

CMS-2238-P-1268

Submitter : Ms. Jeanne LaBrecque
Organization : Indiana Office of Medicaid Policy and Planning
Category : State Government

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1268-Attach-1.DOC

February 20th, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-2238-P

Dear Ms. Norwalk:

The State of Indiana's Office of Medicaid Policy and Planning is submitting comments on the proposed rule pertaining to 42 CFR Part 447, Medicaid Program; Prescription Drugs. The Office has a vested interest in ensuring that CMS carefully considers the merits of all comments prior to issuing a final rule. These comments have been provided to CMS to assist CMS in evaluating the best course of action to pursue while meeting the Congressional intent of the legislation. Should questions arise during CMS review of our comments, the Office has provided contact information at the end of the comments document.

Sincerely,

Jeanne M. LaBrecque
Director of Health Policy and Medicaid

States of Indiana
Office of Medicaid Policy and Planning
Agency Comments Related to 42 CFR Part 447
Medicaid Program; Prescription Drugs; Proposed Rule
File Code: CMS-2238-P

I. "Background"

Agency Comments

None

II. "Provisions of the Proposed Regulations"

Definitions—Section 447.502; Page 77176

Dispensing Fee; Page 77176

Agency Comments

The definition of "dispensing fee" specifies that it is a "fee" that is incurred at the point of sale. Even though this facet of pharmacy reimbursement has historically and colloquially been referred to as a "fee", it more correctly is an administrative allowable paid to pharmacies for certain services they provide. The definition specifies, in part, that the dispensing fee is paying "...for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed". This wording is problematical in a couple of aspects, the first being that it mentions only pharmacy "costs". CMS needs to advise States as to whether or not it is CMS's intent that some profit to the pharmacy be included in the dispensing fee. Obviously, drug component reimbursement (EAC) is to approximate the agency's best estimate of the pharmacy's actual acquisition cost of the drug, and the dispensing fee is, by the CMS definition, to cover certain "costs" that the pharmacy incurs in dispensing the prescription. This leaves the obvious and significant policy question as to whether or not CMS intends that pharmacies are entitled to "profit" (presumably, through the dispensing fee) and, if so, at what level of profitability. A literal interpretation of the EAC and dispensing fee definitions implies that pharmacies are reimbursed at cost for the drug and dispensing fee. CMS needs to establish clear and unambiguous policy in this regard, incorporate it into this rule, and communicate it to States. Conversely, if CMS's intent is that there is to be no profit to pharmacies for Medicaid dispensations, through the dispensing fee or otherwise, CMS should so-specify through this rule and advise States accordingly.

The second problematical aspect to the referenced wording is that it mentions a dispensing fee as being applicable "*each time a covered outpatient drug is dispensed.*" This wording is too prescriptive and would likely prove costly to the federal government and States. In addition, some States have policies such that pharmacies are NOT entitled to a dispensing fee each time they dispense, an example being both long term care and retail pharmacies that dispense to residents of nursing facilities. Some States have adopted fiscally prudent policies that, while ensuring and preserving recipient access to necessary drugs, limit the payment of dispensing fees in such circumstances to, e.g., one

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dispensing fee per recipient per legend drug order (“prescription”) per month. It is up to the pharmacies and the nursing facilities with which they contract to mutually determine how often the pharmacy dispenses to residents of the facility—daily if they so choose, or otherwise on an agreed-upon lesser frequency that meets the needs of the facility and its patients—and this rule should not inadvertently interfere with that relationship such that pharmacies could claim far more dispensing fees than to which they are currently entitled in such States. Basically, the provision as currently worded could significantly increase States’ dispensing fee expenditures and do so at no benefit whatsoever to the States or beneficiaries.

The CMS definition States that the dispensing fee includes “...*only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist’s time in checking the computer for information about an individual’s coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy...*”. This definition is ambiguous, due to the “not limited to” and “reasonable cost” provisions. In order for States to properly administer the benefit, States will need greater specificity and clarity from CMS regarding CMS’s intent pertaining to “pharmacy costs”, and what CMS considers as “reasonable”. Too, this definition seems to be unduly wordy, yet does not provide the clarity needed by States. The CMS definition specifies that pharmacy costs do NOT include “*administrative costs incurred by the States in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.*” That disclaimer seems unnecessary and confusing, since it should be inherently obvious that the referenced States costs are not those of pharmacy providers. In summary, CMS should craft a definition of “dispensing fee” that is brief, clear, fully descriptive as to what CMS considers as “pharmacy costs” and “reasonable”, and provides States with the necessary policy direction regarding whether or not profit is to be included in the dispensing fee or elsewhere. CMS should be aware that one of the major “pushes” by organized pharmacy since the new FUL methodology was announced is for States to increase their dispensing fees to make up for the revenue that pharmacy providers will lose due to the deficiencies of the new FULs. Unless profitability is behind this “push”, it does not make sense because the advent of the new FULs will in no way increase pharmacies’ dispensing “costs”; rather, the new FULs would be removing some level of profitability that pharmacies currently enjoy, and the dispensing fee (which, according to CMS’s definition, apparently reimburses only “costs”) is the target that pharmacies have focused on as the means by which to make up the lost revenue. This leaves a policy disconnect that CMS should remedy via this rule.

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CMS may want to consider defining the dispensing fee solely in terms of its adequacy in ensuring sufficient provider participation to maintain recipient access which is, of course, a requirement of existing Federal law. That is to say, if a pharmacy chooses to participate even in light of a dispensing fee that may not cover their "costs", there should be nothing binding on the States to preclude that from happening. "Cost to dispense" studies, some quite recent, have invariably shown a "cost to dispense" dollar figure that is a multiple of existing fee-for-service Medicaid dispensing fees. Yet, pharmacy participation in Medicaid remains substantial and far more than adequate, even in light of this fact. Moreover, pharmacies that service Medicaid populations in capitated managed care arrangements accept dispensing fees that are a fraction of the fee-for-service dispensing fee—in instances, one-half or less. In light of the fact that pharmacies are apparently more than willing to accept dispensing fees that are far below their purported "cost to dispense", and do so in such numbers that more than adequate beneficiary access has historically been easily maintained, it would be highly advisable for CMS to consider defining "dispensing fee" solely in terms of what States determine to be an adequate rate to ensure necessary access. Doing so would allow States to take full fiscal advantage of the intensely competitive forces at work in the pharmacy marketplace, and eliminate the need for CMS to try to come up with a holistic, all-inclusive definition that would have to address the complicated matter of provider "costs" and what constitutes "reasonable". It should also be noted that CMS has chosen to define dispensing fee in a similar fashion to how it is defined in the Medicare Part D program in 42 CFR 423.100. It is common knowledge that the Medicare prescription drug plans have dispensing fees that are a fraction of current Medicaid dispensing fees. This can be directly attributed to the competitive forces in the pharmacy marketplace that allow the prescription drug plans to contract with an adequate pharmacy provider network in order for beneficiaries to have uninterrupted access to necessary medications. Simply stated, let States do what they do best—manage their pharmacy benefits (and associated costs) by taking full advantage of the competitive forces of the marketplace, and ensuring that rates paid to providers are sufficient to enlist and maintain necessary access to services by beneficiaries. All this can be accomplished by adopting a simplistic and fundamentally clear and sound definition of "dispensing fee".

Innovator Multiple Source Drug; Page 77176

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

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Multiple Source Drug; Page 77177

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition along with the other application types referenced under innovator multiple source drugs and single source drugs. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

CMS should also consider revising or creating separate definitions for this term. One component of the definition should define this term with respect to the establishment of the FUL since the FUL will be applied to a particular date of service on a pharmacy claim. The Office assumes that the new monthly FUL will apply to a particular date of service span that will be provided by CMS. A second component of the definition should be provided that is applicable to the rebate period.

Single Source Drugs; Page 77177

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

Determination of Average Manufacturer Price—Section 447.504; Page 77177

Definition of Retail Pharmacy Class of Trade and Determination of AMP; Page 77178

Agency Comments

CMS states that "*States might use AMP to calculate pharmacy payment rates.*" The Office strongly recommends that CMS consider removing or revising this statement because AMP is not representative of pharmacy provider acquisition costs and would create additional problems over and above those forthcoming with the AMP derived FUL rates as proposed by CMS. The AMP does not take into account the markup that is applied within the distribution chain between the manufacturer and purchasing pharmacy. The Office strongly recommends that CMS consider other mechanisms to calculate

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pharmacy payments rates. In terms of estimating pharmacy acquisition costs, the Office believes that there is no substitute for pharmacy provider acquisition costs surveys.

Upper Limits for Multiple Source Drugs—Section 447.514; Page 77186-77188

Agency Comments

Since CMS is ultimately accountable for the methodology, oversight, and administration of the FUL program, the Office has the following recommendations and suggestions for CMS:

- CMS should operate and staff an FUL call center. Many States utilize call centers to handle provider concerns relating to their SMAC programs. The CMS call center should be available during normal business hours, excluding holidays, via a toll-free number. This call center will triage and address concerns regarding FUL rates that have been established by CMS. These concerns would include, but not be limited to, drug shortages and lack of national availability at the FUL price. If CMS chooses not to establish a call center for this purpose, CMS, at a minimum, should designate a specific individual at each regional office to triage FUL related issues from pharmacy providers.
- CMS should establish a comprehensive quality assurance process for reviewing FUL rates prior to the rates being released to States. Incorrect FUL rates result in pharmacy claims being processed incorrectly. CMS should describe, in detail, the quality assurance process in the final rule. It is unreasonable and inappropriate for pharmacy providers to be reimbursed via the FUL rate if the FUL rate is not accurate. FUL rates that have not undergone a rigorous review for accuracy should not, in any circumstance, be released to States.
- CMS should allow reasonable timeframes for the implementation of new and revised FUL rates. The Office recommends a minimum of 30 calendar days. Particular attention should be focused on rate decreases since these rates are based on monthly AMPs submitted by manufacturers rather than pharmacy purchasing histories. There will most likely be an inherent lag time between the AMP derived FUL rates and what rates pharmacies actually purchase or have purchased the drug products that subject to the FUL rates. In addition, States need ample time to review the impact of the rates as it pertains to their Preferred Drug Lists. It is not uncommon for a State to designate a multi-source brand name drug as preferred when the supplemental rebate offered by a manufacturer results in the brand name drug being less expensive, in the aggregate, than the A-rated generic equivalent. The monthly release of FULs will require States to re-analyze the expenditures, in the aggregate, thus possible requiring States to cancel or amend supplemental rebate contracts with manufacturers. The Office requests that CMS address this issue in the final rule.
- The Office assumes that CMS will apply FUL rates to the full extent in terms of product depth and breadth of covered outpatient drugs as allowed by the

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legislation. In the past, CMS has not assigned FULs to injectable covered outpatient drugs. The Office requests that CMS address this assumption in the final rule.

- Current CMS methodology states that *“If all formulations of a multiple source drug are not A-rated, there must be at least three A-rated versions of the drug listed in ‘Approved Drug Products with Therapeutic Equivalence Evaluations’ for CMS to establish a FUL for the drug.”* A literal reading of the first part of this sentence entails a situation in which there are no A-rated products, and that is likely not what you intended to convey. Suggested corrective wording here would result in the following: *“If not all formulations of a multiple source drug are A-rated, there must be at least three A-rated versions of the drug...(etc.)”*. This statement would make sense in the given context, and correct the currently existing methodology text.
- In general, the Office supports the use of the 9-digit NDC to calculate the AMP for the reasons specified in the proposed rule. However, the Office disagrees with the idea that the most economical package size is always the one with the lowest per unit cost. In particular, for pharmacies serving smaller populations, the package size with the lowest per unit cost may include many more units than is needed for the patient base. Purchase of this package size would lead to waste if that package size is ordered and units have to be later discarded due to product expiration. The expectation that the lowest per unit cost product is always the most economical for the pharmacy can lead to reimbursement that will not fully cover costs for pharmacies that prudently purchase quantities of drugs appropriate for their patient population. The Office requests that CMS should consider and make exceptions to utilizing only the 9-digit NDC for establishing certain FUL rates. CMS should strongly consider that package sizes for creams, ointments, eye drops and IV solutions are traditionally not consistent on a unit cost basis. These products, in the smaller package sizes, are typically more costly on a unit cost basis for providers to purchase as compared to the larger package sizes of identical drug products. Establishing the FUL utilizing the 9-digit NDC will result in reimbursement below pharmacy acquisition costs when the smaller package size is being dispensed. In these instances, it would be prudent for CMS to incorporate 11-digit NDC’s into the FUL process or establish other mechanisms to ensure that pharmacy providers can purchase the smaller package size at or below the established FUL. It should be noted that prescribers dictate the package sizes that are dispensed when the prescription is written, not retail pharmacies. CMS states *“We are proposing to use the currently reported 9-digit AMP for calculating the FUL.”* The Office would recommend that CMS revise this statement to read *“We are proposing to use the AMP associated with the reported 9-digit NDC for calculating the FUL.”*
- Utilizing the February 2007 AMP rates, our analysis showed that over half of all FULs would reimburse below the average retail acquisition cost pharmacies incur to purchase these drugs. These results represent no change from the previous 2

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iterations that were performed by the Office. The Office will provide the February analysis to CMS outside of the public comments due to concerns related to AMP confidentiality.

- We agree that safeguards are necessary to ensure that a drug is nationally available at the FUL price. However, based on our analysis of the Proposed Rule and the February 2007 AMP data supplied to all states, we strongly disagree that the proposed additional criteria (e.g., carve-out policy) will ensure that a sufficient supply of the drug will be available nationally at or near the FUL price for the following reasons:

The Proposed FULs are Extremely Poor Estimations of Pharmacy Acquisition Cost

- 1) Since 2002, the State of Indiana has been collecting drug acquisition cost data from Indiana retail pharmacies. Based on our extensive database of drug acquisition cost data which is currently updated on a monthly basis, we evaluated the retail pharmacies ingredient costs and the proposed FUL reimbursement for over 1,000 of these widely used drugs. Our analysis revealed a wide variance in underpayments and overpayments that will be made with the proposed FULs.
- 2) FUL Underpayment: We found that for **more than 51%** of drugs subject to a new FUL, the FUL reimbursement would be less than the average acquisition cost incurred by retail pharmacies to acquire the drugs from their suppliers. Among these drugs, many highly utilized drugs had FULs that were **less than 60%** of the average retail acquisition cost. In several cases, the FUL was **less than 10%** of the average retail acquisition cost. Underpayments on this scale would force pharmacies to reconsider participation in the Medicaid program or make States increase other payment to compensate for the insufficient ingredient cost reimbursement.
- 3) FUL Overpayment: On the other hand, for **nearly 49%** of drugs subject to a new FUL, the FUL reimbursement would be greater than the average retail acquisition cost. While this allows providers a margin for profit, in many cases, the profit margin can be much larger than intended if the State does not have a robust SMAC program in place. The range of overpayment extended as high as FULs that were **over 400%** of the average retail acquisition cost. The Office strongly recommends that, for this reason, CMS advise States not to discontinue their SMAC programs in lieu of the proposed FUL implementation.

Limited Supply of Drug at the FUL Price

- 1) Of the 1,454 drugs that meet the eligibility for an FUL, the supplier (5-digit NDCs) with the lowest AMP (after applying the proposed carve-out criterion) on average accounted for only 28% of recent claims made for the drug, which is a proxy for the current Medicaid market demand for the drug. That is to

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say, the lowest cost supplier is currently distributing less than three out of ten units dispensed.

- 2) Of the 1,454 drugs that meet FUL eligibility, there are ninety-three (93) drugs where there is only one 9-digit NDC with a reported AMP that is less than the FUL price. These include highly utilized drugs such as Glyburide, Heparin, Mirtazapine, Oxycodone, Prednisone, and Warfarin. For these 93 drugs, the suppliers (5-digit NDCs) account for an average of 44% of recent claims made for the drug. That is to say, the lowest cost supplier is currently distributing about four out of ten units dispensed.
- 3) Of the 1,454 drugs that meet FUL eligibility, there are two hundred and twenty four (224) drugs where less than 40% of the current suppliers (5-digit NDCs) have reported AMPs that are less than or near the projected FUL. These include highly utilized drugs such as Acyclovir, Ciprofloxacin, Fluoxetine, Gabapentin, Lisinopril, Metformin, Nitroglycerin, and Paroxetine. Also, for these 224 drugs, these low price suppliers account for, on average, 40% of recent Medicaid claims for the drugs.

Increase in Price of Lowest AMP Due to Effects of Supply and Demand and Time Lag Before FUL Reflects Price Changes

- 1) Initially, pharmacies will have a large incentive to purchase drugs from the supplier of the drug with the lowest AMP in order to maximize profits. In the short run; however, manufacturers will not be able to increase capacity the nearly fourfold (in the aggregate, see 1 above) necessary to meet the demand for their drug(s). When demand exceeds supply, the manufacturer with the lowest AMPs will increase its price to distributors who will increase their price to retailers. At that point, it is likely that no supplier will have the drug available at the FUL price due to the time lag inherent in reporting AMPs to CMS and CMS communicating new FUL prices.
- 2) As more pharmacies begin purchasing the drug with the lowest AMP, they will likely purchase these drugs in quantities necessary to meet all their client needs, including Medicare, commercial insurers and walk-ins. This will further reduce supply and cause the price of the lowest AMP to increase.

Regarding the exclusion criterion as proposed by CMS, we understand through discussions with CMS that it is meant to be applied only once for each FUL drug. In other words, if the lowest AMP is less than 30 percent of the second lowest AMP, and the second lowest AMP is less than 30 percent of the third lowest AMP, then the FUL would be established based on the second lowest AMP. Please confirm that you plan to apply the exclusion criteria only once. The Office also recommends that CMS utilize simple examples to illustrate the exclusion criterion as the present wording is confusing.

We applied the exclusion criterion in iterations of 40%, 50%, and 60% to the AMP data to gauge the impact of changing the carve-out percentage. We were discouraged to

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discover that increasing the percentage had little impact on increasing the number of FUL drugs where the FUL rate exceeds the average retail acquisition cost of the drug. In summary, using the proposed 30% carve-out percentage resulted in only 49% of FUL drugs having a price greater than the average retail acquisition cost of the drug. Increasing the carve-out percentage to 60% resulted in a modest increase in the number of FUL drugs having a price greater than the average retail acquisition costs (58%).

Based on our analysis, the proposed carve-out approach is not adequate at any percentage to ensure access to drugs at or near the FUL. Therefore, we do not believe that adjusting the percent threshold for the carve-out policy addresses or corrects deficiencies with the AMP data or the proposed outlier approach. Based on our analysis of the data, we believe other safeguards beyond a carve-out approach, are necessary to ensure that a drug is nationally available at the FUL price.

Based on our analysis, we do not believe that the proposed approach for handling outlier AMPs is adequate to ensure that a drug is available nationally at the FUL price. With the stated goal to ensure that a drug is nationally available at the FUL price, we recommend CMS consideration of utilization data as a proxy for marketplace availability. Three suggested utilization data sources to explore are 1) claims data submitted by State Medicaid programs on a regular basis, 2) NDC-level utilization data collected for the Medicare Part D program, and 3) monthly purchase data submitted to CMS by 3 or 4 national drug wholesalers for all purchases made during the prior month.

In an example of using utilization data to ensure marketplace availability, we used State drug utilization data available from the CMS web site and defined the lowest AMP as the AMP where the cumulative claims for its NDC and those associated with lower AMPs was at least 80% of the current Medicaid drug claims (refer to Table 1 below for illustration). This resulted in slightly more than 80% of all FUL drugs having a price greater than the average retail acquisition cost of the drug. We believe this provides a reasonable balance between access to drugs and incentives to encourage pharmacies to acquire less costly generic drugs.

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Table 1. Assuming all NDCs are within the same FUL group, are generic, A-rated, from rebating manufacturers and non-terminated

NDC	AMP	% of Utilization at or below AMP	% of Utilization at or below 10% of AMP	% of Utilization at or below 20% of AMP	% of Utilization at or below 30% of AMP	FUL
12345-6789-10	1.00	--	10%	100%		
98765-4321-01	0.5	-50%	50%	90%		Lowest (FUL:1.25)
56789-1234-11	0.25	-50%	25%	40%		
78910-2345-00	0.09	-36%	15%	15%		Lowest (FUL:0.225)

* Utilization. May be utilization measured by claims data obtained from States, utilization data collected through Medicare Part D, or purchase history obtained from national drug wholesalers.

** The Cumulative Utilization increases from lowest AMP to highest since establishing the FUL based on the lowest AMP where at least 80% of utilization is at or below that AMP would result in a FUL that provides cost coverage for all NDCs at or below that AMP price.

FFP: Conditions Relating to Physician-Administered Drugs—Section 447.518; Page 77188

Agency Comments

The Office requests that CMS specifically clarify in the rule that claims for physician administered drugs must meet all covered outpatient drug requirements. Specifically, the NDC must be from a rebating manufacturer, not have a termination date prior to the date of service on the claim and the drug must not have a DESI value of 5 or 6.

The Office requests that CMS specify, in detail, the required file format for submission of claims for physician administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

The Office requests that CMS require NDCs and NDC quantities on Medicare B claims involving covered outpatient drugs where the beneficiary is dual eligible. This is necessary for provision of services, coordination of benefits and to minimize paper billing of crossover claims to Medicaid where NDCs are not allowed or required by Medicare intermediaries. The paper billing of crossover claims is time consuming, resource intensive and fails to take advantage of the data interchange standards that are available to providers.

The Office requests that CMS provide State Medicaid programs and Medicare intermediaries with a comprehensive list of all HCPCS procedure codes pertinent to covered outpatient drugs. This list should be supplied on a quarterly basis to coincide

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with the release of new HCPCS codes by CMS. This list will ensure consistency across all Medicaid programs as it pertains to the collection of NDC's for physician administered drugs. The Office recognizes the need for collection of NDC's based on wording from CMS in the proposed rule: *"We expect that States will require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States."*

The Office requests that CMS provide State Medicaid programs with a uniform remedy for the collection of NDCs and NDC quantities as it pertains to outpatient hospital claims that will be submitted on the UB-04 claim format. The UB-04 claim format does not accommodate these values and therefore would require each State to develop a non-standard mechanism to collect this information. In particular, this is problematic for providers who work across State lines with multiple State Medicaid programs.

The Office requests that CMS provide State Medicaid programs with a uniform remedy for processing HCPCS claims involving NDCs where the product has been compounded. The Office recommends that CMS only require the NDC and NDC quantity for the NDC that most closely ties the HCPCS narrative description since the various claim forms and electronic data standards do not allow for multiple NDCs to be transmitted for a single HCPCS code. The Office does not consider duplicate submission of a HCPCS coded claim reasonable or efficient for the purposes of collecting NDCs related to secondary ingredients involved in compound claims.

III. "Collection of Information Requirements"

Agency Comments

None

IV. "Response to Comments"

Agency Comments

None

V. "Regulatory Impact Analysis"

Requirements for Manufacturers; Page 77198

Agency Comments

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The CMS text is as follows: “(a) *Quarterly reports. A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period.*” Over the past several months, CMS has been “cleaning up” their MDR file, notifying States of NDCs for products that should not have been considered to be “covered outpatient drugs” but were, nonetheless, somehow included on CMS’s MDR file. This erroneous inclusion and subsequent file clean-up has created confusion, as States have been reimbursing for these products and, apparently, invoicing manufacturers for rebates for the products. We anticipate that the initial inclusion of the NDCs/products on CMS’s MDR file occurred because manufacturers erroneously identified the products as “covered outpatient drugs”, but subsequently disputed rebate invoicings for the products and asked that CMS delete the products from CMS’s MDR file. If that is the case, and in order to preclude future confusion such as caused by CMS’s MDR file clean-up, we suggest that wording be added to this cite that clearly places the responsibility on manufacturers to ensure that they report to CMS only those products/NDCs that are truly “covered outpatient drugs”. Further, that CMS be required to coordinate as necessary with FDA or other federal agencies to ensure that products that manufacturers report to CMS as being “covered outpatient drugs” actually are same. Finally, that if products that are reported to CMS by manufacturers as being “covered outpatient drugs” are subsequently determined to not be same, States are not to be held accountable for any expenditures for, or rebates collected for, the products in the interim.

Overall Impact; Page 77190

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It is not clear that the estimated savings accounts for savings already realized through State Maximum Allowable Cost (MAC) programs operated in most States. If this has not been taken into account then the State and Federal Savings is most likely grossly overstated. In many instances, a lower State MAC rate is already in place and pharmacies will continue to be reimbursed at the lower State MAC rate. These lower State MAC rates would negate some or most of the expected additional savings projected in the Proposed Rule. In addition, analysis of the February 2007 AMP rates shows that many FULs would reimburse pharmacies below their average retail acquisition cost for many drugs. States will receive tremendous pressure to increase their dispensing fees to compensate for deficiencies on the ingredient cost reimbursement, which would significantly diminish the projected savings or possibly end up costing the program more in the long term.

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CMS-2238-P-1269

Submitter :

Date: 02/20/2007

Organization : Daiichi Sankyo, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

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See Attachment

CMS-2238-P-1269-Attach-1.PDF

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Daiichi-Sankyo

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February 20, 2007

VIA HAND DELIVERY AND ELECTRONIC DELIVERY

The Hon. Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-2238-P, Proposed Rule – Medicaid Program, Prescription Drugs

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services (“CMS”) proposed rule on Medicaid Program, Prescription Drugs, the “Proposed Rule”.¹ Daiichi Sankyo, Inc. respectfully submits the following comments to the Proposed Rule regarding Medicaid average manufacturer price (“AMP”) and Best Price (“BP”) calculations. We appreciate the opportunity to submit these comments and are available to discuss them with you at your convenience.

We understand the challenges associated with providing clear guidance with respect to the highly complex issues surrounding the AMP and BP calculations. As a general matter, we are concerned that the Proposed Rule raises several questions that, if unanswered, may lead to inconsistencies in manufacturers’ price reporting. We have set forth some of these issues below for your consideration. Where possible, we have attempted to organize our comments pursuant to the headings in the Proposed Rule.

I. DAIICHI SANKYO, INC. BACKGROUND

Daiichi Sankyo, Inc. is headquartered in Parsippany, New Jersey, and is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., a global pharmaceutical company headquartered in Japan. The company’s strategic focus is on cardiovascular diseases. Research and development of new therapies is also focused in the areas of glucose metabolic disorders, infectious diseases, cancer, immunology and bone and joint diseases. Daiichi Sankyo’s portfolio of covered outpatient drugs currently includes Benicar® (olmesartan medoxomil) and BenicarHCT® (olmesartan medoxomil/hydrochlorothiazide), WelChol® (colesevelam HCl), Evoxac® (cevimeline HCl) and Floxin OTIC® (ofloxacin otic).

II. GENERAL COMMENTS

We respectfully request that CMS define what the terms “include” and “exclude” mean with respect to the dollars and units components of the AMP calculation generally. The Proposed Rule is not clear as to how to treat such terms for purposes of actually performing the AMP calculation. For example, if a discount is

¹ 71 Fed Reg. 50,428 (Dec. 22, 2006), file code CMS-2238-P.

“included” in AMP, does CMS expect manufacturers to deduct the value of the discount from the numerator (dollars) of the AMP equation but keep associated units in the denominator (units)? Similarly, for an “excluded” sale, are the dollars to be subtracted out of the numerator and not reduced by any related discounts, and the associated units to be subtracted from the denominator? If so, in cases where the purchase price associated with an “excluded” sale is not known to the manufacturer (as is often the case with indirect sales), how should a manufacturer value such units – at wholesale acquisition cost (“WAC”)? Alternatively, should “excluded” transactions be ignored (e.g., neither sales dollars, discounts or units deducted from the AMP calculation) in light of the difficulties in valuing the sales? Is there a difference in the treatment of transactions that are “not included” versus transactions that are “excluded”? In some cases the Proposed Rule references including “sales” to certain entities, in some cases it references including “sales and associated rebates, discounts and other price concessions”: does CMS intend there to be a difference in the affect on sales dollars, discounts and units based on the terminology used? In this regard, we request that CMS include both of the following in the final rule: (i) a sample AMP calculation and (ii) a chart indicating for each of the various entities that may affect the AMP and BP calculation whether sales, discounts, and/or units are deducted from the gross ex-factory dollar and unit numbers for purpose of calculating AMP.

III. SPECIFIC COMMENTS

A. Section 447.502 (Definitions)

1. Bona Fide Service Fees

- a. The Proposed Rule states that service and administrative fees are included in AMP. However, the Proposed Rule states that “bona fide” service fees are excluded from AMP, without reference to administrative fees. Can an administrative fee qualify as a “bona fide service fee” that would be excluded from AMP?
- b. If an administrative fee is paid to a group purchasing organization in accordance with the group purchasing organization statutory exception and/or safe harbor to the federal healthcare anti-kickback statute (21 C.F.R. § 1001.952(j)), does it also need to fit the definition of “bona fide service fee” to be excluded from AMP?
- c. When defining the term “bona fide service fees” for purposes of the average sales price (“ASP”) final rule issued on December 1, 2006, CMS included extensive guidance in the preamble interpreting the various components of this term (*see* 71 Fed. Reg. 69623, 69666-70 (Dec. 1, 2006)). We respectfully request clarification as to whether CMS’s guidance on this term issued in the ASP context is relevant to the analysis of service fees in the AMP and BP context. Specifically, we respectfully request CMS to clarify that, as is the case with ASP: “If a manufacturer has determined that a fee paid meets the other elements of the definition of ‘bona fide service fee,’ then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.”
- d. We respectfully request clarification that service and administrative fees, regardless of whether such fees are “bona fide” as defined by CMS, are not “included” in AMP unless paid to an entity included in AMP under Section 447.504(g) of the Proposed Rule. Also, if a service fee is determined not to be “bona fide”, should manufacturers prorate the service fee to apportion it to AMP-included sales only? Because AMP-excluded sales are removed from gross sales, the discounts associated with such sales should be removed from the gross discount dollars before the discounts/rebates being included (dollars being removed) from AMP calculations. Otherwise, it would result in an artificially low AMP number and this AMP number would reflect sales to AMP-included entities and discounts for AMP-included and AMP-excluded entities.

2. Bundled Sale

- a. "Bundling" is defined under the Proposed Rule to include an arrangement where an "other price concession is conditioned upon the purchase of the same drug or drugs of different types..." Does CMS mean to state that a bundle is where the discount on one drug is contingent upon the purchase of another drug (i.e., discount of drug X is contingent upon the purchase of drug Y)? While we do not believe it is the intention of CMS to consider different strengths of the same drug (e.g., same NDA, different NDCs) being offered to a customer as being a bundle, we believe that the definition requires clarification.

B. Section 447.504 (Determination of AMP)

1. (a) AMP means...

- a. As a general comment, while some wholesalers may send a manufacturer detailed reporting as to each entity to which they have sold the manufacturer's product, this is not necessarily a standard for all wholesalers and all manufacturers. As such, manufacturers in many cases rely on chargeback data to identify the retail pharmacy class of trade for AMP calculations. To the extent there is no chargeback associated with a sale, a manufacturer may have no way of knowing whether the end purchaser was "retail". We are seeking confirmation from CMS that this is acceptable.

2. (c) Customary Prompt Pay Discount means...

- a. We respectfully request clarification of the meaning of the word "routinely" when defining customary prompt pay discounts. If a manufacturer offers special or extended terms on a limited basis (e.g., during product launch) would such discounts be considered "routine" and, if, so, how should a manufacturer account for them with respect to AMP and Prompt Pay Discount reporting?

3. (e) Retail Pharmacy Class of Trade means...

- a. The Proposed Rule defines the "Retail Pharmacy Class of Trade" to include a pharmacy benefit manager (or "PBM"). We interpret the Proposed Rule to treat both PBM mail order business as well as other PBM business as retail pharmacy class of trade. If this interpretation is correct, it is logical that CMS should also treat non-staff model managed care organizations and employer group health plans as retail pharmacy class of trade. When a PBM is acting in a mail-order capacity as the rebate contracting agent of a plan, the financial incentives are analogous in many ways to a plan performing its own rebate contracting, and it seems incongruous to treat these two arrangements differently. We seek clarification in this regard.

4. (f) Wholesaler means...

- a. The definition of "wholesaler" appears to be inconsistent with CMS's list of sales included in the AMP calculation under the Proposed Rule. Because the AMP is to reflect the average price "from wholesalers for drugs distributed to the retail pharmacy class of trade" (emphasis added), CMS may need to adjust the definition of "wholesaler" to incorporate some of the entities listed under Proposed Rule § 447.504(g) such as individual patients (see §447.504(g)(7)). Alternatively, we respectfully suggest that CMS reconsider whether all of the sales enumerated under §447.504(g) are appropriately "included" in AMP based on the proposed definition of "wholesaler".

5. Sales, Rebates, Discounts, or other Price Concessions included in AMP

- a. We note that Proposed Rule § 447.504(4) states that nominal price sales to a “covered entity described in section 340B(a)(4) of the Public Health Service Act” are not included in AMP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006)), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children’s hospitals in the definition of “covered entity” for purposes of the Best Price exclusion. However, the definition of “covered entity” under Public Health Service Act was not amended accordingly. Will prices to such children’s hospitals (defined in 42 U.S.C. § 1396r-8(a)(5)(B)) be eligible for the AMP exclusion?
- b. We respectfully request clarification as to CMS’s position on PBM price concessions. In the preamble, CMS states: “We propose to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized the manufacturer for drugs provided to entities in the retail pharmacy class of trade.” Is it CMS’s intent, based on its inclusion of PBMs in the definition of “retail pharmacy class of trade”, that all rebates, discounts or other price adjustments to PBMs be included in (deducted from) AMP, unless specifically excluded? Alternatively, does the language “that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade” place a burden on manufacturers to trace any non-mail order PBM discounts to the ultimate seller to identify whether such seller is an entity in the retail pharmacy class of trade? In the mail order context, chargeback data will generally allow manufacturers to attribute PBM discounts to the ultimate seller of the product. However, in non-mail order arrangements, where the PBM is not a purchaser, there can be difficulties in tracing and classifying such end sales. In many cases, such classification will be impossible. We respectfully request clarification as to CMS’s expectations in this regard.
- c. We request that CMS add the wording “where identifiable and to the extent the data is available” when giving guidance on what items to include or exclude from AMP calculations (e.g., discounts given to an excluded class of trade that cannot be identified in a rebate submission from a PBM).
- d. Section 447.504(7) of the Proposed Rule “includes” direct sales to patients. See the discussion above under regarding the definition of “wholesaler.” We note that “including” these sales and presumably, discounts, in the AMP calculation may potentially serve as a disincentive for manufacturers to offer patients assistance programs or other subsidies to patients. If the intent of the AMP calculations is to determine the net price by wholesalers to the retail class of trade, including sales and discounts directly to patients may improperly lower the AMP.
- e. Section 447.504(10) of the Proposed Rule “includes”: “rebates, discounts, or other price concessions (other than rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade.” We respectfully request that CMS clarify the meaning of the term: “associated with”.
- f. The Proposed Rule states that only manufacturer coupons redeemed directly by the patient can be excluded from AMP and BP:
 - i. We note that manufacturer coupons and vouchers, directly or indirectly redeemed by the patient, serve to provide financial assistance to patients rather than the “retail pharmacy class of trade.” We note that as an administrative matter, manufacturers do not always process patient coupons and vouchers directly. Two scenarios are common: (i) a patient will pay a co-pay for the

product at the pharmacy and then redeem a coupon to a third-party vendor under contract with the manufacturer, and the vendor (not the consumer) will then invoice the manufacturer for the value of the coupon; (ii) a patient will present with a coupon or voucher at the pharmacy, and the pharmacy will supply the drug to the patient out of its inventory, at a reduced cost to the patient according to the terms of the coupon, and the vendor (not the consumer) will then invoice the manufacturer for the reimbursement paid to the pharmacy (which may include a negotiated rate and a dispense fee). Is it CMS's intent that the value of coupons or vouchers redeemed by third party vendors are to be "included" in AMP and BP calculations? We respectfully request that they should not be, in light of the negligible impact such arrangements have at the "retail" pharmacy level versus the tremendous benefit to patients.

- ii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance on how to value such transactions for purposes of the respective calculations. For privacy reasons, manufacturers often do not have full transparency into the dispensing of a coupon or voucher prescription (e.g., how many tablets are dispensed with a particular coupon). Similarly, even if the manufacturer were to have such transparency, other valuation issues should be addressed (e.g., if a single coupon were redeemed for an order of product that has to be filled over two prescriptions due to a pharmacy not having the full amount of medication to dispense at once – how should such coupon be allocated?).
 - iii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance regarding how a manufacturer may properly structure a Patient Assistance Program utilizing coupons (if the coupons are redeemed either at the pharmacy or through an agent of the manufacturer) and still keep its patient assistance program BP and AMP exempt.
 - iv. We respectfully request that CMS define "coupon" and clarify its position with respect to vouchers including the characteristics of a voucher program versus a coupon program.
- g. Section 447.504(12) of the Proposed Rule "includes": "sales and associated rebates, discounts, or other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program (MA-PD), State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations)." We respectfully request that CMS clarify the meaning of the term: "associated with sales of drugs provided to the retail pharmacy class of trade". If a manufacturer were to provide discount to a PBM in connection with its Medicare Part D mail order business, would that discount be "included" in AMP? We further request that CMS clarify the handling of a qualified retiree prescription drug plans for purposes of AMP.
- h. We respectfully request that CMS clarify the meaning of the following statement in the preamble of the Proposed Rule: "Therefore, we would clarify that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that the price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included." This will also effect SCHIP XIX. How are rebates paid to states Medicaid agencies under either the CMS Rebate Agreement or a CMS-approved supplemental rebate agreement (and the associated units) to be

treated for purposes of AMP? Are manufacturers expected to perform some level of diligence to "trace" Medicaid sales to the retail pharmacy class of trade.

6. (h) Sales, Rebates, Discounts, or other Price Concessions excluded from AMP

- a. We respectfully request confirmation that clearly identifiable indirect sales to "excluded" entities should be excluded from AMP calculations (e.g., sales identified through chargeback data). Similarly, please confirm that indirect sales to excluded entities, if not identifiable as such by the data available to a manufacturer, are not required to be "excluded".
- b. We respectfully request that CMS clarify whether the references to health maintenance organizations ("HMOs") and managed care organizations ("MCOs") under section 447.504(h)(5) of the Proposed Rule are limited to so-called "staff-model" HMOs and MCOs that purchase pharmaceuticals for dispensing to their members, or whether they include so-called "IPA-model" HMOs and MCOs that arrange for pharmacy discounts but do not actually purchase drugs.
- c. We respectfully request clarification as to the appropriate AMP treatment of direct and clearly identifiable indirect sales and discounts to entities that dispense to only their own patients (e.g., to physicians, home health care, clinics, long term care, prisons, ambulatory care centers, surgi-centers, and other outpatient health care centers).
- d. We respectfully request clarification as to the appropriate AMP treatment of discounts and administrative fees paid to group purchasing organizations.
- e. We support CMS's determination to exclude returned goods from the AMP calculation. However, we respectfully request additional clarification regarding what it means that goods were "returned in good faith." Assuming that a manufacturer has no evidence to the contrary, may a manufacturer assume that goods are returned in good faith? Alternatively, we request that CMS delete the "good faith" requirement, as this issue is in the purview of the returners and not the manufacturer.
- f. We request clarification on whether a manufacturer may treat all chargeback reversals as returns if data is not available to the manufacturer to indicate otherwise.

7. (i) Further Clarification of AMP Calculation

- a. We understand that the requirement that a manufacturer must adjust the AMP if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized is not new. However, we suggest that CMS consider implementing a tolerance level for quarterly AMP variation, within which an AMP restatement (positive or negative) would not be permitted, in order to reduce the burden on states, CMS and manufacturers.
- b. When calculating quarterly AMP, would CMS consider allowing manufacturers the option of calculating a weighted quarterly AMP based upon the monthly AMPs that were submitted for the quarter? In this regard, we would respectfully request that manufacturers choosing this option not be required to restate AMPs. This would eliminate restating of quarterly AMPs as monthly AMPs are generally not allowed to be restated. This would also reduce the administrative burden on the states, CMS and manufacturers in connection with the restatement of quarterly AMPs.

C. 447.505 (Determination of Best Price)

1. CMS states for Best Price reporting "that the best price includes the lowest price available to any entity..." We respectfully request that CMS clarify that the intent of this provision is that the BP represents the best price *achieved* and consider conforming the proposed regulation to this intent.
2. When referencing "Tricare" after depot throughout the Proposed Rule is CMS stating that all Tricare discounts (mail and retail) are to be excluded from AMP and best price? Further, if CMS is asserting that Tricare's retail discount program (TrXX) is viewed as a depot, we respectfully request that CMS clarify that CMS is interpreting only the Medicaid Drug Rebate Statute and not the Veterans Health Care Act.
3. With regard to a manufacturer's patient assistance program ("PAP"), would reduced charges to recipients be included in best price? The Proposed Rule indicates that only "goods provided free of charge under a manufacturers' patient assistance program" would be exempt. We respectfully request that CMS exclude all prices under manufacturer PAPs from BP determinations.
4. The determination of what constitutes a "state pharmaceutical assistance program" ("SPAP") has been subject to varying guidance from CMS over the years. We are familiar with the several CMS Manufacturer Releases in this regard. We respectfully request that this issue be resolved through the regulatory process. One suggestion would be that manufacturers be allowed to rely on the most current SPAP list published by CMS, and that any deletions from that list apply only prospectively from the first date a manufacturer is able to terminate its contract with that program.
5. See also comments above under AMP discussion.

D. Section 447.506 (Authorized Generic Drugs)

1. The Proposed Rule indicates that, with respect to authorized generics, the original manufacturer must include the authorized generics' manufacturer's data in the calculation of AMP and Best Price. In light of the potentially anticompetitive ramifications of such data sharing, we respectfully request that CMS address an appropriate mechanism to exchange such information within applicable regulatory parameters, including those of the Federal Trade Commission.
2. We request that CMS clarify how manufacturers should handle situations where pricing data is not available from the secondary manufacturer.
3. We request that CMS clarify how manufacturers should account for any transfer pricing of the product when sold from the NDA-holder to the authorized generic manufacturer.
4. We request that CMS clarify that "authorized generic drugs" do not include situations where a drug product is purchased from a branded manufacturer and being marketed under two labeler codes solely during the term while the original product holder sells out its inventory.

E. Section 447.508 (Exclusion from Best Price of Certain Sales at Nominal Price)

1. We note that Proposed Rule § 447.508(a) states that nominal price sales to a "covered entity described in section 340B(a)(4) of the PHSA" are excluded from BP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children's hospitals in the definition of "covered

entity” for purposes of the Best Price exclusion. However, the definition of “covered entity” under Public Health Service Act was not amended accordingly.

2. Separately, 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I) (and Section 447.505(d)(1) of the Proposed Rule) excludes any price to a “covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title).”
3. Will nominal prices to children’s hospitals defined in 42 U.S.C. § 1396r-8(a)(5)(B) be eligible for the BP exclusion? Will such prices be separately reportable under Section 447.510(4) of the proposed rule?

F. Section 447.510 (Requirements for Manufacturers)

1. (a) Quarterly Reports

- a. Can CMS clarify how manufacturers will be required to report the Customary Prompt Payment discount to the agency from an operational perspective? For example:
 - When reporting customary prompt payment discounts, should manufacturers recognize these at the time of the sale of the product to the customer?
 - Do manufacturers report customary prompt payment discounts at the 9 digit NDC, the 11 digit NDC or at the labeler code level?

2. (c) Base Date AMP Report

- a. Due to the intense amount of resources that may be required to restate Base Date AMPs, we respectfully request that CMS offer additional time to complete this process beyond the first full quarter after the final rule has been published. We recommend that manufacturers be given 12 months to accomplish this. It may be difficult and, in some cases impossible, for manufacturers to recalculate Base Date AMPs, due to factors such as the passage of time and product sales and acquisitions. As an alternative to recalculating Base Date AMP, we respectfully request that CMS consider allowing manufacturers to calculate AMP under their current (pre-final AMP rule) methodology, then calculate AMP under the methodology established in compliance with the final AMP rule, when issued. The manufacturer could then use the ratio from that difference and apply it to their original Baseline AMP.

3. (d) Monthly AMP

- a. With respect to price concessions to the retail class of trade, is it acceptable for manufacturers to run monthly reports, and include these sales and discounts in the AMP calculations, based upon the “post” date of chargebacks, which indicates when a chargeback has been “paid”? This would be using the “cash” methodology.
- b. We respectfully request that CMS clarify how a manufacturer may “estimate” their monthly AMP. With respect to using an “estimation” or “smoothing” methodology, we recommend that manufacturers should be permitted to use a four-quarter rolling average of rebates to sales, and apply that percentage to monthly sales. Using a four quarter rolling average for smoothing is operationally more feasible than a 12-month rolling average because rebates and other price concessions are typically invoiced by customers and paid by manufacturer on a quarterly basis. We also request that CMS clarify that manufacturers should be allowed to estimate excluded sales for the month, using a four-quarter rolling average based upon gross

sales units divided by excludable AMP units for determining the ratio of non-eligible AMP sales.

- c. The Proposed Rule requests comment on the issue of estimating the lagged discounts associated with quarterly AMPs in addition to monthly AMPs. We note that in some cases, it may be appropriate for a manufacturer to use the estimation methodology for the monthly calculations and the cash methodology for the quarterly submissions, as, on a quarterly basis, the lagged concessions may be significantly reduced. We note that this may vary from manufacturer to manufacturer, and thus it would make sense for CMS to permit manufacturers to use either cash or estimation for quarterly AMPs, provided the determination as to which method is to be used is consistent.
- d. Regardless of CMS's determination as to timeframe for estimation, we request that CMS clarify whether the current reporting period is included in the estimation (e.g., does the current month data count as one of the twelve months in a twelve-month rolling average?).
- e. We respectfully request that CMS clarify how a manufacturer should treat a negative monthly AMP.
- f. We respectfully request that CMS clarify what it considers to be "lagged price concessions".
- g. CMS Manufacturer Release # 76 (Dec. 15, 2006) states: "Adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission." We respectfully request that CMS confirm whether this is CMS's position under the Proposed Rule as well. If so, we note that the addition of data attributable to a previous month's transactions into a later month's AMP could artificially inflate or deflate the later month's AMP.

4. (e) Certification of Pricing Reports

- a. The requirement in the Proposed Rule that the CEO, CFO or delegated direct report of CEO or CFO certify the AMP and BP submissions seems unnecessary and burdensome to manufacturers. We note that there are already a number of significant legal disincentives to a manufacturer in connection with reporting inaccurate numbers, including civil monetary penalties and various state and federal prohibitions against false claims. As a practical matter, it may be difficult to obtain a signature from such senior executives on a routine basis every month, due to travel schedules. Moreover, such individuals are not necessarily in the best position organizationally to verify the accuracy of the reporting to CMS. Therefore, we respectfully request that CMS reconsider requiring such certification.
- b. In the event that CMS keeps the certification requirement, we note that the references in the Proposed Rule to the CEO, CFO or delegated direct report of CEO or CFO may not fit the organizational structure of all manufacturers. The titles "CEO" and "CFO" are organization-specific, and we note that Daiichi Sankyo, Inc. has neither (rather, we have a President and a Vice President of Finance). We recommend that CMS clarify that the certification may come from an individual within the organization with authority and accountability equivalent to an individual holding such a title.

G. Other Comments

1. We note that there is a strong potential for duplicate discounting by manufacturers in connection with physician-administered drugs that are paid as primary under Medicare and secondary under Medicaid. In some cases, this could result in a manufacturer being required to rebate more than

100% of the WAC of a product on a single claim. We respectfully request that CMS use this rulemaking as an opportunity to clarify that when a state Medicaid program pays on a drug claim in the capacity of a secondary payor, such Medicaid program should not be entitled to a full rebate on the associated unit. We do not believe that it was the intent of the Medicaid Drug Rebate Statute to permit states to claim rebates that are disproportionate to the reimbursement payments made by the states on the drugs.

2. How should manufacturers handle the Health Resources and Services Administration Office of Pharmacy Affairs' ("OPA's") request for a separate AMP calculation (reduced by prompt pay discounts)? How would the OPA AMP number be reported to CMS (if OPA's request stands) so that CMS can use this AMP for their reporting obligations to OPA? This requirement may be burdensome for both manufacturers and for CMS.
3. What is the process for manufactures to dispute a monthly AMP published on the CMS website if they believe it to be incorrect?
4. Will manufacturers be permitted or required to restate their AMP back through 1Q2007 after the AMP rules become final? We respectfully request that CMS clarify that any final rule applies prospectively only. In this regard, we further request that CMS permit manufacturers at least six months from the publication of the final rule to be in compliance with any requirements that are not statutory requirements under the Deficit Reduction Act of 2005.

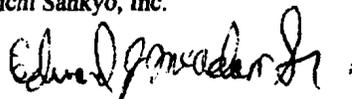
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Leslie Norwalk
February 20, 2007
Page 11 of 11

Please feel free to contact us if you have any questions or require further information in this regard.

Sincerely,

Daiichi Sankyo, Inc.

By: 
Edward J. McAdam Sr.
Director Contract Administration
973-630-2682

CMS-2238-P-1270

Submitter : Mark Kinney
Organization : Independnet Pharmacy Cooperative
Category : Health Care Provider/Association

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Sending a second time since I did not receive a confirmation of receipt.

CMS-2238-P-1270-Attach-1.RTF

February 19, 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

CMS file code: CMS – 2238 – P

Federal Register
Publication Date: December 22, 2006

Re: Prescription Drugs

Dear Acting Administrator Norwalk:

Thank you for the opportunity to comment on the proposed regulations governing the definition of retail class of trade and determination of AMP. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 3200 independent community pharmacies across the country.

The Reason for Ensuring that AMP be an Accurate Reflection of Retail Pharmacy Acquisition Cost

The Average Manufacturers Price (AMP) and the resulting Federal Upper Limit (FUL) impacts not only government Medicaid programs, but now has the far reaching effect of substantially impacting the entire private marketplace as well. Therefore it is essential that the FUL represents an accurate determination of pharmacy's actual acquisition cost. Former CMS administrator McClellan already backed away from posting incorrect AMP data, stating, "They just aren't the right numbers to use... We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement."

1. Rationale Against CMS Redefining Average Manufacturer Price to Lowest Manufacturer Price

In light of a recent Government Accountability Office (GAO) report (*GAO-07-239 Medicaid Federal Upper Limits, December 22, 2006, hereinafter "GAO report"*), it appears that CMS' initial determination at a proper FUL, based on its newly proposed definition of AMP, falls significantly short of an accurate mark. In that report, dated December 22, 2006 the GAO issued a strong rebuttal to CMS's contention that retail pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure.

The GAO report found that on average, FUL, defined as a ceiling of 250% of the proposed lowest AMP for the drug, was still on average 36% below the acquisition cost to pharmacies. CMS notes that rebates were not included in the GAO analysis. However, where independent pharmacies do receive rebates, the amount would not off set this significant short fall.

Most importantly, the issue of generic drug availability makes the CMS defined Lowest Manufacturers Price unworkable. As smaller generic manufacturers seek to capture market share (many from outside the United States, i.e., India) they would be willing to enter the market with a discounted price of 20-30% in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity.** These small generic manufacturers, (and the larger manufacturers as well) do not have the capacity to provide more than just a percentage of the Medicaid population's utilization. This effectively would require many pharmacies to acquire the product at a cost that is significantly higher than the LMP. To mitigate this outcome is the reason the statute defines manufacturer's price as the average. We would ask CMS to apply the plain meaning of the statute and utilize Average Manufacturer Price in their calculation.

It is also foreseeable that this process will stimulate more frequent generic conversions. The multiplicity of dosage shapes and sizes used for a single patient may contribute to a higher potential for medication misadventures, reduced patient confidence and compliance.

2. Retail Pharmacy Class of Trade Definition

IPC requests that CMS change its proposed definition of "retail pharmacy class of trade", proposed 42 CFR Sec. 447.504(e) at p. 130 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, and traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy. This definition currently encompasses over 55,000 retail pharmacy locations.

In passing the DRA, Congress also gave CMS the authority to create a workable definition of AMP.

IPC requests that CMS adjust its proposed definition of AMP, 44 CFR Sec. 447.504 (a) as follows:

(a) AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the federal Food, Drug, and Cosmetic Act) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include retail pharmacy sales only (chain and independent); volume discounts related to retail pharmacies; AMPs for authorized generics; charge-backs to the extent paid to retail pharmacies; contingent free goods; and only adjustments that reduce the actual price paid by retail pharmacy.

IPC recommends that the following elements, which retail community pharmacy does not receive, be excluded from the calculation of AMP:

- Discounts, rebates and price concessions to PBMs/Mail Order
- State supplemental, state only and SPAP prices
- FFS/depot
- Non-contingent free goods
- Price adjustments that do not affect the actual price paid by retail pharmacy

3. The Rational Against Inclusion of PBM Price Concessions and Mail Order Rebates in the Definition of "Retail Class of Trade"

The Omnibus Reconciliation Act of 1990 through amended Section 1927 of the Social Security Act (the Act), created the Medicaid Drug Rebate Program. The rebate legislation became effective on January 1, 1991. **CMS has indicated that the program affords state Medicaid programs the opportunity to pay for drugs at discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.** The rebate agreement attaches to sole-source drugs (new, under patent with no generic equivalents); and innovator multiple-source drugs (drugs that have new-drug FDA approval for which generic equivalents exist). **The rebate also includes non-innovator multiple-source generic drugs at 11%.** The purpose of the rebate for both brand name and generic medications is, and has been since its inception in 1991, to ensure that the government is buying in the marketplace like other large private purchasers. The proposed rule would result in the government "double dipping" by realizing the cost benefit on the front-end reimbursement to pharmacies and the back-end manufacturer rebate.

The PBM/mail order pharmacy business model today is so closely interrelated that the ability to distinguish between price concessions, discounts, rebates and fees of the two entities would likely be impossible.

Mail order pharmacies are frequently owned and/or operated in the HMO and "closed model" systems that are not available to the general public.

In addition, due to the transient nature of the Medicaid population, the mail order pharmacy model has not been found to drive savings and therefore has not been adopted by almost the entirety of state Medicaid programs. Since mail order pharmacies do not service this population, they should not be included in the definition of "retail class of trade".

IPC would recommend that PBM/Mail Order price concessions, discounts, rebates and fees not be included in the "retail class of trade" definition.

4. CMS is Setting an Unrealistic Threshold for Outlier Prices in the FUL Calculation

CMS proposes to set the FUL based on the lowest AMP, as long as that AMP is not more than 70 percent below the second lowest AMP for that drug.

It is particularly harmful to set an outlier exclusion at an AMP that is so much less (70%) than the next lowest AMP. A reasonable outlier exclusion would be no more than 20%.

5. According to the CBO, CMS's Costs Savings Assume that States will Increase Dispensing Fees. If the States do not do so, then Pharmacy Reimbursements will be so Inadequate that Most Pharmacies will not be able to Participate in the Medicaid Program.

From Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932 Deficit Reduction Act of 2005 Conference agreement, as amended and passed by the Senate on December 21, 2005:

Based on administrative data on AMPs and prescription drug spending by Medicaid, CBO estimates that those provisions would reduce Medicaid spending by \$3.6 billion over the 2006-2010 period and \$11.8 billion over the 2006-2015 period. **Those savings reflect CBO's expectation that states will raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.** The estimate also accounts for lower rebates from drug manufacturers resulting from increased use of cheaper generic drugs.

CBO does not reveal to what degree it “expects” states to raise dispensing fees when it calculates its numbers. A study recently completed by one of the four largest world-wide accounting firms, Grant Thornton, has found that the average cost to dispense in the nation was \$10.50. As the current average dispensing fee among the states is only \$4.50, states will be highly challenged to provide an adequate reimbursement to pharmacies, consistent with the documented cost.

6. Definition of “Dispensing Fee” needs to be Inclusive of the True Costs to Pharmacists/Pharmacies to Dispense Medicaid Drugs.

An adequate Dispensing Fee definition includes the true costs of: 1) valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling: communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and 2) other real costs such as rent, utilities and mortgage payments. Perhaps most importantly, pharmacies provide important health, safety and counseling services 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 outcome for the patient.

IPC accordingly recommends that the dispensing fee definition section of the final rule be written as follows:

42 CFR Sec. 447.502 Definitions.

Dispensing fee means the fee which:

Includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient.

Pharmacy costs include, but are not limited to any reasonable costs associated with:

Staffing costs: (a) salaries for pharmacists and technicians, and compensation to other employees such as managers and cashiers; (b) Licensure/continuing education for pharmacists and technicians.

Store operations and overhead: (a) rent or mortgage; (b) Cleaning, repairs, and security; (c) Utilities; (d) Computer systems, software, and maintenance; (e) Marketing and advertising; (f) Accounting, legal and professional fees; (g) Insurance, taxes, and licenses; (h) Interest paid on pharmacy-related debt; (i) Depreciation; (j) Complying with federal and state regulations; and (k) Corporate overhead.

Preparing and dispensing prescriptions: (a) prescription dispensing materials (packages, labels, pill counters, etc.); (b) compounding the Rx when necessary; (c) special packaging (unit dose, blister packs, bingo cards) and special supplies (syringes, inhalers).

Assuring appropriate use of medication: (a) drug use review; (b) consumer/patient counseling; (c) consulting with prescribers, (d) disease management, and (e) education/training.

Adjustment for medical inflation.

A reasonable profit margin to ensure business viability.

7. IPC Supports the use of NDC 11-Digit Codes for Reimbursement Purposes

CMS states that the National Drug Code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For the purpose of this subpart, it would mean the 11-digit code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code) (p. 19). Identifying package size for reimbursement purposes should lead to a more accurate measurement of acquisition costs – i.e. the cost to pharmacy to purchase the medications.

Pharmacies already maximize product buying decisions. For example, an independent pharmacy would like to buy drugs in 1000-count package sizes in order to take advantage of the economies of scale that exist with the larger package size. However, that medication may be used infrequently. A pharmacist that bought the 1000-count size for such a medication might have to destroy significant amounts of unsold medications. In these situations, switching to an 11-digit NDC would fairly reflect the efficient purchasing of pharmacies.

8. IPC Advocates “Smoothing” of AMP Data

There are frequent, sudden changes in drug prices that are not accurately captured by the currently contemplated reporting period. Indeed, prices change on a daily basis, reflecting market place availability and the number of manufacturers supplying the product in question.

Under monthly pricing, manufacturers 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. Invoicing to community pharmacy, however, continues to change daily.

Since frequent changes in drug prices and corresponding changes in AMP could negatively impact community pharmacists. Purchase prices could turn out to be significantly higher than reimbursements that are received after purchase and filling of the prescription. To lessen this unfair outcome, “smoothing” of AMP data is necessary because failure to average out AMP pricing could result in significant fluctuations from month to month. IPC recommends that CMS develop a “smoothing” process for AMP.

Respectfully,

Mark Kinney, R.Ph.
Vice President of Government Affairs
Independent Pharmacy Cooperative

Submitter : Dr. JEFF ANDERSON

Date: 02/20/2007

Organization : ANDERSON DRUGS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-1271-Attach-1.DOC

February 20, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Anderson Drugs a community retail pharmacy located at 725 Tennessee Ave. in Etowah, Tennessee. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy, where 90% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Jeff Anderson
258 County Road 876
Englewood, TN 37329

cc: Senator Lamar Alexander
Senator Bob Corker
Rep. John Duncan

Submitter :

Date: 02/20/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1273-Attach-1.DOC

February 15, 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

1. You have the comments and suggestions filed by the National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) regarding this proposed regulation. We agree with and support the positions represented by NCPA and NACDS.
2. Generic medications average roughly 1/6th of the brand name cost. AMP as currently defined means that pharmacies are much better off dispensing brand name medications rather than losing money on generics. Instead of saving, there is a great chance of spending more. What a waste of tax payer dollars, when governmental policy is only focused on an aspect of cost savings that will ultimately cost more money in total.
3. Can CMS really ignore the report of the General Accounting Office (GAO) and proceed with releasing of AMP as currently defined?
4. The very existence of community pharmacy is at stake by the Federal Government setting such an irresponsible and inaccurate benchmark for community pharmacy cost of goods such as AMP currently is defined
5. The level of customer service and within rural and urban communities is seriously threatened when the AMP being used does not even cover wholesale cost of medication, let alone the cost of filling a prescription.

Please do the right thing for Medicaid Patients to be able to continue to get the medication they need.

Please do the right thing when spending tax payer dollars.

Please do the right thing for community pharmacy.

Sincerely,

Eric L. Graf, M.S., R.Ph.
President & Chief Executive Officer
Ritzman Pharmacies, Inc.

Submitter : Mr. donald haynes
Organization : Don's Pharmacy, Inc.
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

definition of "retail class of trade" - removal of pbm and mail order pharmacies...excluding PBMs and mail order pharmacies recognizes that these are NOT community pharmacies where the heart of the common people go to fill their prescriptions because of trust and face to face relationship comfort. This would be eradicated to the point that the "local pharmacy" would be out of business..The more extensive comments submitted by the Mississippi Independent Pharmacy Assn. has addressed diferentiation, consistency with federal policy, and the benefits of excluding these data elements..This is in regard to DEFINITION OF RETAIL CLASS OF TRADE.. Next is the CALCULATION OF AMP- REMOVAL OF REBATES, CONSESSIONS TO PBMs AND MAIL ORDER PHARMACIES..AMP should reflect prices paid by retail pharmacies..To include these elements is counter to congressional intent.. Next(3) is REMOVAL OF MEDICAID DATA..Including these data elements "bootstrapping" the AMP calculation and does not recognize the Medicaid pricing is heavily regulated by the state and federal governments.. Next(4) is MANUFACTURER DATA REPORTING FOR PRICE DETERMINATION--Address market lag and potential for MANIPULATION...The actual implementation of the AMP could create an avenue for market manipulation. The risk of both price fluctuation and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns the M.I.P.A. proposes a "trigger" mechanism whereby severe price fluctuations are promptly addressed by CMS...Next(5) is USE OF 11 DIGIT VS. 9 DIGIT NDC..We believe that CMS should use the 11 digit 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 size disp. by retail pharmacies..Current regulations specify that the FUL should be set on pkg size of 100 tablets or capsules (most commonly used in retail settings). These entities can only be captured if the 11 digit pkg size is used.. In conclusion, I support the more extensive comments that are being filled by the Mississippi Independent Pharmacy Association regarding this proposed regulation.. I appreciate your consideration of these comments...

Submitter : Mel Brodsky
Organization : Keystone Pharmacy Purchasing Alliance, Inc.
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

See Attached

Collection of Information Requirements

Collection of Information Requirements

See Attached

GENERAL

GENERAL

See Attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attached

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attached

Response to Comments

Response to Comments

See Attached

CMS-2238-P-1266-Attach-1.DOC

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-2238-P
PO Box 8015
Baltimore, MD 21244-8015

Dear Acting Administrator Norwalk:

I thank you for the opportunity to comment on the proposed rule changes that will implement the Medicaid provisions of the Deficit Reduction Act of 2005 (DRA).

It appears that many parts of this proposed rule were written without an understanding of the pharmacy community and its day-to-day operations. The impact of the proposed rule will determine whether Medicaid patients continue to receive counseling and Medicaid drugs from their community pharmacies. In addition, CMS should reconsider the GAO report, *“Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States”* (GAO-05-102), dated February 2005

In CMS press releases throughout the implementation of Medicare Part D, Dr. McClellan personally praised the “heroic” efforts of Community Pharmacy (Chain Store & Independent) for the help they provided seniors during the implementation period. Due to those efforts, millions of seniors have better access to their pharmaceutical needs and billions of dollars have already been saved by the Federal Government. After spending countless hours explaining and helping seniors to choose their Part D plans, waiting months for reimbursements, and continuing to receive lower reimbursement amounts, bleeding \$8.4 Billion additional dollars from Community Pharmacy may break the backbone of our prescription care system.

Here are two overall comments regarding the proposed rule:

1) Need more frequent price updates

The reimbursement cuts come entirely from multiple source drugs (generics), whose prices fluctuate on a daily basis due to market place availability and the number of manufacturers supplying the product. Updating pricing monthly, with a 30 day window for the manufactures to supply pricing data means that pricing will lag as much as 60 days behind the market place.

2) AMP definition includes price concessions not available to community pharmacy

Everyone agrees that Average Wholesale Price (AWP) is no longer an accurate basis for pricing, however, Average Manufacturer’s Price (AMP) is hardly an accurate replacement. The primary flaw I see in your calculation for determining Federal Upper Limit (FUL) using AMP is that distribution costs added to this price by Wholesalers & Distributors is not considered in your formula. While CMS may feel that this is a minimal mark-up (as with Brand Name Products), in reality this figure ranges from a low of 15% to a high of about 35%.

Independents purchase 95% of their generics through Wholesalers & Distributors. Chain stores purchase fewer generics through Wholesalers & Distributors, but their net price (after direct purchase from manufacturers and handling warehousing and distribution internally) is similar to independent pharmacy’s invoice pricing. Wholesalers in the United States enable timely delivery of prescription care and are very important in the day-to-day pharmacy operation.

In light of their contribution of prescription care, I urge CMS to consider the addition of wholesaler markups into the computation of the FUL.

In response to CMS's specific requests for comments:

Including mail-order pricing into the pricing formula to calculate FUL's –

The fact that manufacturers have instituted different prices for different categories is discriminatory. This issue has been litigated in Federal Court for the past 11 years. The inclusion of mail-order pricing in the formula seriously disadvantages brick and mortar retail pharmacy. The Federal Government should mandate a "One Price Policy" by all manufacturers to all categories, thereby lowering the price to the consumer, leveling the playing field and ending discriminatory pricing. It seems to work in Europe and Canada – but influential lobbying interests have spent millions to prevent this from occurring in the United States.

At a minimum, CMS should create a Retail Average Manufacturers Price (RAMP) and a Mail-Order Average Manufacturers Price (MAMP) for reimbursement to these two entities.

Including rebates to PBM's in the calculation of AMP –

CMS states in the proposed rule that it has no way of knowing what portion of these rebates are passed onto Community Pharmacy or the consumer. I want to be completely clear on this point: ***NONE OF THESE DOLLARS ARE PASSED ONTO COMMUNITY PHARMACY OR THE CONSUMER.*** The present day PBM's (which are no longer just an administrator) are big businesses and their astronomical profits are to the point where they are unconscionably increasing the costs of health care. I include an article in the December 29, 2006 issue of the Wall Street Journal for your reference. Additionally, there are frequent newspaper reports on the "settlements" made by PBM's to the States, HMO's, etc for various legal infractions. For your reference, I have attached a review of PBM litigation [the Balto piece or my summary of the Balto piece broken down into pending and settled litigation].

The proposed rule will discourage the generic dispensing

Over the past few years, generic utilization has greatly increased, thus saving the government billions of dollars. This utilization has increased from about 30% of all drugs ten years ago to approximately 55% now. Cutting reimbursement for generics will reverse this increase in utilization very quickly and more than offset any estimated savings.

PBMs use the "charge-back" system to unfairly increase profits

Many PBMs own their own Mail-Order houses, and mail order is done almost exclusively through these PBM-run entities. PBMs mandate the use of the mail-order by consumers through unfair business practices (co-pay differentials) and take advantage of their mail-order category to obtain discriminatory pricing -- which they do not pass on to consumer or the end payor. They do not actually act as a wholesaler, but use the "charge-back system" developed by the wholesalers and manufacturers to greatly increase their profits. They also spend millions of dollars fighting "transparency" lawsuits throughout the country, rather than allowing anyone the ability to see "the money trail."

Allowing each State to set Professional Fees

Many cost surveys over the past few years show that the actual costs by the pharmacy community to dispense a prescription are approximately \$9.50. One widely cited study – done by the University of Texas – estimates the dispensing cost at \$9.62 per prescription. There is no

reason to think that the States will enact a reimbursement formula that covers these costs directly.

This would be an excellent opportunity for CMS to mandate a \$10.00 professional fee for brand products and a \$15.00 professional fee for generics. This would assure that generic utilization increases and patient access to prescription care would not be seriously affected. [Also, states should be encouraged to use Wholesale Acquisition Cost (WAC), which provides an accurate measure of pharmacy's acquisition cost, is published by the pricing guides, and is publicly available. Of course, adequate professional fees must also be included in the formula.]

Items Included in AMP Calculation

CMS proposes to exclude rebates to Medicaid, DoD, HIS, and DVA because prices to these entities are not available to the retail pharmacy class of trade. To be consistent in that reasoning, however, rebates offered to SCHIP, Medicare Part D Plans, PBMs and SPAP Plans should also be excluded as they are also not available to the retail pharmacy class of trade. I would respectfully ask CMS to revisit its assumptions in this portion of the proposed rule.

Initiation of the Definition of Fair Market Value

In this section, CMS discusses Medicare Part B initiating a Fair Market Value for their limited number of drugs and whether this method should be instituted for this rule. My response is that in many cases Part B drugs can not be bought by the pharmacy community at the prices set. Initiating this method would make chain pharmacy stores into variety stores and independent pharmacy would cease to exist. Access to prescription drugs would decrease and hospital emergency rooms would become understaffed clinics. This approach does not make sense.

Pricing for new generic Products entering the Market-Place:

When a brand name product nears the end of its patent, the manufacturer works out a deal with one generic manufacturer to have exclusive rights for a period of about 6 months. In many cases, the brand manufacturer has an equity ownership in the generic manufacturer or the brand name manufacturer shares in the profits during this period through a licensing agreement. Invoice pricing does not fall by any more than 20 – 25% below the branded product during this period. Therefore, an FUL price should not be permitted until at least 2, or preferably 3 manufacturers make it available and affect market-place pricing.

Inclusion of Administration Fees or Service Fees paid to Wholesalers, PBMs or HMOs

These fees are not available to the retail pharmacy class of trade and should be excluded from the calculation. They are kept by the above entities and have no effect on invoice pricing to retail pharmacy.

Nominal Pricing

This pricing is also not available to the Retail Pharmacy Trade and should be excluded from any AMP calculation..

Use of 9-digits NDC versus the 11-digits NDC

Every pharmacy's inventory of a product is determined by actual usage of a product. Proper control of inventory is very important to a store's bottom line. As CMS agrees that keeping the 11-digits NDC is no more work than keeping the 9 digits, I would suggest that the

reason to think that the States will enact a reimbursement formula that covers these costs directly.

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the country.

Outlier Price

When a manufacturer stops manufacturing a product, the pricing services do not necessarily remove the product. In fact, many remain for quite some time. There are many instances where many manufacturers decide to stop producing a drug and the price from the remaining manufacturers increase sharply. The proposed rule does not take into account this very common practice. Under the proposed rule, it could take well over 90 days for CMS to "catch up" while stores would lose money filling these prescriptions.

I respectfully submit that CMS must set up a process whereby pharmacies can fill out a form showing that a product is not available from their distributors at the price CMS is paying. This information can be verified quickly and pricing changed in a timely manner. We presently have a successful program in effect in Pennsylvania with most of the Third Party Plans, including Medicaid Programs and Part D Programs, and have had great success.

Savings Estimates developed by the Office of the Actuary in CMS

In this section CMS mentions the impact on just 3 types of small businesses: (1) small pharmaceutical companies participating in the Medicaid Drug Rebate Program, (2) small retail pharmacies & (3) physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician administered drugs. First, it should be noted that the proposed rule will affect all of Pharmacy, including the large Chain Stores, Wholesalers, Distributors, and most importantly will affect patient ACCESS to prescriptions.

According to the Pfizer/NCPA digest for the year 2005, the average sales in an independent pharmacy are over \$3 million a year. Independent pharmacies provide important, personalized counseling services to Medicaid and Medicare patients and are a vital part of their local economies.

In the summary of this section, CMS states that the reimbursement cuts will result in only a 1% decrease in pharmacy revenue. From what I have seen and heard from others with much more information in hand, however, is that AMP pricing will decrease reimbursement by \$3.00 to \$4.00 per prescription which will decrease gross profits by approximately 15 – 20% for an industry that is seeing its profits decreasing yearly. This is a huge negative impact upon community pharmacies. The loss of patient access to medications when more Independents close their doors CANNOT be picked up by the Chains or mail-order who do not offer the personal services provided by Independent Pharmacy (counseling, pick-up & delivery, house charges, third party administrative help, and the knowledge of their patient needs to name just a few). These closures will put patient health in jeopardy. Antibiotics, to state but one example, are a medicine that should and can be accessed immediately from community pharmacies, instead of having to wait for the drugs through mail order.

III. Additional suggestions:

Include the pharmacy profession in your meetings and allow our national groups to sit in and express their feelings at your meetings before CMS decides on a final rule. Include managers of Chain Stores & owners of Independent Stores that "live" the day-to-day operations of a pharmacy.

With Gross Profits so low in this industry, a fair Federally Mandated Professional Fee must be included in your final rulings. Do the calculations on a drug where a 30 day supply may cost 50 cents, \$5, \$10 etc. One price does not fit all prescriptions-- it never did and it never will. At least a Minimum Professional Fee must be mandated that will allow stores some type of return on investment.

Include Wholesaler & Distributors Mark-Ups in your calculations.

Insist that your employees spend a full day in a Pharmacy before they write up rules.

Members of PHRMA are not affected by these rulings while their products still account for **85%** of your drug costs. Have them explain the much lower pricing they offer other countries. Have them explain why they spend more on TV advertising than they do on Research & Development.

A 5% decrease in pricing from PHRMA will save much more than \$8.4 Billion.

III. Summary

Although this proposed rule will have a devastating effect on many independent pharmacies, I do not know how many pharmacists will submit comments to CMS. In many instances, the implementation of Part D forced community pharmacies to close. Medicare Part D has placed such a burden on Pharmacy that only a very few have the time to read over these 150 pages & express their concerns. I hope my comments and suggestions are considered.

I believe CMS should understand that from the perspective of independent pharmacy, it seems that we are the easiest group to attack and extract money from in order to meet budget cut numbers. Federal Antitrust laws prevent us from working together to battle so what can a "small" Independent do to fight back with any success?

I thank you for this opportunity to express my concerns:

Sincerely,

Mel Brodsky R.Ph.

CEO

Keystone Pharmacy Purchasing Alliance, Inc.

7425 Frankford Ave 2nd Floor

Philadelphia, Pa 19136

Submitter : Mr. Nicholas Karalis

Date: 02/20/2007

Organization : Elwyn Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Elwyn Pharmacy is a busy independent pharmacy the services our local community. We have over 40 employees and cater to needy patients. (i.e. elderly, mental health, and mentally handicap.) We provide services not found in the chain and mail order pharmacies. We deliver directly to the patient, we provide 24-hour emergency service, we offer special packaging, refill reminder programs, and we carry all medications including, injectables, specialty, and hard to find items. We carry a full-line of DME and surgical supplies. All these services are provided to all our patients, private-pay, third party, medicare, and medicaid. CMS's cost savings estimates does not consider the negative impact it will cause to these services. The Government Accountability Office (GAO) findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay open and offer these special services while experiencing a 36% loss on each and every transaction. The definition of "dispensing fee" does not reflect the true costs to pharmacists and pharmacies.

Collection of Information Requirements

Collection of Information Requirements

Calculations of AMP for the "Retail Class of Trade" should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants, and supermarket pharmacies. Mail-order is not a retail class, a patient can not go into a mail order pharmacy, nor can they expect same day service, face-face counseling, and interaction with local community people. CMS should also exclude rebates paid to PBMs from AMP calculations, since these rebates are not available nor shared with the Retail Pharmacy Class of Trade.

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GENERAL

CMS will simply make community pharmacies unable to participate in the Medicaid program. We will lose patients, employees, and eventually our business. The hard-working, tax paying voters in our communities will become un-employed and bitter with Congress and this proposed Medicaid Deficit Reduction Act. Patients will lose the right to choose and their freedom of access to medications.

CMS must define AMP correctly to stop these actions:

1. Exclude all rebates and price concessions made by manufacturers which are not available to retail pharmacy.
2. Exclude all mail order facilities and PBM pricing from AMP calculations. The same pricing is not available to retail pharmacies. Unless Congress controls this pricing and makes it equal for everyone, they should not consider it for AMP calculations.
3. Report AMP at the true and correct 11-digit NDC number to ensure accuracy.

These three simple steps will make for a fair AMP calculation, the only other factor will be to truly reimburse pharmacy for their actual dispensing fee.

Please take these points into consideration for this act will have one of the biggest impacts on community pharmacies.

Provisions of the Proposed Regulations

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CMS must have a frequent pricing update model to accurately capture drug price changes. The monthly proposed reporting system is inadequate and unfair if not illegal in its AMP calculation. AMP pricing must be reported on the 11-digit NDC number to ensure accuracy. Since Congress does not mandate the manufacturer to only make one size or price their medications according to unit of unit, it is again unfair to reimburse on a 9-digit NDC number. CMS and Congress has not made any attempts to save money from the Pharmaceutical Manufacturer (like every other country), who happen to have the largest lobbying organization on capitol hill, and who by far is the most profitable entities in healthcare.

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS and Congress has not made any attempts to save money from the Pharmaceutical Manufacturers (like every other country), who happen to have the largest lobbying organization on capitol hill, and who by far are the most profitable entities in the healthcare industry. This action is a clear message that Congress takes care of the contributors. What independent pharmacy, the direct caregivers of our medicaid patients, is asking for is a fair ruling of AMP. When we voted our lawmakers in office, we expect them to do what is right for the people and not their own pockets. As clearly seen in this last election, the people will not stand for dirty politics and unfair policymakers. To propose a Medicaid Deficit Reduction Act that expects the community pharmacies to bear the burden is unrealistic and will cause local business to close, unemployment to increase, and federal and state tax dollars to be lost. At the same time, the manufacturer will continue to enjoy the same high profit margins without any fear of government intervention.

Submitter :

Date: 02/20/2007

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

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See Attachment

CMS-2238-P-1275-Attach-1.DOC

CMS-2238-P-1275-Attach-2.DOC

February 16, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

My name is Rebecca Poedy and I am the President and CEO of Planned Parenthood of Idaho (PPI), a not for profit outpatient healthcare organization with centers in Boise, Twin Falls, and Nampa, Idaho. PPI provides essential family planning and reproductive healthcare services to low income, uninsured and underinsured women, men, and teens. PPI serves over 8,000 patients in our three healthcare clinics by providing comprehensive family planning care to include annual exams, pap tests, breast exams, sexually transmitted infection testing and treatment, pregnancy testing, and birth control supplies.

Many of the patients we serve are uninsured or underinsured and could not afford the healthcare services we provided – particularly oral contraceptives. For over 33 years, Planned Parenthood of Idaho has served an unaided population of Idahoans who cannot normally afford contraception by providing them access to oral contraceptive pills at prices far lower than what is available in Idaho's retail market. PPI has been able to serve this underprivileged community because we have had the ability to purchase oral contraceptive drugs from drug manufacturers willing to provide them at nominal pricing. The very existence and viability of Planned Parenthood of Idaho is based on the ability to purchase oral contraceptives at less than 10% of the average retail price. Without these steeply discounted drugs, we will no longer be able to serve the most at-risk and in need population in Idaho. Idaho has the 37th highest teen pregnancy rate of any state and one out of six live births per day is to a teenager. In Idaho, 22% of women aged 15-44 have no health care coverage and are in need of publicly supported contraceptive services. These patients desperately need access to low cost or free oral contraceptives to prevent unplanned pregnancy – a service we desperately want to continue to provide.

As you know, the proposed rule -- published by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, to implement section 6001(d) of the Deficit Reduction Act of 2005 ("DRA") -- preserves the ability of three kinds of providers (I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated nursing homes) to purchase drugs at best price ineligible nominal prices. Many of Planned Parenthood of Idaho's sister affiliate healthcare centers across the country are receiving Title X funding and therefore are 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. However, Planned Parenthood of Idaho is not state or federally funded. PPI

relies solely on other private foundation grants, individual contributions, and patient services which are offered on a sliding fee scale based on a patient's ability to pay for services. The vast majority of PPI's patients are not, and therefore receive their services at a steeply discounted or free rate. PPI is not a 340B covered entity eligible under the terms of the proposed rule for nominal prices.

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

The dilemma this poses to PPI and other similarly situated not for profit outpatient healthcare clinics across the nation should provide ample evidence to CMS that the other three categories of health services providers are not "sufficiently inclusive" and do not "capture the appropriate safety net providers." It is simply not the case that deserving, non-profit outpatient clinics like PPI are covered by the entities listed in 6001(d), subsections I, II and III. We and many others like us are left on the outside, looking in – which places our most at-risk populations in desperate need of low cost contraceptives at even greater risk.

Moreover, we have been told by several manufacturers who have historically sold to us at nominal prices that we will have to pay full retail pricing for oral contraceptives going forward. This suggests that CMS's belief that inclusion of non-340B safety net providers in the nominal pricing exception will have an adverse effect on best price (and Medicaid rebate revenues) is misplaced. Eliminating PPI and other entities like it from the nominal price exception will not affect best price at all -- the only consequence of this policy will be to preclude manufacturers from charitably helping safety net providers like PPI to serve our patients.

Planned Parenthood of Idaho is a non-profit outpatient healthcare facility that serves a critical function in the health and well being of over 8,000 uninsured and underinsured women, men, and teens in Idaho. PPI is able to provide these services and deeply discounted oral contraceptive medications to these women only because it can purchase oral contraceptives from drug manufacturers at nominal prices, as we have been doing for over 33 years. Carving safety net providers like PPI out of the nominal pricing exception would be devastating to our mission and to our operations -- without nominally priced drugs we will likely have to close our doors. PPI urges CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

Warmest Regards,

Rebecca L. Poedy
President and CEO
Planned Parenthood of Idaho, Inc.

Submitter : Ms. RoseMarie Babbitt
Organization : Parkland Health & Hospital System
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-2238-P-1276-Attach-1.DOC

February 15, 2007

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

To Whom It May Concern:

On behalf of the Parkland Health & Hospital System, I am responding to the request for comments on regulations proposed to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Parkland Health & Hospital System is a 968 bed teaching hospital located in Dallas, Texas, 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 three principal concerns about the regulations are discussed below.

First, the proposed regulations would create undue financial and administrative burdens for our hospital by requiring the institution to report the NDC information for drugs administered in the hospital outpatient settings ("clinics"), for the following reasons:

- a. Hospital electronic billing systems do not presently have the capability to include NDC numbers identifying clinic-administered drugs. It would require a very substantial investment to change the institution's electronic financial systems to allow inclusion of the NDC number and to perpetuate it throughout all the pathways required to achieve the CMS objective. However, every fiscal year CMS and government agencies decrease or discontinue funding for services needed to take care of the under and uninsured patients who depend on our institution
- b. The clinics where the drugs are administered are located some distance from the offices where the UB-92 billings actually take place. There is no simple way to communicate the NDC number of the drugs being administered by the clinic staff, to the billing office.
- c. Frequently, a multi-drug cocktail is administered and this has but one entry on the UB-92. Which NDC should be used?
- d. The UB-92 billing document, mandated by the Federal Government, has no place on it where an NDC can be entered.
- e. Outs, shorts and backorders of medications create frequent multiple NDC's system wide in different pharmacies. This in turn will create a high potential for error in any system creating a compliance nightmare.
- f. The requirement appears pointless since 340B hospital clinic drugs are exempt from rebates (section 1927j (2) of the Medicare statute applies). If no rebates will be obtained, what is the point of all the expense and disruption which will occur in order to achieve no end?

- g. Finally, in reviewing the 15-second CMS estimate to implement these changes, it appears this is a gross under estimation at best. Taking into consideration the many systems currently in place at each institution, clinic and physician office we doubt it can be accomplished in the 15 seconds recommended. Additionally, the complexity of Medicare regulations will cause hospitals to invest significantly in systems to support data requirements. In a hospital outpatient environment, manual solutions lead to greater errors. Any legislation that suggests a manual solution is helping perpetuate problems instead of helping solve them.

Second, these proposals could have a significant, negative impact on 340B hospitals including a potential loss of hundreds of thousands to millions of dollars annually to institutions and health systems. Again, section 1927j (2) of the Medicare Statute indicates that hospital-based clinics are exempt from rebates.

Third, the proposed changes to the rules related to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP") could raise 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 (e.g., Children's Hospitals) eligible for nominal pricing.

We hope the problems mentioned above will cause serious consideration to be given to the proposed regulations published on December 22 and they will be revised in such a manner as to not harm DSH hospitals and not invalidate the intention to assist indigent patients which Congress established when it passed the Veteran's Health Care Act of 1992 which established the 340B program.

Sincerely,

RoseMarie Babbitt, MA, RPh, CHC
Associate Director of Pharmacy Services