



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

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 vial of liquid medication, but it did not take the entire contents of the vial to fill the syringe, and that vial 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”

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:

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.

⁸Since, 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.

⁹See, 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

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 comports 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

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

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

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.

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Affairs