



Safety Net Hospitals for Pharmaceutical Access

August 15, 2007

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: Katherine Astrich, CMS Desk Officer, CMS-2238-FC
Room 10235
New Executive Office Building
Washington, DC 20503

Re: Comments on Provider Burden Under 42 C.R.F. §447.520; Reference CMS-2238-FC

Dear Ms. Astrich,

This letter responds to the Centers for Medicare and Medicaid Services (CMS) solicitation of further comments in accordance with the Paperwork Reduction Act of 1995 (PRA) on the need for and usefulness of the information collection and the burden to hospital outpatient departments/clinics created by the newly published regulation regarding collection and reporting of NDC numbers of outpatient drugs that are “physician administered” and subsequently billed to Medicaid. See 72 Federal Register 39,227- 39,230 (July 17, 2007)¹. Safety Net Hospitals for Pharmaceutical Access (SNHPA) is an association of hospitals that, based on the high percentage of indigent patients that they serve, are qualified to participate in the federal drug discount program administered under section 340B of the Public Health Service Act.

We offer these comments on behalf of SNHPA and its member hospitals in the hope that responsible government officials will reassess certain aspects of regulatory policy that has been announced by CMS in recent months, and avoid the collection of NDC numbers on Medicaid billing for most hospital outpatient clinic drugs that is *not needed* as a matter of law, *will not be useful* in carrying out the agency function of enforcing valid drug rebate obligations on pharmaceutical manufacturers, and places an *undue burden* on hospitals, as well as the adverse consequences to patient care that will flow from what is surely an overbroad application of the new rule. SNHPA therefore recommends that CMS clarify to the States, the hospital community, and the general public that the “physician administered” drug rule newly codified at 42 C.F.R. § 447.520 does not apply and should not properly be applied to hospital outpatient clinic drugs, except in the rare circumstance that the drugs do not fall within the § 1927(j)(2) rebate exemption (42 U.S.C. § 1396r-8(j)(2)) — that is, where the hospital does not use formulary systems or bills Medicaid in excess of the estimated acquisition cost level established under an applicable Medicaid State plan.

¹ These comments are also being transmitted to the Centers for Medicare and Medicaid Services (CMS).

The regulation at issue, published in final form in the Federal Register of July 17, 2007, and codified at 42 C.F.R. § 447.520, requires States to collect National Drug Code (NDC) information on all single source and the most widely used multiple source outpatient drugs that are “physician administered” and billed to Medicaid. If this rule were to be properly construed and applied, in light of other related provisions of the Medicaid statute, we would not regard the specific language of the regulation *per se* to impose undue burdens on hospital providers. Our understanding of CMS’ intended policy, however, is that the regulation will be applied to drugs administered in, among other settings, most hospital outpatient clinics and departments, and we believe this policy will impose an unnecessary and inappropriate burden on hospitals that will be highly detrimental to those providers and the patients they serve.

Our comments submitted in response to the Federal Register Notice proposing to promulgate § 447.520 (relevant excerpts of which are attached and which we intend to incorporate by reference into this letter) have already discussed our strong disagreement with the CMS conclusion that application of NDC reporting requirements to the hospital outpatient clinic setting will not impose significant new burdens or costs on hospital providers. To briefly reiterate and summarize points we, and others representing the hospital provider community, have made:

- CMS has failed to provide an accurate assessment of the practical and financial burdens that will be created by application of the new rule to hospital outpatient clinic drugs.
- The cost and staff-time estimates CMS has stated for short-term “manual” compliance by a hospital with the NDC reporting requirement, as well as for long-term reconfiguration of electronic billing systems to achieve compliance, are vastly inaccurate and understated, lack any apparent foundation, and do not take into account any of a long list of practical and logistical problems that will make meaningful compliance by hospitals very difficult, expensive, and staff-resource-intensive.
- The information collection that would impose this burden and additional cost in the hospital outpatient clinic setting is not necessary or even appropriate under the governing law, as the new rule is not properly applicable to drugs administered in most such settings due to an exemption from rebates established by § 1927(j)(2) of the Social Security Act.

In the course of promulgating and discussing the final rule, CMS has inadequately considered and responded to these comments, and – at least to the extent CMS still intends to apply § 447.520 to most hospital clinic drugs – has fallen short of legal prerequisites for valid rulemaking. We point out that under § 607 of the Regulatory Flexibility Act (RFA), 5 U.S.C. § 607, an agency is obligated to provide “either a quantifiable or numerical description of the effects of a proposed rule . . . or more general descriptive statements if quantification is not practicable or reliable” before it may

finalize a regulation.² Thus an agency must either quantify the effects of a new rule or provide some sufficient basis for a conclusion that such “quantification is not practical or reliable.” CMS has done neither.

The agency has persisted, instead, in making conclusory assertions that costs of manually adding NDC numbers to each claim would be “small,” despite providing no information or analysis whatsoever that casts doubt on the accuracy of hospitals’ contentions that manual reporting of NDC’s in Medicaid billings would in fact consume massive amounts of staff time to address and overcome a vast array of practical obstacles and problems. Equally inadequate is the manner in which CMS has addressed the issue of cost for long-term billing system changes to achieve hospital compliance with the NDC reporting rule. On this topic, CMS, at various points in the regulatory preamble, acknowledges that it “may have underestimated the costs to outpatient departments of hospitals” (see 72 Fed. Reg. 39,229), states that it does “not accept that the cost would be [as] high” as the American Hospital Association (AHA) has estimated based on historical data (*id.*), seemingly relies on an ongoing transition of hospitals to bar-coding of dispensed drug products as grounds to reject the validity of AHA’s cost estimates (see 72 Fed. Reg. 39,230), and predicts how many hospitals will be affected by the final rule (see 72 Fed. Reg. 39,228), but nevertheless states that it is “not able to estimate the cost to make needed systems changes” for long-term hospital compliance with NDC reporting requirements.

Yet if CMS has legitimate grounds to determine that the AHA estimate is incorrect, genuinely believes the practical problems of hospital compliance with the NDC reporting rule will be solved by bar-coding, and knows roughly how many hospitals will need to attain bar-coding equipment and capacity to achieve compliance, there seems no valid basis to conclude that quantification of the cost by CMS is impossible or “impractical.” Surely costs of the transition to bar-coding technology for a hospital can be estimated with some reliability, and the CMS failure to either quantify its assumptions regarding compliance costs for hospitals or explain why it cannot, as a practical matter, provide some such quantification is unaccountable and impermissible.³ To the extent CMS still intends to apply § 447.520 to most hospital clinic drugs, CMS must complete the cost analyses necessary to comply with legal prerequisites for valid rulemaking under the Regulatory Flexibility Act and the Paperwork Reduction Act, and republish these analyses in the Federal Register before submitting any final collection of information request to OMB .

² The Regulatory Flexibility Act requires regulatory flexibility analyses for all proposed and final rules unless the head of the agency promulgating the rule certifies that the rule will not have a significant economic impact on a substantial number of small entities. CMS has not made such a certification. Moreover, § 1102(b) of the Social Security Act, 42 U.S.C. § 1302(b), provides that such analysis must be made for any rule that has a significant impact on the operations of a substantial number of small rural hospitals, which CMS has acknowledged the rule does.

³ The failure to quantify also seems to violate the provisions of Executive Order 12866 (see 58 Fed. Reg. 51,735, amended by Exec. Order No. 13,258, 67 Fed. Reg. 9,385), which requires each agency to “assess both the costs and the benefits of the intended regulation” and “base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.”

The issue of excessive cost and burden to hospitals warrants particularly careful scrutiny in this instance because, contrary to CMS' suggestion at several points in its regulatory discussion, statutory law does not require those costs and burdens to be imposed on most hospital outpatient clinics and departments. As even CMS recognizes at certain points in its regulatory analysis, neither manufacturer rebate obligations nor the new NDC collection requirement properly applies to the category of hospital outpatient drugs exempted from Medicaid rebates under §1927(j)(2) of the Social Security Act. Since, as CMS also acknowledges in the regulatory preamble (see 72 Fed. Reg. 39,219), that exemption extends to a hospital outpatient clinic drug that is dispensed using a drug formulary system and is billed to Medicaid at no more than the hospital's "purchasing cost" or acquisition cost "**as determined under the State plan,**" most outpatient hospital clinic drugs are exempt. This is so because virtually all hospital clinics use formulary systems and the only drug "purchasing" or "acquisition" cost to hospitals for outpatient drugs that is "determined under the [applicable Medicaid] State plan" is an "estimated acquisition cost" or "EAC" level (447.502) that federal regulations prescribe as an upper limit to Medicaid billing whenever a hospital's "usual and customary" charges for a drug exceed that limit (see 42 C.F.R. § 447.518, referencing § 447.512 and § 447.514).

In summary – and to more succinctly address the specific issues on which further comments have been solicited pursuant to the PRA – the collection of NDC numbers on Medicaid billings for hospital outpatient clinic drugs is not needed as a matter of law, and will not be useful in carrying out the agency function of enforcing valid drug rebate obligations on pharmaceutical manufacturers. This is true because, as the foregoing comments combined with the attached comments already submitted to CMS in response to the proposed rule explain in greater detail, most hospital outpatient clinic drugs are properly and legally exempt from rebates and from the new NDC reporting rule. The information collection burden associated with implementing the new rule in this particular setting has not been estimated with sufficient accuracy to meet applicable statutory standards, and indeed no such estimate has been seriously attempted by the agency.

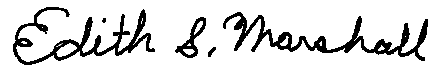
Finally, practical and logistical obstacles to collecting accurate NDC data in the hospital outpatient clinic setting would be so numerous and serious as to render a great deal of the data collected of very limited reliability and, consequently, of very low quality, utility, and clarity (see page 3 of attachment for further discussion and commentary). All of these considerations counsel in favor of clarifying to the States, the hospital community, and the general public that the "physician administered" drug rule newly codified at 42 C.F.R. § 447.520 does not apply and should not properly be applied to hospital outpatient clinic drugs, except in the rare circumstance that the drugs do not fall within the § 1927(j)(2) rebate exemption—that is, where the hospital does not use formulary systems or bills Medicaid in excess of the EAC level established under an applicable Medicaid State Plan.

We appreciate consideration of these views by both CMS and OMB and would be pleased to discuss any aspect of these comments or provide any further information that may be useful to future agency deliberations. Should you wish to contact SNHPA

regarding the subject of this letter, please contact Edith S. Marshall (SNHPA Director of Legal and Regulatory Affairs) at 202-552-5851 or edith.marshall@safetynetrx.org.



William von Oehsen
President and General Counsel



Edith S. Marshall
Special Counsel and Director of
Legal and Regulatory Affairs

Attachment



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.

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

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.

* * * * *

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