

CMS-2238-P-1289

Submitter : Mr. James Quirk  
Organization : Alliance of Dedicated Cancer Centers  
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

Had difficulty with previous attempt to submit (temporary comment number 111763), please see attached pdf comments.

CMS-2238-P-1289-Attach-1.PDF

**The Alliance of Dedicated Cancer Centers:**

**Arthur G. James Cancer Hospital and Richard J. Solove Research Institute  
City of Hope National Medical Center  
Dana-Farber Cancer Institute  
Fox Chase Cancer Center  
H. Lee Moffitt Cancer Center and Research Institute  
M.D. Anderson Cancer Center  
Memorial Sloan-Kettering Cancer Center  
Roswell Park Cancer Institute  
Seattle Cancer Care Alliance  
Sylvester Comprehensive Cancer Center**

February 20, 2007

**BY ELECTRONIC MAIL**

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

**Re: CMS-2238-P; Medicaid Program; Prescription Drugs; Proposed Rule**

Dear Acting Administrator Norwalk:

On behalf of the Alliance of Dedicated Cancer Centers (the "Centers"), an alliance of ten nationally recognized institutions that specialize in providing state-of-the-art cancer care, I am writing to comment on the Centers for Medicare & Medicaid Services' proposed rule (the "Proposed Rule") that implements provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to payment for prescription drugs under the Medicaid Program.<sup>1</sup> Under the DRA, hospitals would be required to provide National Drug Code (NDC) information on a claim submitted to state Medicaid agencies. Specifically, the proposal requires the reporting of an 11-digit unique NDC number for each drug administered to Medicaid patients.

The Centers are very concerned with this proposed requirement because it is operationally untenable given that each HCPCS-coded drug has anywhere from one (although this is quite rare) to hundreds of NDC codes depending on the number of manufacturers producing the drug, the variety of package or vial sizes available, and the way in which the drug is prepared for each patient. In light of the current shortage of qualified pharmacists, this requirement would add

<sup>1</sup> 71 Fed. Reg. 77173 (Dec. 22, 2006).

enormous administrative burdens to pharmacists' already numerous responsibilities.

We fail to understand the rationale behind this administrative requirement given that HCPCS codes were created to identify each drug administered to patients. Taken together with the units of service and the charges reported, CMS has the data it needs to identify the drugs that patients receive. We speculate that CMS may not be fully aware of how hospital pharmacies function in purchasing and preparing drugs. We describe these operational issues below to provide CMS with a better understanding of why this proposed requirement to report NDC codes should be eliminated.

### **1. Operational Challenges**

CMS first proposed to require NDC numbers for each drug as part of the HIPAA transaction set rule, but the concept was ultimately abandoned due to the complexity and operational burden such a requirement would place on hospitals and physician offices. Therefore, the Centers cannot understand why CMS is again proposing to require NDC code reporting. Nor do we understand why CMS is unable to estimate the burden or effect of this change on hospitals or physicians. CMS appears to believe that providers can either manually report NDC codes or implement a one-time information systems fix to accommodate NDC reporting. However, the problem with NDC reporting goes well beyond expanding hospital billing systems to accommodate it. For example, the current UB-92 form (as well as its upcoming successor, the UB-04 form) does not allow for NDC level reporting. Moreover, as illustrated by the following examples, we believe that, by better understanding internal pharmacy operations and work flow, CMS will be able to see why we believe the NDC reporting requirement is not feasible.

HCPCS-coded drugs are available from one to multiple manufacturers, resulting in multiple NDC codes in the case of generic drugs. While most providers aim to purchase drugs from only a few manufacturers, this is not always possible due to distributor availability. In addition, most drugs are available in different package or vial sizes, each with its own NDC code. Therefore, each package or vial of each drug produced by each manufacturer has its own NDC code, resulting in as many as several hundred NDC codes for a particular drug.

To track the exact NDC code for a drug administered to a patient on any given day becomes a virtually impossible task. For example, panitumumab (Vectibix-®) and Oxaliplatin are both new, single-source drugs produced by a single manufacturer, yet the drugs are produced in two or more vial sizes and each vial size of each drug has its own separate and distinct NDC number. In these seemingly, and relative to generic medications, simple examples, the provider still has at least two to three NDC codes to contend with. This situation becomes even more complicated if the provider has to open two different vials to prepare the dose administered to the patient, resulting in a single HCPCS code reported with the appropriate units corresponding to the actual dose administered and two NDC codes.

CMS may believe that its HCPCS to NDC cross-walk can facilitate the reporting of NDC codes. However, this is simply not the case because the cross-walk only identifies the different NDC codes associated with each HCPCS-coded drug but does not inherently provide any

manner in which to report the NDC codes accurately. In fact, the cross-walk helps illustrate the sheer number of NDC codes that are available for each HCPCS-coded drug, which is particularly large in the case of generic drugs.

For example, Table 1 below shows the example of Paclitaxel, the generic equivalent for Taxol, which is currently produced by 7 different manufacturers, available in a variety of formulations or package sizes, each with its own NDC code. This example illustrates that at least 26 different NDC codes are linked to a single HCPCS J-code, J9265. Even more illustrative, Carboplatin is available from 8 manufacturers with 62 formulations. See Table 2.

**Table 1**

HCPCS CODE	SHORT DESCRIPTOR	LABELER NAME	NDC2	DRUG NAME	HCPCS DOSAGE	PKG SIZE
J9265	Paclitaxel injection	BRISTOL-MYERS SQUIBB	00015-3479-11	Taxol	30 MG	50
J9265	Paclitaxel injection	BRISTOL-MYERS SQUIBB	00015-3476-30	Taxol	30 MG	16.7
J9265	Paclitaxel injection	BRISTOL-MYERS SQUIBB	00015-3475-30	Taxol	30 MG	5
J9265	Paclitaxel injection	MAYNE PHARMA	00074-4335-04	Paclitaxel	30 MG	50
J9265	Paclitaxel injection	UDL	51079-0963-01	Paclitaxel	30 MG	50
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0114-50	Paclitaxel	30 MG	50
J9265	Paclitaxel injection	AMERINET CHOICE	55390-0314-50	Paclitaxel	30 MG	50
J9265	Paclitaxel injection	MAYNE PHARMA	61703-0342-50	Paclitaxel	30 MG	50
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0114-20	Paclitaxel	30 MG	16.7
J9265	Paclitaxel injection	AMERINET CHOICE	55390-0314-20	Paclitaxel	30 MG	16.7
J9265	Paclitaxel injection	MAYNE PHARMA	61703-0342-22	Paclitaxel	30 MG	16.7
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0114-05	Paclitaxel	30 MG	5
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0314-05	Paclitaxel	30 MG	5
J9265	Paclitaxel injection	MAYNE PHARMA	61703-0342-09	Paclitaxel	30 MG	5
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0514-20	Paclitaxel	30 MG	1
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0514-50	Paclitaxel	30 MG	1
J9265	Paclitaxel injection	BEDFORD LABORATORIES	55390-0514-05	Paclitaxel	30 MG	1
J9265	Paclitaxel injection	UDL	51079-0962-01	Paclitaxel	30 MG	16.7
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3753-77	Onxol	30 MG	50
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3753-96	Onxol	30 MG	50
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3755-31	Onxol	30 MG	16.7
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3754-73	Onxol	30 MG	5
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3754-94	Onxol	30 MG	5
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3756-95	Onxol	30 MG	25
J9265	Paclitaxel injection	IVAX PHARMACEUTICALS	00172-3756-75	Onxol	30 MG	25

HPCS	SHORT	DESCRIPTION	LABELER NAME	NDC2	DRUG NAME	HPCS	DOSAGE	PK	SIZE
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3216-30	Paraplatin	50 MG	6			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3212-30	Paraplatin	50 MG	4			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3212-76	Paraplatin	50 MG	4			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3211-30	Paraplatin	50 MG	1			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3211-76	Paraplatin	50 MG	1			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3210-30	Paraplatin	50 MG	5			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3210-76	Paraplatin	50 MG	5			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3215-30	Paraplatin	50 MG	1			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3214-30	Paraplatin	50 MG	1			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3213-30	Paraplatin	50 MG	1			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3233-11	Carboplatin	50 MG	60			
J9045	Carboplatin injection	SICOR	00703-3249-11	Carboplatin	50 MG	60			
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0156-01	Carboplatin	50 MG	60			
J9045	Carboplatin injection	Abraxis Pharmaceutical Products	63323-0172-60	Carboplatin	50 MG	60			
J9045	Carboplatin injection	OTN	67817-0067-12	Carboplatin	50 MG	60			
J9045	Carboplatin injection	MAYNE PHARMA	61703-0339-56	Carboplatin	50 MG	60			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3232-11	Carboplatin	50 MG	45			
J9045	Carboplatin injection	SICOR	00703-3248-11	Carboplatin	50 MG	45			
J9045	Carboplatin injection	SICOR	00703-3278-01	Carboplatin	50 MG	45			
J9045	Carboplatin injection	SICOR	00703-4248-01	Carboplatin	50 MG	45			
J9045	Carboplatin injection	BAXTER	10019-0912-03	Carboplatin	50 MG	45			
J9045	Carboplatin injection	PLIVA	50111-0967-76	Carboplatin	50 MG	45			
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0155-01	Carboplatin	50 MG	45			
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0222-01	Carboplatin	50 MG	45			
J9045	Carboplatin injection	MAYNE PHARMA	61703-0339-50	Carboplatin	50 MG	45			
J9045	Carboplatin injection	AMERICAN PHARMACEUTICAL PARTNERS	63323-0169-45	Carboplatin	50 MG	45			
J9045	Carboplatin injection	Abraxis Pharmaceutical Products	63323-0172-45	Carboplatin	50 MG	45			
J9045	Carboplatin injection	OTN	67817-0066-12	Carboplatin	50 MG	45			
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3231-11	Carboplatin	50 MG	15			
J9045	Carboplatin injection	SICOR	00703-3246-11	Carboplatin	50 MG	15			
J9045	Carboplatin injection	SICOR	00703-4246-01	Carboplatin	50 MG	15			
J9045	Carboplatin injection	BAXTER	10019-0912-02	Carboplatin	50 MG	15			
J9045	Carboplatin injection	PLIVA	50111-0966-76	Carboplatin	50 MG	15			
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0154-01	Carboplatin	50 MG	15			
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0221-01	Carboplatin	50 MG	15			
J9045	Carboplatin injection	MAYNE PHARMA	61703-0339-22	Carboplatin	50 MG	15			
J9045	Carboplatin injection	AMERICAN PHARMACEUTICAL PARTNERS	63323-0169-15	Carboplatin	50 MG	15			
J9045	Carboplatin injection	OTN	67817-0063-12	Carboplatin	50 MG	15			
J9045	Carboplatin injection	AMERICAN	63323-0167-20	Carboplatin	50 MG	10			

Table 2

HCPCS CODE	SHORT DESCRIPTOR	LABELER NAME	NDC2	DRUG NAME	HCPCS DOSAGE	PK SIZE
		PHARMACEUTICAL PARTNERS				
J9045	Carboplatin injection	BRISTOL-MYERS SQUIBB	00015-3230-11	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-3244-11	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-4244-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BAXTER	10019-0912-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	PLIVA	50111-0965-76	Carboplatin	50 MG	1
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0153-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0220-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	MAYNE PHARMA	61703-0339-18	Carboplatin	50 MG	1
J9045	Carboplatin injection	AMERICAN PHARMACEUTICAL PARTNERS	63323-0169-05	Carboplatin	50 MG	1
J9045	Carboplatin injection	OTN	67817-0061-12	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-3265-71	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-3268-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-3268-71	Carboplatin	50 MG	1
J9045	Carboplatin injection	BAXTER	10019-0917-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0152-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	AMERICAN PHARMACEUTICAL PARTNERS	63323-0168-00	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-3266-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BAXTER	10019-0916-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0151-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	AMERICAN PHARMACEUTICAL PARTNERS	63323-0167-21	Carboplatin	50 MG	1
J9045	Carboplatin injection	SICOR	00703-3264-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BAXTER	10019-0915-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	BEDFORD LABORATORIES	55390-0150-01	Carboplatin	50 MG	1
J9045	Carboplatin injection	AMERICAN PHARMACEUTICAL PARTNERS	63323-0166-10	Carboplatin	50 MG	1

Other relevant examples include:

- *Cefazolin* (also known as Ancef) – a widely-used antibiotic that is available from 10 manufacturers and 29 NDC numbers.
- *Ondansetron* (also known as Zofran) – a medication used for treating a number of symptoms, including nausea and vomiting resulting from chemotherapy and/or surgery. This medication is vital to cancer patients and is often used multiple times per day. Even though this drug only became generic in December 2006, it is already available from 9 manufacturers producing 55 different NDC numbers.

- *Ciprofloxacin* (also known as Cipro) – another widely-used antibiotic that is available from 19 manufacturers with 87 NDC numbers.
- *Fluconazole* – a widely used antifungal medication with oral and intravenous dose forms. This medication is available from 12 manufacturers with 93 different NDC numbers.
- *Ranitidine* (also known as Zantac) – a widely-used medication for gastrointestinal symptoms with both oral and intravenous formulations. This medication is available from 15 manufacturers with 99 NDC numbers.

The combination of manufacturers and drug packages/vial sizes available can result in large numbers of NDC codes. This is further exacerbated by the fact that hospitals may have to use multiple smaller package sizes or vials to prepare the appropriate drug doses for the patient, and to decrease waste.

For example, if a patient requires a 700 mg dose of a particular drug, the pharmacy may prepare that dose by combining one 500 mg and two 100 mg vials. If these are produced by the same manufacturer, then the hospital would report two NDC codes, but if the 100 mg vials were produced by two different manufacturers, then the hospital could have up to three NDC codes to report. Or, if the hospital used seven 100 mg vials, each from a different manufacturer, there could be up to seven different NDC codes reported. In addition, for certain drugs that are in short supply, if administered multiple times per day over multiple days, a hospital may have to borrow the drug supply of another hospital and the NDC numbers relevant on one day may not be the same as on another day. For example, the morning dose on one day may come from a different manufacturer than an evening dose administered the night before. Requiring hospital pharmacists to keep track of NDC numbers at this level at the point of drug preparation and dispensing is nearly impossible. Even if pharmacists were available to report each NDC, the hospital would still need to implement mechanisms by which the single HCPCS code and the multiple NDC codes flow to the final claim form. With existing billing systems, this is just not possible.

From the above example, it should be clear that the number of NDC codes used by our institutions goes well beyond the number of manufacturers and package sizes available and can be exponentially problematic given the existing nationwide shortage of certain drugs as well as the attention hospitals place on minimizing drug waste, often resulting in the use of multiple smaller package sizes of a given drug to prepare the correct dosage for each patient.

The reality is that hospital pharmacy formularies (i.e., the approved list of medications by drug molecule, and not by brand or NDC number) contain thousands of medications, and hospital pharmacies stock tablets, capsules, injectable drugs and other formulations that could translate into several thousand NDC codes. For example, one of our member Centers currently has 3400 individual drugs in its formulary database, resulting in thousands of NDC codes. Thus, the sheer number of NDC codes in our formularies makes complying with CMS's proposed requirement of reporting an NDC code for each drug administered virtually impossible.

## 2. Impact on Claims Submission

In the Proposed Rule, CMS states that, "we believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change."<sup>2</sup> CMS goes on to state that the change could be done either manually or through a one-time systems change. The Centers disagree with this assertion as it is simply not possible for hospitals to report NDC codes for drugs, given the billing information systems that are currently in place at hospitals.

Automating this process would require the implementation of bar-coding in a manner that simply does not exist in hospitals today so that each drug pulled from a pharmacy storage bin (such as ibuprofen) or prepared by a pharmacy technician in a chemo or IV hood, for each and every dose, and then administered to a patient is recorded in a manner that reflects what the patient actually receives during the encounter. This is enormously difficult given the existing information systems capability in hospitals today where the pharmacy computer system is different from the hospital's billing system.

To help CMS better understand this, we describe the following work flow. A physician orders a drug. The drug order (generally on paper) is received by the pharmacist who checks the order (clarifying and/or correcting it with the physician as necessary) and then enters the information into the pharmacy computer system. This system generates a label, or multiple labels, which pharmacy technicians receive in order to prepare the drugs/doses. Pharmacy technicians begin preparing the drug by pulling whatever is currently in stock by looking at the storage bins which are simply labeled with the drug name and the vial size, not the NDC number. This means that a single dose of a drug may be prepared from any one of various manufacturers and vial sizes, or multiple vial sizes made by one or more manufacturers (depending on the size of the dose) may be needed. This information would need to be bar coded in order to track what was used to prepare the order. If the order for a particular patient requires multiple doses (e.g., every six hours, every eight hours, etc.) for administration during a single patient encounter or hospitalization, then the situation becomes even more complicated as the pharmacy technician will prepare all of the doses (made up of one or more NDCs) for each 24 hour period and will deliver them to the nursing station. These medication doses will be stored by patient name and drug name/dose, not by NDC numbers. The nurse will administer the doses as ordered but the order in which the doses are administered does not matter from a clinical perspective as the same drug and same dose is being administered multiple times, even though each dose could have a different NDC number. It is not clinically relevant to the physician, nurse, pharmacist *or patient* which NDC number dose is given when, since all of the doses (although from different manufacturers) are made per FDA requirements and are therapeutically equivalent.

Without bar coding at the patient's bedside, the medication administration record nursing computer screen (or paper documentation) may indicate that pharmacy has the drug available from four different manufacturers, and nursing will need to select the same one as what the technician selected but to ask the busy bedside nurse to look for patient name, drug name, drug dose *and* an 11-digit NDC number and document medication administration based on the NDC number is extraordinarily burdensome to nursing staff and completely unrealistic. Moreover, if the pharmacy technician and pharmacist prepared the dose from multiple vials from one or more

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<sup>2</sup> *Id.* at 77193.

manufacturers, nursing staff will not have any way to know what to select and will essentially be forced to just pick one of the four available choices. Also, without bar coding, the NDC code(s) registered in the pharmacy system cannot match what crosses to the billing system in a dose by dose manner. To correct this mismatch will require a manual override of the system and clarification notes, which can occur thousands of times a day. Moreover, the aggregate impact of lost time away from patient care functions for nurses, pharmacists and pharmacy technicians just to accurately track a clinically meaningless data element (the NDC number specific to the vial size, etc.) is unquantifiable, but staggeringly high. Given the nationwide shortages of nurses and pharmacists that are well documented by government agencies, the impact on patient care would be extremely burdensome.

Thus, the proposed NDC requirement would add *enormous* staffing and administrative cost to our current processes that are already stressed with existing coding, billing, and reporting requirements. Simply put, the level of bar coding required to meet CMS's requirement for NDC reporting is years beyond what is currently practical given existing systems in place in hospitals today.

### **3. Reduced Incentives to Lower Costs**

Most hospital personnel who are responsible for purchasing drugs attempt to obtain the best price they can for a given drug. As a result, they place their orders with a wide number of manufacturers to keep costs down (based on best pricing at the time the order is made). If hospitals were required to report NDC codes and comply with accurate reporting, there would be an incentive to use a single vendor. While this would reduce the significant variation in NDC numbers, it would also reduce the incentive to use multiple vendors to achieve cost savings.

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Based on our extensive experience providing high quality cancer care, this requirement in the Proposed Rule will place a grave and significant administrative burden on hospitals and pharmacy departments. Therefore, the Centers urge CMS not to implement such an onerous change without further, specific efforts to accurately gauge the administrative cost and operational burden of doing so.

The Centers appreciate the opportunity to comment on this Proposed Rule. Thank you for your willingness to consider our views. We hope that CMS will consider the concerns and recommendations described above as it prepares the Final Rule. If you have any questions or require additional information, please contact the Alliance's consultant on these matters, Jugna Shah of Nimitt Consulting, at 215.888.6037.

Sincerely,  
/s  
James S. Quirk  
Executive Director  
Alliance of Dedicated Cancer Centers

**Submitter :** Mrs. Megan Jolley Milne  
**Organization :** National Community Pharmacists Association  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**Background**

**Background**

As a student at the University of Utah College of Pharmacy and a pharmacy health care professional, I have an interest in the proposed changes to Medicaid reimbursement rates in the form of AMP. My concerns are in line with the opinions of the National Community Pharmacist Association (NCPA), the American Pharmacist Association (APhA), and the Utah Pharmacists Association (UPhA). UPhA is a state pharmacy organization that represents over 450 Chain and independent retail pharmacies in the state of Utah. These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBMs, regional and national health plans, and various governmental organizations.

In the meeting with Dennis Smith of CMS on February 1, 2007, he requested information and documentation of how the proposed definition of AMP will affect pharmacies in Utah. We are providing that information in the form of this letter, a petition from the students of the University of Utah College of Pharmacy, and multiple other letters from pharmacists in Utah, delineating the impact of reimbursements to our pharmacies according to the Government Accounting Office's study. One pharmacist owner calculated that if he loses an average of 36% from his cost of the drug per generic prescription that falls under FUL, his two pharmacies in rural Utah will lose \$116,667 in total profit per year. That is more than most pharmacy owners pay themselves! Pharmacies cannot be expected to operate at a loss.

Therefore, we ask you to please review our comments about the proposed enactment of the Deficit Reduction Act with the current definition of AMP. Please follow these suggestions:

**Collection of Information Requirements**

**Collection of Information Requirements**

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

PBM Transparency is Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, neither at the federal nor state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. PBMs have been allowed, due to a lack of regulation, to keep most, if not all, of their information hidden; thus there is no transparency in the PBM Industry.

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

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

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

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

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-digit NDC would NOT adequately cover pharmacy acquisition cost. The 11-digit NDC must be used when calculating the FUL.

**Financial Impact on Pharmacies**

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

The impact on pharmacies also cannot be mitigated by an increase in state-set dispensing fees. If state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is unlikely that Utah, or any other state, would set their Medicaid dispensing fee high enough to cover the average \$12.39 per prescription cost of dispensing for pharmacies as determined by the most recently completed Grant Thornton, LLP Cost of Dispensing Study.

We respectfully ask that CMS consider what is fair and equitable for retail pharmacies as they determine what and how AMP should be calculated.

Impact on small pharmacies demonstrated by GAO findings

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

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

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for t.

**GENERAL**

**GENERAL**

See attachment.

**Provisions of the Proposed Regulations**

**Provisions of the Proposed Regulations**

A UPHA BOARD MEMBER WHO OWNS TWO PHARMACIES IN CEDAR CITY, UTAH DID THE FOLLOWING STUDY TO DETERMINE THE EXACT FINANCIAL IMPACT ON HIS GROSS AND NET PROFIT:

1. Medicaid represents 12.0% of the total prescriptions dispensed and 11.4% of the total prescription volume. 91% of the total business in these two stores is prescriptions.
2. 65.1% of all Medicaid prescriptions dispensed are generic.
3. Current average gross profit per Medicaid prescription is:
  - a. Brand Prescriptions \$6.64
  - b. Generic Prescriptions \$19.10
  - c. Brand and Generic Prescription overall average gross profit \$16.75 which allows for a \$4.36 profit on each Medicaid prescription using the Grant Thornton \$12.39 average cost of dispensing calculation for Utah pharmacies.
4. Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:
  - a. \$8.54(average acquisition cost on each generic Medicaid prescription) x 36%=\$5.47 (average FUL per generic Medicaid prescription)
  - b. \$5.47 x 250% = \$13.68 (average AMP per generic Medicaid prescription)
  - c. \$13.68 + \$4.90 (current Utah Medicaid dispensing fee is \$3.90 and it has been indicated to UPHA by the Utah State Medicaid Division that they are considering giving the pharmacies a \$1.00 increase to cover AMP deficits) = \$18.58 (average total reimbursement per generic Medicaid prescription)
  - d. \$18.58-\$8.54 (current average acquisition cost of each generic Medicaid prescription)=\$10.04 (average gross profit per generic Medicaid prescription after AMP is implemented)
  - e. Brand and Generic Medicaid Prescription overall gross profit will be \$8.85 per prescription after AMP is implemented. This will result in a net loss of \$3.54 on every Medicaid prescription dispensed using the Grant Thornton Cost of Dispensing Study. This will result in a net loss of \$116,667 in total profit to these two small pharmacies.

AS YOU CAN SEE FROM THESE CALCULATIONS THAT THE IMPLEMENTATION OF AMP AS IS CURRENTLY OUTLINED WILL HAVE A DISASTROUS EFFECT ON PHARMACIES, ESPECIALLY INDEPENDENT PHARMACIES. NCPA, APHA, UPHA, AND PHARMACIES IN UTAH ARE WILLING TO HELP IN REDUCING THE COST OF HEALTH CARE TO THE AMERICAN PEOPLE AND ARE WILLING TO FURTHER INCREASE GENERIC UTILIZATION AND THERAPEUTIC SUBSTITUTIONS THAT WILL DRASTICALLY DECREASE THE COST OF MEDICAID PRESCRIPTION DRUGS. IT IS OUR BELIEF THAT AMP WILL GREATLY DECREASE THE NUMBER OF RETAIL PHARMACIES IN UTAH AND THE NATION AND THUS DECREASE PATIENT ACCESS TO HEALTH CARE. WE RESPECTFULLY ASK THAT CMS CONSIDER THE DETRIMENTAL OUTCOMES THAT WILL BE REALIZED IF AMP IS IMPLEMENTED AS CURRENTLY OUTLINED.

**Summary of Key Points:**

- q The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- q Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- q To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
  1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
  2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

**Regulatory Impact Analysis**

**Regulatory Impact Analysis**

**Definition of Retail Pharmacy Class of Trade and Determination of AMP**

CMS believes, based in part on the OIG and GAO reports, that sales and discounts to mail order pharmacies shall be included in the AMP price calculation along with independent and chain retail pharmacies.

Retail Pharmacy Class of Trade means that sector of the drug marketplace which dispenses drugs to the general public and which includes all price concessions (except prompt pay discounts) related to such goods and services. CMS proposes to exclude from AMP the prices of sales to nursing home pharmacies. CMS

will include in AMP the prices of sales and discounts to mail order pharmacies. Inclusion of these lower mail order pharmacy prices would decrease AMP, thereby decreasing manufacturers current rebate liabilities the State Medicaid programs and other entities.

Comments:

Mail order pharmacies should be excluded for the following reasons:

1. All major mail order pharmacies in the U.S.A. are owned by PBM s. The alignment of the PBM, its customer,s and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies.
2. CMS states that the exclusion of mail order and PBM prices would substantially reduce the number of transactions included in AMP. Mail order pharmacies provide some prescriptions to Medicaid patients. PBM mail order companies provide approximately 20% of the prescriptions dispensed to the non-Medicaid market.
3. Mail order pharmacies favor the purchase in very large package sizes (NDC-11) yielding the lowest per unit price in the marketplace. These package sizes are not accessible to, nor feasible in a typical independent retail pharmacy due to smaller sales volume, inventory management and return on investment factors. It is not economically feasible for small independent pharmacies to purchase large package sizes as a standard of operations.
4. PBMs operate mail order facilities in the U.S.A. and they earn certain rebates, discounts, and other price concessions that are not available to retail pharmacies. Inclusion of PBM price concessions in the calculation of AMP places retail pharmacies at a significant price disadvantage because these price concessions are not available to our pharmacies.
5. PBMs do not distribute drugs except through their privately owned mail order facilities. Drugs dispensed and distributed through retail pharmacies are purchased and owned by the retail entities. PBMs credit their sales revenues as if they own the inventory, but they do not. Rebates earned by a PBM for sales of drugs at the retail pharmacy are not, in any fashion, shared with the pharmacy.
6. PBMs are not wholesale distributors therefore there is no method for distributing these lower cost drugs to the retail sector.

As a result mail order pricing should NOT be considered in the AMP calculations.

Conclusion:

If the Final Rule permits the inclusion of mail order pricing in the calculation of AMP then these mail order pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access these products.

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

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

AMP Must Differ From Best Price

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

CMS should exclude rebates paid to PBMs from AMP calculations: These rebates are not available to our retail pharmacies, and indeed, none of these funds are ever received by our pharmacies. The Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale

Response to Comments

Response to Comments

If the proposed definition of AMP is enacted, I can only see three possible outcomes:

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2. Pharmacies in rural areas where a majority of their patients are Medicaid beneficiaries will be forced to operate at a loss. They will be forced to close their doors, and Medicaid beneficiaries will have no other pharmacies to access their health care needs. The Medicaid beneficiaries will either have to drive hundreds of miles to the next nearest pharmacy, because their former pharmacy has been forced to close.
3. Pharmacies will have a perverse incentive to dispense brand prescriptions which cost ten times more than generic prescriptions affected by FUL. This will drive up the cost of Medicaid.

\* Due to both #1 and #2, Medicaid beneficiaries will lose access to prescription coverage. These same patients who would be treated at a marginal cost with prescription drugs will now show up in emergency rooms, thus driving up the cost of Medicaid exponentially.

MEGAN JOLLEY MILNE  
975 EAST 400 SOUTH #13, SALT LAKE CITY, UTAH 84102  
MEGAN.JOLLEY@PHARM.UTAH.EDU

February 20, 2007

Centers for Medicare and Medicaid Services

File Cod: CMS-2238-P

Department of Health and Human Services

(42 CFR Part 447)

Attention: CMS-2238-P

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, Md 21244-1850

To Whom It May Concern:

As a student at the University of Utah College of Pharmacy and a pharmacy health care professional, I have an interest in the proposed changes to Medicaid reimbursement rates in the form of AMP. My concerns are in line with the opinions of the National Community Pharmacist Association (NCPA), the American Pharmacist Association (APhA), and the Utah Pharmacists Association (UPhA). UPhA is a state pharmacy organization that represents over 450 Chain and independent retail pharmacies in the state of Utah. These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBMs, regional and national health plans, and various governmental organizations.

In the meeting with Dennis Smith of CMS on February 1, 2007, he requested information and documentation of how the proposed definition of AMP will affect pharmacies in Utah. We are providing that information in the form of this letter, a petition from the students of the University of Utah College of Pharmacy, and multiple other letters from pharmacists in Utah, delineating the impact of reimbursements to our pharmacies according to the Government Accounting Office's study. One pharmacist owner calculated that if he loses an average of 36% from his cost of the drug per generic prescription that falls under FUL, his **two pharmacies in rural Utah will lose \$116,667 in total profit per year**. That is more than most pharmacy owners pay themselves! Pharmacies cannot be expected to operate at a loss.

Therefore, we ask you to please review our comments about the proposed enactment of the Deficit Reduction Act with the current definition of AMP. Please follow these suggestions:

**Definition of Retail Pharmacy Class of Trade and Determination of AMP**

CMS believes, based in part on the OIG and GAO reports, that sales and discounts to mail order pharmacies shall be included in the AMP price calculation along with independent and chain retail pharmacies.

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CMS should exclude rebates paid to PBMs from AMP calculations: These rebates are not available to our retail pharmacies, and indeed, none of these funds are ever received by our pharmacies. The Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices and therefore these transactions should also be excluded from AMP calculation.

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

**PBM Transparency is Necessary to Assess Manufacturer Rebates**

PBMs are not subject to regulatory oversight, neither at the federal nor state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. PBMs have been allowed, due to a lack of regulation, to keep most, if not all, of their information hidden; thus there is no transparency in the PBM Industry.

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

**AMP Must be Reported at the 11-Digit NDC to Ensure Accuracy.**

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

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

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Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-digit NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

### **Financial Impact on Pharmacies**

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

The impact on pharmacies also cannot be mitigated by an increase in state-set dispensing fees. If state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is unlikely that Utah, or any other state, would set their Medicaid dispensing fee high enough to cover the average \$12.39 per prescription cost of dispensing for pharmacies as determined by the most recently completed Grant Thornton, LLP Cost of Dispensing Study.

**We respectfully ask that CMS consider what is fair and equitable for retail pharmacies as they determine what and how AMP should be calculated.**

### **Impact on small pharmacies demonstrated by GAO findings**

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

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

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

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive

MEGAN JOLLEY MILNE  
975 EAST 400 SOUTH #13, SALT LAKE CITY, UTAH 84102  
MEGAN.JOLLEY@PHARM.UTAH.EDU

definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

**Summary of Key Points:**

- ❑ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
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- \* Due to both #1 and #2, Medicaid beneficiaries will lose access to prescription coverage. These same patients who would be treated at a marginal cost with prescription drugs will now show up in emergency rooms, thus **driving up the cost of Medicaid exponentially.**

We as taxpayers cannot afford these disastrous outcomes! We as healthcare practitioners cannot be expected to fund the Medicaid benefit at a loss. Please consider these comments and suggestions in enacting the Deficit Reduction Act.

If you have any questions, please feel free to contact me at 801-891-5509 or [megan.jolley@pharm.utah.edu](mailto:megan.jolley@pharm.utah.edu).

Respectfully,

Megan Jolley Milne  
Pharm.D. Candidate 2009  
President of Student Chapter of NCPA  
Student of University of Utah College of Pharmacy

**Submitter :** Patricia Andersen

**Date:** 02/20/2007

**Organization :** Oklahoma Hospital Association

**Category :** Health Care Provider/Association

**Issue Areas/Comments**

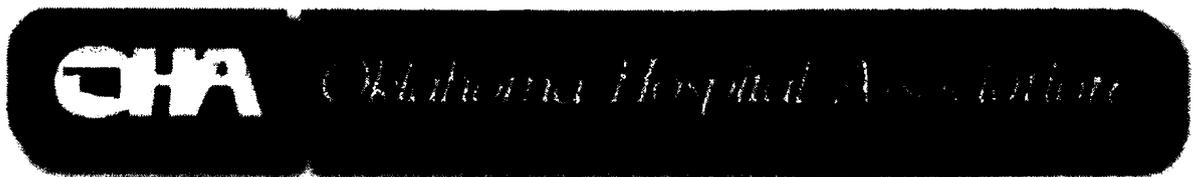
**GENERAL**

**GENERAL**

I received an error message which indicated it was for the CMS website manager.

If my comments were not received (a Word Document attachment) please contact me at 405-427-9537 when your web problem s resolved.

CMS-2238-P-1291-Attach-1.DOC



February 20, 2007

Leslie Norwalk  
Acting Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

**Re: (CMS-2238-P) Medicaid Program: Prescription Drugs, Proposed Rule, (Vo. 71, NO. 246), December 22, 2006**

Dear Ms. Norwalk:

The Oklahoma Hospital Association (OHA), on behalf of our member hospitals, appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule implementing provisions of the *Deficit Reduction Act of 2005* (DRA) that pertain to the Medicaid prescription drug program. Our comments address CMS' interpretation of Section 6002 of the DRA and the new requirement that hospitals report physician-administered drugs using the National Drug Code (NDC). We will focus on two issues:

1. The legal premise upon which CMS has based its interpretation of Section 6002, and
2. The significant administrative burden these new reporting requirements impose on hospitals.

**FFP: CONDITIONS RELATING TO PHYSICIAN-ADMINISTERED DRUGS – SECTION 447.420**

Section 6002 of the DRA added a new requirement to the Medicaid statute specifically to enhance the ability of state Medicaid programs to secure rebates from drug manufacturers under the Medicaid drug rebate law. This section ties Medicaid rebate payments for covered outpatient drugs that are physician administered, as determined by the Secretary, to "the collection and submission of such utilization and coding data (such as J-codes and NDC numbers) ....as necessary to identify the manufacturer of the drug." The data collection requirement extends to both single and multiple source drugs. However, in the proposed rule, CMS does not define "outpatient drugs that are physician administered" as the statute clearly states that the Secretary must do. Instead, the rule's preamble indicates that CMS intends to interpret Section 6002 to require submission of the NDC numbers for outpatient drugs furnished as part of a physician's service to Medicaid beneficiaries in hospital outpatient clinics and departments – not solely in physicians' offices. CMS' proposal to apply Section 6002 so broadly is inappropriate as it is not supported by the statute's plain language, it is inconsistent with congressional intent, and it would nullify the *Social Security Act of 1965* exemption of hospital outpatient clinics and departments from Medicaid rebate program obligations.

**Section 6002 does not apply to outpatient drugs administered in hospital outpatient clinics and departments.**

Section 6002 requires only the collection of utilization and coding data for drugs that are subject to a rebate requirement under Medicaid statute provisions that predate the DRA – a position that CMS acknowledges in the proposed rule. Under Section 6002, state Medicaid programs are expressly directed to provide for the submission and collection of drug utilization and coding data “as necessary to identify [manufacturers of drugs] in order to secure rebates” under the Medicaid rebate law. In other words, the data collection requirement applies only if the state Medicaid agency finds it necessary to obtain a drug’s NDC number in order to identify the responsible manufacturer and enforce a Medicaid rebate payment obligation. On the other hand, for outpatient drugs that are not subject to a rebate payment requirement – like those dispensed in hospital outpatient clinics and departments – the collection of NDC information with respect to that drug plainly is not necessary to securing a rebate, and the law does not require submission or collection of NDC data on the drug.

The statutory language, in fact, does not directly compel states to collect only NDC information on drugs subject to the rebate requirement. While reporting of the NDC numbers is preferred after January 1, 2007, the statute clearly authorizes the Secretary to allow for an alternative coding system. The statute states that the purpose of the data collection is “as necessary to identify” the manufacturer of the drug in order to collect Medicaid manufacturer rebates. The statute mentions J-codes and NDC numbers as examples of the type of “utilization and coding data” that could be collected. To the extent that J-codes can be used to identify a drug for Medicaid rebate purposes, continued use of J-codes to identify drugs is consistent with statutory compliance.

Further, the Secretary is authorized to delay applying the data reporting requirement in order to prevent hardship to any states that require additional time to implement the reporting system. Such hardship is not expressly limited in the statute and may encompass the state’s consideration of difficulties in obtaining data from reporting hospitals and the time needed to reconfigure the systems of reporting hospitals.

**Section 6002 was enacted to address a problem with rebate collection on drugs administered in physicians’ offices – not hospital outpatient clinics and departments.**

In the proposed rule, CMS seeks to give a much broader application to physician-administered drugs. By including all covered outpatient drugs that “are typically furnished incident to a physician’s service,” the agency expands the scope of Section 6002 well beyond the problem it was designed to address. Precise congressional impetus for enactment of Section 6002 appears to be the April 2004 report “Medicaid Rebates for Physician-administered Drugs” from the Department of Health and Human Services Office of the Inspector General (OIG). In that report, the OIG projected that the states were losing millions of dollars in Medicaid rebate payments due to their failure to collect rebates on physician-administered drugs. The OIG report expressly defines the physician-administered drugs of concern as “drugs that a medical professional administers to a patient in a physician’s office.”

In the proposed rule, CMS acknowledges the relationship between this OIG report and enactment of Section 6002. The preamble makes numerous references to the “physician-administered drugs” covered by the OIG report, including a statement that current estimates of Medicaid savings from implementing Section 6002 are based on the 2004 OIG report. CMS’ discussion appears to directly equate the physician-administered drugs that were the subject of the OIG report with those that are subject to Section 6002 and its proposed regulation.

Thus, the intent of Congress in enacting Section 6002 will be faithfully executed, and CMS' projected savings fully realized, if the proposed new NDC submission and collection requirements are construed as applicable only to drugs administered in physician's offices, and inapplicable to drugs administered in hospital outpatient clinics and departments.

**Section 6002 does not affect the existing rebate exemption for drugs administered to patients in hospital outpatient clinics and departments.**

Nothing in Section 6002 casts doubt on the continuing existence of the Medicaid statute's pre-existing exemption from drug rebate requirements for outpatient drugs established by Section 1927(j) of the *Social Security Act*. Section 6002's language is entirely silent as to any legislative intent to repeal or amend this pre-existing exemption, which expressly identifies outpatient drugs dispensed through hospital outpatient clinics and departments as not subject to the Medicaid drug rebate requirements.

The DRA Conference Report explicitly states that hospital outpatient clinic and managed care drugs described in Section 1927(j) are exempt from rebate requirements, and that the Section 6002 data collection requirements are intended to pertain only to physician-administered drugs for which there is no statutory exemption from rebate requirements (See H.R. Report. No. 109-362 accompanying S.1932, December 19, 2005) Although the conference report does not directly cite Section 1927(j) *per se*, it expressly acknowledges the existence of exemptions from rebate requirements for outpatient prescription drugs using terms that unmistakably mirror the descriptions of managed care drugs in Section 1927(j)(1) and hospital drugs in Section 1927(j)(2).

Notwithstanding this clear legislative intent, CMS' proposed rule to implement Section 6002 makes no mention of the statutory exemptions from rebate requirements for either hospital outpatient clinic drugs or outpatient drugs dispensed by managed care organizations. The fact that neither exemption is addressed in the proposed rule is, at best, confusing, but clearly evidence that CMS overlooked the entire matter of these statutorily exempt physician-administered drugs in construing how Section 6002 should be properly applied, as opposed to having simply construed Section 1927(j)(2) to have severely limited application to hospital outpatient clinic drugs.

It is clear that the physician-administered drug provision enacted by Section 6002 can only be read to impose a data collection requirement with respect to drugs that are not within the Section 1927(j) (2) exemption. Because the subsection (j) remains unchanged in the Medicaid rebate law, CMS cannot ignore the statutory exemption. The agency must continue to give subsection (j) the same meaning it had prior to the enactment of the DRA as the agency applies Section 6002. In doing so, CMS is compelled to draw meaning from Section 1927(j) (2) in a concrete way by referring to drugs dispensed or administered in an actual hospital setting.

Section 1927(j)(2) specifically exempts from the rebate requirements outpatient drugs that are administered in a "hospital ... that dispenses covered outpatient drugs using formulary systems, and bills [the Medicaid State Plan in the relevant state] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan)." This section cannot plausibly be construed as a reference to hospitals participating in the 340B federal drug discount program because the 340B program did not exist at the time Section 1927(j) was enacted.

On the other hand, drugs administered by medical professionals to patients on an outpatient basis in hospital clinics and departments generally have not been subject to Medicaid rebate

collections, and fall squarely within the (j)(2) exemption, as properly construed. Drugs administered in the hospital outpatient clinic setting are dispensed almost always within a formulary system – thus meeting the first statutory criterion for inclusion in the (j)(2) exemption. Covered outpatient drugs administered in hospital clinic settings also are billed to Medicaid in a manner that meets the description of the second (j)(2) criterion, namely that the hospital “bills the [Medicaid State Plan] no more than the hospital’s purchasing costs for covered outpatient drugs (as determined under the state plan).” Most, if not all, drugs administered to Medicaid-eligible patients in hospital outpatient clinics and departments fall within the (j)(2) exemption from rebates, and accordingly **must be excluded** from the physician-administered drugs to which Section 6002 applies.

#### **ADMINISTRATIVE BURDEN FOR HOSPITALS**

Many state Medicaid programs have moved forward with implementing this new NDC reporting requirement. Hospitals in these states have been instructed to bill outpatient drugs using the drug manufacturer’s 11-digit NDC number. The OHA is concerned because these instructions fail to recognize the significant difficulty, burden and cost imposed upon the hospital community in order to meet these new billing requirements. Most, if not all, hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer’s NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS), in particular, the HCPCS J-codes to report a particular drug or biologic rendered to a patient. The J-code is not exclusive to a particular drug manufacturer but rather used to describe the general ingredient and dosage of a drug. Patient accounting systems can easily report HCPCS codes, but not the NDC.

To be able to report the NDC, hospitals must make major revisions to their charge description master (CDM), including significant increases to the CDM in order to include multiple manufacturers of a particular type or category of drug. Additionally, any manufacturer changes in the packaging, dosage and/or ingredients would require adding another NDC to the CDM and thereby increase the frequency of updating the CDM.

It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must “provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered.” The DRA further states that the “reporting would include J-codes and NDCs.” As such, the OHA believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take roughly 500 to 1,500 work hours to design, build and test a short-term work around. Even with these changes, there are no assurances that the NDC indicated on the claim reflects the manufacturer of the drug that was given to the patient. Many hospital pharmacy acquisition systems have limited record keeping ability and can assign only a primary NDC for a particular drug. The primary NDC reflects the manufacturer of a particular type of drug. When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital’s need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. This is a common occurrence. Consequently, the hospital pharmacy’s record keeping systems will need

Leslie Norwalk  
February 19, 2007  
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the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

During the past several years many hospitals have introduced new automated drug dispensing systems in an effort to reduce medication errors. Many of these systems also would require costly modifications. For example, these drug dispensing systems have bins for each specific drug based on ingredient and dosage – not on manufacturer NDC. There also is a human cost since hospitals that are interested in acquiring such systems to reduce medication errors would have to postpone their acquisition until the vendors make all of the system modifications.

**We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient or clinic settings.**

Sincerely,  
Oklahoma Hospital Association



Patricia D. Andersen, CPA  
VP-Finance & Information Services  
Oklahoma Hospital Association  
4000 Lincoln Blvd.  
Oklahoma City, OK 73105  
405-427-9537

**Submitter :** Ms. Deborah Lydon  
**Organization :** Dinsmore & Shohl, LLP  
**Category :** Attorney/Law Firm

**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-1292-Attach-1.DOC

CMS-2238-P-1292-Attach-2.DOC

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**Dinsmore & Shohl** LLP  
ATTORNEYS

Deborah R. Lydon  
513-977-8344  
deborah.lydon@dinslaw.com

February 20, 2007

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

SENT BY EMAIL: [www.cms.hhs.gov/eRulemaking](http://www.cms.hhs.gov/eRulemaking)

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

Dear Ms. Norwalk:

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

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

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

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

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

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

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

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

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

CMS has enunciated in the commentary accompanying the Proposed Rule the informal position CMS staff members have previously expressed -- *i.e.*, that manufacturer coupons not affecting the drug prices paid by a pharmacy should not be included in the manufacturer's determination of the drug's best price.<sup>2</sup> But, consistent with this policy, redemption by the consumer "directly" to

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<sup>2</sup> In the preamble to the Proposed Rule, CMS states:

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

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

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

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

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

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

The language of Proposed Reg. §447.505(d)(7), which excludes from best price "[p]rices negotiated under a manufacturer's sponsored Drug Discount Card Program," is confusing and overly narrow. The only definition of "drug discount card program" in existing regulations refers to the Medicare-endorsed discount card program, which was discontinued when Medicare Part D took effect on January 1, 2006. The form a consumer drug discount takes (e.g., discount card, voucher, coupon, etc.), and whether the "sponsorship" resides in the retailer or manufacturer, should not dictate whether it is includable or excludable for purposes of

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determining best price. The relevant inquiry under the statute is whether the price concession affects the pharmacy price from the manufacturer. A consumer drug discount card program would not affect the pharmacy price if the discount is passed through 100% to the consumer. Accordingly, the best price exclusion under Proposed Reg. §447.505(d)(7) should include prices under any manufacturer-sponsored discount program where 100% of the manufacturer's discount is passed through to the consumer. Alternatively, CMS should consider eliminating this exclusion and expanding the coupon exclusion in subparagraph (d)(8) to include all point-of-sale discounts.

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

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### III. Provisions of the Proposed Regulations

#### Determination of AMP -- Proposed Reg. §447.504

##### *Additional Guidance on AMP for Determination of 340B Discount Program Prices*

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

#### Background -- Need for Guidance

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

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

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

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

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

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

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

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

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

In 2005 testimony before the Congress on the 340B program, a Deputy Inspector General of HHS told Representatives that "[b]oth the Government and the manufacturers calculate 340B ceiling prices using **the same statutorily-defined formula and the drug pricing data that**

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

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

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

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

manufacturers report to [CMS] for the purposes of the Medicaid drug rebate program."<sup>7</sup> Within weeks thereafter, DRA was enacted. Among the amendments to the Medicaid rebate statute included in DRA are:

- a new definition of AMP that ends the deduction of customary prompt pay discounts from gross sales and requires manufacturers to combine sales and price data for brand drugs and their authorized generics into a single AMP;
- a new definition of best price that includes prices for authorized generic drugs approved under the same NDA as a brand drug in the determination of the brand drug's best price;
- a limitation on which sales at nominal prices may be excluded in the determination of best price and
- the addition of certain children's hospitals to 340B covered entities in the section requiring manufacturers to extend 340B discounts to safety-net providers.

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

#### Support for a Single AMP for Medicaid and 340B Programs

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

(1) AMP is computed as provided under the Medicaid rebate statute that is current on the date of calculation, but to find what section that is in, you refer to Section 1927(c) of the Social Security Act (42 USC 1396r-8(c)) in 340B Enactment Date form, even if later legislative changes mean that the formula is in a different section of the Social Security Act currently.

(2) Some, but not all, elements of the 340B Enactment Date substantive provisions of the Medicaid rebate pricing scheme are frozen in time for purposes of 340B pricing, so, even though the Medicaid and 340B prices were the same in 1992, any future change in the

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

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

AMP formula under the Medicaid rebate statute has the effect of creating two different pricing schemes, **without any Congressional expression of an intent to do so.**

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

- Manufacturers who have overhauled their Medicaid price reporting systems to accommodate the new AMP definition and CMS's new DDR software system must retrieve their discarded pre-existing price reporting systems for use under 340B and make additional changes to disregard amendments to the Medicaid rebate statute since the 340B Enactment Date.
- The pricing provisions of existing 340B Pharmaceutical Pricing Agreements will be inconsistent with 340B program requirements.
- OPA and HRSA will be unable to calculate the 340B ceiling prices by using publicly-available AMP data and, as a result, must either forgo the calculation or institute a whole new data collection program, file Paperwork Reduction Act forms that estimate the burden upon manufacturers of the new data collection and obtain approval from the Office of Management and Budget.
- The 340B pricing scheme, unlinked from the AMP reported to Medicaid, will be based upon one of the following two formulas, depending upon the interpretation given to the phrase "average total rebate required under section 1927(c) of the Social Security Act ... during the preceding calendar quarter"<sup>9</sup>:

Alternative Formula 1:

340B price  $\leq$  AMP calculated as defined on the 340B Enactment Date - (Medicaid rebate actually paid / AMP calculated as defined on the 340B Enactment Date)

Alternative Formula 2:

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

(a) Alternative Formula 1 uses the following:

- the AMP definition in effect on the 340B Enactment Date;

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

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

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

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

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

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

- Post-340B Enactment Date changes to the definition of "federally qualified health care center" and to the requirements for disproportionate share hospitals to qualify as 340B "covered entities" will not be given effect under the 340B Discount Pricing Program unless Section 340B of the Public Health Service Act is amended.

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

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

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***The Paperwork Reduction Act Notice and Regulatory Impact Analysis accompanying the Proposed Rule should incorporate the additional burden on manufacturers in making the calculations necessary to compute both the Medicaid AMP, best price and rebate and the 340B ceiling price if the OPA's interpretation of the 340B statute is given effect.***

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

\* \* \* \* \*

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

Leslie V. Norwalk, Administrator (Acting)  
February 20, 2007  
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Sincerely,

Deborah R. Lydon

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

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

Submitter : Mr. Ronald Davis  
Organization : -  
Category : Attorney/Law Firm

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1293-Attach-1.DOC

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COMMENTS ON PROPOSED RULE:

42 C.F.R. PART 447

CMS-2238-P

Submitted to

Centers for Medicare and Medicaid Services

U.S. Department of Health & Human Services

**Ronald W. Davis**  
ATTORNEY

1619 McLendon Ave., N.E.  
Atlanta, GA 30307  
404 687-8641  
[rdavis1@earthlink.net](mailto:rdavis1@earthlink.net)

In response to the notice of proposed rulemaking published by the Centers for Medicare and Medicaid Services (CMS), 71 Fed. Reg. 77173 (Dec. 22, 2006), CMS-2238-P, these comments are submitted by the undersigned on behalf of an undisclosed client.

As CMS moves toward introduction of a final rule implementing the Deficit Reduction Act (DRA), a key challenge will be the need to take into consideration the fact that there are multiple classes of trade performing the service of getting generic drugs to retail pharmacies. As with any competitive environment, within those classes of trade are more efficient and less efficient channels.

Providing pharmaceutical products to independent retail pharmacies incurs the most costs, yet the participation by independent pharmacies is considered essential for the viability of the Medicaid drug program. Given the logistical challenges of supplying and keeping stocked thousands of independent pharmacy businesses, it is not surprising that the cost of doing business in this channel is greater than for retail warehousing chains or mail order distributors—and hence the prices charged to the members of this channel are higher than for retail warehousing chains or mail order distributors. Those higher costs are incurred by both the manufacturers and the wholesalers who supply the independent pharmacies.

Where distribution channels have been able to gain efficiency, and that efficiency results in lower costs of doing business to both the channel and the manufacturers, that efficiency is reflected in lower cost of goods.

In implementing the DRA, CMS seeks to gain the benefit of those efficiencies achieved by certain distribution channels and apply them to the reimbursement model. This creates a challenge for CMS because a reimbursement rate reflecting the efficiency of mail order and warehousing chains does not automatically apply to the more expensive, yet critical distribution outlet, namely wholesalers who supply the vast majority of independent retail pharmacies.

To illustrate this point, there is the distinct possibility that a reimbursement rate based upon average manufacturer price (AMP) that reflects pricing to the efficient channels could be lower than the actual acquisition cost of independent pharmacies. At that point each independent pharmacy could be losing money on every prescription it fills.

We note that CMS has indicated that they are also studying the viability of using a retail selling price "RSP" for computing reimbursement rather than AMP. We note that a switch to such a system would if done properly ameliorate many of the problems outlined herein. An RSP based system would by definition focus on the major wholesalers as the source of most drugs offered to the retail trade. Using their average retail selling price would factor in the costs of doing business with the independent retail pharmacies and would therefore allow for a more accurate reimbursement rate to those independent retail pharmacies. A second benefit of using RSP would be that it would remove from the

reimbursement calculation the depressing impact of mail order pricing, which as pointed out above benefits from efficiencies not available to wholesalers servicing the thousands of independent retail pharmacies.

We ask that as CMS defines AMP reimbursement and sets the dispensing fee, it recognizes that levels of reimbursement must be sufficient to compensate independent retail pharmacies who provide most of the prescription drugs to people in the Medicaid program and who will not be offered pharmaceutical products from their suppliers at AMP, or at prices close to AMP.

Ronald W. Davis

**Submitter :** Mrs. Jan Hamilton  
**Organization :** Hemophilia Federation of America  
**Category :** Consumer Group

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

The Hemophilia Federation of America wishes to comment on this issue. Our comments are in the form of an attachment. We are also submitting our comments by Federal Express.

"See Attachment"

CMS-2238-P-1294-Attach-1.DOC

CMS-2238-P-1294-Attach-2.DOC



# Hemophilia Federation of America

Advocacy For Persons With Clotting Disorders

February 19, 2007

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

**Sent by Federal Express and via electronic transmission**

To Whom it May Concern:

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

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

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

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

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

1405 W. Pinhook Road Suite 101 • Lafayette, LA 70503  
337-261-9787 1-800-230-9797 FAX 337-261-1787  
Web Site: [www.hemophiliafed.org](http://www.hemophiliafed.org)

#12

Please consider referencing the formula for a furnishing fee as seen in Medicare that some states have already introduced as part of Medicaid.

We appreciate the opportunity to provide comments regarding the proposed rule of the Deficit Reduction Act of 2005.

Sincerely,

Jan Hamilton  
Advocacy Director  
Hemophilia Federation of America

**Submitter :** Mrs. CELESTE WATTS

**Date:** 02/20/2007

**Organization :** BI-LO

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-2238-P-1295-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 at Bi-Lo, a community retail pharmacy located at 841 Hwy 411N 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 the pharmacy where I work, where I work. 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,

Celeste Watts  
1213 Pennsylvania Ave.  
Etowah, TN 37331

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

**Submitter :** Ms. Sharilyn Reese  
**Organization :** Gaston Memorial Hospital  
**Category :** Hospital

**Date:** 02/20/2007

**Issue Areas/Comments**

GENERAL

GENERAL

See Attachment

CMS-2238-P-1296-Attach-1.PDF

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

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

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

**Submitter :** Cynthia Padgett  
**Organization :** RxCrossroads  
**Category :** Other Health Care Provider

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1297-Attach-1.PDF

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

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

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

CMS-2238-P-1298

Submitter : Dr. Nancy Nesser

Date: 02/20/2007

Organization : Oklahoma Health Care Authority

Category : State Government

**Issue Areas/Comments**

**GENERAL**

GENERAL

Comments are attached.

CMS-2238-P-1298-Attach-1.DOC

MIKE FOGARTY  
CHIEF EXECUTIVE OFFICER



BRAD HENRY  
GOVERNOR

STATE OF OKLAHOMA  
OKLAHOMA HEALTH CARE AUTHORITY

February 20, 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

**Re: Proposed Rule: Medicaid Program; Prescription Drugs**

Dear Ms. Norwalk:

The Oklahoma Health Care Authority (OHCA) respectfully submits this comment letter on the regulations proposed affecting the Medicaid prescription drug benefit. OHCA is commenting on the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS). OHCA is the designated single state agency that administers the Medicaid program in Oklahoma. Please be assured that OHCA is fully committed to implementing the prescription drug related provisions of the Deficit Reduction Act of 2005 (DRA) and other ongoing initiatives that seek to improve the efficiency and effectiveness of the Medicaid pharmacy benefit.

OHCA believes that the DRA includes important provisions that may facilitate increased transparency in prescription drug pricing in the Medicaid program and gives us tools needed to improve the accuracy of our reimbursement methodologies. We also recognize that these are essential steps in providing quality, affordable care to Medicaid consumers.

Our comments are based on the discussion provided in the preamble to the proposed regulations and follow the outline provided in that section.

**Provisions of the Proposed Regulations**

**Definitions – Section 447.502**

***Dispensing Fee***

While we generally agree with the definition of dispensing fee proposed by CMS, we offer two points of distinction for your consideration. First, the comparison to the Medicare Part D Prescription Drug benefit

is possibly overstated. Medicaid pharmacy programs have fewer options to ensure appropriate and cost effective utilization than a privately managed Part D Prescription Drug Program (PDP). These differences may lead to higher costs of dispensing for the Medicaid program.

Second, the absence of a profit component in the calculation of the dispensing fee has been raised by the pharmacist association in Oklahoma. If the pharmacy may only receive cost-based reimbursement for both the ingredient and the overhead, how are they to stay in business? We request that CMS provide clarification on this point so that states will know how to respond to these questions from our providers.

#### **Determination of Average Manufacturer Price – Section 447.504**

##### ***Definition of Retail Pharmacy Class of Trade and Determination of AMP***

CMS has asked for comments regarding which sales should be included in the Retail Pharmacy Class of Trade for the determination of AMP. It is our assertion that along with sales to nursing home pharmacies, sales, rebates, and discounts to mail order pharmacies and pharmacy benefit managers (PBM's) should be excluded from the definition of Retail Class of Trade for the purpose of determining the AMP.

While the case for exclusion from the AMP calculation may be stronger for PBM's, neither mail order nor PBM's sell prescription medications directly to the general public. PBM's do not sell medications to anyone, but as their name implies, *manage prescription benefits* for employers and other payers. They certainly do not directly influence the prices paid by true retail pharmacies to their suppliers and wholesalers. Similarly, mail order pharmacies are generally integrated with a PBM or other large payer, meaning that most of their customers are enrolled in a specific benefit program which mandates the use of mail order pharmacy.

CMS cites their publications from almost a decade ago, Manufacturer Releases 28 and 29, to support their proposed inclusion of PBM rebates, charge backs, and discounts in the calculation of AMP. We would support the inclusion of the transactions described in those publications, specifically, from Release 28:

“Drug prices to PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement.”

And from Release 29:

“In other words, where the effect on the manufacturer for using the PBM is to adjust actual drug prices at the wholesale or retail level of trade, such adjustments need to be recognized in best price calculations.”

However, in 2007, we are not aware of any PBM arrangements that currently exist where the PBM is acting as a wholesaler, as they do not buy pharmaceuticals directly from the manufacturer and resell them to pharmacies, who then dispense them to the general public. Therefore, in our opinion, there is no need to include a group of transactions for which there are no qualifying sales and for which there remains significant potential for manipulation of both the monthly and quarterly AMP calculations by manufacturers.

CMS has also invited comments on the operational difficulties of including PBM arrangements within the AMP calculation. Speaking from our point of experience with the Drug Rebate Program, retroactive adjustments in pricing and rebate calculations are endless and voluminous. While we do not know the cause for these adjustments, it can be assumed that the lag time between the quarterly rebate reporting periods and the PBM contracted reporting can be a significant source of these discrepancies. Although the 30 day limit on changes to the monthly AMP should hold these prices somewhat more level than the

current quarterly-reported rebate prices, operational issues should be considered. CMS states that excluding these sales from the AMP calculation will allow faster and simpler processing for the pharmaceutical manufacturers and fewer changes for state drug rebate personnel to handle, which we believe strengthens the case for excluding PBM sales, rebates, and discounts.

We request clarification of the intent CMS attributes to Congress in this section. As a justification for including a number of non-wholesaler based transactions in the determination of AMP, CMS states that it is their belief that Congress intended to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer. We encourage CMS to examine the legislative intent within the framework of the *retail pharmacy class of trade*.

CMS proposes to include prices negotiated by a Medicare Part D Prescription Drug Program (PDP), a Medicare Advantage Prescription Drug Plan (MA-PD), or a qualified retiree prescription drug plan for covered Part D drugs in the calculation of AMP. While this is consistent with their inclusion of PBM rebates and discounts, we believe it is inconsistent with the marketplace. PBM's, PDP's, MA-PD's and qualified retiree drug plans do not act as wholesalers in the pharmaceutical supply chain. Including any non-wholesaler sales in the monthly AMP calculation tends to negatively affect the true retail class of trade, that is, community retail pharmacies, whether chain-based or independently owned. Conversely, CMS proposes to exclude Part D related pricing from the calculation of Best Price, which uniformly favors the pharmaceutical manufacturers.

We urge CMS to reconsider this definition for the monthly AMP calculation to exclude sales, rebates, and discounts to PBM's, mail order pharmacies, Part D qualified plans of all types, and nursing home pharmacies.

#### **Requirements for Manufacturers – Section 447.510**

##### ***Accountability for Accurate Data***

We respectfully request that CMS assist in verifying the accuracy of the data by implementing accountability measures for manufacturers. We understand from the CMS call held on January 4, 2007, that the agency believes that the transparency of AMP information should help to reduce the erroneous data problem. However, states remain concerned by the lack of controls and accountability measures for manufacturers. In addition, our historical experience indicates that existing CMS processes have been insufficient in monitoring and managing the prescription drug data files. The lack of updated data can reasonably be expected to result in inappropriate FUL calculations and impose an unforeseen burden on states to identify and subsequently report any inaccuracies to CMS. As a result, states urge CMS to implement systems checks and measures to hold manufacturers accountable for the quality of data they provide.

##### ***Implementation Timeline***

We are concerned that the final regulation may not be published until July 1, 2007 and that many questions essential to implementation of the proposed rule will remain unanswered until this time. We understand that this is the date specified in the DRA. However, we urge CMS to consider and account for the steps we will need to take in order to operationalize the final rule and meet this deadline.

We may not have the processes and systems in place for a number of reasons, including:

- 1) We must wait for CMS to finalize the provisions of this rule before we can develop the MMIS systems and manual processes to implement it.
- 2) The implementation timeframe is short and we may not have the staff and funding resources to meet the deadline.

- 3) Although we received AMP data in 2006, this was sample data, so we will have insufficient time to evaluate the monthly fluctuations in AMP and any impact on various facets of our pharmacy program. As noted above, the sample data was inaccurate and insufficient to make firm policy decisions. Any changes that we will need to make to our state Medicaid plan or reimbursement structure will take considerable time.

OHCA has decided to raise the dispensing fee for drugs reimbursed with FUL pricing. Our dispensing fee for these drugs will be increased from \$4.15 to \$9.00 per prescription upon implementation of the new FUL pricing. However, until we have some experience with the FUL prices, we do not know if this will be too much, not enough, or just right to compensate pharmacies for their time, effort, and overhead required to serve their Medicaid consumers.

As a general comment, the reporting of the monthly AMP and the subsequent FUL prices as proposed will create a significant lag in pricing between the published FUL and reality of the market on any given day. For example, under the proposed reporting requirements, a manufacturer has until March 2, 2007 to report their AMP for January 2007. CMS has not proposed a timeline from their receipt of the AMP data to publishing the FUL. Using a best case scenario of another 30 days, the January AMP will become the April FUL.

We offer two suggestions to ease this lag time:

1. Manufacturers should be required to report any upcoming price increases. If a manufacturer is aware that they will be raising their price for a particular product or updating their price list in general within the next 90 days from a reporting period, these changes should be submitted to CMS along with their monthly AMP data.
2. CMS should impose a time limit of 7-10 days on their own process which would reduce the lag time by approximately 3 weeks. From our experience setting our own State Maximum Allowable Costs in Oklahoma, we know that the process can be largely automated.

While the proposed regulation deals primarily with the monthly AMP in the context of the creation of FUL pricing, CMS does encourage states to consider using AMP as the basis for reimbursement for all drugs. This lag time seriously inhibits the likelihood that states will be able to use the monthly AMP for all reimbursement because single source pharmaceutical pricing is much more volatile than multiple source pricing.

#### ***Transfer of AMP Files***

The proposed rule states that CMS will distribute the monthly AMP file to states. We are concerned that the monthly file that CMS intends to send will contain only the drug name and price, consistent with the current FUL files. Alternately, it may only contain the NDC and the price, as the AMP files now contain. Either way, states will have to translate the drug descriptions and/or NDC's in the file into the corresponding FUL category in order to enter the pricing information into the claims processing system and to analyze the impacts of the FUL with our processed claims. In addition, providing the file to us in such a fashion may lead to misinterpretations which may require us to invest in new resources to manage this information.

We believe CMS can and should assist in making this process more efficient. We request that CMS consider alternative mechanisms to facilitate our utilization of workable data in a timely fashion. Additionally, for newly released drugs, a mechanism is needed that applies the rate to the NDC's that meet the criteria listed in the proposed rule. One possibility is to provide the file at least monthly to the nationally recognized pricing compendia who, in turn, could provide descriptive drug information, unique identifiers and pricing data, including updated NDC codes, within the file that would be distributed to states.

At a minimum, we request for each FUL that we receive drug name, dosage form, strength, 11 digit NDC, and the two major proprietary grouping code systems: First Data Bank's GCN and Medispan's GPI system. This will facilitate our processing of the pricing as well as analysis of the impact of the new reimbursement scheme.

*Reporting discrepancies and shortages to CMS*

CMS requested suggestions on how best to accomplish the goal of assuring that a drug is available nationally at the FUL price. This is a particularly important goal if the intention of the legislation is to be met. One suggestion is to allow state programs to investigate reported shortages and make changes to the FUL on a state by state basis. Even with the current FUL definition and calculation, there have been instances where Oklahoma replaced the FUL with a higher State Maximum Allowable Cost (SMAC) or Estimated Acquisition Cost (EAC) due to product shortages or marketplace changes.

In these instances, the state was able to meet the FUL "in the aggregate" because the vast majority of products subject to an FUL were reimbursed substantially lower than FUL using the SMAC price. Our analysis of the recently released AMP data indicates that we will not be able to meet the aggregated FUL requirement if we replace an FUL with SMAC or EAC pricing. Overall, we estimate that an aggregated pharmacy spend based on the SMAC price is 10-25 percent higher than the aggregated pharmacy spend based on FUL for the same products during the same time period. While there are isolated products for which the SMAC is lower than 250% of the lowest AMP reported, the majority of products will be reimbursed significantly lower using the FUL formula as stated in the DRA. We recognize that the reformulated AMP, as proposed here, will differ from the AMP pricing so far received by the states. However we are unable to gauge the impact of the proposed AMP at this time.

We encourage CMS to consider which entities can or should report FUL discrepancies and what documentary evidence will be required to update an inaccurate FUL. As noted previously, the time lag will substantially effect the ability of the FUL to match current marketplace conditions.

**FFP: Conditions Relating to Physician Administered Drugs – Section 447.520**

The DRA called for a number of changes to the billing methodologies for physician administered drugs. OHCA is prepared to work with CMS to implement systems and processes that will ensure these provisions are implemented effectively.

*Provider education*

Oklahoma is concerned that the proposed rule does not take into account the extensive education and systems updates that will be required to ensure that physician providers can comply with the new drug billing methodologies. A standardized rebating labeler list would help avert denied claims several months after services have been rendered. We expect the change in the billing system and practices to be an especially acute problem in situations of small provider groups or among providers that utilize separate contractors for their billing systems.

As such, we respectfully request that CMS create a list of the Healthcare Common Procedure Coding System (HCPCS) codes which will require a National Drug Code (NDC) for Medicaid billing and make this list available to medical providers. As stated above, without this information, providers may not know which products are and are not from a rebating labeler.

We are attempting to create such a list in Oklahoma, but it is a very slow and tedious process. First, we must sort through the HCPCS codes to determine which of them include a prescription drug product. Although many drug product codes are grouped within the J series of HCPCS codes, they are not all within that subset, therefore all of the HCPCS codes must be considered. Next, each code that represents a billable drug product must be matched to a drug grouping scheme. In Oklahoma, we use First Data

Bank's proprietary grouping system called the GCN. Within each GCN, there are many NDC's. Each NDC must then be checked to determine whether it is from a rebating labeler. Surely it is more effective and efficient to have one agency do this task than asking every state to perform it independently.

In addition, we believe that it is an onerous requirement to mandate that each state – without any assistance from CMS – work with physician providers to ensure that these codes are collected for rebatable drugs. States believe that since this is a national issue impacting all states and providers in the same way, it is reasonable to request that CMS develop standardized literature to educate providers rather than requiring each Medicaid agency to develop its own materials.

States also believe that CMS has significantly underestimated the burden of this provision on states if it is implemented as proposed. At a minimum, CMS should revise its burden estimate to account for the extensive education and outreach that states will ultimately be required to undertake.

#### ***Aligning Medicare and Medicaid rules***

OHCA also requests that CMS provide clarification and guidance on the rule's impact and interaction with Medicare. There are a significant number of providers that will be impacted because of Medicaid's role in providing coverage for individuals dually eligible for Medicare and Medicaid. We are concerned that the proposed rule does not address the impact on Medicare carriers and, in turn, this will create obstacles in our ability to efficiently comply with these provisions. In fact, based on previous experience working with Medicare providers, some states believe that Medicare carriers are not prepared to provide detailed NDC information that is necessary to ensure that Medicaid can obtain the rebate, when applicable. Without this information, there could be a significant number of denied claims that may not be able to be resolved. In turn, beneficiaries could receive bills for denied claims or be refused treatment.

We urge CMS to use its authority to ensure that the Medicare and Medicaid rules align so that state Medicaid agencies can comply in a timely, efficient manner. That is, CMS should require Medicare to do a "crosswalk" and address Medicare's responsibility in providing rebate information for certain prescription drugs provided to a dually eligible beneficiary.

We also request that CMS consider a longer implementation period for the Medicare crossover claims due to the complex nature of these transactions. We believe that we will be ready to submit detailed information for rebate collection on physician administered drugs for Medicaid-only recipients, but cannot be certain that the Medicare carriers will be able to meet our need for data by 1-1-08.

#### ***Impact on Durable Medical Equipment Regional Carrier (DMERC)***

Many states currently do not receive an NDC from the DMERC. However, states believe that the standardization of claims and billing for physician administered drugs necessarily should impact DMERCs and that there may be a multitude of requirements needed for DMERCs. As such, states also request that CMS provide clarification and guidance on the role and responsibilities of DMERCs with regard to the provisions of the proposed rule.

#### ***NDC requirement for HCPCS drugs***

In addition, we note that there will be operational challenges associated with the NDC requirements for HCPCS prescription drugs. Currently, there are two types of claim forms used to collect HCPCS codes and NDCs: the physician claim form and the outpatient hospital claim form. The physician forms (electronic 837-P and paper CMS-1500) will accommodate the entry of both an NDC and an NDC Units Quantity in the shaded areas of Data Elements 24D and 24G respectively. However, the outpatient hospital form (electronic 837-I and paper UB-04 = CMS-1450) does not have a space for this information in Data Elements 44 and 46.

CMS has indicated that each state should develop its own unique form. The outpatient hospital forms (837-I, UB-04 = CMS-1450) appear to be poorly conceived, as far as capturing specific NDC and NDC Units. One solution would be to have the form designed similarly to the physician form, which uses two lines (a shaded line and a non-shaded line) for each data entry line. This would allow for the entry of the four necessary data elements, the HCPCS procedure code, HCPCS Units, NDC and NDC Units. We would also like to see a data field to accommodate Unit of Measure (UOM) abbreviations e.g. grams, milliliters, kits, syringes, etc. One problem with current unit of measure fields is that the NCPDP unit of measure for EACH is not specific and can represent a number of items, such as kits, syringes, vials, etc.

We urge CMS to reconsider this issue, particularly given the limited timeframe available to adopt a new form. Due to the administrative procedures and existing demands on state staff, we face great challenges in meeting this requirement. Instead, we respectfully request that CMS develop a standard UB04 form that provides for a way to indicate the NDC quantity and unit of measure. This will guarantee uniformity across states and ensure that states are not subject to lose any rebates or revenues.

#### ***Hardship waiver***

CMS, in the proposed rule and in its verbal communication with states, indicated that the agency does not expect that states will need a hardship waiver to meet these requirements. For the reasons stated above and other factors impacting state Medicaid programs, such as the concurrent implementation of the National Provider Identification number (NPI) and ongoing systems upgrades that cannot accommodate the change in the specified timeframe, we respectfully request that CMS be amenable to the possibility that a hardship waiver may be needed and be prepared with a hardship waiver process.

#### **Regulatory Impact Analysis**

##### ***Overall Impact***

OHCA respectfully requests that CMS reconsider or clarify the level of administrative costs associated with this regulation. Specifically, CMS should provide estimates of the federal and state administrative costs. This estimate should reflect the fact that AMP-based FUL pricing is not in effect, states have invested significant time and resources assessing the impact of AMP and the proposed rule, and that with respect to collecting rebates on physician administered drugs, there is much work to be done, not only to implement the requirement but to continue the process.

We are especially concerned with the UB-04 claims and the Medicare crossovers in terms of regulatory impact. If each state is required to set up their own UB-04 process, or to use separate attachments as suggested by CMS on the aforementioned call, it is possible that the cost of these processes will overcome any savings generated from the rebate.

##### ***Anticipated Impacts***

###### **Effects on Retail Pharmacies**

CMS has asked for information that may help better assess the effects of this proposed regulation on small pharmacies, especially low-income areas where there are high concentrations of Medicaid beneficiaries. We provide the following information in response to this request, and would be pleased to provide more detailed information if needed.

Based on State Fiscal Year 2005 data, Choctaw County, in southeastern Oklahoma, had the highest percentage of Medicaid recipients. At 35.37% covered by Medicaid, over one third of all county residents were covered by Medicaid. There are three contracted pharmacy providers in Choctaw County. One is an Indian Health Service facility and so only serves qualified recipients at their pharmacy. One pharmacy is independently owned and provided service to 2,353 Medicaid clients during calendar year

2006, with over 22,000 paid claims for these members. The single chain pharmacy served 2,093 clients during calendar year 2006, with about 12,400 paid claims for these members. It is highly unlikely that the single chain store could absorb the volume of the independent store without sacrificing some client services.

Another example is McCurtain County, located just east of Choctaw County. With 33.19% of their residents enrolled in Medicaid, McCurtain County ranked fourth in the state for percentage covered by Medicaid during State Fiscal Year 2005. During calendar year 2006, 13 pharmacies filled prescriptions for McCurtain County Medicaid members. There are 11 independent pharmacies and 2 chain stores in the county. The independents average 545 Medicaid clients per store per year and over 4,400 paid claims at each store. The range of clients is from 187 to 1,225 per store. The total number of claims paid for the independent stores was 48,605.

The two chain stores combined served over 3,500 clients and had over 20,000 claims. Again, it is unlikely that the two chain stores could absorb the volume of prescriptions filled in the county without decreasing services or increasing their own overhead by hiring more pharmacists and other staff.

#### *Alternatives Considered*

We respectfully request that CMS reconsider the possibility of defining monthly and quarterly AMP's differently. With respect to the realities of the marketplace, manufacturers seem to have some difficulty arriving at quarterly prices now, and increasing the frequency of the reporting will only make that worse. In order to protect small pharmacies, monthly AMP should be truly the basic retail sales market, which is driven by wholesalers purchasing from manufacturers and reselling to individual pharmacies. In order to protect manufacturers from drastic increases in rebates, include the mail order and PBM sales in the quarterly AMP calculation. Until we all have some experience looking at monthly vs. quarterly AMP's, no one can say for sure what the effect of these changes will be – whether there will be savings for Medicaid, whether there will be reimbursement decreases for pharmacy providers, whether there will be increases in rebates for manufacturers, whether there will be access to care issues for patients.

We would be pleased to provide any additional information that may helpful to you on these matters. Thank you for considering our comments. If you have any questions, please do not hesitate to contact me at (405) 522-7325 or via e-mail at [Nancy.Nesser@okhca.org](mailto:Nancy.Nesser@okhca.org).

Sincerely,

Nancy Nesser, Pharm.D., J.D.  
Pharmacy Director

**Submitter :** Lonnie Morgan  
**Organization :** Lonnie Morgan  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-2238-P-1299-Attach-1.PDF

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

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

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

**Submitter :** Mrs. Amanda Hayes  
**Organization :** Little Drugs  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1300-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**

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 student pharmacist at the Samford University McWhorter School of Pharmacy and am interested in community retail pharmacy practice. I work at Little Drugs, a community retail pharmacy located at 510 South Main Street Sweetwater, TN and I am familiar with the challenges in retail pharmacy practice.

**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 a 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 the pharmacy in which I work, where the majority 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,  
Amanda Hayes  
704 Overlook Drive  
Morristown, TN 37813

cc: Senator Lamar Alexander  
Senator Bob Corker  
John Litz