regulation would base reimbursement for generic medications on 250% of the Average Manufacturer's Price (AMP), moving away from the current Average Wholesale Price (AWP) model. While APhA appreciates the Agency's efforts to implement the provisions of the DRA and establish a more transparent system for Medicaid prescription medication payments, we are extremely concerned with how the proposed regulation defines AMP and dispensing fees. Our comments will also address authorized generic drugs, exclusions from best price calculations, requirements for manufacturers, Federal Upper Limits (FUL) calculations, physician-administered medications, and specific concerns raised by pharmacies that participate in the 340B Drug Pricing Program within the proposed regulations.

Section 447.502 - Definitions

Dispensing Fee

The proposed regulation carries with it significant responsibility – to establish a fair method to reimburse pharmacies in the Medicaid program for the products they dispense and for services required to ensure safe medication delivery. One of the major goals of Medicaid pharmacy payment reform was to pay pharmacies more accurately for the cost of the drug they dispense as well as more accurately for

their cost of dispensing. Product reimbursement plus dispensing fees should cover the costs and services related to providing medication to Medicaid patients. Unfortunately, the proposed regulation does not give states specific guidance for setting a “reasonable” dispensing fee, and it continues to allow states to determine the “reasonable” dispensing fee required to pay pharmacists. In addition to the product cost component, APhA stresses that pharmacy reimbursement must also include reimbursement for pharmacist services required to dispense the product. Failing to provide guidance on determining an adequate dispensing fee within the overall reimbursement equation may lead payors and policymakers to incorrectly believe that the proposed definition of 250% of AMP would yield sufficient overall reimbursement.

The proposed regulation defines dispensing fee as:¹

- Fee incurred at the point of sale and includes costs other than ingredient cost of a covered outpatient medication each time such medication is dispensed
- Pharmacy costs associated with ensuring that possession of the appropriate covered outpatient medication is transferred to a Medicaid beneficiary. Pharmacy costs include but are not limited to:
 - Reasonable costs associated with a pharmacist’s time checking the computer for an individuals coverage
 - Performing activities related to drug utilization review and preferred drug list review
 - Measuring, mixing, filling, counseling, delivery, providing special packaging, and providing a completed prescription for a covered outpatient medication for a Medicaid beneficiary, and
 - General overhead associated with maintaining the facility and equipment necessary to operate the pharmacy
- Does not include administrative costs incurred by the State in the operation of the covered outpatient medication benefit including systems costs for interfacing with pharmacies.

By comparison, a January 2007 study, *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, identifies the following five main factors that should be included for cost-to-dispense studies:²

- Prescription Department Payroll
- Prescription Department Costs:
 - Prescription containers, labels and other pharmacy supplies
 - Professional liability insurance for pharmacists
 - Prescription department licenses, permits and fees
 - Dues, subscriptions and continuing education for the prescription department
 - Delivery expenses (only prescription-related)
 - Computer systems (related only to the prescription department)
 - Bad debts for prescriptions (including uncollected co-pays)
 - Transaction fees
 - Other prescription-department-specific costs
- Facilities costs

¹ 42 CFR § 447.502.

² Grant Thornton LLP; *National Study to Determine the Cost of Dispensing Prescription in Community Retail Pharmacies*. January 2007.

- Other store/location costs
- Corporate costs allocated to prescription departments

The above five factors include several important elements related to overall pharmacy department overhead and costs not specifically identified in the proposed regulation, including expenses related to: pharmacy payroll; department costs incurred through pharmacy supplies, liability, state and federal fees, continuing education requirements, computer/phone system, debts, and transaction fees. This added detail is a much better representation of the costs that should be included when determining dispensing fees. It is important for the Agency to recognize the broad scope of expenses involved with providing prescription medications to patients which go well beyond the simple cost of the product.

Pharmacies should be paid a fair dispensing fee based on their actual cost of dispensing. The dispensing fee, which reflects professional services associated with providing the product, should be determined annually by an independent actuary (or other contractor) who meets specific criteria and with whom CMS would contract to do cost-to-dispense studies on a regional and/or state basis. States should then be required to either utilize these figures to set their dispensing fees or conduct their own state-specific cost-to-dispense study based on the criteria that CMS outlines. States should be encouraged to account for variances such as urban versus rural and geographical cost differences. However, dispensing fees should not be decreased for safety-net pharmacies that help to provide care for the nation's most vulnerable patients. APhA urges CMS to require states to pay all pharmacies a fair and accurate dispensing fee that actually reflects the pharmacy's true costs for providing medications and services to Medicaid patients. This would help to ensure fair compensation and the continued viability of the pharmacy community. Finally, it would help correct the existing problem that few states currently pay a dispensing fee that is fair and reflective of the services provided.

APhA is concerned that that lack of guidance for defining a dispensing fee would permit state Medicaid programs to underpay pharmacists for their dispensing-related services. While the Medicaid program will be paying pharmacies less for the generic drug ingredient cost, CMS should encourage states to ensure that dispensing fees are adequate and accurate for all pharmacies. For example, the average State Medicaid program pays approximately a \$4 dispensing fee. Unfortunately, based on the recent national study, the average cost to dispense a medication is approximately \$10-12³. The proposed regulations offer no incentives or guarantees for states to provide appropriate reimbursement through dispensing fees to pharmacies. There is also no system in place to penalize states who fail to adequately reimburse pharmacies. Without assurances that community pharmacies will receive adequate reimbursement for pharmacists' dispensing-related services and assurances that pharmacy remains a financially viable practice, Medicaid beneficiaries may unfortunately be faced with decreased access to pharmacist services. Additionally, those pharmacies that continue to work with Medicaid patients may be penalized for continuing to offer their services.

Section 447.504(e) – Determination of Average Manufacturer Price (AMP)

Definition of Retail Pharmacy Class of Trade

The proposed regulation defines AMP as the average price received by a manufacturer from wholesalers for drugs distributed to the retail pharmacy class of trade. The proposal then defines "retail pharmacy class of trade" as:⁴

³ Grant Thornton LLP; *National Study to Determine the Cost of Dispensing Prescription in Community Retail Pharmacies*. January 2007; 15.

⁴ 42 CFR § 447.504(e). 22 December 2006

- Any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public

Unfortunately, the proposed definition of retail pharmacy, which would be used to calculate AMP, includes prices given to mail-service pharmacies and pharmacy benefit managers (PBMs). APhA is concerned with the Agency's suggestion that these types of pharmacies fall within the definition of retail pharmacy. PBMs do not sell or provide medications to the general public. Additionally, mail-service pharmacies do not dispense medication to the general public and are not accessible in the same manner as community pharmacies. Neither model offers patients the opportunity for face-to-face interaction and consultation with a pharmacist. It is unreasonable to include these entities in the definition of retail pharmacy. These groups may have access to rebates and price concessions that may not be available to community pharmacy. Consequently, APhA is concerned that by including sales to such pharmacies, the AMP-based reimbursement rate may be set lower than the price at which community pharmacies can purchase generic medication products.

Recent reports from the Congressional Budget Office (CBO) and the U.S. Government Accountability Office (GAO) highlight dramatic price differences in the various pharmacy settings. The CBO report noted that community pharmacies do not have access to prescription medication pricing and manufacturer rebates available to mail-service pharmacies.⁵ In addition, the GAO study found that estimated reimbursement calculations, based on the new AMP-based calculation, for 77 of the most frequently dispensed generic medications would be on average 36% below the actual acquisition costs for community pharmacies.⁶ While the studies may not have combined all pricing and medication factors, they illustrate the urgent need to reevaluate how the new AMP-based calculations could negatively impact pharmacy.

As APhA expressed during the Congressional debate on the DRA and in its discussions with the Office of Inspector General (OIG) for its study on this issue, we strongly recommend that the elements used to define and calculate AMP reflect prices actually available to community pharmacy. Otherwise, the reimbursement calculations may not adequately cover the cost to obtain the product. It is critical for the Agency to ensure fair compensation and thus viability of the pharmacies providing services to Medicaid patients, by evaluating all of the costs relative to actual community pharmacy settings.

In the preamble, the Agency states that the majority of the savings to be realized through implementation of the proposed regulation would be felt in pharmacy, based on decreased payments to pharmacies. America's pharmacies should not be asked to bear the brunt of these proposed savings. The Agency estimates that pharmacy revenue may decrease by nearly \$800 million in 2007, despite the fact that no other health care provider or system is asked to manage such changes.⁷ Pharmacy plays a central role for the health care community, especially in rural and low-income settings where the pharmacist may be the only health care provider in the local area. By not providing adequate reimbursement to pharmacy, the changes proposed may negatively impact the ability of pharmacy to continue to serve the Medicaid patient population.

⁵ Congressional Budget Office (CBO). Pub No 2703. Prescription Drug Pricing in the Private Sector. January 2007.

⁶ Government Accountability Office (GAO). GAO-07-239R Medicaid Federal Upper Limits. December 22, 2006

⁷ 42 CFR § 447 p77192-3. 22 December 2006

**Section 447.504 (g) – Determination of Average Manufacturer Price
Sales, rebates, discounts, or other price concessions included in AMP**

The proposed regulation defines the Federal Upper Limit (FUL) reimbursement rate at 250% of the lowest AMP for a dosage form and strength of a drug. APhA is concerned with the following elements that are included in the calculation of AMP:⁸

- Sales to wholesalers and manufacturers acting as wholesalers, discounts, rebates or other price concessions to Pharmacy Benefit Manager (PBM), sales to mail-service pharmacies, sales to clinic pharmacies and hospital outpatient pharmacies, manufacturer coupons redeemed by any entity other than the consumer.

Unfortunately, these elements do not reflect actual acquisition costs for most community pharmacies. The proposal to include price concessions and rebates available to PBMs, sales to mail-service pharmacies, manufacturer coupons, and sales to clinic and hospital pharmacies does not reflect retail pharmacy costs. Retail pharmacy does not have access to these price concessions, sales or rebates and consequently, APhA is concerned that AMP may be set at a rate lower than what community pharmacy can purchase generic medication products.

Within the preamble discussion of this section, the Agency debates what elements to include in the calculation of AMP and discusses the challenges with developing the proposed regulations. While APhA appreciates the Agency's discussion, we disagree with the conclusion and believe there is insufficient evidence provided for including the listed elements. The discussion noted that by not including the full list of elements for calculating AMP, there may be a risk of an inflated calculation of AMP. Nonetheless, APhA opposes including these elements due to the lack of transparency and consistency from manufacturers in reporting AMP and the lack of understanding of what the calculations will be. This lack of evidence creates an even greater unfair burden on pharmacy to manage decreased reimbursement rates. The decision of what elements to include in the calculation of AMP should ensure appropriate reimbursement to pharmacies and should be based on what rates are accessible to the retail pharmacy class of trade. APhA recommends that the following list be removed from the inclusion list and be added to the exclusion list for the calculation of AMP:

- Sales to wholesalers and manufacturers acting as wholesalers, discounts, rebates or other price concessions to Pharmacy Benefit Manager (PBM), sales to mail-service pharmacies, sales to clinic pharmacies and hospital outpatient pharmacies, manufacturer coupons redeemed by any entity other than the consumer.

We acknowledge the challenges of making the revisions to Medicaid work when AMP was never intended to be used as a benchmark for calculating Medicaid reimbursements. We also realize that Congress established specific requirements for some of these provisions. However, the Agency was given discretion to define AMP and retail pharmacy class of trade, and we urge you to use that discretion carefully. Your decisions on these matters are crucial to the nation's pharmacies, making it absolutely essential that such a shift in reimbursement calculations be determined correctly.

In addition, APhA asks the Agency to consider providing safety-net pharmacies, such as those which participate in the 340B Drug Pricing Program, an exception to use 11-digit National Drug Codes (NDC) numbers for AMP-based reimbursement calculations. While the rule calls for calculations using 9-digit NDC numbers, the 11-digit NCD numbers more accurately reflect actual acquisition costs for 340B

⁸ 42 CFR § 447.504(g)

programs as they capture package size. This exception would apply only to 340B programs as such a change could have significant and unintended consequences for other pharmacies.

Generic Utilization

Additionally, APhA is concerned that the proposed regulations significantly decrease any existing economic incentive for generic utilization for Medicaid patients. The proposed rule does not align with previous efforts and policy to utilize generic medications. The use of AMP to calculate product reimbursement may result in significantly lower reimbursement for dispensing generic medications than brand medications. With this proposal CMS has unfortunately created what may be a disincentive for pharmacy to dispense generic medications. APhA strongly encourages CMS to consider including an incentive for dispensing generic medications by calculating a higher dispensing fee for these drug products. Increasing the dispensing fee for generic medications would create an incentive for pharmacists to dispense these less costly medications that provide savings to the Medicaid program. The increased fee could apply to the dispensing of new and refill prescriptions. Unfortunately, the proposed regulation provides a negative incentive to dispense generic medications to Medicaid beneficiaries. At a minimum, APhA recommends that due to the possible impact on generic utilization, CMS monitor generic utilization rates to determine if there is a decrease in dispensing rates based on the impact of implementing the proposed regulations.

Section 447.506 - Authorized Generic Drugs

The proposed rule states that CMS will interpret the language of section 6003 of the DRA to include in the best price and AMP calculations of the branded drugs the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand manufacturer. APhA realizes that Congress required this change, nonetheless we are concerned that the proposed regulation would result in new AMP-based calculations that will apply to more medications, thus compounding the problem of decreased reimbursement to pharmacy for authorized generic medications. This broadened definition of authorized generic medications could create a disincentive for generic utilization, thus increasing costs to the Medicaid program. Again, APhA recommends that due to the possible impact on generic utilization, CMS monitor generic utilization rates based on the impact of implementing the proposed regulations.

Section 447.508 - Exclusion from Best Price of Certain Sales at a Nominal Price

The DRA permits nominal price sales (less than 10% of AMP) for certain listed types of facilities. The DRA also gave the Secretary the authority to designate other types of entities for the exemption. It appears that in this proposed rule, the Agency chose not to exercise that authority. That decision is problematic for two reasons. First, the Agency's decision has created some concern that the Agency does not intend to implement the provision authorizing discretionary exemptions. APhA suggests that the Agency add stronger language in the preamble, or in the text of the Final Rule to clarify that CMS does intend to retain such authority, even if it chooses not to exercise it at this time.

Second, APhA encourages the Agency to exercise that authority and specifically permit nominal price sales to Children's Hospitals without risk of setting a new Best Price. In Section 6004 of the DRA, Congress added Children's Hospitals to the list of entities eligible to participate in the 340B Drug Pricing program. Unfortunately, the DRA amended the Social Security Act, not the Public Health Service Act, which implements 340B. HRSA is working on guidance that would permit Children's Hospitals to participate in 340B, and to require the hospitals to meet all of the requirements of the program. However, in the meantime, Children's Hospitals are not yet permitted to participate in 340B,

and most are no longer receiving nominal price sales on many of their outpatient medications. Consequently, the costs of their medications have risen dramatically. APhA asks the Agency to reconsider its position and use its statutory authority to permit nominal price sales to Children's Hospitals with exemption for Best Price. This action would also alleviate concerns about whether the Agency intends to implement and use the statutory authority, and would help achieve Congressional intent, of providing discounted outpatient drugs to Children's Hospitals under the 340B Drug Pricing Program.

Section 447.510 - Requirements for Manufacturers

APhA is concerned about how safety-net pharmacies, such as those which participate in the 340B Drug Pricing Program, may be effected by the proposed regulation. HRSA uses AMP in the formula to establish the ceiling price for covered outpatient drugs under 340B. The proposed regulatory clarifications of AMP (such as including PBM rebates and price concessions, mail-service prices, administrative and service fees) may lead to changes in how some manufacturers calculate their ceiling prices. In general, it is better for the safety-net community if AMP remains low, because it maximizes the benefit of participation in the 340B program. However, the benefits to the uninsured and other vulnerable patients would be severely minimized if the Medicaid reimbursement cuts had the effect of reducing access to pharmacists.

Another matter for consideration concerns the definition of AMP for the Public Health Service Act (PHSA.) Although the DRA amended the statutory definition of AMP for purposes of Medicaid by removing the deduction for prompt pay discounts, Section 340B(c) of the PHSA states, "Any reference in this section 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 the enactment of the section." Accordingly, HRSA and specifically, the Office of Pharmacy Affairs (OPA) must continue to have access to the data on AMP calculations prior to enactment of the DRA in order to continue calculating the 340B ceiling price according to their statute. APhA urges CMS to work with HRSA to ensure that OPA still has access to the crucial data that is required by statute to calculate the 340B ceiling price.

Section 447.520 - Conditions Relating to Physician-Administered Drugs

The proposed rule also implements a provision of the DRA that requires States to collect rebates on physician-administered drugs (both single source and multiple source drugs) using the NDC numbers or an alternative specified by the Secretary. In the proposal, the Secretary did not specify an alternative coding system, due to the prevalence of the NDC numbers and that they provide the data states need to collect rebates. However, there are significant problems for many hospitals and other healthcare facilities that provide physician-administered drugs. This is the first time states have sought rebates on such medications, and there are technological and other policy concerns.

The technological concerns arise because many states do not currently have Medicaid processing systems that allow for billing National Drug Codes (NDC) for physician-administered drugs, and will need to conduct significant upgrades to their systems and new billing instructions for their providers. Currently, many hospitals bill for their outpatient medications using J-Codes, established by the Healthcare Common Procedure Coding System (HCPCS). Hospitals typically only use NDC numbers for medication ordering and inventory processes. Additionally, there is limited capacity to match J-Codes to NDC numbers for brand products, and none for generics.

Physician-administered drug claims typically use the physician's Medicaid provider number, not the clinic or hospital's Medicaid provider number, which appears in the 340B Medicaid exclusion file. The policy implication for collecting rebates on physician-administered drugs is that it severely diminishes the benefit of the 340B Drug Pricing Program for eligible covered entities. Currently, disproportionate share hospitals (DSH), federally-qualified health centers (FQHC) and other 340B covered entities do not pay rebates on physician-administered drugs. Instead, they are able to purchase these (often high priced) drug products with the 340B discount, which garners considerable savings for the entity. The purpose of 340B was to generate savings for the eligible covered entities, which they can choose to reinvest to the benefit of the entity *and the vulnerable patients that these facilities serve*. The savings generated by participation in 340B can permit a health center to provide free (or greatly reduced) medications and other services to their patients, many of whom are not able to pay. Participation in 340B is a prudent measure for the federally-funded entities that provide care to the underserved, to stretch the Federal dollars. However, if covered entities are now forced to give up the opportunity to purchase these medications under 340B, the impact on the facilities and their patients could be dire. The 340B program protects manufacturers from paying a duplicate discount on the same product (i.e. 340B discount for the entity AND rebates to state Medicaid Agencies.) It would be a perverse result if a statute designed to "reform" Medicaid ended up hurting the neediest patients and the few providers where they receive their care. We urge the Agency to delay implementation of this provision to design an alternative system that will resolve these issues.

Increasing return on investment through medication therapy management (MTM)

Unfortunately, the proposed regulations focus on the medication product and the cost to provide the product, not improving medication use. Simply providing the medication product to a patient may not always be enough to help a patient manage their medication. Patient self-management of medication has proven to be a weak link in the health care system. Pharmacist-provided medication therapy management services can help patients use their medications correctly. Modifications to the Medicaid payment system should consider the role of pharmacists in ensuring appropriate medication use. Studies have shown that for every dollar spent on medications, another dollar of spending results from "drug misadventures."⁹ And others have calculated that drug-related morbidity and mortality in ambulatory patients alone costs an estimated \$177 billion annually.¹⁰ But, nearly 60% of such adverse medication-related outcomes could be eliminated by providing pharmacist care through MTM services.¹¹

As the Agency continues to review potential areas for long-term savings in the Medicaid program, APhA urges the Agency to consider the role of the pharmacists in ensuring appropriate medication use through pharmacist-provided medication therapy management (MTM) services. MTM services for Medicaid beneficiaries would offer a way to improve patient care and reduce health care expenditures in the overall Medicaid program.

MTM programs compensate pharmacists for providing a range of clinical services to patients, including thoroughly educating a patient about their medication and the condition for which it is prescribed, reviewing a patient's medication regimen and developing a medication action plan to address identified

⁹ Brooks JM, McDonough RP, Doucette W. Pharmacist reimbursement for pharmaceutical care services: Why insurers may flinch. *Drug Benefit Trends*; June 2000; 45-62

¹⁰ Ernst FR, Grizzle, AJ. Drug-Related Morbidity and Mortality; Updating the Cost-of-Illness Model. *Journal of the American Pharmaceutical Association*; 2001 Mar-APR; 41(2);192-199.

¹¹ Johnson JA, Bootman JL. Drug related morbidity and mortality and the economic impact of pharmaceutical care. *American Journal of Health System Pharmacy*; 1997; 54:554-558.

issues, monitoring the patient's drug therapy over time, screening for potential adverse effects of medication, and monitoring a patient's ability to take their medications correctly.¹² By providing an incentive for pharmacists to spend additional time with patients, Medicaid programs could optimize therapeutic outcomes, improve medication use, reduce the risks of adverse events and drug interactions, and increase patient adherence and compliance with medications. Again, APhA emphasizes that future Medicaid payment reform should include compensation for pharmacist-provided MTM services.

In the DRA and the proposed rule to implement it, Congress and the Agency have suggested that savings to the Medicaid program could largely be realized through reduced Medicaid payments to pharmacies for generic medications and that reimbursement based on 250% of AMP should be sufficient to reimburse the pharmacy. However, this assumption was challenged in the recent GAO report that found that the new reimbursement formula may result in an in reimbursement of community pharmacies at 36% below their average acquisition cost for generic medications.¹³ Pharmacy should not be forced to choose between participating in the Medicaid program and receiving fair and adequate reimbursement for costs associated with providing services to Medicaid patients.

Thank you for the opportunity to provide comments on this important issue. APhA supports the Agency's intent to implement a more transparent system for paying for medications but the system also must provide adequate payment to cover pharmacies' costs. With inadequate payment, pharmacies may be forced to limit access to pharmacy services for Medicaid beneficiaries.

APhA recommends that the Agency continue to work with pharmacist and pharmacy organizations to establish an appropriate payment formula. To that end, we offer our assistance as you continue your important work to impellent an appropriate payment system for prescription mediations through the Medicaid program.

We look forward to continuing to work with the Agency. If you have any questions or require any additional information, please contact Marcie Bough, Director of Federal Regulatory Affairs at (202)429-7538 or at MBough@APhAnet.org.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Catherine M. Polley, RPh, Senior Vice President, Government and Professional Affairs, Chief Policy Officer
Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs.

¹² Bluml B. Definition of medication therapy management; development of profession-wide consensus. *Journal of the American Pharmacists Association*. 2005;45:566-72.

¹³ Government Accountability Office (GAO). GAO-07-239R Medicaid Federal Upper Limits. December 22, 2006

Submitter : Mr. James Martin

Date: 02/20/2007

Organization : SCPHA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

CMS must realize that one AMP cannot apply for independent, hospital, chain, and mail order pharmacies. An independent pharmacy cannot get the price offered to these other groups so using average prices from these areas are not accurate or fair. One AMP cannot fit all because all do not have the same price offered to them. An AMP for independents would have to be determined by the cost that are being offered to independent pharmacies. Right or wrong mail order, hospital, and chains are often given better prices than the independents can get no matter what quantity the independent pharmacy buys. So why would you use cost by these other groups when independent pharmacies do not have access to the pricing of other groups? The federal government has not been very kind to independent pharmacies. It was the independent pharmacies that made medicare part D work by loaning medicine, taking out loans to make ends meet, etc. Don't you think it is time to be fair with us? If not, we want be around very long to beat up on. Thanks-James Martin

Submitter : Ms. Lorrie Kaplan

Date: 02/20/2007

Organization : National Home Infusion Association

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

The National Home Infusion Association (NHIA) submits these comments on the proposed rule amending payment policies for prescription drugs under the Medicaid program, as issued in the Federal Register on December 20, 2006.

NHIA is a national association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with acute or chronic conditions. Currently, NHIA has 2,000 members.

Infusion drugs and therapies provided in the home have proven to be a cost-effective alternative to providing these intensive therapies in inpatient hospital settings. Infusion technology in the home setting is most frequently used to administer infusion drugs, parenteral nutrition and enteral nutrition.

In particular, we address in our comments two issues raised by the proposed regulation:

- (1) the revised methodology for determining average manufacturer price and its applicability to infusion drugs; and
- (2) the new dispensing fee definition and its appropriateness for infusion drugs.

In our comments below, we point out that home infusion pharmacies do not clearly fit the definition of retail pharmacies for the purposes of this regulation. We note moreover that the functions and services required of infusion pharmacies in support of infusion patients far exceed retail pharmacy dispensing. We are particularly concerned about the application of AMP combined with the lack of differentiation between retail and infusion pharmacy dispensing fees. Therefore, to ensure continued Medicaid patient access to infusion therapies, we urge CMS to develop a separate dispensing fee recommendation for the States for the provision of infusion therapy.

GENERAL

GENERAL

See Attachment

CMS-2238-P-1400-Attach-1.PDF



February 20, 2007

VIA EMAIL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: Comments on Proposed Rule—Medicaid Program; Prescription
Drugs, CMS-2238-P**

Dear Ms. Norwalk:

The National Home Infusion Association (NHIA) submits these comments on the proposed rule amending payment policies for prescription drugs under the Medicaid program, as issued in the Federal Register on December 20, 2006.¹

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- (1) the revised methodology for determining average manufacturer price and its applicability to infusion drugs; and
- (2) the new dispensing fee definition and its appropriateness for infusion drugs.

¹ 71 Federal Register 77174 (Dec. 22, 2006).
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• Fax: 703-683-1484 • www.nhianet.org

In our comments below, we point out that home infusion pharmacies do not clearly fit the definition of retail pharmacies for the purposes of this regulation. We note moreover that the functions and services required of infusion pharmacies in support of infusion patients far exceed retail pharmacy dispensing. We are particularly concerned about the application of AMP combined with the lack of differentiation between retail and infusion pharmacy dispensing fees. Therefore, to ensure continued Medicaid patient access to infusion therapies, we urge CMS to develop a separate dispensing fee recommendation for the States for the provision of infusion therapy.

I. Comments on Determination of Average Manufacturer Price—Section 447.504

The proposed revisions for determining the average manufacturer price (AMP) create significant ambiguities as to their applicability to infusion drugs. The AMP determinations are based on sales to the "retail pharmacy class of trade". Both in the marketplace and in other federal and state policies, infusion pharmacies are not considered to be retail pharmacies and thus do not appear to satisfy the proposed definition of that term. This creates a dilemma for NHIA's members, as it is not clear whether and how AMP could function accurately as a payment mechanism for the infusion drugs that infusion pharmacies provide.

Under existing law, rebates paid by manufacturers of outpatient drugs to State Medicaid programs are calculated based on the difference between AMP and best price.² The Deficit Reduction Act of 2005 (DRA) also applied AMP to the determination of upper limits for outpatient drug payments, previously calculated based on published prices.³ In addition, the DRA revised the definition of AMP.⁴

Prior to the DRA, the AMP for a covered outpatient drug was "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts."⁵ The DRA amended this definition by eliminating the deduction of prompt pay discounts; AMP is now determined "without regard to customary prompt pay discounts extended to wholesalers."⁶

The proposed rule implements these DRA amendments. It defines for the first time "retail pharmacy class of trade," an important definition since manufacturers' sales to this class of pharmacies are used to establish AMP. Under the proposed new definition, this class would include "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."⁷ The Centers for Medicare & Medicaid Services (CMS) intends that this definition exclude nursing home pharmacies or other pharmacies that "do not dispense to the general public."⁸

² 42 U.S.C. § 1396r-8(c).

³ Pub. L. No. 109-171 (Feb. 8, 2006), § 6001(a).

⁴ *Id.* at § 6001(c).

⁵ 42 U.S.C. § 1396r-8(k)(1).

⁶ DRA, Pub. L. No. 109-171, § 6001(c) (amending 42 U.S.C. § 1396r-8(k)(1)).

⁷ 71 Fed. Reg. at 77196 (proposed 42 C.F.R. § 447.504(e)) (*italics added*).

⁸ 71 Fed. Reg. at 77178.

Home infusion therapy pharmacies do not “sell or provide drugs to the general public,” and therefore are not within the proposed definition of retail pharmacy class of trade.⁹ Unlike retail pharmacies, infusion pharmacies treat only a specialized class of patients who rely on these pharmacies for services that support their therapy regimen as a substitute for hospitalization. Patients who require retail drugs cannot obtain them from infusion pharmacies. In addition to infusion drugs, infusion pharmacies provide extensive professional pharmacy services, care coordination, infusion nursing services and supplies and equipment. Infusion pharmacies are responsible for the care of their patients 24 hours a day. They must maintain facilities and equipment for preparing and storing sterile parenteral drug solutions. These features distinguish their patients and their services from those of retail pharmacies, which are not able or expected to provide such comprehensive services.

In other contexts, infusion pharmacies clearly have been excluded from the retail pharmacy class of trade. For instance, CMS excluded infusion pharmacies from this classification for purposes of Health Insurance and Portability and Accountability Act (HIPAA) standards when it established the National Council for Prescription Drugs Program (NCPDP) claim format for retail pharmacy claims. Infusion pharmacies also are distinguished from retail pharmacies under the Healthcare Common Procedure Coding System (HCPCS). HCPCS provides approximately 80 “S” codes for home infusion therapy services that may not be used by retail pharmacies for their drug claims.

Further, the National Uniform Claims Committee (NUCC) has defined “taxonomy code” definitions that are included by CMS in its HIPAA National Provider Identifier data set. The NUCC develops standardized data sets for health care claims and “is chaired by the American Medical Association (AMA), with the Centers for Medicare and Medicaid Services (CMS) as a critical partner” and “includes representation from key provider and payer organizations as well as standards setting organizations, state and federal regulators and the National Uniform Billing Committee (NUBC).”¹⁰ This coalition of industry and government representatives has recognized that the home infusion therapy pharmacy and community/retail pharmacy are distinct, and describes the differences as follows:

Home Infusion Therapy Pharmacy

Pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance.

⁹ NHIA does not believe that infusion pharmacies clearly satisfy the existing standard for retail pharmacy class of trade as that term appears in the statute. See 42 U.S.C. § 1396r-8(k). Until now, however, that term has not been extensively described, and we agree with CMS that manufacturers have determined AMP inconsistently.

¹⁰ Quoted material from the National Uniform Claim Committee (www.nucc.org).

Community/Retail Pharmacy

A pharmacy where pharmacists store, prepare, and dispense medicinal preparations and/or prescriptions for a local patient population in accordance with federal and state law; counsel patients and caregivers (sometimes independent of the dispensing process); administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes.

The apparent exclusion of infusion pharmacies from AMP determinations raises significant questions. In particular, excluding infusion pharmacies would have more significant implications than the exclusion of nursing home pharmacies or other pharmacies that do not dispense to the general public. The exclusion of nursing home pharmacies merely eliminates certain transactions involving drugs that may have been purchased at lower cost than the price typically paid by retail pharmacies. Their exclusion, however, still leaves many transactions of therapeutically equivalent drugs to be considered in determining the AMP for each drug class.

In contrast, infusion pharmacies are typically the only providers of traditional infusion drugs. Independent or chain retail pharmacies rarely dispense traditional infusion drugs. Since infusion pharmacies are not within the retail pharmacy class of trade, there may not be a sufficient sample of sales of therapeutically equivalent drugs to determine the AMP for each class. As a result, it is not clear how an appropriate upper payment limit could be determined for these traditional infusion drugs. Without clarification, manufacturers may adopt inconsistent practices in reporting sales of infusion drugs.

Our basic concern on these issues involves the impact of these proposed policies on State Medicaid payment rates for infusion drugs and related services. This issue involves not only the application of the AMP and FUL provisions, but the proposed definition of dispensing fee as well, which we discuss in the next section of these comments.

We note that in the discussion about the dispensing fee definition in the preamble to the proposed regulation, CMS cites the recently issued Government Accountability Office (GAO) report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005."¹¹ In that report, the GAO found that many AMPs will be lower than the average acquisition costs of many retail pharmacies. Clearly, CMS shares our concern that the real world consequences of AMP determinations, FUL determinations and classes of trade determinations may be inadequate reimbursement levels that prevent pharmacies of all types from being able to provide drugs and services to Medicaid recipients. Ultimately, this is the most important issue for infusion pharmacies and the Medicaid recipients they treat. The payment levels that result from the policies and guidance contained in the proposed rule must be sufficient to enable infusion pharmacies to provide infusion drugs and services to Medicaid recipients. Nothing in the proposed rule should be interpreted to preclude that.

¹¹ GAO Report A-06-06-00063 (May 30, 2006) (<http://oig.hhs.gov/oas/reports/region6/60600063.pdf>).

II. Comments on Definition of Dispensing Fee—Section 447.502

CMS proposes a definition of “dispensing fee” to “assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers.”¹² The dispensing fee description set out in the proposed rule is similar to the dispensing fee definition in the regulation implementing the Medicare Part D outpatient prescription drug program.¹³

We understand why CMS has chosen this particular definition, since it probably would be adequate for most retail pharmacies.¹⁴ It is far from adequate or accurate, however, for infusion therapy pharmacies. We believe strongly that CMS should adopt a separate definition for dispensing fee for infusion pharmacies to account for the significant differences between the functions of an infusion pharmacy and a retail pharmacy.

Since CMS is using the Part D definition of dispensing fee as a guide for this regulation, it is worth noting that the proposed Part D rule set out several options for defining dispensing fee. One of those options was limited largely to home infusion therapy pharmacies, and would have included the retail dispensing fee functions *plus* “activities associated with ensuring proper ongoing administration of the drugs, such as . . . ongoing monitoring by a clinical pharmacist.” Although CMS stated that this option was a reasonable approach in light of the particular functions of an infusion pharmacy, CMS ultimately decided in the final Part D regulation to limit the dispensing fee to reflect only the retail-like dispensing functions – not because CMS determined that this option did not accurately reflect the activities of an infusion pharmacy, but because CMS decided that Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003¹⁵ did not give CMS the authority to capture those functions in its dispensing fee.

That limitation does not apply here as far as a dispensing fee definition for State Medicaid programs is concerned. We believe CMS’ objective is to provide the States with an accurate framework for the determination of a dispensing fee that captures the costs associated with the provision of prescription drugs. The dispensing fee definition contained in this proposed rule does not do so for infusion pharmacies, and thus we urge CMS to supplement the proposed definition for infusion pharmacies with the functions and activities described below.

Payers, clinicians and clinical societies, providers and accrediting organizations share a common understanding of what is involved in providing infusion therapies in outpatient settings. The basic functions of an infusion pharmacy include the dispensing functions already listed in the proposed rule, *plus* clinical monitoring, care coordination, quality assessment and improvement programs, and an array of other support tasks. These functions, taken as a whole, are widely accepted by private payers and managed care organizations, including Medicare Advantage plans, for the proper provision of infusion therapy to patients in their homes.

¹² 71 Fed. Reg. at 77176.

¹³ See 42 C.F.R. § 423.100.

¹⁴ 71 Fed. Reg. at 77196 (proposed 42 C.F.R. § 447.502).

¹⁵ Pub. L. No. 108-173.

NHIA has described these functions in greater detail in its National Definition of Per Diem Services, which reflects the standard of care provided by infusion pharmacies, as follows:

1. **Professional Pharmacy Services**

a. **Dispensing**

- Medication profile set-up and drug utilization review
- Monitoring for potential drug interactions
- Sterile procedures including intravenous admixtures, clean room upkeep, vertical and horizontal laminar flow hood certification, and all other biomedical procedures necessary for a safe environment
- USP-797 compliant sterile compounding of medications
- Patient counseling as required under OBRA 1990

b. **Clinical Monitoring**

- Development and implementation of pharmaceutical care plans
- Pharmacokinetic dosing
- Review and interpretation of patient test results
- Recommending dosage or medication changes based on clinical findings
- Initial and ongoing pharmacy patient assessment and clinical monitoring
- Measurement of field nursing competency with subsequent education and training
- Other professional and cognitive services as needed to clinically manage the patient pharmacy care

c. **Care Coordination**

- Patient admittance services, including communication with other medical professionals, patient assessment, and opening of the medical record
- Patient/caregiver educational activities, including providing training and patient education materials
- Clinical coordination of infusion services care with physicians, nurses, patients, patient's family, other providers, caregivers and case managers
- Clinical coordination of non-infusion related services
- Patient discharge services, including communication with other medical professionals and closing of the medical record
- 24 hours/day, 7 days/week availability for questions and/or problems of a dedicated infusion team consisting of pharmacist(s), nurse(s) and all other medical professionals responsible for clinical response, problem solving, trouble shooting, question answering, and other professional duties from pharmacy staff that do not require a patient visit
- Development and monitoring of nursing care plans
- Coordination, education, training and management of field nursing staff (or sub-contracted agencies)
- Delivery of medication, supplies and equipment to patient's home

- d. **Supplies and Equipment**
 - DME (pumps, poles and accessories) for drug and nutrition administration
 - Equipment maintenance and repair (excluding patient owned equipment)
 - Short peripheral vascular access devices
 - Needles, gauze, non-implanted sterile tubing, catheters, dressing kits and other necessary supplies for the safe and effective administration of infusion, specialty drug and nutrition therapies
- e. **Multiple Categories of Pharmacy Professional Services**
 - Maintaining comprehensive knowledge of vascular access systems
 - Continuing education to professional pharmacy staff
 - Removal, storage and disposal of infectious waste
 - Maintaining accreditation, including:
 - Outcomes assessments and analysis
 - Ongoing staff development and competency assessment
 - Continuous quality assessment and performance improvement programs
 - All other policies and procedures necessary to remain in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Community Health Accreditation Program (CHAP), Accreditation Commission for HealthCare (ACHC), and other professional accreditation standards
 - Certification fees and expenses
 - Other applicable accreditation expenses
 - Maintaining the substantial insurance requirements (e.g. liability), including compliance with all state and federal regulations related to minimal insurance coverage

2. **Administrative Services**

- Administering coordination of benefits with other insurers
- Determining insurance coverage, including coverage for compliance with all state and federal regulations
- Verification of insurance eligibility and extent of coverage
- Obtaining certificate of medical necessity and other medical necessity documentation
- Obtaining prior authorizations
- Performing billing functions
- Performing account collection activities
- Internal and external auditing and other regulatory compliance activities
- Retrieval and storage of medical and reimbursement records
- Maintaining inventories of drugs, equipment, administration supplies and office supplies
- Maintaining physical plant and offices, including building, equipment and furnishings, utilities, telephone, pagers, office supplies, etc.
- Maintaining computer clinical and administrative information systems
- Postage and shipping

- Design and production of patient education materials
 - Quality assessment and improvement activities
 - Continuing education to administrative staff
 - Legal and accounting services
 - Licensing application activities and fees
3. **Other Support Costs**
- Wages, salaries, benefits, payroll taxes, FICA, unemployment insurance, and workers compensation premiums
 - Property taxes
 - Asset depreciation
 - Inventory carrying costs
 - Accounts receivable carrying costs associated with carrying of large accounts receivable balances
 - Costs of insurance coverage per state regulations
 - Costs of maintaining accreditation (JCAHO, CHAP, ACHC, etc.)
 - New product research and development
 - Sales, advertising, and marketing
 - Community commitment and charitable donations
 - Cost of bad debt (uncollectible accounts receivable)
 - Other applicable overhead and operational expenses

The proposed dispensing fee definition falls far short of capturing the service-intensive nature of infusion therapy that is reflected in these standards. In addition, we refer CMS to the national standard for sterile preparation compounding published by the U.S. Pharmacopeia, which became legally enforceable on January 1, 2004. Again, the dispensing fee definition in the proposed rule falls far short of the functions described in that national standard. For these reasons, we urge CMS to develop a separate dispensing fee recommendation for the States for the provision of infusion therapy that reflects the services and other functions already captured in the approximately 80 per diem "S" HCPCS codes.

* * * *

NHIA welcomes the opportunity for further communication regarding these issues and would be pleased to provide any additional information you might need. Please feel free to contact me at 703-838-2658 if you have any questions or requests.

Sincerely,



Lorrie Kline Kaplan
Executive Director
National Home Infusion Association

::ODMA\PCDOCS\WSH\414203\2

Submitter : Mr. Leon Nuvayestewa, Sr.

Date: 02/20/2007

Organization : Hopi Tribe, Office of Elderly Services

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

CMS Rulemaking on proposed rule Medicaid Program; Prescription Drugs 42 CFR Part 447 [CMS-2238-P] RIN 0938-A020

Collection of Information

Requirements

Collection of Information Requirements

Regulations to implement provisions in the Deficit Reduction Act of 2005 per prescription drugs providing State Medicaid agencies certain authority for reimbursement levels and dispensing fees paid to pharmacists.

GENERAL

GENERAL

See attachment

Provisions of the Proposed

Regulations

Provisions of the Proposed Regulations

None required

Regulatory Impact Analysis

Regulatory Impact Analysis

Hopi Tribe supports comments and recommendations of the National Indian Health Board and Tribal Technical Advisory Group to the Centers for Medicare and Medicaid Services.

Response to Comments

Response to Comments

Possible impacts to tribal and Indian Health Services health center may be negative to tribal Medicaid beneficiaries. Financial viability to remote and isolated tribal health facility operations will be greatly impact if State Medicaid agencies does not consult with tribes on implementation of new regulations.

CMS-2238-P-1401-Attach-1.DOC

February 20, 2007

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

RE: Comments on proposed rule Medicaid Program; Prescription Drugs
 71 Federal Register 77174 (December 22, 2006); File Code: CMS-2238-P

Dear Ms. Norwalk,

We have been informed about the proposed regulations published in the Federal Register on December 22, 2006, at Vol. 71, No. 246, implementing provisions of the Deficit Reduction Act (DRA) pertaining to prescription drugs under the Medicaid program. These proposed regulations will limit, in part, State Medicaid expenditures for certain multiple source drugs. States will retain authority to set their own reimbursements levels and fees paid to pharmacists, including Indian Health Service (IHS) and tribally operated pharmacies. We are very concerned that without State consultation with Arizona Tribes the negative impacts of these changes will be much greater than expected.

Our IHS Hopi Health Care Center located on the Hopi Reservation in Northern Arizona is dependent on reimbursements from the Arizona Health Care Cost Containment System (AHCCCS) the State Medicaid agency to supplement existing IHS appropriations that continue to be under funded. It is therefore highly desirable that AHCCCS consults with our tribe to avoid negative consequences on our health facility operations.

Financial sustainability in remote rural areas such as the Hopi Reservation is a major challenge. We have a large Medicaid beneficiary population that need to be protected from rules that may have unintended negative consequences on services to them.

Therefore we appreciate the November 9, 2006 letter issued to State Medicaid Directors, SMDL #06-023, encouraging States to consult with Indian Tribes when implementing Deficit Reduction Act and amending State Medicaid plans.

We request CMS insert language in the final rule encouraging States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies to protect this safety net for our Medicaid beneficiaries.

Your consideration of our comments and recommendations is appreciated.

Sincerely,

Mr. Todd D. Honyaoma, Sr., Vice Chairman/CEO
The Hopi Tribe

Cc: Robert Sakiestewa, Jr., Chairman, Hopi Health Advisory Council
Marlene Sekaquaptewa, Chair, Arizona Indian Council on Aging
Melvin George, Chairman, Hopi Elderly Organization
Herman G. Honanie, Director, Dept. of Community Health Services
Leon A. Nuvayestewa, Sr., Director, Office of Elderly Services
Bruce Talawyma, Hopi Health Care Center
File

CMS-2238-P-1402

Submitter : Louise Jones

Date: 02/20/2007

Organization : Alabama Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1402-Attach-1.TXT

CMS-2238-P-1402-Attach-2.TXT



ALABAMA PHARMACY ASSOCIATION

Alabama's Professional Society of Pharmacists

March 27, 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 Alabama Pharmacy Association is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

The Alabama Pharmacy Association (APA) continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. While we are supportive of these 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. §447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 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 in §447.510 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 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates 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. Additionally APA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

Comments regarding Section 6001 (c) (1) of the DRA amending 1927 (k) (1) of the Act which revises the definition of AMP as it relates to "Definition of Retail Class of Trade and Determination of AMP" state that: "We believe, based in part on the OIG and GAO reports, that retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. As such, we would exclude the prices of sales to nursing home pharmacies (long term care pharmacies) because nursing home pharmacies do not dispense to the general public. We would include in AMP the prices of sales and discounts to mail order pharmacies."

Proposed Section 447.504(e) comprises an overly inclusive definition of "retail class of trade." The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition.

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: "*Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*," the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

APA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. APA 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).

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 rely greatly on the ability of the pharmacy to play a significant roll in determining which medications are dispensed. These same types of discounts are not available to traditional retail pharmacies.

As with the nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail class of trade. As such, we believe 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. Since there would be fewer transactions, fewer records will need to be maintained by manufacturers and reported to CMS, thus reducing the reporting requirements of manufacturers. Since mail order pharmacies are most likely to participate in discounts, rebates and other forms of price concessions, the nature of these complex contractual arrangements are more likely to lead to misstatements and errors in accounting and the need for re-statement of pricing information – particularly between quarters - creating pricing volatility and fluctuations in AMP values. Excluding mail order and PBM pharmacies from AMP calculations thus assists to provide greater certainty and reliability in pricing data. Vertical integration between manufacturers and mail order pharmacies creates transactions that are not arms length and thus afford opportunities for market manipulation. In the future, CMS would likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that “removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29.” Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

It is our belief that 447.504(g)(12) should exclude Medicaid from AMP Data. Unlike Medicare Part D and non-Medicaid SCHIP, which have private party negotiators on formularies and reimbursement rates, Medicaid reimbursement structures vary state-to-state, with some having non-market based reimbursement rates. Moreover the inclusions of Medicaid data more likely than not would create a circular loop negating the validity of AMP. Given the above statements it is clear that counting Medicaid will have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

Discounts, Rebates and Price Concessions

APA 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 APA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors, and, thus, they are not available to the “general public.” Since PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, chargebacks and other price concessions.

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 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, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."¹ Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."² The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§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 'claw-back' 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. The following comments address each of these areas of concern.

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".³ 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.

As the entities engaged in the profession of pharmacy become more vertically integrated the potential for misuse of this dual reporting mechanism increases. Potentially, 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. This undue flexibility, afforded to find a market

¹ Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.

² GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

³ §447.510(d)(2)

price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'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 manufacturers ability too restate AMP would be to 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). It is recommended that CMS clearly define the stakeholders empowered to alert CMS of significant price shifts. Once alerted the IG would research and then recommended an updated AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to-date calculation of AMP. 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 ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. 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's AMP. Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

The proposed regulation states in §447.510(f)(1) that "[a] manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period". This time requirement is unduly burdensome and a substantial departure from the Internal Revenue Services' seven (7)

year standard for audit record keeping. We recommend that CMS adjust the record keeping requirement in the proposed regulation to be consistent with the widely accepted seven (7) year standard.

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-digit level for generic drugs in determining FULs.

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

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

Sincerely,

Louise F. Jones
Executive Director

Submitter : Dr. Timothy Jennings
Organization : Sentara Healthcare
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

2/19/07

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 Sentara Norfolk General Hospital, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the DRA), published in the Federal Register on December 22, 2006. Sentara Norfolk General Hospital is a 650 bed hospital located in Norfolk, Virginia that qualifies as a disproportionate share hospital (DSH) under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. The hospital IT system, that we use at Sentara, (TDS/ medipac), does not have the capability to utilize an NDC number. The workaround for this would be very labor intensive, and would require specialized training to carry out this task. As well the labor pool for this process would require a specific amount of skill set that would end up competing with an already short supply of either pharmacists or technicians.

Second, CMS s proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. Our system would loose an additional \$ 240,000 annually on these medicaid patients&

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. As a result of this change Sentara would be adversely affected by an additional \$100,000 in expense.

Furthermore , the loss of nominal pricing contracts in non-340B participating parts of the Sentara, equate to over a \$500,000 annually. While these savings may not seem that large, with increasing percentages of self pay patients each year coming to our institution, these savings at least help to offset some of the loss in payment that is not received. As well our DSH % has increased since becoming eligible in 2003 (13.9% in 2nd Qtr 2003 to 16.9% 1st qtr 07).

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

Sincerely,

Timothy S. Jennings, Pharm.D.
Director of Pharmacy Services
Sentara Healthcare

Submitter : Mr. Matthew Eyles
Organization : Wyeth Pharmaceuticals
Category : Drug Industry

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

Wyeth Pharmaceuticals appreciates the opportunity to comment on the proposed rule. Our detailed comments are provided in the attached document.

Submitter : Mr. Matthew Eyles
Organization : Wyeth Pharmaceuticals
Category : Drug Industry

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

Wyeth Pharmaceuticals appreciates the opportunity to comment on the proposed rule. Our detailed comments are provided in the attached document.

CMS-2238-P-1405-Attach-1.RTF

Wyeth Pharmaceuticals

500 Arcola Road
Collegeville, PA 19426

Matthew D. Eyles

Assistant Vice President
Public Policy
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Wyeth

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

**Re: Proposed Rule CMS-2238-P (42 CFR Part 447):
Comments Regarding Medicaid Program; Prescription Drugs**

Dear Ms. Norwalk:

Wyeth Pharmaceuticals appreciates this opportunity to submit comments on the proposed rule published in the Federal Register on December 22, 2006, to implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program (Proposed Rule). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research-driven pharmaceutical and health care products companies with leading products in areas of women's health, central nervous system, inflammation, hemophilia, transplantation, oncology and vaccines.

The Proposed Rule covers a broad range of topics relating to the calculation of Average Manufacturer Price (AMP) and Best Price (BP) and imposes a number of new requirements on manufacturers. Once finalized, the Proposed Rule will dramatically change the way in which Medicaid rebates are calculated and claims for multiple source drugs are reimbursed.¹ Wyeth commends CMS for its efforts to standardize the definition of AMP and to clarify and codify existing guidance with respect to BP. We also appreciate CMS' decision to seek public input on several issues addressed in the Proposed Rule. At the same time, we are concerned that certain provisions raise a number of significant interpretive and implementation issues. Wyeth also believes that some provisions in the Proposed Rule affecting pharmacy reimbursement may adversely impact Medicaid

¹ See Deficit Reduction Act of 2005, Pub. Law No. 109-171, §§ 6001-04 (2006).



beneficiary access to clinically appropriate drugs and biologicals. Our comments are arranged in the order of the Proposed Rule, and they address the following sections:

- Retail Pharmacy Class of Trade Definition and Related Issues
- Treatment of Particular Transactions for AMP and Best Price Purposes
- Manufacturer Requirements
- Patient Access to Medicines under the Medicaid Program

I. Retail Pharmacy Class of Trade Definition and Related issues

Wyeth requests that CMS provide additional guidance regarding the treatment of certain entities under the new definition of retail pharmacy class of trade.

Retail Pharmacy Class of Trade Definition

The DRA requires the Secretary “to clarify the requirements for, and the manner in which, AMP is determined” in a formal regulation. The DRA also requires the Secretary to take into consideration the Office of Inspector General’s (OIG) recommendations regarding the requirements for and manner in which AMP is determined.

Section 1927(k)(1) of the Social Security Act defines AMP as “the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts”. The Proposed Rule redefines retail pharmacy class of trade to include not only sales to traditional retail pharmacies but also sales to entities that dispense drugs to the general public.

Specifically, the Proposed Rule redefines pharmacy class of trade as “any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.” The preamble to the Proposed Rule further clarifies that “the retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services.”



Wyeth commends CMS for its efforts to seek accuracy and consistency in the calculation and submission of AMP, but we also request that CMS clarify the status of certain additional entities and organizations in the Final Rule, discussed below.

PBM Rebates, Discounts, and Other Prices Concessions

Wyeth requests that CMS provide additional guidance regarding the inclusion of PBM price concessions in the calculation of AMP.

The Proposed Rule states that “[d]iscounts, rebates, or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade” are included in AMP.² We thank CMS for inviting comment on this particularly complex issue as to whether the inclusion of PBM price concessions in the calculation of AMP is “operationally feasible”.³ In past guidance, CMS has suggested that whether a certain manufacturer payment should be taken into account in the manufacturer’s AMP calculations may depend on whether the payment is passed through by its recipient to another party.⁴ To its credit, CMS recognizes the difficulty in making such a distinction by noting in the preamble to the Proposed Rule that “manufacturers typically do not know what price concession paid to PBMs are passed on to the PBM’s network pharmacies or member plans.”⁵

As CMS recognized in the preamble to the Proposed Rule, Wyeth concurs that it is difficult for manufacturers to obtain sensitive information from downstream entities regarding the use of manufacturer price concessions.⁶ In addition, assuming data sharing of PBM price concessions were administratively feasible, it is likely that the data could be compromised due to potential system incompatibilities and timing issues. Given the inherent difficulties in isolating and reporting PBM price concessions, Wyeth requests that CMS clarify this reporting requirement.

² Proposed 42 C.F.R. pt. 447.504(g)(3)).

³ Id. at 77,179

⁴ Medicaid Rebate Release No. 29 (1997)

⁵ 71 Fed. Reg. at 77,179.

⁶ Id. at 77,179

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Hospital Sales

Wyeth requests that CMS allow manufacturers to exclude both inpatient and outpatient sales from AMP.

The Medicaid rebate agreement and past CMS Policy indicate that sales to hospitals should be excluded from the AMP calculation without regard to whether the product sold was used in the inpatient or outpatient setting.⁷ The Proposed Rule makes a clear distinction between the two settings and provides that the calculation of AMP shall include sales to hospitals “where the drug is used in the outpatient pharmacy,” while continuing to exclude sales to hospitals for inpatient use.⁸

Wyeth does not support the proposed change to hospitals sales in AMP due to the incremental administrative burden and operational complexity imposed upon hospitals and manufacturers. Most manufacturers are unable to distinguish between units purchased by hospitals for inpatient use and units purchased for use in the outpatient setting. Our experience is that most hospitals do not distinguish inpatient from outpatient purchases. In general, because it is a prerequisite for participation in the 340B Drug Discount Program, only those Disproportionate Share (DSH) hospitals or hospitals that otherwise offer outpatient services as “covered entities” differentiate between inpatient and outpatient use. Given these significant administrative and operational challenges, Wyeth requests CMS confirm that manufacturers may continue to exclude all hospital sales and price concessions from AMP.

Managed Care Organizations

Wyeth requests that CMS provide additional guidance regarding the treatment of certain managed care organizations.

The Proposed Rule seeks to exclude sales to health maintenance organizations (HMOs) from the AMP calculation.⁹ However, the Proposed Rule does not address the intended scope with adequate detail.

⁷ 56 Fed. Reg. at 7050 (Medicaid Rebate Agreement at I(a)); Medicaid Drug Rebate Program Release #29 for Participating Drug Manufacturers (1997).

⁸ *Id.* at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(3), (h)(4)).

⁹ 71 Fed. Reg. at 77,179.

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For example, the exclusion contained in the Proposed Rule does not distinguish between HMOs that purchase drugs and distribute them to members through the HMO's own closed-door pharmacies from HMOs that do not purchase drugs or take possession but rather act as third-party payors. Sales to HMOs that do not take possession of products are essentially third-party payors that reimburse retail pharmacies for drugs dispensed to members. Therefore, HMOs should be treated like Medicaid sales to the extent they concern sales at the retail pharmacy class of trade. Wyeth requests clarification as to whether rebates and units associated with HMOs that do not purchase drugs should be specifically excluded from the calculation of AMP.

Specialty Pharmacy

Wyeth requests that CMS confirm including specialty pharmacy customers in the definition of Retail Class of Trade.

Wyeth appreciates CMS' efforts to clarify the term "retail class of trade," as it provides much needed guidance requested by the OIG and the Government Accountability Office (GAO). However, the Proposed Rule does not seem to specifically address the treatment of specialty pharmacies.

Specialty pharmacies provide biopharmaceutical products and may also provide bona fide services to the "general public." However, specialty pharmacies typically provide injectable drugs and biologicals for the treatment of more complex chronic conditions that require specialized delivery and administration on an ongoing basis. Most commonly, they include injectable and infusion therapies and therapies that require complex care. In addition, they often provide patient education, personalized medication management, adherence monitoring and other services that distinguish them from other drug distributors.

Wyeth requests that CMS confirm in the final rule that specialty pharmacy sales and price concessions should be included in AMP and Best Price calculations. Wyeth also requests that CMS confirm in the final rule that, consistent with CMS guidance, payments for specialty pharmacy services that satisfy the definition of bona fide service fee should be excluded from the calculations of AMP and Best Price.



Patient Coupons

Because consumers—not other entities—are the ultimate beneficiaries of manufacturer patient coupons, Wyeth recommends that CMS exclude all patient coupon programs from AMP and Best Price calculations regardless of how such coupons are redeemed.

The Proposed Rule seeks to include manufacturer patient coupons redeemed by all entities other than the consumer and exclude from AMP and Best Price manufacturer patient coupons redeemed by a patient.¹⁰ This distinction presumes that the involvement of third-party entities results in a benefit to non-patient entities. Although we appreciate CMS' concerns regarding these types of patient transactions, Wyeth disagrees with CMS' decision to include in AMP and Best Price coupon programs that are adjudicated by a third party even when that entity does not benefit financially from the transaction. Wyeth believes that patient coupon programs, whether redeemed by patients or third-party entities, provide significant benefits to patients and do not impact prices to third-party entities.

For years, manufacturers have developed and maintained patient coupon programs designed to address the needs of low-income and other patients who may lack third-party coverage for prescription medicines or patients who have significant cost-sharing burdens under their insurance programs. Under these programs, qualifying patients may often receive certain products without charge or at reduced cost sharing levels. Without such programs in place, patients may be forced to forego treatment or receive less than optimal care. Wyeth believes that the Proposed Rule could unintentionally penalize uninsured and underinsured individuals by including such programs in AMP and Best Price calculations, thereby making them less appealing and more costly to administer. Therefore, CMS should exclude these transactions from AMP and Best Price in the final rule.

II. Treatment of Particular Transactions for AMP and Best Price Purposes

Definition of Bundled Sales

Wyeth requests additional guidance through notice of proposed rulemaking (NPRM) procedures on the definition of bundled sales.

¹⁰ Id. at 77,181, 77,183.

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Wyeth agrees that clear and predictable guidelines regarding the definition of “bundled sales” and the methodology for reporting them are needed. We note that the proposed regulation makes a number of significant changes to current guidelines and believes that these changes could have significant unintended consequences. Wyeth believes any such changes would be better suited to the notice-and-comment rulemaking process.

Nominal Sales

Wyeth requests additional guidance through NPRM procedures on the use of nominal prices as a marketing tool.

The DRA mandated that nominal price be defined as less than ten percent of AMP to certain specified entities.¹¹ The DRA also authorized the Secretary to identify additional categories of safety-net providers that could be excluded from Best Price in the event they receive a nominal price.¹² CMS indicated in the preamble to the Proposed Rule that it would not expand upon the existing statutory list of safety net providers because the existing list is sufficiently inclusive.¹³

The preamble also included remarks regarding use of the nominal price exception as a marketing tool. Specifically, CMS observed that “using nominal price for marketing is not within the spirit and letter of the law” and indicated that it is considering issuing additional guidance on this topic.¹⁴

Wyeth disagrees with CMS’ observation that such practices are contrary to the current letter of the law and asks CMS to issue any further guidance on the use of nominal prices as a marketing tool through formal notice-and-comment rulemaking.

Returns

Wyeth supports CMS’ decision to exclude returns made in good faith from AMP.

Wyeth supports CMS’ decision to exclude returns made in good faith from AMP.¹⁵ Wyeth requests clarification that a return processed consistently with the

¹¹ Deficit Reduction Act of 2005, Pub. Law No. 109-717, §6001(d)(2).

¹² Id.

¹³ 71 Fed. Reg. at 77,184-85.

¹⁴ Id. at 77,185.

¹⁵ Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(13)).



manufacturer's return policy is sufficient to meet the CMS requirement for a return made in good faith.

III. Manufacturer Requirements

Estimation Process

Wyeth supports CMS' proposal to allow manufacturers to use an estimation process to allocate lagged price concessions in monthly and quarterly AMP determinations.

Wyeth appreciates CMS' recognition that industry pricing practices include processing rebates or other price concessions on a lagged basis. We concur with CMS' suggestion that some estimating process to allocate lagged price concessions "...to maximize the usefulness of the monthly AMP and minimize volatility in the prices" is appropriate.¹⁶

Wyeth encourages CMS to allow manufacturers to implement a 12-month rolling average estimate of all lagged discounts for both the monthly and quarterly AMP. Wyeth requests that CMS permit any 12-month rolling average estimate, which is consistent with US GAAP standards and a manufacturer's products and business practices. The ability for each manufacturer to determine an appropriate estimation process consistent with CMS guidance (rather than a proscribed process) and their own business practices should minimize some of the incremental operational complexity which may be required to implement a 12-month rolling average estimate of all lagged discounts for both the monthly and quarterly AMP.

Wyeth concurs with CMS's proposal that "...the monthly AMP will be calculated the same as the quarterly AMP, with the following exceptions. The time frame represented by the monthly AMP would be one calendar month instead of a calendar quarter and once reported, would not be subject to revision later than 30 days after each month."¹⁷ Wyeth supports this proposal and asks CMS to include it in the final rule.

¹⁶ 71 Fed. Reg. at 77,186.

¹⁷ 71 Fed. Reg. at 77,185



Workload Estimates

CMS' assessment that the new reporting requirements would not require new data collection is inaccurate.

Although welcomed, clarifications from CMS on the determination of AMP in the Proposed Rule would require manufacturers to systematically collect new or more detailed customer sales, discount and rebate data. In addition, manufacturers would be required to submit two new data elements—customary prompt pay discount dollars and nominal price sales to entities listed in the DRA definition—for each of their drugs on a quarterly basis. Additional reporting and data requirements may require significant investment in changes to standard operating procedures, government pricing systems, and employees dedicated to Medicaid Drug Rebate Program price reporting.

Reporting of Customary Prompt Pay Discounts

CMS should confirm that invoiced customary prompt pay discounts are sufficient for meeting the requirement to report such discounts on a quarterly basis.

Wyeth requests CMS confirm that customary prompt pay discounts (as that term is defined in a manufacturer's standard operating procedures) that are invoiced to AMP eligible customers who purchased product directly from the manufacturer in the rebate period are sufficient to meet the CMS requirement to report customary prompt pay dollars quarterly.

Restatement of Baseline AMP

Wyeth supports CMS' decision to allow manufacturers to recalculate base date AMP. Wyeth requests additional time to report revised base date AMP of up to two quarters.

In order to reflect the changes to AMP set forth in the DRA, CMS has included a provision in the Proposed Rule giving manufacturers the option to recalculate their base date AMPs.¹⁸ Wyeth supports this provision and asks CMS to include it in the final rule. Wyeth also requests additional time beyond the proposed first full calendar quarter following the publication of the final rule to report the

¹⁸ Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(c)).

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restated base date AMP values. We anticipate that the recalculation process may require a potential number of systems and operational changes to complete accurate, one-time, base date AMP restatement calculations. Wyeth suggests reporting with the third full calendar quarter following the publication of the final rule.

Coordination of AMP and Best Price Data with HRSA

Wyeth requests that CMS develop guidelines with the Health Resources Services Administration (HRSA) to coordinate the use of AMP and Best Price data in the setting of quarterly 340B Ceiling Prices.

The Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA) has recently notified manufacturers that the DRA definition of AMP may not be used in setting quarterly 340B Ceiling Prices. Under HRSA's proposal, manufacturers will have to comply with two separate definitions of AMP— one for DRA and CMS' new monthly and quarterly AMP guidance for purposes of Medicaid Drug Rebate Program and another separate and distinct quarterly AMP to calculate quarterly 340B Ceiling Prices. This unusual situation would result in confusion and level of operational complexity that was not intended by any of the parties involved in updating the definition of AMP. We urge CMS and HRSA to work together to identify a solution so that manufacturers do not have to calculate a separate quarterly AMP in order to fulfill obligations in the calculation of 340B Ceiling Prices.

Additional Guidance

Wyeth believes that CMS should rely more upon NPRM procedures in promulgating future rules.

The preamble to the Proposed Rule includes a discussion of future clarifications of AMP. In that discussion, CMS stated it believes that the agency needs "to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace of the sale of drug. We plan to address further clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed."¹⁹

¹⁹ 71 Fed. Reg. at 77,181.

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Wyeth encourages CMS to consider providing continuing guidance on other elements of the rebate program as well, not just the definition of AMP. While we agree it is often necessary to issue timely guidance via the use of program releases and/or question and answer documents, given the liability inherent to manufacturers in the submission of AMP and best price data, Wyeth asks that CMS utilize NPRMs to the extent possible.

IV. Patient Access to Medicaid Prescription Drugs

Wyeth urges CMS to carefully consider the overall impact of AMP being used as a reimbursement metric by states on Medicaid beneficiaries and pharmacies.

As required by the DRA, CMS proposes to set the federal upper limit (FUL) for multiple source drugs at 250% of AMP for the least costly therapeutic equivalent when at least two suppliers list the drug in a nationally available price compendium.²⁰ In addition, the Proposed Rule would allow states to use AMP as their payment methodologies for outpatient drugs not on the FUL list. This change will result in lower FULs for most drugs subject to these limits, thus reducing Medicaid payments to pharmacies for prescription drugs.

Wyeth is concerned that this reduction—coupled with the other DRA reforms and marketplace challenges—could have serious implications for Medicaid and pharmacy patients. Although CMS anticipates that the effects of the changes will be small on most pharmacies, CMS noted in the preamble that “we are unable to estimate quantitatively effects on small pharmacies, particularly those in low-income areas where there are high concentrations of low-income Medicaid beneficiaries.”²¹ Therefore, Wyeth urges CMS to carefully consider the overall impact of AMP being used as a reimbursement metric by states.

Conclusion

Wyeth appreciates the opportunity to comment on the issues outlined in the CMS-2238-P (Medicaid Program; Prescription Drugs Proposed Rule). We look forward to our continued work with CMS to ensure that Medicaid beneficiaries receive appropriate access to vital drug and biological therapies covered under the

²⁰ 71 Fed. Reg. at 77,192

²¹ *Id.* at 77, 193.

Leslie Norwalk, Esq.
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Medicaid program. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,

Matthew D. Eyles

Matthew D. Eyles