Submitter : Ms. Christine Bronson **Date:** 02/20/2007

Organization : Minnesota Department of Human Services

Category : State Government

Issue Areas/Comments

Background

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Thank you for the opportunity to comment on the proposed regulation. Minnesota supports efforts to ensure appropriate payment for Medicaid services. This has been a challenge in the area of pharmacy services for many years and we look forward to receiving regular updates on Average Manufacturer Prices. We also support the agency s goal of paying appropriately for generic drugs.

For many years, Minnesota has implemented fairly aggressive pricing policies for generic drugs. Currently, many of our Maximum Allowable Cost (MAC) limits are close to 40 to 60 percent below the Federal Upper Limit (FUL) amounts and have been applied to more products than are on the FUL list. We have also implemented MAC price controls for drugs earlier than CMS has included them in the FUL list, routinely implementing MAC pricing when one generic equivalent was widely available.

Minnesota, like many other states, has a significant rural population and must be cognizant of access issues for our Medicaid beneficiaries living in non-urban areas. Therefore, we must continuously balance our efforts to reduce costs with our responsibility to set reimbursement amounts sufficient to ensure that all Medicaid beneficiaries have access to prescription drugs. With that in mind we have the following comments on specific provisions of the proposed regulation.

Collection of Information Requirements

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Definition of Retail Class of Trade, Determination of Average Manufacturer Price
Mail Order and PBM CMS is proposing to include in the calculation of AMP mail order discounts and pharmacy benefit manager (PBM) rebates, discounts and fees in the calculation of AMP. We are concerned about the inclusion of these discounts and rebates in the AMP calculation when used in conjunction with the FUL process. While we understand that including these discounts in the AMP may be appropriate from a rebate perspective, we are concerned that their inclusion in AMP for purposes of the FUL may affect access.

Direct Sales Please clarify the meaning of direct sales as it will be used in the AMP calculation. Will manufacturer patient assistance programs be considered direct sales?

Bundling We support the inclusion of bundled sales in the determination of AMP.

Rolling Average for AMP We support the use of a rolling average for AMP prices, however, we suggest that CMS specify in the final regulation the precise methodology that will be used. For example, CMS should clarify if it intends to use AMP data from periods prior to the implementation of the new definition of AMP in the post-implementation rolling averages. It would also be helpful to include the entire discussion of rolling averages in both the AMP definition and the FUL sections of the preamble text in the final regulation.

Federal Upper Limits
Nine Digit Level NDC CMS currently uses the 100 count package size in calculating the FULs. Please include a discussion of how using the nine digit level codes, which essentially average the effects of package size, will affect the FUL prices in the final regulation. We are concerned that using large package sizes more commonly used by mail order services rather than retail, would skew the AMP toward a price that is lower than may be available to retail pharmacies.

Rolling Average for AMP As noted above, we support the use of a rolling average for AMP but ask that CMS specify the methodology to be used and include a discussion of it in this section of the final regulation.

Systems Issues MAC and FUL We have already noted our concerns as to the possibility that FUL limits for some drugs could be below pharmacy acquisition cost within some chemically equivalent groups. While we understand the aggregate nature of the FUL limits, we have historically ensured our compliance with the FUL limits by setting our MAC limits using the FUL methodology within the chemically equivalent groupings. If we find that we must adjust a significant number of our MAC rates to account for the FUL being below acquisition costs, we will also have to completely retool our system to recalculate our aggregate FUL limits.

Dispensing Fees In the preamble section of the regulation defining dispensing fees, CMS seems to imply that dispensing fees might be used to cover some of the shortfall in Medicaid payments for drugs where actual acquisition costs are above 250% of the AMP. Yet in the regulatory language section, dispensing fees are clearly defined as being limited to only those costs associated with dispensing the medication. Both the preamble to this regulation and Drug Rebate Program Release #144 contain suggestions that states evaluate their dispensing fees to ensure that the fees are reasonable. We are concerned that some would interpret these statements as encouraging states to increase dispensing fees to offset potential losses on ingredient costs due to the new FUL limits.

GENERAL

GENERAL

See Attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Physician-Administered Drugs

Information Required to Claim Rebates There are several pieces of information that will be required in order for states to claim rebate amounts on physician-administered drugs. Because many of the claims will be for services provided to beneficiaries that are eligible for both Medicare and Medicaid, CMS should ensure that Medicare providers or claims processors have processes in place to collect and transmit this information to state Medicaid agencies.

" CMS must ensure that the National Drug Code (NDC) numbers are reported on all Medicare claim forms. States cannot process rebates for multiple source drugs without the NDC information.

" CMS should also ensure that the NDC Quantity, in addition to the HCPCS Quantity is reported on all claims forms.

" CMS should ensure that standard billing instructions are followed for reporting NDC and NDC Quantity.

" States will also need to know the Medicare payment amount for each drug administered. The most common reason manufacturers cite in rebate disputes is that the rebate amount is not proportional to reimbursement. If states do not have ready access to the Medicare paid amount, manufacturers will have no incentive to refrain from disputing the Medicaid rebate requests.

Guidance to CAP Vendors Medicare has recently implemented the Competitive Acquisition Program (CAP) for Part B drugs. We recommend that Medicare issue guidance to or work with CAP vendors to ensure that they collect and transmit to state Medicaid agencies all of the information required for states to cover the Medicaid share of the drug costs and collect the rebate from the manufacturer.

Proportionality of Rebates Collected The proposed rule does not address the proportionality of the rebate to the amount paid by Medicaid for physician-administered drugs. Historical practice has been for states to claim Medicaid rebate on the full amount paid for the drug, rather than Medicaid paid amount. We support continuation of the historical practice of claiming rebates based on the total amount paid by all parties.

CMS-2238-P-1346-Attach-1.PDF

1346

Minnesota Department of **Human Services**

February 20, 2007

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

Minnesota Department of Human Services Comments:
Docket: CMS-2238-P, DRA Provisions Pertaining to Prescription Drugs

Dear Ms. Norwalk:

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Sincerely,

Christine Bronson

Christine Bronson
Medicaid Director

Submitter :

Date: 02/20/2007

Organization : Safety Net Hospitals for Pharmaceutical Access

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1347-Attach-1.DOC

#1349

Safety Net Hospitals for Pharmaceutical Access

COMMENTS IN RESPONSE TO NOTICE OF PROPOSED RULEMAKING OF DECEMBER 22, 2006 TO IMPLEMENT THE DEFICIT REDUCTION ACT OF 2005

RE: CMS File Code 2238-P

Safety Net Hospitals for Pharmaceutical Access (SNHPA) submits these comments in response to the Notice of Proposed Rulemaking published in the Federal Register on December 22, 2006, regarding regulations to implement the Deficit Reduction Act of 2005 (DRA). SNHPA, formerly known as the Public Hospital Pharmacy Coalition, is a non-profit association of safety-net hospitals that qualify as disproportionate share hospitals (DSH) for purposes of Medicare reimbursement, and participate as covered entities under the federal drug discount program established by Section 340B of the Public Health Service Act (the "340B program").

SNHPA and its members believe that several aspects of the proposed regulations need to be substantially revised in order to avoid adverse consequences that include: (1) unrealistic requirements and undue burdens in hospital operation and administration, (2) interference with or confusion in program operations administered by the Centers for Medicare and Medicaid Services (CMS), but which are nevertheless the responsibility of the Department of Health and Human Services (HHS), (3) negative impact on delivery of patient care, and (4) ineffective execution of Congressional intent in the governing legislation. As is explained below, certain of the proposed regulatory provisions reflect a failure to take cognizance of significant practical and legal obstacles, or to give adequate consideration to ways in which implementation of policies in the Medicaid program will affect other important HHS programs

I. (Proposed §447.520) – "Physician Administered" Drugs

Of particularly grave concern to SNHPA and its member hospitals is the proposal to require State Medicaid agencies to collect National Drug Code (NDC) information with respect to outpatient drugs administered to patients incident to a physician's service in physicians' offices, hospital outpatient clinics and departments, and other outpatient settings. We strongly oppose the proposed application of this requirement to drugs administered in hospital outpatient settings. The proposed requirement threatens to impose a burden on hospitals that is not only significant but severe, and to have serious negative effects on the 340B program and its participating providers. In addition, as applied to hospital outpatient clinics and departments, we believe the proposed requirement is entirely unnecessary and indeed contrary to Congressional intent.

A. Background

Proposed Section 427.520 of the DRA regulations ostensibly implements Section 6002 of the Act, which amended Section 1927(a) of the Social Security Act to require State Medicaid agencies to collect NDC information on so-called "physician administered" drugs, so that manufacturer rebates can subsequently be collected on those drugs. The published rulemaking Notice makes it clear that CMS intends the requirement to apply to drugs administered in hospital outpatient settings, as well as physicians' offices and other locations where drugs are furnished incident to a physician's service. In recent months, SNHPA, whose membership includes the majority of hospitals qualified (by virtue of the high percentage of indigent patients they serve) to participate in the federal 340B drug discount program, has received a steady stream of e-mails and telephone calls from member hospitals that are strongly opposed to the proposed rule on "physician administered" drugs.

CMS has indicated that it does not expect the administrative burden imposed by this new requirement to be significant, or for the associated expense to be very great. It has estimated that the cost to providers of reporting NDC numbers on all "physician administered" drugs will be approximately 9 cents per claim, and that an average of 15 seconds of staff time per claim will need to be devoted to manually accomplish reporting of NDC numbers on Medicaid billing submissions. CMS acknowledges that compliance with the requirement will ultimately require an overhaul of most providers' electronic billing systems, but offers no estimates of the time or expense that would be involved in this eventuality. Yet CMS nevertheless takes the position that reporting NDC numbers will not have a significant impact on providers.

B. The Proposed Requirement Would Place an Unreasonable Burden on Hospitals

According to our member hospitals - and contrary to the assumptions made by CMS - the burden associated with providing NDC numbers in Medicaid billing submissions for drugs administered in hospital outpatient settings would be extraordinary, and the task would be virtually impossible to accomplish with any meaningful degree of accuracy. The 15 second per claim estimate advanced by CMS with respect to manual billing is vastly understated;[1] and, in any event, electronic billing requirements imposed under HIPAA make manual billing procedures an unrealistic solution for anything but the short term. The expense of adapting hospital billing systems to accommodate the new NDC reporting requirement would in fact average in the hundreds of thousands of dollars for each hospital, and this is an expense many hospitals – especially small facilities and institutions already struggling to stretch their resources to serve large indigent populations – can ill-afford.[2]

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[1] Indeed, even from a purely common-sense perspective, the 15 second estimate seems oddly divorced from reality. The NDC number for a drug will be an eleven-digit number that conveys a good deal of information about a drug, including information as to the form and packaging of the product. Just to copy an eleven digit code by hand with any degree of care would normally take something like two-thirds of the 15 second time frame CMS would allocate to the task – leaving virtually no time for the undoubtedly more time consuming demands of finding and verifying the accuracy of the numbers to be copied onto a Medicaid billing form.

[2] It should be noted that seven years ago, when a similar specter of having to associate NDC numbers with hospital outpatient drugs was raised (and ultimately rejected) in connection with proposed regulations to

The present proposal seems to overlook much of the financial and administrative burden that, as a practical matter, would face hospitals if they were forced to change their current systems and begin using NDC numbers to bill Medicaid. Currently, hospitals use NDC numbers for two purposes: drug purchasing and inventory maintenance. NDC numbers are rarely, if ever, utilized in hospital accounting or billing systems. Instead, the somewhat less specific, HCPCS codes known as "J-codes" are generally utilized to bill outpatient clinic drugs for Medicaid purposes. In order to incorporate NDC data into billing submissions, nearly all practice management systems would need to be re-adapted to accommodate expanded fields and larger databases to display and store thousands of NDC numbers. For these reasons, the billing system changes needed to accommodate association of NDC numbers with hospital outpatient clinic drugs billed to Medicaid would be complex, comprehensive, and extremely costly.

Moreover, not only is the technical and logistical task of recording and reporting NDC numbers on hospital clinic drugs highly problematic, but the accurate determination of those numbers presents equally intransigent difficulties. Because NDC numbers both identify a drug substance and convey information about its dosage, form, and packaging, there are many possible NDC designations that may pertain to the same pharmaceutical product. When drugs are sold directly to patients for self-administration, such as regularly occurs in hospital outpatient pharmacies, this is not ordinarily a problem, because drugs will generally be sold in a form and quantity with which a specific NDC is associated. However, in an outpatient treatment setting, patients will frequently be administered a limited amount or dose of a drug that the hospital purchased in bulk, or at least in larger quantity, and generally not in single-dose packaging. Thus there simply may not be an accurate NDC designation for a given incidence of drug administration in an outpatient clinic.

For example, if a syringe were to be filled with an injectable medication from a vile of liquid medication, but it did not take the entire contents of the vial to fill the syringe, and that vile had been packaged with nine other, similar vials in their original packaging, assigning an accurate NDC number to the drug treatment actually administered to a patient could be difficult or impossible. Hospital staff would have to calculate how much of the vial, from the box of ten vials, was used to treat the patient, and attempt to associate an NDC number with their best approximation of the form and quantity of the drug. But depending upon the exact amount of the drug used, it might be impossible to achieve accuracy, because there might not be a specific NDC number for the drug in the form and quantity actually used.

Where (as is frequently the case with cancer treatments and many other drug therapies administered to patients on an outpatient basis) a patient receives a pharmaceutical "cocktail" of multiple medications through one infusion or other drug treatment modality, the NDC reporting difficulty would be compounded exponentially. Indeed, drugs are often administered in hospital outpatient clinic settings with the use of pre-mixed, infusion "bags"

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implement HIPAA, the American Hospital Association's information indicated an average cost of roughly $200,000 to each hospital subjected to the new requirement. That figure would, of course, be substantially higher in current dollars.

consisting of a combination of various drug substances in various quantities, the precise formulation of which even a prescribing doctor may not be specifically aware when he orders the treatment. Furthermore, hospitals very often purchase the same medications in a variety of package forms and sizes, depending on the hospital's needs and the relative cost and availability of different forms and packaging options at various times. In order to comply with an NDC reporting requirement for Medicaid billing, hospital staff would have to meticulously monitor each package of medication and determine which patient receives precisely what quantity of medication from what type of package, in order to bill Medicaid properly for that patient's treatment.[3] Tracking these matters with the requisite level of care and precision in an outpatient hospital treatment setting would be a logistical and administrative nightmare. The burden, in terms of staff time and effort would be enormous, and even with the best of intentions and efforts, a great deal of inaccurate or misleading information would still in all likelihood be communicated to State Medicaid agencies.

There is also legitimate cause for concern that patient care might suffer as a result of NDC reporting requirements being imposed on hospital outpatient clinics and departments. The need for constant vigilance and tracking of drug packaging and use information would be an additional task for physicians and other medical personnel, and the attendant delay and diversion of staff attention and resources could detract from the efficacy of patient care. The magnitude of the additional administrative burden and expense associated with NDC data collection is of especially great concern to the safety net hospitals that SNHPA represents, because the limited resources of these hospitals are already strained by the demands of caring for a patient population that includes a high proportion of uninsured or underinsured individuals unable to pay for their own care.

C. The Proposed Extension of NDC Reporting Requirements to Hospitals Is Unnecessary and Improper

Not only are the administrative difficulties of the proposed new requirement on hospitals prohibitive from a practical standpoint, but there is no need to impose the administrative and financial burdens described above on hospital outpatient clinics at all. Indeed, it would be improper under the law to do so, since the purpose of NDC reporting -- enabling States to collect manufacturer rebates on drugs that are "physician administered" -- does not apply to drugs administered in most, if not all, hospital outpatient clinics. Correctly read, the DRA does not mandate submission of NDC numbers in billing Medicaid for drugs administered incident to physicians' services in hospital outpatient settings; but the numerous factors that support this conclusion appear to have been overlooked by CMS in promulgating its proposed rule.

First, Section 6002 of the DRA amended the rebate provisions of the Medicaid statute to require States to collect drug utilization and coding data "such as NDC numbers *or J-Codes* for drugs that are physician administered." Accordingly, collection of J-Codes with respect to

[3] It may be that some similar problems could affect NDC reporting in physicians' offices to some degree as well, but the problems and complexities of tracking and monitoring drug packaging sources and sizes is obviously magnified in the hospital context, because of bulk purchasing and supply issues, as well as the greater possibility of affording drug treatment to patients in need of emergency outpatient care.

drugs administered in hospital outpatient clinics would comply with the letter of law, even assuming drugs administered in that setting were intended to fall within the statutory meaning of "physician administered" drugs. Since virtually all hospital billing systems are now configured to bill for outpatient clinic drugs with the HCPCS codes known as "J-Codes," compliance with the new law, on its face, does not necessitate the burdensome changes that, as we have explained above, would be involved in submission and collection of NDC numbers.[4]

Second, and more importantly, CMS appears to be misconstruing the "physician administered" drug provision to pertain to hospital outpatient clinic drugs. The purpose of the NDC submission and collection requirement, as expressed by Congress in the words of the statute itself, is to better enable States to collect manufacturer rebates on drugs pursuant to Section 1927 of the Social Security Act.[5] However, drugs administered on an outpatient basis in most hospital clinic settings have long been exempt from application of the Medicaid rebate laws pursuant to Section 1927(j)(2) of the Medicaid Act. Thus, since as a general rule manufacturer rebate obligations do not apply to hospital outpatient clinic drugs, Congress could not have intended to require NDC number information to be collected by States in order to pursue rebates on those drugs.

D. Accurate Construction of DRA Section 6002

In construing Section 6002, a starting point is the heading on the section as it was enacted by Congress in the DRA. That heading plainly indicates that Congress did not intend the provision to apply to *all* "physician administered drugs," but rather to some subset described in the DRA as "*certain*" physician administered drugs. It is also extremely important to note that Section 6002 expressly amended Section 1927(a) of the Social Security Act (SSA), but did not purport to amend or repeal any other, pre-existing provision of the Medicaid statute. In particular, the relevant provisions of the DRA made no reference to, and accordingly did not alter the continuing legal force and effect of, Section 1927(j) of the SSA, which expressly exempts drugs used in certain types of outpatient care settings from rebate requirements.

The Conference Report accompanying the bill enacted as the DRA makes the point quite clearly. In a section-by-section analysis of the bill, the Conference Committee prefaced discussion of Section 6002 with a description of "current law," noting that the law expressly exempts drugs provided through managed care organizations and in certain outpatient hospital settings from manufacturer rebate requirements.[6] Thus the Conferees acknowledged the existing exemptions from rebate requirements that are established in Section 1927(j) of the Medicaid statute, which provides, in pertinent part, as follows:

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[4] The statute directs the use of NCD numbers unless the Secretary, in his discretion, chooses to instruct that alternative information be utilized. Thus the Secretary plainly has authority to direct that J-Codes, and not NDC's, continue to be the data reported to Medicaid on clinic administered drugs. This is the case even if clinic administered drugs are regarded as falling within the statutory reference to "physician administered" drugs – which as we explain they should not be.

[5] Section 1927 of the Social Security Act is codified at 42 U.S.C. §1396r-8.

[6] *See* H. R. Rep. No. 109-362, at 262 (2005)

(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.-
(1) Covered outpatient drugs dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m), are not subject to the requirements of this section.
(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

The Conferees went on in the Report expressly to distinguish between these statutorily exempt drugs and the drugs to which the new provision was intended to apply, described as "[c]ertain drugs administered by physicians in their offices or in another outpatient setting, such as chemotherapy [that] have often been excluded from the drug rebate program although there is no specific statutory exclusion."[7] In other words, the Conference Report confirms that it was only drugs for which "there is no specific statutory exclusion" from rebates, that Congress intended to subject to NDC reporting (and subsequent rebate collection) through the DRA. Accordingly, in the remainder of the discussion of the provision in the Conference Report, it is clear that the references to "physician administered outpatient drugs" (with respect to which Congress intended the new law to require collection of NDC numbers) refer to the drugs that as a practical matter had generally not been subjected to rebate requirements by the States, despite the absence of any applicable statutory exemption.

Given the Conference Report's explicit acknowledgement of exemptions from rebate requirements in current law, the absence of any reference in the text of the DRA to repealing or altering those exemptions can only be construed as a conscious decision to leave the exemptions in place.[8] The salient inquiry for purposes of determining the impact of DRA Section 6002 on hospital clinic administered drugs, therefore, is whether those drugs fall within the Section 1927(j) exceptions from rebate requirements. This is so because, under basic tenets of statutory construction, statutes must be read as a whole, and each part of a statute is to be construed in the light of the other provisions of the same statute,[9] so as to reconcile competing

[7] Id.

[8]Since, as the Conference Report demonstrates, the legislators responsible for enacting the DRA were fully aware of the preexisting provisions at SSA Section 1927(j) creating statutory exemptions from rebate requirements in Medicaid law, their failure to amend or even mention those provisions in Section 6002 itself cannot reasonably be construed as an oversight. If Congress had wanted to repeal or amend these provisions, it most certainly would have said so.

[9]*See, e.g., Dolan v. U.S. Postal Service*, 126 S.Ct. 1252, 1257 (2006) ("The definition of words in isolation, however, is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis."); *Lexecon v. Millberg Weiss Bershad Hynes*, 118 S.Ct. 956, 962, 523 U.S. 26, 36 (1998)(A central tenet of construction is that a statute is to be considered in all of its parts when construing any one of them).

provisions and, to the extent possible, give all parts of the same statute a harmonious meaning.[10] It follows that whatever drugs fall within the purview of the Section 1927(j) exemptions from the rebate law cannot be regarded as "physician administered drugs" within the meaning of the SSA Section 1927(a), as amended by the DRA, since Congress apparently intended those drugs (unlike those exempt under subsection (j)) to be subject to rebates.

E. Hospital Clinic Administered Drugs are Ordinarily Exempt from Rebates

Clinic administered drugs generally fall within the scope of subsection (j)(2) and are not subject to Medicaid rebates. To reiterate, section 1927(j)(2) excepts from rebate requirements drugs used by :

> ...a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan).

Drugs administered by medical professionals in hospital outpatient clinic settings are virtually always subject to hospital formulary systems, so this first statutory criterion is easily met by clinic administered medications in most if not all hospitals. Proper application of subsection (j)(2) turns, then, on the meaning of the language describing rebate-exempt hospital outpatient drugs as ones for which the hospital "bills [Medicaid] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan)." Consistent with this standard, hospital outpatient clinic drugs are characteristically billed to state Medicaid programs at or below levels defined by Title XIX state plans as the estimated acquisition costs (EACs) for the drugs, plus a reasonable dispensing fee.[11]

Importantly, hospital "purchasing costs" within the meaning of subsection (j)(2) cannot reasonably be construed to be their actual acquisition costs (AACs) of obtaining the

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[10] *See, e.g., Schmitt v. City of Detroit*, 395 F.3d 327, 330 (6th Cir. 2005); *United States v. Stauffer Chemical Co.*, 684 F.2d 1174, 1184 (6th Cir. 1982), aff'd 464 U.S. 165, 104 S. Ct. 575 (1984).

[11] Under regulations at 42 C.F.R. 447.331 and 447.332, Medicaid payments to hospitals for most covered outpatient drugs administered to Medicaid beneficiaries are limited to the lower of the provider's "usual and customary charges to the general public" and the "estimated acquisition costs" (plus reasonable dispensing fees) for the drugs, as established by the State Medicaid agency. Thus, while a hospital's billing submission to Medicaid for reimbursement of costs of administering outpatient drug treatment to a Medicaid beneficiary may reflect the provider's "usual and customary" or "chargemaster" charge for the drug utilized, this is in fact the information needed by the State in order to apply the relevant federal regulation and pay the provider at or below a level estimated by the State to represent "acquisition cost" (plus a dispensing fee) for the drug. In effect, then, a hospital's submission of its chargemaster or "usual and customary" charges to a Medicaid State agency represents its request for payment at the lower of that rate or the EAC that is determined by the State agency and specified in the applicable Medicaid State plan. While the uniform "chargemaster" rate representing the hospitals "usual and customary" charge may appear on the bill sent to Medicaid, what the hospital is seeking is payment at the Medicaid rate of reimbursement, established under the relevant State Plan. A hospital thus "bills" Medicaid for outpatient drug treatments no more than the applicable, state-determined EACs, by providing the requisite billing information to enable the State to make payment at the proper rate (*i.e.,* at the EAC level if it is lower than the provider's usual and customary charges, or at the usual and customary charge rate in the event it is lower than EAC).

pharmaceutical products administered in outpatient settings, which may be lower or in some instances higher than EAC levels for the same drugs. This is plain on the face of the statute by virtue of Congress' inclusion in (j)(2) of the parenthetical language "as determined under the State plan." If this language is to be ascribed any meaning or effect at all, it must be read to clarify Congressional intent that a "hospital's purchasing costs" as referenced in the statute are not costs that are fixed as a factual matter or by market forces external to Medicaid (*i.e.*, such as the actual prices paid by a provider to obtain drugs), but are rather cost levels specifically determined under the provisions of a reimbursing State's Medicaid plan, such as EACs defined under most states' Title XIX plans as the maximum proper billing and reimbursement rates for hospital outpatient drugs administered to Medicaid beneficiaries . Any other construction renders the parenthetical language in (j)(2) utterly meaningless and completely superfluous, contrary to well-established canons of statutory construction.[12]

That 1927(j)(2) exempts most hospital clinic administered drugs from Medicaid rebate requirements is also a conclusion comporting with the structure and internal logic of the Medicaid law. The subsection (j) exemptions address a marketplace reality that is common to both the managed care and hospital outpatient clinic settings for pharmaceutical care, both of which are encompassed by the exemption. Specifically, these are settings in which the drugs that providers utilize are especially likely to have been obtained from drug manufacturers at negotiated prices that are relatively favorable to the purchaser. Health maintenance organizations (HMOs) and other managed care organizations (MCOs) generally are able to negotiate lower prices based on high-volume purchasing, and hospitals utilizing formulary systems can leverage more favorable pricing on drugs through inclusion or exclusion of specific products in developing and maintaining their formularies. Implicit in Section 1927(j) is the Congressional purpose to protect manufacturers from being required, in effect, to afford two separate discounts on the same drugs. If manufacturers were to sell drugs to MCOs at prices lowered by high-volume discounts, and sell outpatient drugs to hospitals at prices discounted so as to gain placement on the hospitals' formulary systems, but then be required to pay Medicaid rebates on the same drugs, the manufacturers would be, in essence, discounting their products twice. The subsection (j) exceptions plainly anticipate and correct for this potential unfairness.

Another point worth noting is that under Section 1927(k)(1) of the statute, AMP is based on the average price paid by wholesalers for a covered outpatient drug distributed to "the retail pharmacy class of trade." AMP calculation does not take into account, in other words, drugs purchased and utilized by HMOs or hospitals for outpatient clinic use, because these settings are not part of the "retail pharmacy class of trade." Pursuant to Section 1927(c) of the Social Security Act, the Medicaid rebate on a covered outpatient drug is calculated according to a formula that is based on the drug's AMP. It would therefore be anomalous for rebates to be calculated for drugs, (such as those dispensed by health maintenance organizations or administered in hospital clinics) that are excluded from the calculation of AMPs due to not

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[12] *See, e.g., Cooper Industries, Inc. v. Aviall Services, Inc.*, 125 S.Ct. 577, 584 (2004); *TRW Inc. v. Andrews*, 534 U.S. 19, 122 S. Ct. 441, 449 (2001); *Duncan v. Walker*, 533 U.S. 167, 174, 121 S. Ct. 2120, 2125 (2001).

being dispensed "in the retail class of trade," and consequently with respect to which there is, in effect, no relevant AMP figure.

Thus, as has been explained above, hospital clinic administered outpatient drugs continue to be exempt from rebate requirements, and DRA Section 6002 could only have been intended to subject "physician administered drugs" in non-hospital settings to NDC reporting and rebate payment requirements. The historical backdrop to enactment of DRA Section 6002 further supports this conclusion. Section 6004 was drafted soon after and in apparent response to issuance of a Report by the Office of Inspector General (OIG) of the HHS, finding that the States were losing millions of dollars in Medicaid funds by their failure to collect rebates on "physician administered drugs." CMS makes frequent reference to this OIG Report in the Federal Register issuance explaining the proposed DRA regulations, and seems to acknowledge the relationship between the OIG Report and the purpose of Section 6002. In fact, CMS has indicated that cost estimates for savings to be achieved through implementation of the "physician administered drug" rule are based on the cost estimates made by the OIG in connection with its report on the same topic. The subject of this report, however, *was limited to drugs administered to patients in physician offices*; and indeed the report explicitly defined the "physician administered drugs" with which it was concerned as "drugs that a medical professional administers to a patient in a physician's office." [13]

This same definition of "physician administered" drugs should also be applied in implementing Section 6002 of the DRA. But even if there are some outpatient treatment settings other than physicians' offices to which the "physician administered drug" rule should properly apply, it is at least clear that hospital outpatient clinics – which are exempt from rebate requirements under Section 1927(j)(2) of the Medicaid Act – are not among those treatment settings; and the final regulation should be revised to reflect this point.

F. Misapplication of DRA Section 6002 Undermines the 340B Drug Discount Program

Yet another concern raised by misinterpretation and misapplication of the "physician administered" drug provision is the negative impact the proposed rule would have on the 340B drug discount program. The fundamental purpose of the 340B program is to afford deep discounts to qualifying "safety net" health care providers on drug purchases so that these facilities will better be able to stretch their limited resources and care for indigent and uninsured patients. For many 340B covered entities, which by definition are facilities that serve large indigent populations, much of the benefit of 340B program participation derives from savings achieved by purchasing drugs at discounted 340B prices for outpatient clinic use, including use in treating Medicaid beneficiaries.

For many of these entities, the 340B program assists in stretching their resources largely because hospital outpatient drugs are not "rebatable." If rebates were to be collected on those drugs in the future, 340B providers would lose a substantial part or in some cases virtually all of their 340B savings, which have been an important support to these facilities for

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[13] Office of Inspector General, Department of Health and Human Services., OEI 03-02-00660, *Medicaid Rebates for Physician Administered Drugs (2004)*

more than a decade and on which they have come to rely. This is because the law prohibits subjecting manufacturers to "double discount" obligations. That is, manufacturers may not be both charged Medicaid rebates and required to afford 340B discounts on the same drugs. Consequently, collection of rebates on clinic-administered hospital outpatient drugs would likely force 340B entities to give up the benefit of discounted purchases they make under the 340B program for Medicaid patient treatments.[14] This would represent a sufficiently large part of the 340B benefit to many of our member hospitals that a high percentage of them have indicated they would seriously consider dropping out of the program as a result.

The problem is one particularly likely to have a negative impact on children's hospitals, which, as Congress provided in the DRA, are now to have access to 340B discounts on drug purchases. Because many children's hospitals have an exceptionally high percentage of Medicaid patients, and because few of them operate outpatient pharmacies that dispense drugs for self-administration, the loss of potential benefit to those hospitals from discounted 340B purchases of clinic drugs for their Medicaid patients could render 340B participation all but pointless for many of the children's facilities that have waited so long to gain much-needed support from 340B authorities.

The problems created in the 340B program, moreover, would not be limited to diminishing the number of safety net providers that participate in or benefit from the program. The usual process for avoiding duplicate discounts in the 340B program with respect to drugs bought by Medicaid patients from 340B participating outpatient "retail" pharmacies involves use of an "exclusion file" maintained by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA). Pharmacies dispensing 340B drugs are listed in the OPA exclusion file, and these pharmacies are identified to State Medicaid agencies as entities whose purchases should not be subjected to rebates, so that duplicate discounts can be avoided. However, clinic administered drugs are sometimes billed by a hospital and sometimes by physicians that staff the hospitals. Consequently, OPA's exclusion file and its system for transmitting information to States is not capable of recording and identifying the hospital clinic drugs purchased under 340B authorities that would need to be afforded "special handling" by States to avoid the duplicate discount problem if rebates were collected on those drugs. Thus application of the "physician administered drug" rule to hospital outpatient clinics will cause a severe problem for OPA in fulfilling its administrative responsibilities in the 340B program. Furthermore, SNHPA is already hearing that some drug companies, anticipating the fact that OPA will be unable to avoid a double discount effect respecting 340B drugs, have suggested they may respond by simply refusing to sell 340B drugs to hospital outpatient clinics in the future.

Before turning to the next section of these comments, we would like to briefly summarize the above points. First, the explanation provided by CMS for the proposed rule on physician administered drugs fails to accurately quantify or characterize the administrative and financial burdens on hospitals that would be associated with an NDC reporting requirement on clinic administered Medicaid drugs. Second, there is no need to impose the new NDC

[14] This would have to be accomplished either by the providers "carving out" their Medicaid inventories from 340B purchases, and not using 340B drugs for Medicaid patients, or by the State foregoing rebates and reimbursing 340B providers at their 340B discounted drug price levels.

reporting requirement in the hospital outpatient clinic context, because in that setting the law precludes the rebate collection that is the *raison d'être* of the NDC reporting provision in the first place. Lastly, CMS overlooks the significant adverse impact of the proposed rule on operations and administration of the 340B program.

II. Provisions of the Proposed Rule Relating to AMP Calculation and Reporting (Proposed §447.504)

The proposed regulation also should be revised or clarified in other important respects. CMS has not included in its cost estimates any recognition of the fact that the new statutory and regulatory formula for computation of Average Manufacturer Price (AMP) (to the extent it no longer takes prompt pay discounts into account) would tend to drive up drug price ceilings under the 340B program if it were applied in the 340B pricing formula. This would result in significant additional costs to 340B covered entities. That result should not come about because, by application of subsections (b)and (c) of Section 340B,[15] AMP must continue to be calculated as it was prior to passage of the DRA, for purposes of determining the 340B ceiling price of covered outpatient drugs. This needs to be made clear in the issuance of final regulations, however, in order to avoid confusion and the possibility of undue and improper increases in the costs of drugs to safety net healthcare facilities.

The 340B provider community is also deeply distressed by the proposed policy choice of requiring manufacturers to identify drugs for purposes of AMP calculations through NDC numbers that consist of only 9 digits, instead of the 11 digits that fully identify a drug in terms of package size. As CMS expressly acknowledges in its published regulatory proposal, an 11-digit NDC is critical to providing additional pricing transparency in the 340B program,[16] and utilization of a 9-digit AMP sacrifices this much-needed transparency. It is difficult to comprehend the basis for CMS' apparent conclusion that Congress did not intend AMP to be calculated and reported in the expanded form that would enhance transparency in the 340B program.

Any such conclusion seems especially unfounded in light of hearings held before the House Energy and Commerce subcommittee towards the end of 2004, at which the urgent need for greater transparency in 340B pricing was prominently discussed by members of Congress and witnesses from HHS and from its OIG. Furthermore, the part of the Social Security Act to be implemented by these new regulations (Section 1927) is a section of law expressly concerned with the 340B program as well as the Medicaid rebate program. Thus there is no indication of Congressional intent that the less informative 9-digit NDC form be used in AMP calculation; and some indication that Congress intended the utilization of data in a form more conducive to 340B pricing transparency. To the extent Congressional intent is ambiguous on the point of whether a 9-digit or 11-digit NDC number should

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[15] Section 340B(b) incorporates by reference the definition of AMP in Section 1927(k) of the Social Security Act. Subsection (c) makes it clear that the reference must be read as one to the un-amended Section 1927(k) effective in November, 1992.

[16] Even though in the future the AMP figures relevant to 340B price calculations will differ from the AMP calculated for Medicaid rebate determination purposes, HRSA will presumably need to calculate 340B ceiling prices based on an AMP figure derived from AMP data provided by manufacturers to CMS. The specificity and accuracy of AMP information therefore remains an important concern of 340B providers, irrespective of the fact that ultimately two AMP figures will need to be calculated for each drug. The publicly reported AMP figures, if computed with appropriate specificity instead of as weighted averages, would still enhance 340B program transparency.

be used, there is no question HHS has authority to construe the AMP reporting to pertain to a package-size specific AMP, and there seems no valid rationale for a policy choice by the HHS that consciously undermines the potential for enhancing compliance and efficient administration of a program for which the Department is responsible, *i.e.*, the 340B drug discount program. In fact, CMS had exercised its discretion specifically to define NCD numbers as 11-digit codes in §447.502 of the proposed regulations; and not to apply this definition to AMP calculation therefore seems all the more anomalous. The various factors cited by CMS in the Federal Register Notice as pertinent to its policy choice on this matter weigh decidedly in favor of utilization of an 11-digit NDC, and consequently this is plainly the direction in which the Secretary should exercise his discretion.

III. Nominal Pricing Provisions (Proposed §447.508)

In addition, the proposed regulations explicitly decline to exercise the HHS Secretary's statutory discretion to identify additional "safety net" providers that may receive nominal pricing on drugs without those prices being included in calculations of "best price." This failure to exercise authority seems to us ill-advised and fundamentally unfair to many providers that are mainstays of our nation's health care safety net, but receive inadequate support and assistance in their service to indigent and uninsured citizens. Many of these health care providers are neither qualified to be covered entities under the 340B program nor otherwise specified in the DRA provision on nominal pricing, but nevertheless play a vitally important role in the care of indigent and vulnerable populations. These providers, whose scarce budgetary resources are strained by rising costs of pharmaceutical products, include childrens' hospitals, psychiatric facilities, critical access hospitals, and a wide range of other providers that do not technically qualify as "DSH" facilities or 340B covered entities, but need and deserve the price "break" on drugs that access to nominal pricing can provide.

The statutory changes defining limits on best-price-exempt nominal pricing have already had a negative effect on manufacturers' willingness to provide such pricing, even to the facilities that continue to be eligible for nominal prices on a best-price-exempt basis. This appears to be a consequence of the fact that permissible nominal pricing is now so limited that manufacturers are inclined to avoid the complexities of administering a nominal pricing program by simply terminating all nominal pricing contracts altogether. Congress clearly intended, in passing the DRA, that providers representing the healthcare safety net for our nation's poor and uninsured would be identified and given access to nominal pricing, beyond those providers expressly specified in the law. The agency's failure to exercise its discretion in this regard gives inadequate recognition to the contributions and the budgetary burdens of numerous facilities that serve large indigent populations. It also has a ripple-effect on even those facilities that are technically eligible to receive nominal pricing, because the shrinking scope of nominal pricing programs previously operated by drug companies is being felt in the entire safety net provider community.

A further issue that needs to be clarified in the regulations relating to nominal pricing is the scope of the best price exemption for which the designated safety net providers qualify. The regulations should clarify, for example, that the best price exemption for nominally priced products sold to a qualified hospital would also apply to nominally priced drugs purchased for inpatient use by the same safety net hospital. The rules should also clarify that eligibility for best-price-exempt nominal pricing may extend to other components of a larger health system of which a 340B entity is a

part. This is especially important because in many cases the larger health systems of which 340B entities are a part serve the same vulnerable and largely indigent patient populations served by the 340B facility. While not technically part of the discrete facility qualified for 340B pricing, they nevertheless comprise a larger safety net entity that should qualify for nominal pricing, consistent with congressional intent in the DRA.

IV. Participation of Children's Hospitals in the 340B Program

Finally, Section 6004 of the DRA expressed clear Congressional intent that children's' hospitals serving a high proportion of indigent patients be afforded the discounts on covered outpatient drugs provided to covered entities under the 340B program. The Social Security Act was amended to provide that in order for a manufacturer's drugs to be covered under Medicaid and Medicare Part B, the manufacturer must have an Agreement with the Secretary of HHS to provide 340B discounts to qualifying children's hospitals. In addition, the statute made this new requirement applicable to purchases of outpatient drugs by children's hospitals, effective February 8, 2006. Although the 340B program is administered by HRSA, the DRA provisions regarding discounts for children's hospitals were enacted as amendment, not to the Public Health Service Act, but to the Medicaid statute, which is administered by CMS.

It has now been more than a year since the date when Congress intended qualifying children's hospitals to begin receiving 340B discounts, and yet this expansion of the program has not been implemented in any respect and remains mired in confusion and beurocratic delay. Given this circumstance, and the clarity of Congressional intent that manufacturers' products should not now be covered by Medicaid or Part B Medicare if children's hospitals are not being given access to 340B discounts on those manufacturers' products, we believe it is incumbent on CMS as well as HRSA to take whatever steps are necessary to assure actual implementation of DRA Section 6004 as promptly as possible. The absence from proposed regulations to implement the DRA of any provisions concerning, or even any reference to, 340B discounts for children's hospitals is thus a serious omission, and should be corrected in the final regulations.

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We believe all of the above-mentioned matters need to be addressed and revised or clarified in a final regulatory issuance. We hope that these comments are clear, that they will receive your full and careful consideration in deliberating upon final policies respecting DRA implementation, and that as a result the proposed regulations published on December 22 will be substantially revised in their final form.

William von Oehsen
President and General Counsel

Edith S. Marshall
Special Counsel and Director of Legal Affairs

CMS-2238-P-1348 Prescription Drugs

Submitter : Dr. Jennifer Barker **Date & Time:** 02/20/2007

Organization : Morehead Clinic Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

1. The formula for AMP-based FULs in the proposed rule will not cover pharmacy costs for multiple-source generic medications. 2. AMP was never intended to serve as a basis for reimbursement. 3. To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplised by: a.excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy. b.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. c.reporting AMP at the 11-digit NDC level to ensure accuracy.

Submitter : Ms. Jeanne LaBrecque **Date:** 02/20/2007

Organization : Indiana Office of Medicaid Policy and Planning

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"
Second Submission of Comments. Received error message on 1st attempt.

CMS-2238-P-1349-Attach-1.DOC

Attach # 1547
1349

February 20th, 2007

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

Attention: **CMS-2238-P**

Dear Ms. Norwalk:

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

Sincerely,

Jeanne M. LaBrecque
Director of Health Policy and Medicaid

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

I. "Background"

Agency Comments
None

II. "Provisions of the Proposed Regulations"

Definitions—Section 447.502; Page 77176

Dispensing Fee; Page 77176

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

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

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

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

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

Innovator Multiple Source Drug; Page 77176

Agency Comments

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

Multiple Source Drug; Page 77177

Agency Comments

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

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

Single Source Drugs; Page 77177

Agency Comments

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

Determination of Average Manufacturer Price—Section 447.504; Page 77177

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

Agency Comments

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

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

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

Agency Comments

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

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

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

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

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

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

The Proposed FULs are Extremely Poor Estimations of Pharmacy Acquisition Cost

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

Limited Supply of Drug at the FUL Price

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

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

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

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

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

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

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

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

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

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

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

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

NDC	AMP	Diff %	Util*	Cumul. Util.**	Lowest AMP (30% carve out considered)	Lowest AMP (80% util.)
12345-6789-10	1.00	--	10%	100%		
98765-4321-01	0.5	-50%	50%	90%		Lowest (FUL:1.25)
56789-1234-11	0.25	-50%	25%	40%		
78910-2345-00	0.09	-36%	15%	15%	Lowest (FUL:0.225)	

* Utilization. May be utilization measured by claims data obtained from States, utilization data collected through Medicare Part D, or purchase history obtained from national drug wholesalers.
** The Cumulative Utilization increases from lowest AMP to highest since establishing the FUL based on the lowest AMP where at least 80% of utilization is at or below that AMP would result in a FUL that provides cost coverage for all NDCs at or below that AMP price.

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

Agency Comments

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

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

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

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

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

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

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

III. "Collection of Information Requirements"

Agency Comments
None

IV. "Response to Comments"

Agency Comments
None

V. "Regulatory Impact Analysis"

Requirements for Manufacturers; Page 77198

Agency Comments

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

Overall Impact; Page 77190

Agency Comments

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

Alternatives Considered; Page 77194

Agency Comments

We are also concerned that a sufficient supply of drugs be available nationally at or near the FUL price and believe an exception is warranted. However, based on our analysis, we do not believe in any way, shape or form that the proposed carve-out policy will ensure that a sufficient supply of the drug will be available nationally at or near the FUL.

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Submitter : Dr. Scott Bergman **Date:** 02/20/2007

Organization : Southern Illinois University Edwardsville

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I recently moved to Illinois to serve as a faculty member for the new school of pharmacy at Southern Illinois University Edwardsville. I live in Springfield and work with the physicians in the Division of Infectious Diseases at the SIU School of Medicine. I help treat patients with life threatening infections everyday. I also teach about antibiotics, antivirals, antifungals and vaccines. Student pharmacists learn not just about the medications, but how to use these anti-infectives in a cost-effective manner that will benefit patients and the health care system. In their last year of pharmacy school students will come to learn from me at the clinic and hospitals in Springfield. Today, it takes a minimum of six years to earn a Doctor of Pharmacy (PharmD) graduate degree in order to practice pharmacy. I am a clinical pharmacist trained to make medication recommendations to physicians. This is the future of pharmacy practice. Pharmacists work with physicians to develop medication regimens that lead to successful, cost-effective patient outcomes. My wife, Jessie, is a community pharmacist that has experience counseling diabetic patients about their disease as well as their medications. Before we moved to Illinois, we lived in West Virginia where Jessie was able to earn additional reimbursement for the extra time she spent counseling diabetic patients. This practice was based on a successful model shown to lower overall health care expenses in Asheville, NC. If pharmacists are allowed into the health care decision making process earlier in a patient's care, we can save the system money and improve outcomes. Unfortunately, Illinois is not yet progressive enough to reimburse pharmacists for their clinical knowledge and patient counseling skills. Chicago is participating in a 10 city trial to prove once again that paying pharmacists to educate patients can lower overall health care costs. I encourage you to support efforts such as these that provide pharmacists incentives to improve patient outcomes. Medicare Part D has opened a few doors, but there is still a long way to go before pharmacists are recognized for the professional services they provide. At this time, payment is linked only to dispensing a product and does not take into account the value of a professional service. It has come to my attention that the President's defefit reduction act intends to cut reimbursement to pharmacies. The proposed reductions will lower Medicaid payments for generic medications which are the most affordable products available. This seems counter productive to me. The pharmacists I train make every attempt to lower health care expenses by recommending cost-effective therapies. If the government decreases generic medication reimbursements, then pharmacists will actually be punished for using cheaper medications. The proposed budget cuts also plan on basing reimbursement on 'average manufacturer price'. This value is much lower than what most local pharmacies are able to dispense the product for. Pharmacists are the most accesible health care professionals, but these prices are based partially on what mail order pharmacies are able to purchase their medications at. With these reimbursement rates, local pharmacies that actually see patients and make a difference in their lives will not be able to compete with discount mail order warehouses and patient care will suffer. I hope you take the time to consider this matter.
Thanks, Scott

Submitter : Dr. Eric Lee **Date:** 02/20/2007

Organization : Lees Total Health Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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 : Mr. James Abrams **Date:** 02/20/2007

Organization : Mylan Pharmaceuticals Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1352-Attach-1.DOC

CMS-2238-P-1352-Attach-2.DOC

Attach #1552

February 20, 2007

ELECTRONIC COMMENTS
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments to Medicaid Program; Prescription Drugs Proposed Rule (CMS-2238-P)

Dear Sir or Madam:

Mylan Pharmaceuticals Inc. ("Mylan") is pleased to have this opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") on the *Medicaid Program; Prescription Drugs Proposed Rule (the "Proposed Rule").*[1] Mylan is a leading manufacturer of prescription medicines specializing in developing and manufacturing generic pharmaceuticals. Mylan's customers include wholesalers, distributors, retail drugstore chains, and government agencies. Mylan manufactures and markets 160 generic products in nearly 400 product strengths, covering 46 therapeutic categories. As generics have become a more critical component of the health care system, consumers, insurers, and other prescription drug buyers have saved billions of dollars each year with the use of generics. These savings have resulted in critical savings to the Medicaid program and private drug benefit plans.

As a manufacturer of both generic and branded pharmaceuticals and a participant in the Medicaid Drug Rebate Program (the "Rebate Program"), Mylan strongly shares CMS' commitment to bring clarity and uniformity to the issues relating to Medicaid prescription drug pricing. The Proposed Rule, the issuance of which was mandated by the Deficit Reduction Act of 2005 (the "DRA"), was intended to "clarif[y] the requirements for, and manner in which, average manufacturer prices [AMPs] are determined..." as well as implement the DRA provisions relating to the various aspects of Medicaid prescription drug pricing.[2]

We appreciate the opportunity to comment on the Proposed Rule and look forward to working with CMS in bringing both clarity and operational feasibility to the Rebate Program. As a company, in general, we endorse the comments that have been submitted by the Generic Pharmaceutical Association ("GPhA"), of which we are a member. We are, however, taking this opportunity to submit additional comments that are more specific to our concerns relating to the Proposed Rule. In particular, we have two primary concerns. First, it is important to recognize

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[1] 71 Fed. Reg. 77174 (Dec. 22, 2006).
[2] Deficit Reduction Act ("DRA") § 6001(c).

that AMP only reflects a snapshot in time that may not bear any relevance to market prices. In addition, as a complicating factor in the calculation of AMP and further limitation on the number's usefulness, manufacturers are often not privy to downstream (or indirect) sales and, thus, do not always have the data necessary to comply with CMS' proposed policies with respect to calculating AMP. Second, given the limitations inherent in AMP, manufacturer-specific AMP should not be made available to the "public," nor was that the intent of the DRA, which we discuss in detail below.

In addition to these fundamental considerations, however, which we have set forth in the beginning of our comments, we have organized our other concerns in their respective sections of the Proposed Rule.

I. Overall Concerns

A. AMP Is An Imprecise Number.

Our primary concern with respect to the Proposed Rule relates to the misconception that AMP is necessarily a price reflective of market prices. A myriad of business transactions cause periodic changes in AMP from month-to-month. Examples of such transactions include – backorders, temporary discontinuation of a product, low demand, and swings in sales and credits. As such, at any particular point in time, AMP may be different from the average price received by the manufacturer. Illustrative of this issue is the example below that demonstrates how the AMP of a single product could change as a result of transaction flow and timing:

- Manufacturer Sells to Wholesaler January 28 $100 / 100 units, January AMP = $1.00
- Wholesaler sells to eligible indirect customer on contract Feb 10 $80 / 100 units, February AMP after chargeback would be $.80
- Manufacturer pays Wholesaler a 10% rebate on purchases made during the quarter on March 31, March AMP after chargeback and rebate would be $.70

In this example, AMP is dependent on the timing of the original sale and downstream transactions that occur after the original sale, perhaps over multiple periods. This example also assumes that data is readily available during the relevant reporting period.

In addition, as mentioned above, while manufacturers have access to information concerning direct sales, they often do not have any information on indirect sales (unless there is a chargeback or some other mechanism to track the sale). Although intending to clarify the determination of AMP, instead, CMS proposes to include in, and exclude from, AMP calculations data that are not readily available, if at all, to manufacturers. As an example, CMS proposes to include Medicare Part D rebates[3] in the calculation of AMP provided that such rebates are applicable to product sold to an eligible Medicare Part D beneficiary. However, manufacturers are rarely aware of whether their products are ultimately sold to an eligible

[3] Our comments with respect to Part D sales are discussed in detail in the "Determination of AMP – Section 477.504" section of this comment letter.

Medicare Part D beneficiary, making this policy operationally infeasible. Consequently, although some of these Medicare Part D rebates will be correctly included as proposed, most Medicare Part D rebates will be inadvertently excluded by manufacturers. Either way, the resulting AMPs submitted to CMS will be inconsistent, at best, across manufacturers.

As such, CMS will need to be exceedingly clear in the guidance that it provides to manufacturers in calculating AMP to ensure that manufacturers are able to determine the sales and associated price concessions that should and should not be included in AMP and to ensure consistency in AMP calculations across all manufacturers.

B. <u>The Publication Of Manufacturer-Specific AMPs To All Purchasers, Payers, And Consumers Is Unintended Under The DRA.</u>

The DRA sets forth that –

> Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States … the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website….[4]

In a subsequent provision, the DRA sets forth that the Secretary is to disclose "(through a website accessible to the public) average manufacturer prices."[5] Based on these provisions it is clear that Congress intended that AMP data be made available to States and the "public." However, there is no basis to believe that Congress intended to make manufacturer-specific AMP information available on a website accessible to the "public."

We believe that Congress' intent to make AMPs publicly available was to improve the transparency of drug pricing under the Rebate Program for the benefit of payers, which would be accomplished by permitting only States and their Medicaid programs to access manufacturer-specific AMP information on the CMS website. Accordingly, by providing manufacturer-specific AMP data on the agency's public website in a manner that allows only State Medicaid programs (or other authorized users) access, CMS would be in compliance with Congress' directive, as well as with the intent of the statute.

In addition, as addressed by GPhA in its comments, publishing manufacturer-specific AMP information to the public is fraught with significant concerns, including, reduced competition, anticompetitive concerns, and confusion among purchasers and payers. For these reasons, we ask CMS to take a reasonable interpretation of the statute and publish only the aggregated industry-wide weighted average AMPs for multiple source drugs. Publishing manufacturer-specific AMP information would negate other applicable confidentiality provisions

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[4] DRA § 6001(b)(1)(B).
[5] DRA § 6001(b)(2)(C).

that the DRA did not change. A statute should not be accorded a meaning that eliminates the effect of certain of its provisions.

We also believe that these disclosure provisions must be implemented through notice and comment rulemaking, and the failure to do so violates the Administrative Procedure Act ("APA").[6] The APA requires agencies to give interested parties the right to participate in rulemaking through publication of a proposed rule, which includes "the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[7] As explained above, as well as in the comments from GPhA, there are many different possible means by which this provision can be implemented. As such, regulated businesses have a statutory right to notice as to how the information will be presented and to comment on the legal and policy implications of such decisions.

II. Comments to Specific Sections of the Proposed Rule

As mentioned above, AMP is not necessarily reflective of market prices. There are two key drivers of this number: (1) customer classification (e.g., eligible versus ineligible class of trade); and (2) transaction treatment (e.g., inclusion and timing). It is vital that these two components of AMP be applied in a uniform manner to ensure that the AMPs for the same products can be compared consistently across manufacturers. To this end, it is critical that CMS clearly define certain significant terms that are contemplated in the Proposed Rule. The remainder of our comments will address our concerns in the order that is set forth by CMS.

A. Determination of AMP – Section 447.504

1. Bundled Sales

CMS proposes that AMP calculations should be adjusted for bundled sales "by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations."[8] That is, the aggregate discount would be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. In the case of multiple discounted products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all of the drugs in the bundle. The Medicaid Drug Rebate Operational Training Guide (the "Guide") defines the term "bundled sales" as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."

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[6] 5 U.S.C. Chap. 5.
[7] 5 U.S.C. § 553.
[8] 71 Fed. Reg. at 77177.

As proposed, CMS seems to broaden the definition of the term "bundled sales" to potentially include routine multiple drug sales to entities such as wholesalers and group purchasing organizations ("GPOs"). We do not believe that the intent of the Proposed Rule was to require that manufacturers allocate on an item-by-item basis the original price of the drug product had it been sold separately. Accordingly, we recommend that CMS should not broaden the definition of the term "bundled sales."

2. Retail Pharmacy Class of Trade – Nursing Home Pharmacy

In the Proposed Rule, recognizing the concerns that have been raised relating to the inconsistencies in the way manufacturers determine AMP, CMS proposes to clarify such determination by revisiting the definition of "retail pharmacy class of trade." CMS proposes to define the retail pharmacy class of trade as "that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services."[9] Given this definition, CMS proposes to exclude prices to long-term care ("LTC") (or nursing home) pharmacies because LTC pharmacies do not dispense to the general public.

We are concerned that CMS has not clearly identified those entities that would be considered LTC (or nursing home) pharmacies.[10] Mylan encourages CMS to clearly define the attributes of entities that qualify as LTC pharmacies to avoid disparate treatment among manufacturers as they exclude prices to LTC pharmacies in calculating AMP. If manufacturers were to use different criteria for determining whether an entity is a LTC pharmacy, manufacturers' AMPs would not uniformly reflect the exclusion that CMS intended in the Proposed Rule. As such, CMS should clearly define the term "LTC pharmacy."

In addition, we recommend that CMS establish a list of those LTC pharmacies that should be excluded from the calculation of AMP in a "List of Excluded Class of Trade Entities," similar to the type of document attempted by the Office of Pharmacy Affairs's ("OPA's") list of eligible 340B entities.[11] This list would specify for manufacturers those entities that should be excluded when calculating AMP. As a result, CMS would ensure that manufacturers consistently categorize customers included in and excluded from AMP calculations as there are several types of entities that could (or could not) qualify as LTC pharmacies, depending on the interpretation. For instance, it is not clear whether the following would be considered a LTC pharmacy under the Proposed Rule – LTC pharmacies owned by a hospital, infusion centers, and rehabilitation centers.

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[9] 71 Fed. Reg. at 77178.

[10] According to MedPAC, there are approximately 15,000 skilled nursing facilities. See MedPAC Report to the Congress: Medicare Payment Policy (March 2006). In addition, according to the Long Term Care Pharmacy Alliance ("LTCPA"), there are five major national LTC pharmacies – Kindred Pharmacy Services, Omnicare, NCS Healthcare, NeighborCare, and PharMerica. These LTC pharmacies serve more than 1.5 million people including more than two-thirds of all nursing facility residents. See LTCPA website available at http://www.ltcpa.org/mission/pharmacy/default.asp.

[11] For the reasons addressed in this section, we recommend that CMS establish a similar list for all entities that should be excluded from AMP calculations as guidance to manufacturers.

Further, as we have mentioned, it is often operationally infeasible for manufacturers to identify those sales that are made to a particular type of entity (e.g., a LTC pharmacy), as opposed to another type of entity that might not satisfy the definition of a LTC pharmacy. Manufacturer sales data are captured at the contract level, but any included or excluded class of trade customer could purchase products from any wholesaler source contract. Thus, manufacturers have no way of determining whether final sales are made to excluded customers. Given this inherent difficulty with calculating AMP, it is imperative that CMS provide mechanisms by which manufacturers can calculate AMP as consistently as possible.

3. Pharmacy Benefit Manufacturers ("PBM") Price Concessions

CMS addresses in the Preamble to the Proposed Rule the difficulties involved in the treatment of PBMs for purposes of determining AMP. Both the U.S. Government Accountability Office ("GAO") and the Office of the Inspector General ("OIG") have recognized that the Rebate Program does not clearly address certain financial concessions negotiated by PBMs, and have recommended that CMS clarify the treatment of PBM rebates.[12] According to the OIG, manufacturers treat rebates and fees paid to PBMs in one of three ways – (1) not subtracting rebates or fees paid to PBMs from the AMP calculation; (2) subtracting the rebates or fees paid to PBMs; or (3) subtracting a portion of the PBMs rebates or fees from the AMP calculation.[13]

Based on these inconsistencies, CMS considered both the inclusion and exclusion of all rebates, discounts, and other price concessions to PBMs in the determination of AMP. Although CMS acknowledges the difficulty manufacturers face in determining the apportionment of PBM price concessions to the PBM, the insurer, and, if any, to the pharmacy, CMS states that excluding all PBM price concessions could result in an artificial inflation of AMP. As such, CMS proposes to include all rebates, discounts, or other price concessions provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to the retail pharmacy class of trade.

For several of the reasons addressed by CMS in the Proposed Rule, Mylan agrees that it is necessary to clarify the treatment of PBM rebates and fees in the calculation of AMP. However, the Proposed Rule does not effectively accomplish this goal. That is, CMS fails to define the term "PBM" for the purpose of AMP calculations, which effectively allows manufacturers to include the sales from any entity that a manufacturer considers to be a PBM, including sales to managed care organizations, which are specifically excluded from AMP under the national rebate agreement.[14] We believe that CMS needs to clearly define the attributes of entities qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities as we discussed in the section above. Doing so will enable

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[12] See GAO, "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns About Rebates Paid to States," (GAO-05-102) (February 2005); see also OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).

[13] 71 Fed. Reg. at 77179.

[14] Id.

manufacturers to use uniform criteria to distinguish between PBMs and non-PBMs for purposes of incorporating rebates and fees into AMP calculations. If, however, CMS fails to set forth guidance regarding PBMs, manufacturers will continue to treat PBM price concessions disparately, resulting in inconsistent AMP calculations across manufacturers. Therefore, it is imperative that CMS clearly identify factors that manufacturers should use in determining whether an entity is in fact a PBM.

As an additional matter, the Proposed Rule seems to include in the calculation of AMP PBM price concessions, but limits this inclusion to those rebates relating to PBM sales to the retail pharmacy class of trade.[15] If this is indeed CMS's intent, then the agency's proposal would not be practicable because manufacturers do not have information concerning these indirect sales. Manufacturers cannot ascertain whether PBMs' downstream sales are to the retail class of trade or not. Thus, they would not be able to ensure that their AMP calculations include only those price concessions related to sales to the retail pharmacy class of trade.

4. Identification of Sales

The Proposed Rule requires that AMP include only those sales to wholesalers "for dispensing to the general public," e.g., sales to wholesalers that result indirectly in sales to the retail pharmacy class of trade.[16] Often, however, a manufacturer will not know if the sale from a wholesaler is to an entity in the retail pharmacy class of trade. Generally, there are three types of direct sales involving manufacturers – direct sales to retail pharmacies, direct sales to wholesalers where wholesalers then sell to retail pharmacies, and direct sales to wholesalers where the wholesaler then sells to an entity that is unknown to the manufacturer. The third arrangement is the one that makes CMS' proposed policies operationally infeasible. That is, once a manufacturer sells to a wholesaler, the wholesaler may then sell to any number of entities.

Manufacturer sales data are captured at the wholesaler-manufacturer level, but any subsequent sale from the wholesaler could be to any entity – one that is either included or excluded from the retail class of trade. A manufacturer would have data to identify downstream indirect sales if they were processed by a wholesaler through a chargeback for a wholesaler program sale or a manufacturer-established contract sale. However, a manufacturer would not have sufficient data to identify indirect sales made by a wholesaler or distributor if a chargeback is not processed for the sale.[17] In the latter case, the manufacturer would not be able to identify the purchaser in the second sale or to assess whether the entity was in the retail pharmacy class of trade. This is also true of SPAP and Part D rebates, which we discuss below.

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[15] Id.

[16] Id.

[17] See Medicaid Drug Rebate Program Release #29 (acknowledging manufacturers' need to often recalculate or refine pricing data due to the improper inclusion or exclusion of certain sales.).

5. State Pharmaceutical Assistance Program ("SPAP") Rebates

As further clarification of the determination of AMP, CMS proposes to include SPAP price concessions in the calculation of AMP. CMS states that similar to the Medicaid program, Medicare Part D prescription drug plans ("PDPs"), Medicare Advantage prescription drug plans ("MA-PDs"), and SPAPs do not directly purchase drugs. Instead, SPAPs are generally third-party payers. Therefore, CMS believes that these sales should be included in AMP to the extent that the sales are to an entity included in the retail pharmacy class of trade. Accordingly, CMS proposes that SPAP sales, as well as rebates paid by the manufacturer to the SPAP, be included in the AMP calculation.

We, however, do not agree with CMS' proposed treatment of SPAP rebates. As CMS mentions, SPAPs are similar to the Medicaid program in that SPAPs represent third-party government payers. Therefore, because Medicaid rebates would be excluded from AMP calculations, the same should be true for SPAP rebates. SPAP data is only available on a quarterly basis with a considerable lag period and no correlation to a SPAP eligible sale. Manufacturers also have the opportunity to refile SPAP data for the quarterly reporting requirement. Accordingly, SPAP rebates should be excluded from monthly AMP calculations.

In addition, CMS' proposed treatment of SPAP rebates conflicts with the treatment required under previous CMS Manufacturer Release #68, which instructs manufacturers to distinguish between "qualified" and "unqualified" SPAPs, based on criteria listed in such release. Under this program release, only rebates to qualified SPAPs are excluded from AMP, whereas rebates to unqualified SPAPs are included in AMP. We request that CMS revisit this program release to address this inconsistency. If CMS ultimately decides to include all SPAP rebates in the calculation of AMP, then the agency should provide guidance regarding the method of inclusion.

6. Treatment of Medicare Part D Rebates

CMS proposes to clarify in the Proposed Rule that the treatment of prices of sales through a PDP, MA-PD, or a qualified retiree prescription drug plan for covered Medicare Part D drugs provided on behalf of Medicare Part D eligible individuals should be included in the AMP calculation. CMS states that similar to the Medicaid program, PDPs and MA-PDs do not directly purchase drugs, but are usually third-party payers. As is the case with Medicaid sales, CMS believes that these sales should be included in AMP to the extent that the sales are to the retail pharmacy class of trade. As such, CMS proposes that these prices, as well as rebates paid by manufacturers to the PDP or MA-PD, should be included in AMP calculations.

Similar to the discussion above concerning SPAP rebates, we recommend that CMS exclude Medicare Part D rebates from AMP calculations. Because Medicare Part D rebates are similar to Medicaid program rebates, which are excluded from AMP calculations, Medicare Part D rebates should be treated similarly.

Further, Medicare Part D rebates are excluded from best price, and the resulting inconsistent treatment of Medicare Part D prices in AMP and in best price calculations would be unjustified. As CMS acknowledges in the Proposed Rule, the law requires that "prices negotiated by a prescription drug plan, by an MA-PD plan . . . or by a qualified retiree prescription drug plan . . . with respect to such drugs on behalf of Medicare Part D eligible individuals, shall . . . not be taken into account for the purposes of establishing the best price...."[18] Because of this statutory mandate concerning best price, we believe CMS should treat Medicare Part D rebates in the context of AMP similarly to ensure parity for both AMP and best price calculations. Thus, we recommend that CMS use its authority to exclude Medicare Part D rebates from AMP.

7. Returned Goods

According to the Proposed Rule, CMS proposes to exclude returned goods from AMP calculations provided that such goods are returned in "good faith."[19] We recommend, however, that CMS clarify that products destroyed by purchasers (and, thus, not returned to the manufacturer) should be treated the same way as returned goods – e.g., excluded from AMP. Likewise, we recommend that recalls be treated the same as returned goods and excluded from AMP. We also urge CMS to clarify the treatment for AMP calculation of any return fees or reasonable recall fees paid by manufacturers.

8. Manufacturer Coupons

In the Proposed Rule, CMS proposes to clarify the way in which manufacturer coupons should be treated. CMS proposes to include coupons redeemed by any entity other than the consumer in the calculation of AMP. Accordingly, CMS proposes that coupons that are redeemed by the consumer directly to the manufacturer would not be included in AMP calculations. We recommend that CMS make clear that manufacturer coupons redeemed by a consumer, whether directly ***or indirectly*** to the manufacturer (e.g., through a pharmacy) should be excluded from AMP calculations.

9. Administrative and Service Fees

According to current policy under the Rebate Program, "administrative fees, which include service fees and distribution fees, incentives, promotional fees, chargebacks, and all discounts or rebates, other than rebates under the [Rebate Program]..." should be included in AMP calculations, provided those sales are to an entity included in the calculation of AMP. The OIG, however, noted that there is confusion among manufacturers regarding the treatment of

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[18] 71 Fed. Reg. at 77183; see Social Security Act ("SSA") § 1927(c)(i)(VI); see also Medicaid Drug Rebate Program Release # 63 (Feb. 19, 2004).

[19] 71 Fed. Reg. at 77181.

such fees.[20] Given the OIG's report, CMS proposes to clarify the treatment of administrative fees by including all such fees in the calculation of AMP.

CMS proposes, however, to exclude from AMP fees paid for *bona fide* services. CMS proposes to define *bona fide* service fees as "fees paid by a manufacturer to an entity, which represent fair market value for a *bona fide*, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, regardless of whether the entity takes title to the drug."[21]

We strongly recommend that CMS clearly set forth guidance as to what constitutes a *bona fide* service fee. Although CMS attempts to make this clear in its proposed definition, it would be more helpful for CMS to provide additional parameters and/or specific examples to assist manufacturers in making this determination. Further, we encourage CMS to work with the OIG to establish a "safe harbor" for *bona fide* service fees. We believe that the payment of *bona fide* service fees by manufacturers could implicate the anti-kickback statute.[22] That is, *bona fide* service fees could be viewed as an incentive to purchase drug products from manufacturers. Given the potential for widely varying interpretations of the definition of *bona fide* service fees and the potential anti-kickback concerns, it is important that CMS and the OIG work together to provide clear guidelines and a safe harbor for this term.

B. Authorized Generics – Section 447.506

In the Proposed Rule, CMS proposes to require the primary manufacturer (NDA holder) to include, in its calculations of AMP and best price, sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary. CMS believes that to limit the applicability of the Proposed Rule to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the DRA by licensing rather than selling the rights to such drugs. As is currently required, the secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source or innovator multiple source rebate for the authorized generic products based on utilization under its own NDC number.

CMS, however, makes no mention in the Proposed Rule of sales from the brand manufacturer to the authorized generic manufacturer (e.g., sales at the "transfer price").[23] For purposes of consistency, we recommend that CMS also include the transfer price of the NDA holder to the authorized generic manufacturer in the NDA holder's best price calculations.

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[20] OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).
[21] 71 Fed. Reg. at 77180.
[22] SSA § 1128B(b).
[23] DRA § 6003.

III. Con

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C. Requirements for Manufacturers – Section 447.510

In the Preamble, CMS sets forth the reporting requirements for manufacturers with regar to pricing data. Specifically, CMS proposes that AMP would be reported both on a monthly an quarterly basis to CMS. CMS proposes that the monthly AMP would be calculated using th same methodology as the quarterly AMP. In an effort to minimize the price fluctuations and t maximize the usefulness of the monthly AMP, CMS proposes to allow manufacturers to estimat the impact of their end-of-quarter rebates or other price concessions and to allocate these rebate or other price concessions throughout the quarter in the monthly AMPs reported to CMS. CM invites comments on allowing the use of 12-month rolling average estimates of all lagge discounts for both the monthly and quarterly AMP. CMS also seeks comments on allowin manufacturers to calculate the monthly AMP based on updates of the most recent three-mont period (i.e., a rolling three-month AMP).

While smoothing is a helpful mechanism to adjust for fluctuations in the calculatio resulting from the timing of sales and credits, smoothing does not necessarily result in AM bearing a more precise market price. Smoothing is dependent on historical data that may or ma not be completely applicable to current business activity. However, in order to adjust fc variability in monthly reporting periods, we agree with CMS' proposal to allow the "smoothing of AMP data. In addition, we recommend that CMS permit four quarter smoothing to ensure more consistent application of a percentage during the months of a quarter. We believe that thi is a reasonable smoothing mechanism that would be beneficial to manufacturers and that woul enhance the AMP data that are received by CMS.

D. Upper Limits for Multiple Source Drugs – Section 447.514

The currently reported AMP is based on the nine-digit NDC, combining all package size of the drug into the same computation. CMS proposed to continue this policy and solicite comments on the alternative approach of using 11-digit NDC to calculate AMP as well a comments on the merits of using both approaches in calculating AMP for the FUL calculation.[24]

In response to CMS' request for comments on the appropriate NDC level for calculatin AMP, we support the use of the 11-digit NDC. The primary benefit of the 11-digit NDC, a CMS notes, is the inclusion of package size in the AMP calculation. Also, CMS observes thi the 11-digit NDC would align with the State Medicaid drug payments that are based on packag size, as well as allow greater transparency. Further, taking into consideration different custom types, e.g., small and large retail pharmacies, and different life cycle management, applying th 11-digit NDC would promote greater consistency and accuracy among AMPs. Accordingly, w recommend the use of the 11-digit NDC for calculating AMP.[25]

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[24] 71 Fed. Reg. at 77187.

[25] See 42 C.F.R. § 447.332(b)(2006).

Submitter : **Miss. Dana Thomas** **Date: 02/20/2007**

Organization : **National Association of Community Health Centers**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

The National Association of Community Health Centers is pleased to submit comments on the proposed rule requiring changes to drug pricing calculations in the Medicaid program.

CMS-2238-P-1353-Attach-1.DOC

Attach # B53

National Association of
Community Health Centers, Inc.

February 20, 2007

BY ELECTRONIC MAIL
http://www.cms.hhs.gov/eRulemaking

U. S. Department of Health and Human Services
Att: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: CMS-2238-P
Proposed Rule on Medicaid Program: Deficit Reduction Act; Prescription Drugs

RINs 0938-AO20
71 Fed. Reg.77174 et seq. (December 22, 2006).

Dear Sir/Madam:

The National Association of Community Health Centers ("NACHC") appreciates the opportunity to submit comments on the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on implementing the Medicaid drug pricing calculations, sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 ("DRA") (Pub. L.109-171). NACHC is a membership organization that represents Federally Qualified Health Centers (FQHCs) nationally. At present, approximately 1,000 FQHCs with 5,000 sites serve 16 million patients across the country. The vast majority of these patients are impoverished individuals living in medically underserved areas. More than 35 percent of health center patients are Medicaid beneficiaries and close to 40 percent are uninsured.

Approximately one-third of health centers operate pharmacies and almost all of them participate in the 340B Drug Pricing Program. The 340B Program provides health centers with discounts on drugs ranging from 15% to 60%. Under Section 340B of the Public Health Service Act (PHSA), drug manufacturers must enter into agreements with the U.S. Department of Health and Human Services (HHS) to provide drugs to "covered entities" at discounted prices. Health centers are considered covered entities, and thereby able to purchase drugs at discounted prices for the patients they serve. In addition to centers with their own licensed pharmacies, many health centers contract with community pharmacies to dispense prescription drugs that the centers purchase at 340B prices and have shipped to their contracted pharmacy for dispensing to health center patients in accordance with Health Resources Services Administration (HRSA)-issued guidelines.

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OVERALL COMMENTS

The proposed rule implements sections of the Deficit Reduction Act (DRA) that are designed to reduce overall pharmacy costs in the Medicaid program. **Taken together, the various provisions of the DRA are projected to negatively impact the financial solvency both of health centers with their own licensed pharmacies and the community pharmacies with which many health centers contract for provision of pharmaceutical services to their patients.** This is likely to occur because of the ratcheting down of reimbursements for generic drugs (health centers purchase and dispense high percentages of generic drugs in order to keep costs down), the lack of any requirement that dispensing fees must reflect actual costs of providing pharmaceutical services, changes in the calculations for Average Manufacturer's Price for community retail pharmacies that often contract with health centers, and the proposal to make physician-administered drugs subject to a Medicaid rebate.

Thus, the final rule issued by CMS to implement the DRA provisions should take into consideration these projected negative impacts on safety net pharmacies and include provisions to ensure that safety net pharmacies do not bear a disproportionate burden of reductions in Medicaid payments to the extent that their solvency is threatened. Safety net pharmacies are unique in that they are located near and serve the most vulnerable, low-income patients. They have established the capacity to provide linguistically and culturally appropriate pharmacy services for highly diverse patient populations with limited financial means, including homeless individuals, migrant farm-workers, the elderly on fixed incomes, single parents with dependent children, and members of many ethnic and linguistic groups. These safety net pharmacies need to be preserved in order to assure the disenfranchised of the country access to needed pharmaceuticals.

AVERAGE MANUFACTURERS PRICE

There are a number of ways in which the proposed rule will impact health centers. The statute and proposed rule revise the current definition of AMP and require that drug manufacturers remove the customary prompt payment discount from their AMP calculations. In effect, the new rule would increase the AMPs and consequently manufacturers' rebate payments to the states. This would have the effect of increasing 340B prices and could mean the loss of significant savings to 340B safety net entities. However, a letter to manufacturers distributed on January 30, 2007 by HRSA has indicated that calculation of 340B prices must be based on the provisions of the 1992 340B statute which included prompt pay discounts. This interpretation would enable 340B entities to retain the savings which they already receive by continued inclusion of prompt pay discounts in the calculations. **We would urge CMS to support HRSA's interpretation and to provide the data required for calculation of two AMPs, one for 340B entities, and another for other providers.**

In addition, the proposed rule will lower the Federal Upper Limit (FUL) for a number of drugs and thus reduce Medicaid payment for drugs to thousands of small pharmacies. This change in the rule will substantially reduce Medicaid payments to health center pharmacies that purchase both 340B and non-340B stock. A number of health centers operate pharmacies that

maintain 340B drugs for their patient populations that are uninsured or lack sufficient drug coverage, as well as retail pharmacy stock for other health center patients. By maintaining the different drug stocks, health centers can offset some of the prescription drug losses they experience serving their uninsured and underinsured patients with small margins from other payers.

Furthermore, a number of health centers contract with local community pharmacies to provide their patients with easier access to prescription drugs. The proposed rule may force many pharmacies to close their doors due to lack of profitability, particularly those in rural underserved areas, thus jeopardizing these contractual arrangements. A report released by the Government Accountability Office (GAO) estimates that the proposed rule will result in pharmacists being paid substantially less for their Medicaid patients. A number of pharmacists have indicated that this reduction in reimbursement may prevent them from serving Medicaid beneficiaries. **It is imperative that the final rule safeguard against the potential harm caused to Medicaid beneficiaries by a decrease in reimbursement for safety net pharmacies – both health center pharmacies and community pharmacies.**

340B DRUG CALCULATIONS

The practical effect of the interpretation of the 340B statute and the DRA and proposed rule regarding prompt pay discounts will necessitate manufacturers to calculate different AMPs for 340B covered entities and non-340B providers. The rule reads, "prices to these entities [340B covered entities] should be excluded from AMP because the prices to these entities are not available to the retail pharmacy class of trade." 71 Fed Reg. at 77197. In order to implement these provisions, it is absolutely critical that HRSA have access to the data they need to calculate the 340B prices. We urge CMS to require that drug manufacturers submit both sets of drug prices to CMS/HRSA so that HRSA may accurately calculate 340B ceiling prices for covered entities. The information should include specific prompt pay discount information on drugs by NDC so that 340B prices may be accurately computed. Currently, there is no mechanism in the regulations mandating that this information be provided to HRSA. If HRSA does not receive the requisite data, they will be unable to supply heath centers and other safety net providers with the appropriate 340B drug pricing. Health center pharmacies and their patients depend on the 340B drug program in order to provide prescription drugs to their patients at discounted prices. The new AMP should in no way impede the ability of 340B patients to access their drugs. **The final rule should specify that HRSA will receive from manufacturers and/or CMS the specific needed data by NDC code to calculate 340B prices, and the rule should establish a mechanism for doing so on a timely basis.**

DISPENSING FEES

The DRA does not guarantee that pharmacies will receive cost-based or related reimbursement for their dispensing fees. However, the final rule should establish such a guarantee. Dispensing fees should include reimbursement for dispensing and associated costs such as patient counseling, packaging, inventory management, ordering and billing,

and overhead costs. Given the reductions in reimbursement for generic drugs and other provisions of the DRA, health centers and other 340B providers will have to rely upon reasonable, cost-based dispensing fees to stay in business. Safety net pharmacies that serve a high proportion of Medicaid providers will be disproportionately affected by the lack of any guarantees as to reasonable cost for dispensing.

PHYSICIAN-ADMINISTERED DRUGS

There are not reliable data available on the extent to which health centers provide physician or clinic-administered drugs in health center and other ambulatory settings; nonetheless, depending on their size and sophistication, we know that some health centers do provide such drugs in the clinic setting. In the past, these have not been subject to a Medicaid rebate, and thus health centers have either billed them distinctly on a fee for service basis or, more likely, they have bundled the cost of provision of such drugs into their all-inclusive Medicaid and Medicare reimbursement rates which are either cost-based or cost-related. Making these drugs subject to rebates would most likely trigger a requirement that they be billed at acquisition cost to avoid a "duplicate discount" with the Medicaid rebate program. This could significantly reduce reimbursements to health centers and other 340B covered entities, such as disproportionate share hospitals that are an important part of the pharmaceutical care safety net. These physician-administered drugs include many drugs that are essential to treatment for significant diseases and conditions, including chemotherapy drugs for cancer patients. There is no system in place at this point to implement such changes; implementation now could likely result in chaos and disruption of care for vulnerable patients. **We would urge CMS to change the proposed rule and exempt such drugs administered by 340B covered entities from the definition of drugs subject to the Medicaid rebate. Furthermore, if CMS insists on including physician-administered drugs in the rebate program, CMS should guarantee pharmacy dispensing fees that adequately compensate for the cost of the drug and other costs associated with providing it to patients.**

HHS/CMS have an obligation to ensure that the safety net provider structure for the medically underserved throughout the country is not dismantled or significantly weakened through reimbursement policies. The safety net provider structure saves taxpayers on health care costs in the long run by providing needed health services and prescription drugs to low-income and vulnerable populations on an ongoing basis, diverting them from emergency rooms, and preventing and controlling conditions that, if left unattended, often result in inpatient hospitalizations and more costly surgeries and treatments.

NOMINAL PRICE EXEMPTIONS

The proposed rule appears to waive away HHS's authority to establish nominal price exemptions for additional classes of providers beyond those specified in the DRA. Health center nominal prices are exempted from best price calculations in the DRA (which is good), but health centers procure prescription drugs at local levels through a variety of arrangements – including relationships with family planning purchasing groups and other such organizations. Some of these relationships depend upon long-established patterns of nominal pricing from

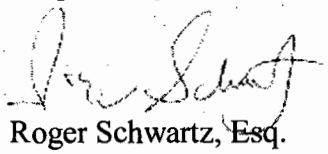
manufacturers. We cannot understand why HHS/CMS would want to relinquish its authority to establish such exemptions on a case by case basis for different categories of entities – such as free clinics – or other safety net providers that play a major role in pharmaceutical access for low-income patients. **We urge CMS not to relinquish, through the rule-making process, this important authority delegated by the DRA to HHS to establish additional nominal price exemptions, but rather, to preserve it, and use it as needed to extend the pharmaceutical safety net.**

ELEVEN DIGIT NATIONAL DRUG CODE

NACHC notes that use of 11-digit National Drug Codes (NDC) to calculate the AMP most likely would result in the greatest transparency and accuracy for calculation of 340B prices, a desired 340B program integrity goal. On the other hand, it appears that the use of the 9-digit NDC favors smaller volume purchasers (such as health centers), and that many health centers could experience revenue losses if the 11-digit NDCs were used.

For further information, feel free to contact NACHC staff Dana Thomas, JD., Associate Director of Regulatory Affairs or Freda Mitchem, Director of Systems Development and Policy Administration at 301-347-0400.

Respectfully submitted,



Roger Schwartz, Esq.
Director of State Affairs

Submitter : **Mr. Bradley Crump** **Date: 02/20/2007**

Organization : **Fairmount Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FML) program for generics. My pharmacy is located in Fairmount,IN. We are a major provider of pharmacy services for this community and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade"- Removal of PBM's and Mail Order Pharmacies

Excluding PMBs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public". The more extensive comments submitted by Indiana Pharmacy Assoc. have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculations of AMP-Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies.

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent. (as well as detrimental to a retail pharmacy such as ours that cannot obtain this same pricing advantage).

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize the Medicaid pricing is heavily regulated by the state and federal authorities.

4. Manufacturer Data Reporting for Price Determination-Address Market Lag and Potential 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, Indiana Pharmacy Assoc. proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

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

In conclusion, I support the more extensive comments that are being filed by the Indiana Pharmacy Association regarging this proposed regulation. Please remember we who carry the load of this job are retail pharmacies, not PBMs or Mail Order. Pricing formula should reflect retail pharmacies true purchase ability, not diluted by other minor or non-participating purchase entities. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Bradley Crump RPh
Fairmount Pharmacy
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Fairmount, IN
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fairmountrx@yahoo.com

Submitter : Ms. Annette Mann **Date:** 02/20/2007

Organization : Solvay Pharmaceuticals, Inc.

Category : Drug Industry

Issue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1355-Attach-1.DOC

Background

- The DRA requires AMP to be calculated on a monthly basis. This will increase the frequency of calculations from four per year to 16 per year (12 monthly and four quarterly) for every manufacturer. This dramatic increase in work is extremely resource intensive, especially for small to medium sized manufacturers who have limited staff. We will have to increase staff or shift responsibilities to comply with the monthly calculations. In addition, the systems we have in place cannot calculate AMP on a monthly basis and will require an upgrade or the installation of a replacement solution. The increased staffing and system support will increase our expenses significantly.

- The DRP requires that manufacturers submit to CMS the CPP discount each month. However, there is no direction on what format the information should be provided, such as, in whole dollar or unit or by percentage. In addition, the Drug Data Reporting System (DDR) does not contain a field for CPP. CMS needs to clarify what format CPP is to be submitted to CMS and how it is to be submitted to them.

- Our system does not capture actual CPP discount paid on an NDC level but, rather, only in total dollars paid. Will reporting an accrued amount by NDC suffice?

Regulatory Impact Analysis

- The Office of Pharmacy Affairs (OPA) is insisting that the AMP calculation utilized for 340B pricing be calculated using pre-DRA methodology. The result is that manufacturers will have to calculate AMP using two separate methodologies each quarter resulting in 20 calculations per year (one per month plus two per quarter). This is extremely burdensome to our limited staff. Further, our system can only calculate the quarterly AMP using a single methodology. Maintaining two different AMP methodologies will require system upgrades or replacement systems. Having two different AMPs for each quarter will no doubt cause confusion and potential errors in the future. It is extremely burdensome and problematic to maintain two separate methodologies for calculating AMP. There needs to be one single guideline for determining AMP.

- CMS has proposed that manufacturers can restate Baseline AMPs using the DRA methodology (currently, this opportunity has been postponed). Given that most of our products are more than 15 years old, the change in technology, systems, and resources makes this burdensome at best and, more likely, impossible to find the appropriate transactions and calculations. Furthermore, for products acquired from other manufacturers, the Baseline AMP was inherited and the original data is not available. Not being in a position to restate Baseline AMP will increase Medicaid rebate liabilities; the proposed AMP would exclude Customary Prompt Pay (CPP) discounts while the original Baseline AMP will include CPP discounts. For older products and transferred products, CMS needs to consider an alternate

methodology to restate Baseline AMP when the original source data or systems are not available. A simple calculation that increases the Baseline AMP by 2% or the normal CPP discount is one possible solution.

Provisions of the Proposed Regulations

- The proposed CMS guidelines allow for certain eligible Rebates to be deducted in determining AMP. But the vast majority of Rebate payments are made on a quarterly basis while the AMP calculation represents monthly results. Manufacturers will need to determine a methodology to convert the quarterly data into appropriate figures for monthly reporting. Without clear CMS guidelines, manufacturers will have differing methodologies for converting rebate data, resulting in discrepancies across different drugs. CMS needs to provide clear options as to how manufacturers should allocate quarterly rebates into monthly calculations.

- The proposed DRA requires that the CEO, CFO, or one of their direct reports certify the AMP calculations and submission. Obtaining an actual physical signature from one of these limited sources on a monthly basis will be a significant challenge. Will an electronic signature or e-mail suffice in complying with this requirement?

- Without clear and concise guidance from CMS as to how AMP is to be calculated, including what Classes of Trade (COT) are eligible and which COT are not eligible, manufacturers who compete in the same therapeutic area could have differing methodologies resulting in unfair physician reimbursement calculations. CMS needs to provide clear guidance on the calculation of AMP in order to maintain a fair and level playing field for physician reimbursement.

- CMS is requiring that manufacturers submit the monthly Pricing Data via the Drug Data Reporting System (DDR). The instruction to access the DDR state that use of an SSN is voluntary, but when we inquired CMS told us that providing a SSN is required to access the DDR and that the DDR is required to submit Pricing and Product Data. This puts manufacturers in an awkward position of requiring staff to submit personal information when they are not comfortable doing so. Manufacturers access many systems that contain confidential data without requiring the use of an SSN. Would CMS consider an alternate identification to allow manufacturer's access to the DDR such as the Federal EIN which is unique to each manufacturer?