

Submitter : Mr. Kenneth Cross
Organization : Phoenix Children's Hospital
Category : Pharmacist
Issue Areas/Comments

Date: 02/20/2007

GENERAL

GENERAL

See Attached

CMS-2238-P-1406-Attach-1.DOC

CMS-2238-P-1406-Attach-2.DOC

CMS-2238-P-1406-Attach-3.DOC

February 19, 2007

Melissa Musotto
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development--A
Centers for Medicare and Medicaid Services, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Musotto:

As President and CEO of Arizona's only children's specialty hospital, I am compelled to provide you my thoughts regarding a proposed data submission requirement that would mandate collection of National Drug Code (NDC) information by State Medicaid agencies with respect to covered outpatient drugs that are "physician administered." The Notice appeared at 71 Federal Register pages 71178 to 71179.

On behalf of Phoenix Children's Hospital, I strongly oppose application of the new data submission requirement to drugs administered by medical professionals to patients in hospital outpatient clinics or departments. The enormous increase in administrative tasks will shift models of care away from being patient-centric. For an industry that faces continual fiscal challenges, incurring expenses for administrative processes and not for the improved health and well-being of our patients is action we cannot support.

The purpose of the proposed data submission is to enable State Medicaid agencies to collect rebates on drugs that are "physician administered" within the meaning of Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA. Although Arizona is not a Medicaid state, our understanding has been that drugs administered in outpatient settings in hospitals, use a formulary system for outpatient drugs and bills Medicaid as prescribed under the applicable Medicaid state plan, are exempt from the rebate requirements of Section 1927 of the Act. Accordingly, the very burdensome task of submitting NDC numbers on hospital-administered outpatient drugs would not serve the purpose of facilitating rebate collection, as drug manufacturers' statutory rebate payment obligations do not extend to these drugs in the first place.

Thank you for your consideration of these views in connection with the recently published Paperwork Reduction Act Notice.

Sincerely,

Robert Meyer
President and CEO

February 19, 2007

Melissa Musotto
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development--A
Centers for Medicare and Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Musotto:

As Operations Manager Outpatient Pharmacy for Phoenix Children's Hospital, and as the past president of the Arizona Pharmacy Alliance I am submitting this letter in response to the Notice published in the Federal Register on December 8, 2006, pursuant to the Paper Work Reduction Act, requesting comment on a proposed data submission requirement that would mandate collection of National Drug Code (NDC) information by State Medicaid agencies with respect to covered outpatient drugs that are "physician administered." The Notice appeared at 71 Federal Register pages 71178 to 71179.

On behalf of Phoenix Children's Hospital, I am strongly opposed to application of the new data submission requirement to drugs administered by medical professionals to patients in hospital outpatient clinics or departments because of the enormous additional administrative and paperwork burdens such a requirement will place upon our staff.

In addition, it is unnecessary to subject hospitals and their outpatient clinics and departments to the paperwork and administrative burdens associated with the proposed NDC data submission requirement. The purpose of the proposed data submission is to enable State Medicaid agencies to collect rebates on drugs that are "physician administered" within the meaning of Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA. Although Arizona is not a Medicaid state, it has been our understanding that drugs administered in outpatient settings in hospitals, which uses a formulary system for outpatient drugs and bills Medicaid as prescribed under the applicable Medicaid state plan, are exempt from the rebate requirements of Section 1927 of the Act. Accordingly, the very burdensome task of submitting NDC numbers on hospital-administered outpatient drugs would not serve the purpose of facilitating rebate collection, as drug manufacturers' statutory rebate payment obligations do not extend to these drugs in the first place.

Thank you for your consideration of these views in connection with the recently published Paperwork Reduction Act Notice.

Sincerely,

Ken Cross, R.P.h.
Operations Manager Outpatient Pharmacy

February 19, 2007

Melissa Musotto
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development--A
Centers for Medicare and Medicaid Services, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Musotto:

As Phoenix Children's Hospital's CFO, and a health care administrator for more than 20 years, I am submitting comment on a proposed data submission requirement that would mandate collection of National Drug Code (NDC) information by State Medicaid agencies with respect to covered outpatient drugs that are "physician administered." The Notice appeared at 71 Federal Register pages 71178 to 71179.

On behalf of Phoenix Children's Hospital, I am registering strong opposed to application of the new data submission requirement to drugs administered by medical professionals to patients in hospital outpatient clinics or departments because of the enormous additional administrative and paperwork burdens such a requirement will place upon our staff. The financial burden of implementation coupled with the impact to employees including technical support and pharmacy personnel creates an environment where patient care must share its resources with bureaucracy.

In addition, it is unnecessary to subject hospitals and their outpatient clinics and departments to the paperwork and administrative burdens associated with the proposed NDC data submission requirement. The purpose of the proposed data submission is to enable State Medicaid agencies to collect rebates on drugs that are "physician administered" within the meaning of Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA. However, our understanding has always been that drugs administered in outpatient settings in hospitals, like ours which uses a formulary system for outpatient drugs and bills Medicaid as prescribed under the applicable Medicaid state plan, are exempt from the rebate requirements of Section 1927 of the Act. Accordingly, the very burdensome task of submitting NDC numbers on hospital-administered outpatient drugs would not serve the purpose of facilitating rebate collection, as drug manufacturers' statutory rebate payment obligations do not extend to these drugs in the first place.

Thank you for your consideration of these views in connection with the recently published Paperwork Reduction Act Notice.

Sincerely,

Larry J. Smith
Chief Financial Officer



Submitter : Mr. David Schwed

Date: 02/20/2007

Organization : Woodruff Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1407-Attach-1.DOC

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, SW
Washington, DC 20201

GENERAL COMMENTS

Re: CMS-2238-P: Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005

Dear Acting Administrator Norwalk

As a pharmacist, a pharmacy owner, a taxpayer and a consumer, I submit the following comments regarding CMS-2238-P, the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program. The move to AMP will result in a significant reduction in Medicaid reimbursement for multiple source generic medications, removing any incentive to participate in Medicaid for marginal providers and threatening the viability of pharmacies in rural and urban settings with significant Medicaid volume, particularly those with practices similar to ours, which serve as safety-net providers.

I am a consultant for PSSC (the 340B program technical assistance contractor), as well as the lead community (retail) pharmacist in New Jersey working with CMS (NY Regional Office) in a consortium of interested parties to facilitate Medicare Part D implementation. I assumed the burden of Part D volunteer activity despite a calculated Part D transition loss (2005 vs. 2006) of approximately \$170,000. This crippling loss was largely offset by increased volume attributable to the demise of the other two independent pharmacies in the county, arguably as a result of Part D implementation; as well as the loss of a staff pharmacist, shifting more of the enormous workload to the remaining two pharmacists in the practice, thus straining our capacity to provide clinical pharmacy services beyond OBRA '90 mandates.

My practice, Woodruff's Drugs a small apothecary style practice established in 1887, located in rural Bridgeton, Cumberland County, New Jersey, provides unique services to a largely poor, Hispanic and African-American patient base. We are the sole access point within the county for:

- Patients of our FQHC as its 340B contact pharmacy;
- Persons with cancer in need of emergency medications in collaboration with the South Jersey Cancer Fund
- Indigent persons in need of emergency medications in collaboration with the Cumberland County Health Department;
- People living with HIV in need of emergency medications in collaboration with the Cumberland County Health Department (Ryan White Title I);
- Patients with HIV/AIDS to interact with pharmacists with specialized training in anti-retroviral therapy and treatment adherence strategies;
- Education and training in medication use for persons qualifying under the Older Americans Act (Title IID) in collaboration with the Cumberland County Office on Aging; and
- Extemporaneous compounded medications tailored to the individual patient in collaboration with the attending physician.

From the perspective discussed above and as a pharmacy owner contemplating whether he will be in business in 2008, please evaluate the following comments.

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

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

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

Although I read Acting Administrator Norwalk's comment letter responding to these finding, I feel the GAO's computation to be comprehensive and authoritative, in fact validating community pharmacy's contention that AMP as defined in the proposed rule is not appropriate as a baseline for reimbursement and must be defined to accurately reflect pharmacy acquisition cost in the open-access segment of the retail market.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

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

Summary of Key Points:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by:
 - Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
 - Excluding all mail order facilities and PBM pricing from AMP as applied to the “retail pharmacy class of trade” 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 and must be subject to their own AMP calculation.

- Small, independent, inner-city and rural pharmacies must be supported through firm action by CMS to maintain beneficiary access to comprehensive pharmacy services.

Respectfully submitted by:

David H. Schwed BPharm FACA FAPhA
President, Woodruff's Drugs
30 N. Laurel St. Bridgeton, NJ 08302
856-451-6755
856-451-8209 fax

BACKGROUND

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement and 2) as an index for manufacturer rebates paid to states. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102).

In testimony before the House Oversight and Government Reform Committee Hearing on Financial Impact of Fraud, Waste, Abuse in Pharmaceutical Pricing, February 9, 2007, according to an observer, many of the witnesses and the Members were very concerned about the effect that the lack of transparency in pricing has on the Medicare Part D program. Their reasoning was that if such fraud and abuse exist in Medicaid and 340B, which are Government-run, the opportunities for fraud and abuse in a private, market-based Medicare Part D are significantly greater. Noting the questionable transparency of existing AMP reporting as it relates to Government-run programs, one might question its use as an accurate tool for Medicaid pharmacy reimbursement.

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

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

Please see the following responses to CMS requests for comment:

Specific CMS requests for comment (in bold, with page reference) are followed by a response.

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

Public Access Defines Retail Pharmacy Class of Trade

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

Mail order presents barriers specific to the Medicaid population including but not limited to; use by beneficiaries with limited literacy or who are illiterate, beneficiaries frequently change residence or lack a permanent place of residence, lag time between prescription order and mail delivery, and vulnerability to theft of prescription drugs delivered by mail. Additionally, the mail order model is more likely to have special “administrative and service fee” arrangements with manufacturers, largely not available to brick and mortar pharmacies, particularly independent pharmacies, which serve rural and urban Medicaid populations. Sales to mail order facilities should not be included in “retail pharmacy class of trade” AMP.

I suggest that AMP be applicable to mail order pharmacies, as a SEPERATE retail class for data gathering, public reporting and application, to effectively control Medicaid program costs for prescriptions obtained through mail order and to provide transparency for fraud and abuse enforcement in Government-run programs.

I recommend “retail pharmacy class of trade” include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

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

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

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

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

AMP Must Differ From Best Price

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

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE... to the Department of Veterans Affairs (VA), and 340B programs. PBMs are claims administrators and therefore never hold title to the product which is dispensed in the community retail pharmacy. PBMs only participate in retail sale by purchasing product if they have a mail order subsidiary. PBM manufacturer rebates affect the cost of goods ONLY through that subsidiary and only if their business model passes such rebates on to the subsidiary pharmacy.

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 a “retail pharmacy class of trade” AMP calculation that 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.

COLLECTION OF INFORMATION

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

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

AMP Must Be Reported Weekly

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

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

AMP Must Be Reported at the 11-Digit NDC to Ensure Accuracy

I agree with the reasoning used by CMS 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.

However, CMS must mandate that all manufacturer package sizes be made available to all segments of the market to minimize “gaming” the AMP system by using unique NDCs to enable cost shifting between individual providers or provider segments of the retail pharmacy class of trade.

REGULATORY IMPACT

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

CMS discusses impact on pharmacy:

- **“Actual revenue losses would be smaller” —pg. 109**
- **On independents: potential “significant impact on small, independent pharmacies.”— pg. 101**
- **On all retail: \$800 million reduction in revenue in 2007; \$2 billion annually by 2011 (“a small fraction of pharmacy revenues”).—pg. 108**
- **We are unable to estimate quantitatively effects on ‘small’ pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries.”—pg. 110**

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees. Though we have to stock a product, pharmaceuticals, to complete the dispensing part of comprehensive pharmacy services, the contention that inadequate payment for the provision of those pharmaceuticals can be off-set by sales of “goods other than prescriptions” should be offensive to every pharmacist ever who graduated from a college of pharmacy and strives to improve patients’ lives through clinical patient interventions. Even looking at the business end of the profession, independent and franchise pharmacies, lease-based supermarket pharmacies, and some specialty chain drug store outlets have apothecary style practices, with little “front-end”, generally limited to over-the-counter drugs, including drugs that require pharmacist intervention for sale under state or federal regulation. My practice revenue is well over 95% prescription-based.

The impact on independent pharmacies may not be adequately mitigated, solely by increased state-set dispensing fees as suggested in the CMS Medicaid Roadmap. Many states believe they are prohibited from exceeding the FUL in the aggregate on prescription reimbursements. CMS must determine that dispensing fees are NOT to be included under the FUL cap and must fully inform each state's Medicaid administrator of this policy.

Additionally, it is unlikely that states would set dispensing fees high enough to cover the per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study without strong guidance from CMS.

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 study found the mean Cost of Dispensing in my state, New Jersey, is \$12.62. 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 accurate drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program.

As the owner pharmacist of a "small, independent pharmacy" meeting the SBA definition, one that by New Jersey Regulation is classed as an "impact pharmacy" having greater than 50% of its volume in Medicaid fee-for-service or associated programs, I can offer a snapshot, using this real world example. I am aware that CMS disagrees with the GAO report, but lacking another comprehensive and authoritative study, the following applies:

- Our GAO (-36%) estimated loss per prescription attributable to drug acquisition cost (DAC) = \$4.43
- Grant Thornton Cost of Dispensing (COD*): NJ mean COD = \$12.62
- New Jersey's present baseline dispensing fee (NJDF) = \$3.73
- Calculation of average estimated loss per prescription:
(L/Rx) with AMP applied = DAC + COD - NJDF = L/Rx
 $\$4.43 + \$12.62 - \$3.73 = \13.32

*Please note that not COD nor, by extension, the computed loss per Medicaid multi-source prescription does not take into account ROI, capital improvement, or lost opportunity costs, much less a fair profit.

Therefore, our small community practice would lose an estimated \$13.32 per Medicaid multi-source prescription dispensed for the fee-for-service program. With a count of 7,000 Medicaid multi-source fee for service prescriptions dispensed (annualized from 7/1/06 to 12/31/06 data to minimized Medicare Part D distortion), that computes to a \$93,248 loss for my pharmacy should I chose to continue to participate in the Medicaid program. This loss could be partially offset if we were to perversely detail our top Medicaid provider Physicians to prescribe much more costly Brand Name, single source pharmaceuticals, where FULs do not apply. The bottom line is that if there isn't a significant adjustment to the dispensing fee by New Jersey DMAHS coinciding with the implementation of AMP related FULs, it will be an immediate challenge to remain in business. Even a short delay to study reimbursement post-implementation could spell disaster to pharmacies already challenged by low to non-existent PDP reimbursement levels under Medicare Part D and low reimbursement for commercial business by PBMs, who have for years unfairly profited from cost-shifting to public programs and cash paying consumers.

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 and CMS must issue much stronger guidance than offered in the CMS Medicaid Roadmap that states MUST adjust dispensing fees to maintain beneficiary access to comprehensive pharmacy services.

Strategies to protect small, independent pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries may include:

- A fair definition of “retail pharmacy class of trade” AMP excluding all sales except to independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies.
- Guidance to the states that the aggregate FUL cap for federal match does NOT apply to dispensing fees.
- Guidance to the states to establish a meaningful “impact adjustment” to dispensing fees for pharmacies with significant Medicaid volume.
- Guidance to the states to establish a meaningful percentage differential to be applied to all FULs for all small pharmacies meeting the SBA definition. (CMS determine it wise to exempt this differential from the aggregate FUL cap by regulation or by considering such payment part of the dispensing fee).
- Grants to the states to develop separate, differentiated payment to pharmacies for clinical services provided to Medicaid beneficiaries beyond OBRA '90 mandates.
- Grants to the states to develop differential payments based on quality measures and implementation of patient safety measures.

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.

Submitter : Mr. Jim Sherrill
Organization : Cowlitz Indian Tribe
Category : Other Health Care Professional

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1408-Attach-1.TXT

TO: Centers for Medicare and Medicaid Services
<http://www.cms.hhs.gov/eRulemaking>
FROM: Jim Sherrill
DATE: February 20, 2007
RE: Comments on proposed rule Medicaid Program; Prescription Drugs
71 Federal Register 77174 (December 22, 2006); File Code: CMS-2238-P

Good afternoon, My name is Jim Sherrill, and I am the Health and Human Services Director of the Cowlitz Indian Tribe. I am providing comments to 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.

It is my understanding that this proposed rule, in part, will limit State Medicaid expenditures for certain multiple source drugs. States will retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists, and may pay above or below the Federal upper payment limit (FUL) as long as overall payments for drugs subject to a FUL are under the annual aggregate cap. About 600 drugs are initially subject to the FULs, including drugs for the treatment of asthma, hypertension, pain relief, and depression. States can vary reimbursement levels and can, for example, target more favorable reimbursement to pharmacists in rural or inner city areas or to independent pharmacists. To implement these regulations, each State must amend their State Medicaid Plan and describe their approach.

The Indian Health Service (IHS) and tribally operated pharmacies have authority to dispense, bill, and receive reimbursement from State Medicaid agencies for drugs prescribed to Medicaid beneficiaries. The State Medicaid agencies reimburse IHS and tribal pharmacies at cost per a payment methodology outlined in the State plan. IHS and tribal programs depend on the Medicaid reimbursements to supplement existing IHS appropriations to the IHS and tribal programs that are currently under funded. Many of these pharmacies are small and operate in remote rural areas. As such, any changes in Medicaid reimbursements can have a negative effect on their financial sustainability. The complexities of Indian health financing make it imperative that States consult with Tribes before and during the development of any amendments to their state plans. Without this consultation, implementation of this rule may have unintended negative consequences on Indian health programs.

On November 9, 2006 Dennis Smith, Director, Centers for Medicaid and State Operations issued a State Medicaid Directors' letter, SMDL #06-023. This letter encourages States to consult with Indian Tribes when implementing Deficit Reduction Act and submitting State Medicaid plan amendments. Specifically the letter states:

"In light of the new Deficit Reduction Act of 2005 (DRA) and our continued desire for Medicaid programs to effectively serve Tribal communities, CMS is taking this

opportunity to again encourage States to consult with Tribes in open, good faith dialogue, as a number of provisions within the DRA have the potential to impact Tribes and American Indian and Alaska Native (AI/AN) Medicaid beneficiaries. Given the States' new flexibility to change their Medicaid programs through State Medicaid plans rather than through Medicaid demonstrations, maintaining ongoing communication between States and Tribes in the redesign of Medicaid programs and services is even more important...CMS strongly encourages all States to consult with Tribes as they implement the DRA."

Consistent with CMS policy, I am requesting that CMS insert language in the final rule that would specifically remind States to consult with Tribes in the development of any State plan amendment to modify existing payment methodologies for prescription drug reimbursements. This reminder will allow each Tribe the opportunity to work with the State to assess local impacts and identify options prior to submission of State Plan amendments.

I am also requesting that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filing fees to Tribal and IHS pharmacies because they are important safety net providers and will be harmed by the reductions. Because of the limited capacity of many Tribal and IHS pharmacies, and their dependence on prescription drug reimbursements to meet overhead and administrative costs, we believe that implementation of this proposed rule will result in Tribal and IHS pharmacies shouldering a disproportionate share of Medicaid prescription drug reductions. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

I appreciate the opportunity to comment on these rules.