



Safety Net Hospitals for Pharmaceutical Access

To: SNHPA Allies
From: SNHPA
Re: CMS Clarifies NDC Reporting Requirements
Date: November 3, 2009

Last month, the Centers for Medicare and Medicaid Services (CMS) sent a transmittal to every state Medicaid agency in the country clarifying the National Drug Code (NDC) reporting requirements applicable to hospitals when billing Medicaid for infusion products, injectibles and other physician administered drugs. Issuance of the transmittal represents the culmination and conclusion of a lawsuit brought by SNHPA and a member hospital more than a year ago challenging CMS's interpretation of a 2005 federal law directing states to collect NDCs for physician administered drugs. As explained in more detail in the attached documents, CMS has acknowledged, for the first time, that states have the authority to exempt all or a subset of hospital clinic drugs from the NDC reporting requirements without risking the loss of federal matching funds. This development creates a significant opportunity to work with states to implement this newly-recognized exemption.

The attached material should provide you with all the information necessary to educate your state about the CMS clarification. Attachments include:

- a copy of the CMS transmittal;
- SNHPA's press release;
- a chronology of key events;
- two sets of talking points – one summarizing the opportunity for states to exempt hospitals from NDC reporting and the other enumerating the kinds of burdens the requirements create for hospitals; and
- a 10-page legal analysis.

Please feel free to share this information with your state Medicaid agency, any relevant state associations, state lawmakers and any other interested party.

If you think your state may be interested in implementing the exemption, please let us know so that we can work with you to capitalize on the opportunity. Implementation of the exemption may be as expansive as protecting all hospitals in your state from having to comply with NDC reporting requirements, or as modest as limiting the exemption to just 340B hospitals. And if your state insists that 340B discounts must be passed onto the Medicaid program, you can propose that, rather than billing Medicaid at actual acquisition cost, 340B hospitals should be able to provide the savings through a quarterly or year-end settlement process. Other changes that could be suggested might include requiring NDC reporting only on a periodic (quarterly) basis, only on more costly drugs, or only on brand name drugs with higher rebates.

Please do not hesitate to contact us. You may direct your questions to Stuart Gordon at (202) 552-5851 or stuart.gordon@snhpa.org.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244 -1850

October 16, 2009

MEDICAID DRUG REBATE PROGRAM

Release No. 153



For State Medicaid Directors



Clarification of NDC Requirement for Physician-Administered Drugs

Section 6002 of the Deficit Reduction Act (DRA) and 42 CFR Part 447.520 set conditions for States to obtain FFP for physician-administered drugs. States must collect National Drug Codes (NDCs) on claims submitted for physician-administered drugs in order for the States to bill manufacturers for rebates. Section 1927(j)(2) of the Social Security Act exempts certain hospitals from the rebate requirement as long as the hospitals bill Medicaid for covered outpatient drugs at no more than the “hospital’s purchasing costs for covered outpatient drugs (as determined under the State plan).”

We are clarifying a State’s obligation to collect NDCs under Section 6002 and 42 C.F.R. § 447.520. This obligation must be read in conjunction with the Section 1927(j)(2) exemption described above. A hospital’s claims for covered outpatient drugs are not subject to the NDC reporting requirement if the hospital meets the criteria of Section 1927(j)(2). States are therefore not required to collect NDCs under the DRA for these claims.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group



Safety Net Hospitals for Pharmaceutical Access

For Immediate Release

Oct. 8, 2009

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Settlement Relieves Safety-Net Hospitals of Burdensome and Costly Reporting Mandate

(Washington, DC) Hundreds of hospitals serving low-income and uninsured patients expect a soon-to-be-issued Center for Medicare & Medicaid Services (CMS) directive to provide them relief from a controversial reporting policy that would have cost some hospitals millions of dollars to implement.

CMS will notify state Medicaid programs within the next 30 days clarifying that states may exempt hospitals from a federal mandate to collect national drug codes (NDCs) on physician-administered drugs if such drugs are billed at their “purchasing cost” as defined under a state’s Medicaid plan. The CMS transmittal will also advise the states that if a hospital drug qualifies for the exemption, it is not subject to a rebate under the Medicaid drug rebate program.

The CMS action follows settlement of August 2008 litigation filed against the federal agency by the Safety Net Hospitals for Pharmaceutical Access (SNHPA), representing about 500 safety-net hospitals, and the University Medical Center of Southern Nevada (UMCSN) in Las Vegas. That lawsuit attempted to reverse the implementation of the July 2007 CMS Medicaid regulation mandating the NDC reporting by hospitals. The hospitals said the reporting requirement would cost them millions of dollars and would be very difficult to implement, and sought a permanent injunction prohibiting the federal government from requiring and encouraging state Medicaid agencies to collect the information.

In their original complaint, the plaintiffs contended CMS had ignored or misinterpreted an existing Medicaid law that exempted drugs dispensed by hospitals from rebates when the hospitals billed for those drugs at their purchasing costs. The American Society of Health-System Pharmacists, which represents 35,000 pharmacists from hospitals and other health care facilities, had estimated the reporting requirement was going to require hospital systems to make changes that would add costs of \$10 per prescription.

The drugs for which CMS was demanding NDCs included infusion products and injectables, which are liquid products or compounds of different drugs that do not lend themselves easily to the mandated reporting.

SNHPA President and General Counsel William von Oehsen called news of the CMS transmittal “an important step by federal authorities in recognizing and publicizing states’ pre-existing right to exclude hospital drugs from Medicaid rebate requirements, including NDC reporting, without risking the loss of federal matching funds.” Mr. von Oehsen urged states to take advantage of the CMS clarification to eliminate a difficult and costly administrative burden on all hospitals, especially those participating in the 340B drug discount program by virtue of serving large numbers of uninsured and underinsured patients.

SNHPA is a national association of about 500 hospitals that, based on the high percentage of indigent patients they serve, are qualified to participate in the federal drug discount program administered under Section 340B of the Public Health Service Act.

Safety Net Hospitals for Pharmaceutical Access

October 1990	Congress enacts Medicaid rebate law as part of OBRA '90. Section 1927(j)(2) exempts from rebates those covered outpatient drugs that are dispensed by hospitals that use drug formulary systems and bill the state Medicaid program at no more than the hospital's purchasing costs (as determined under the State plan). The Centers for Medicare and Medicaid Services (CMS) never issues federal regulations to implement the exemption.
June 1997	CMS issues Drug Rebate Program Guidance Transmittal No. 29, which states that hospital drugs are not subject to rebates unless the drug is used in the outpatient pharmacy and the hospital bills Medicaid for reimbursement for dispensing the outpatient drug. The hospital community assumes this exemption is based on section 1927(j)(2).
April 2004	Health and Human Services Office of the Inspector General (OIG) report "Medicaid Rebates for Physician Administered Drugs" reveals 24 states are not collecting any Medicaid rebates on physician-administered drugs costing the states \$125 million. Report focuses on drugs administered in physicians' offices, not physician-administered drugs administered in hospital outpatient clinics. "Physician-administered drugs" are defined under the report as "drugs that a medical professional administers to a patient in a physician's office".
February 2006	Deficit Reduction Act of 2005 (DRA) enacted. In response to 2004 OIG report, section 6002 of the DRA requires states to collect utilization and coding data such as national drug codes (NDCs) or J-codes for drugs that are physician-administered. Purpose of the data collection is to enable states to identify and collect rebates on those drugs.
July 2007	<p>CMS issues regulations implementing the DRA provisions, including the NDC reporting provisions. New regulation 42 CFR 447.520 warns that states that do not implement an NDC reporting requirement for physician-administered drugs will lose their federal Medicaid funding match on those physician-administered drugs. Regulation authorizes states to apply to CMS for extensions in the time for implementation</p> <p>Regulations do <u>not</u> exempt hospitals billing at purchasing costs from the requirement. CMS does acknowledge the existing statutory exemption in the preamble to the regulations, but confuses the statutory term "purchasing costs" with the long-used regulatory term "actual acquisition cost".</p>
January 1, 2008	Regulatory deadline for states to require providers to submit codes for 20 multiple source drugs identified by CMS as having the highest dollar volume. CMS regulation also sets out two additional deadlines already passed: January 1, 2006 for submitting NDCs or J-Codes for single source physician-administered drugs; and January 1, 2007 for requiring providers to submit NDCs for claims for single source and the 20 highest dollar-volume multiple source drugs
July 2007 to June 2008	Half of the state Medicaid programs apply for and are granted extensions of time for implementation. Seven additional states simply delay implementation. CMS grants no extensions beyond June 2008. Throughout this period, CMS suggests to states that hospitals could be exempted from reporting requirements only if they bill Medicaid at "actual acquisition cost (AAC)

**SNHPA NDC
CHRONOLOGY
(cont'd)**

July 2008	A broad-based coalition of hospital, manufacturer and pharmacist groups, including SNHPA, meets with CMS Deputy Administrator to present case against imposition of NDC reporting mandate against hospitals. CMS never responds formally to issues raised at meeting.
July 2008	CMS begins requiring all states to implement NDC reporting requirements. Hospitals begin compliance. State implementation varies widely: some states exempt hospitals that bill at AAC, others require hospitals to report NDCs <u>AND</u> bill at AAC, while others delay implementation beyond July 2008.
August 2008	SNHPA and University Medical Center of Southern Nevada bring suit against HHS and CMS in U.S. District Court for the District of Columbia to permanently enjoin enforcement of the NDC reporting requirement for hospitals and to issue a declaratory judgment that drugs dispensed by hospitals using their formularies and billed to Medicaid at purchasing costs are exempt from NDC reporting.
November 2008	CMS responds to complaint by bringing a motion to dismiss. According to the motion, plaintiffs have no cause of action because the states – not the federal government – are responsible for the manner in which the NDC information is being collected by the states.
November 2008 to August 2009	In subsequent filings by CMS with the court, the agency acknowledges that it has “not had occasion to set forth a definitive interpretation” of the 1927(j)(2) exemption for drugs dispensed by hospitals and billed at purchasing costs as determined under the State plan. The government retreats from CMS’s pre-litigation position in other areas as well.
October 2, 2009	As a condition of settling the SNHPA litigation, CMS agrees to issue a Medicaid transmittal confirming that states should read the NDC reporting mandate within the context of the existing statutory exemption for hospitals. CMS states that physician-administered drugs administered by hospitals that meet the conditions of section 1927(j)(2) are not subject to rebates, and therefore not subject to the NDC reporting requirements. States that do not require NDC reporting requirements for hospitals that meet the statutory exemption will not lose their federal matching funds for physician-administered drugs.
October 16, 2009	CMS issues Medicaid Drug Rebate Program Release #153, “Clarification of NDC Requirement for Physician-Administered Drugs,” to State Medicaid Directors.



Safety Net Hospitals for Pharmaceutical Access

CMS CLARIFIES THAT STATES MAY EXEMPT HOSPITALS FROM FEDERAL REQUIREMENT TO COLLECT NDCs ON PHYSICIAN-ADMINISTERED DRUGS

On October 2nd, Safety Net Hospitals for Pharmaceutical Access (SNHPA) and University Medical Center of Southern Nevada settled their joint lawsuit against the Centers for Medicare and Medicaid Services (CMS) seeking to enjoin CMS from implementing its national drug code (NDC) reporting requirements applicable to hospitals when billing Medicaid for physician-administered drugs (PADs). Under the terms of the settlement, CMS agreed to issue a clarification to state Medicaid agencies acknowledging, for the first time, a state's right to exempt hospitals from these reporting requirements.

If States Exercise This Right, Drugs Administered by Physicians in a Hospital Setting Are No Longer Rebatable – As a result of the SNHPA litigation, CMS retreated from its original position that made it virtually impossible for a state to exempt hospital PADs from NDC reporting requirements. CMS's clarification acknowledges that the NDC reporting requirements must be read in conjunction with section 1927(j)(2) of the Social Security Act. Section 1927(j)(2) specifically exempts from Medicaid rebate requirements those Medicaid hospitals that (1) dispense covered outpatient drugs using formulary systems and (2) bill the state at no more than the hospital's purchasing costs as determined under the state plan. Every hospital meets the first criteria, so whether a hospital's PADs are exempt from the rebate program depends on whether the second criterion can be satisfied. If states interpret their state plans such that states can treat all or a subset of hospital PADs as being billed at the drug's "purchasing cost," then the drugs are no longer rebatable under Medicaid which, in turn, means that they are no longer subject to NDC reporting. States can achieve this result by construing "purchasing costs" to include expenses beyond simply the actual acquisition cost of the drug. They can include, for example, hospital salary and overhead costs associated with operating a purchasing department, hospital drug delivery and storage costs, etc.

States Would No Longer Be at Risk of Losing Federal Matching Funds for Failing to Collect NDCs and to Request Manufacturer Rebates for Such Drugs – When CMS issued regulations implementing the NDC reporting provisions under the Deficit Reduction Act of 2005 (DRA), it not only failed to explain the opportunity for states to exempt hospital PADs from such requirements under 1927(j)(2), it warned that federal matching funds would not be available to states that failed to collect NDCs for such drugs. Almost two thirds of states sought to delay compliance with the new NDC reporting law suggesting that they were either unprepared or unwilling to implement the new law. CMS refused to grant extensions beyond June 30, 2008 and the rule went into effect the next day. If CMS had properly informed states of their rights under 1927(j)(2) to permanently exclude some or all hospital PADs from the rebate program, many states may have exercised their rights without fearing the loss of federal matching funds. But it is not too late! CMS's clarification provides an opportunity for states to exercise their 1927(j)(2) rights to spare themselves and their hospitals from the burden of collecting NDCs for purposes of requesting manufacturer rebates.

Hospital Claims Would No Longer Be Denied if They Lack NDC Information – Hospitals continue to struggle with the extraordinary amount of time and resources necessary to comply with NDC reporting requirements. Less than 10 percent of hospitals have bedside bar-coding capabilities, so most rely on their clinical and administrative staff to research, retrieve and report the relevant product codes. Complicating compliance further are the difficulties in identifying NDCs for compounded drugs and drug admixtures in which different package sizes of the same drug are combined, when different suppliers of the same generic drug are used, or if partial quantities are included. For these reasons, hospitals are fearful of misreporting NDCs and, to avoid potential liability, have sometimes opted not to bill Medicaid for PADs altogether. In addition, few hospitals have electronic billing systems and pharmacy purchasing programs that are sufficiently linked to allow the hospital to capture and report NDCs when billing Medicaid, absent a significant overhaul of the hospital’s underlying information technologies. CMS’s clarification provides a path for states to shield hospitals from these unreasonable and costly implementation problems.

Disproportionate Share Hospitals Would Not Have to Adjust How They Bill Medicaid for Physician-Administered Drugs Purchased Through the 340B Program – Pursuant to section 340B of the Public Health Service Act, a drug purchased through the 340B program may not be subject to both a 340B discount and a Medicaid rebate. The purpose of this requirement is to protect drug manufacturers from being unfairly penalized by “duplicate discounts” for the same drug – a 340B discount “upfront” and a Medicaid rebate paid to the state after the drug is billed to Medicaid. To prevent such duplicate discounts, some states require 340B hospitals to bill Medicaid at the actual acquisition cost of the drug, which results in the hospital “passing on” its 340B savings to the Medicaid program. Because the prohibition against duplicate discounts only applies where a drug is subject to both a 340B discount and a Medicaid rebate, then, pursuant to CMS’s clarification that drugs administered in outpatient hospital settings are not subject to the Medicaid rebate provisions under section 1927(j)(2), there is no longer a risk of duplicate discounts for these drugs. Accordingly, 340B hospitals do not need to adjust their Medicaid billing practices to avoid a duplicate discount problem.



Safety Net Hospitals for Pharmaceutical Access

The NDC Reporting Requirement Places an Unreasonable Burden on Hospitals, and Proves Especially Onerous for Safety Net Hospitals

The accurate reporting of national drug code (NDC) information for physician-administered drugs has not only proven costly to implement for hospitals participating in Medicaid, it has proven logistically difficult – impossible in some cases – to execute. The result is that, in many instances, hospitals are choosing not to file claims for physician-administered drugs in order to avoid potential liability arising from charges that they have improperly reported the NDCs for those drugs. These unfiled Medicaid claims for physician-administered drugs are leading hospitals to lose hundreds of thousands of dollars – losses at levels that cannot be long-sustained by safety net hospitals in this state.

Bar-Coding Technology at Bedside Not Widely Available -- Not only has the task of researching and reporting NDC numbers on hospital clinic drugs proven highly problematic, the accurate determination of those numbers at bedside and their subsequent transmittal to hospital billing departments has presented intransigent difficulties. The NDC bar-coding read by the hospital pharmacist in preparing a drug or drug mix for administration may not be affixed to drugs administered at bedside in the outpatient clinic. Few hospitals have the in-house capability or technology to affix product bar codes to infusion bags and other physician-administered drugs at bedside that can accurately identify the ingredients of drug mixes and their associated NDCs at bedside, or for reporting much later to and by the hospital billing department. Further, it may be logistically difficult for the dispensing pharmacist to communicate this information to bedside even in a more rudimentary fashion.

The Identical Drug in Different Packaging Will Be Mixed – Drugs sold by hospital outpatient pharmacies directly to patients for self-administration are sold in a form, dosage, and package size with which a specific NDC is associated. By contrast, in an outpatient clinic setting, patients are frequently administered a limited amount or dose of a drug that the hospital originally purchased in bulk – or at least in larger quantity – and not in single-dose packaging. There may be a number of different NDC designations for different package sizes of the same pharmaceutical product that are eventually mixed and administered in the same clinic bedside infusion. Hence, it is often unclear what NDC to report when the product administered is derived from different package sizes.

Combining Generic Equivalents with Different NDCs – Hospitals very often purchase multiple-source equivalent medications in a variety of packaging forms and sizes, depending on the hospital's needs and the relative cost and availability of different forms and packaging options at various times. Until now, there has been no need for hospitals to distinguish between different generic equivalents. To comply with the NDC reporting requirement for purposes of Medicaid billing, hospital staff has to carefully monitor to determine what quantity of which generic medication is administered, and from what package size. This information then must be transmitted to the billing department for submission of claims to the Medicaid program. Tracking these matters with the requisite

level of care and precision in an outpatient hospital treatment setting is a logistical and administrative nightmare.

Identifying Specific NDCs for Products Combined in a Cocktail – It is frequently the case with cancer and HIV treatments and other drug therapies administered to patients on an outpatient basis that a patient will receive a pharmaceutical “cocktail” of multiple medications through one infusion. Indeed, drugs are often administered in hospital outpatient clinic settings with the use of prepared infusion “bags,” consisting of a combination of various drug substances in various quantities, and even the prescribing doctor may be unaware of the precise formulation to be administered when he orders the treatment for administration by the nursing staff. Under these circumstances, the NDC reporting difficulty is compounded exponentially, as staff attempts to identify the different drugs, dosages, and package sizes included in the prepared bag.

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In conclusion, the burden of identifying NDCs in each of the above circumstances is enormous, and requires significant staff time. Even with the best of intentions and efforts, a hospital may inadvertently report inaccurate or misleading information to state Medicaid agencies. To avoid these burdens, and to avoid liability for inaccurate billing, many hospitals are foregoing filing claims for physician-administered drugs, and suffering losses in the hundreds of thousands of dollars. These losses cannot be long-sustained, particularly by disproportionate share hospitals that are highly dependent on Medicaid reimbursement as a result of the large numbers of low-income patients they serve.

For additional information, please contact Stuart Yael Gordon, Director of Legal and Regulatory Affairs, Safety Net Hospitals for Pharmaceutical Access, at 202-552-5851 or stuart.gordon@snhpa.org.



Safety Net Hospitals for Pharmaceutical Access

LEGAL ANALYSIS OF THE NDC REPORTING ISSUE

I. Background

In August 2008, Safety Net Hospitals for Pharmaceutical Access (“SNHPA”), together with member hospital University Medical Center of Southern Nevada (“UMC”), filed suit against the Centers for Medicare and Medicaid Services (“CMS”) in order to enjoin the agency from implementing a new regulation that required hospitals, along with other providers, to submit National Drug Code (“NDC”) information when billing Medicaid for certain physician administered drugs.¹ The regulation, found at 42 C.F.R. § 447.520, was intended to implement Section 6002 of the Deficit Reduction Act of 2005 (“DRA”), which amended Section 1927(a) of the Social Security Act to require states to collect NDC information from healthcare providers for certain physician administered drugs.² The purpose of Section 6002 was to facilitate states’ collection of rebates for physician administered drugs by giving states the NDC data necessary to identify the relevant drugs and their manufacturers.

The crux of SNHPA’s argument was that CMS, in applying the regulation to drugs administered in hospital outpatient settings (as opposed to simply in physician’s offices or other outpatient settings), had interpreted the regulation in a manner that was in direct conflict with Section 1927(j)(2) of the Social Security Act (“SSA”), which specifically exempts from Medicaid rebate requirements those Medicaid-participating hospitals that dispense covered outpatient drugs using formulary systems, and which bill the state at no more than the hospital’s purchasing costs “as determined under the state plan.”³

On October 2, 2009, SNHPA and UMC settled their joint lawsuit against CMS. Pursuant to the terms of the settlement, CMS has issued a clarification to state Medicaid programs, confirming that a state’s obligation to collect NDC information under Section 6002 of the DRA and 42 C.F.R. § 477.520 must be read in conjunction with the exemption set forth at Section 1927(j)(2).⁴ Accordingly, the clarification states that a hospital’s claims for covered outpatient drugs are not subject to the NDC reporting requirement if the hospital meets the criteria of Section 1927(j)(2). Below, we outline various changes in the government’s position as a result of the SNHPA/UMC litigation, and explain why CMS’ pre-litigation position on NDC reporting was untenable. We also discuss the discretion that states may now exercise to exempt hospital clinic drugs from Medicaid rebate and NDC reporting requirements.

¹ Complaint at 2-3, *Univ. Med. Ctr. of S. Nev. v. Leavitt*, No. 1:08-cv-01456-CKK (D.D.C. Aug. 21, 2008).

² See Deficit Reduction Act of 2005 § 6002, 42 U.S.C. § 1396r-8(a); see also 42 C.F.R. § 447.520.

³ Social Security Act § 1927(j)(2), 42 U.S.C. § 1396r-8(j)(2).

⁴ Release No. 153, Medicaid Drug Rebate Program, Clarification of NDC Requirement for Physician-Administered Drugs (Oct. 16, 2009) (“CMS Clarification”).

II. Government's Changed Position as a Result of the SNHPA Litigation

CMS has changed its position on a variety of issues during the course of the SNHPA/UMC litigation. In this section, we discuss three important “evolutions” in the government’s perspective, pertaining to: (1) CMS’ role in extending the NDC reporting requirement to hospitals; (2) application of the Section 1927(j)(2) exemption to reporting requirements; and (3) interpretation of the term “purchasing costs” under Section 1927(j)(2).

A. CMS’ Role in Extending NDC Reporting Requirements to Hospitals

At the outset of the litigation, CMS argued that SNHPA and UMC lacked standing to pursue their claims against CMS because “the NDC reporting requirement has been *imposed by Congress* and cannot be lifted by the Secretary,” and “the regulation that the Secretary, through CMS, promulgated to implement the [NDC reporting requirement] did not require anything more than *what the statute itself requires*.”⁵ Thus, CMS’ position was that the broadly-construed NDC reporting requirement was *mandated by Congress* by way of Section 6002 of the DRA and implemented by states, and therefore that the CMS regulation was not the source of hospitals’ injury.

CMS’ argument was without basis. In fact, prior to the passage of the DRA, Congress had specifically *exempted* from Medicaid rebate requirements – pursuant to Section 1927(j)(2) – those hospitals that dispense covered outpatient drugs using a formulary system and bill their drugs to the state at no more than their purchasing costs, as determined under the state plan. It therefore cannot be said that Congress mandated reporting of NDCs by hospitals because Congress had already exempted hospitals meeting the terms of Section 1927(j)(2) from the entire Medicaid rebate program, including the NDC reporting requirements. Notwithstanding, in direct contravention of Congressional intent and existing law, CMS interpreted its regulation to mandate that hospitals be subjected to the NDC reporting requirement, without incorporating or even referencing the exemption provision at Section 1927(j)(2). In the preamble to the final regulation, CMS made clear that, in its view, *any* provider that bills Medicaid must use NDC codes for physician administered drugs, and asserted that “the statute... *does not differentiate between providers* in requiring that states collect [NDC information].”⁶ CMS further stated that, although it “[recognized] the operational difficulties that may exist for some hospitals [due to the need to submit NDC information]...the law, as amended by the DRA, *makes no exceptions* for physician administered drug claims billed by hospital outpatient departments.”⁷

However, in CMS’ reply brief in support of its motion to dismiss, filed in January 2009, the agency articulated a different position, and acknowledged the applicability of Section 1927(j)(2) in construing the NDC reporting requirement.⁸ In its brief, CMS asserted that states are not required to collect NDC information from hospitals or other providers of covered outpatient drugs “unless

⁵ Plaintiffs’ Memorandum in Opposition to Defendants’ Motion to Dismiss at 12, Univ. Med. Ctr. of S. Nev. v. Leavitt, No. 1:08-cv-01456-CKK (D.D.C. Dec. 18, 2008) (“Plaintiffs’ Opposition to Defendants’ Motion to Dismiss”).

⁶ 72 Fed. Reg. 39,142, 39,219 (July 17, 2007) (emphasis added).

⁷ *Id.* at 39,220 (emphasis added).

⁸ Defendants’ Reply in Support of Motion to Dismiss at 8, Univ. Med. Ctr. of S. Nev. v. Leavitt, No. 1:08-cv-01456-CKK (D.D.C. Jan. 16, 2009) (“Defendants’ Reply Brief”).

the drugs in question are among those for which the states must collect rebates.”⁹ The agency affirmed this position in its clarification to states, wherein it writes that a “hospital’s claims for covered outpatient drugs are not subject to the NDC reporting requirement if the hospital meets the criteria of Section 1927(j)(2).”¹⁰ In binding the agency to a settlement and undertaking the issuance of a clarification, CMS has clearly assumed responsibility for the erroneous interpretation of the NDC reporting requirement and can no longer claim that it was simply carrying out the will of Congress and deferring to state discretion with respect to implementation of the requirement.

B. Application of Section 1927(j)(2) Exemption to Reporting Requirements

With respect to the application of the Section 1927(j)(2) exemption to reporting requirements, CMS initially took the position that the exemption set forth in Section 1927(j)(2) applied only to the Medicaid rebate requirement, and not to the NDC reporting requirement established under the DRA. This position is nonsensical in light of the fact that the primary purpose of the reporting requirement, pursuant to both the DRA and CMS’ regulation, is to facilitate the states’ collection of manufacturer rebates. If a hospital is exempt from the Medicaid rebate provisions under Section 1927(j)(2), the impetus for requiring the hospital to submit NDCs is eliminated.

Nonetheless, in the government’s brief in support of its motion to dismiss, dated November 17, 2008, CMS asserted that, as stated in the preamble to the final regulation and in subsequent CMS correspondence “though hospital outpatient clinics *were not categorically excluded from the NDC reporting requirement*, existing provisions that remove such clinics from rebate requirements continued to apply.”¹¹ Thus, pursuant to CMS’ initial analysis, the Medicaid rebate and NDC reporting requirements were bifurcated, representing two separate and distinct requirements that could be separately applied. The Medicaid statute, however, makes no such distinction, and mandates that hospitals meeting (j)(2) exemption criteria be exempt from all requirements imposed by the Medicaid rebate law, including both rebate and reporting requirements.¹²

CMS has recently amended its position on this issue, and recognized that the NDC reporting requirement need not apply where a hospital meets the criteria for exemption from Medicaid rebate requirements. As noted above, in the government’s reply brief of January 2009, CMS stated that “42 C.F.R. § 447.520 does not impose on states a requirement that they collect NDC numbers from hospitals or any other provider...unless the drugs in question are among those for which the states must collect rebates pursuant to 42 U.S.C. § 1396r-8.”¹³ Further, in its recent clarification to states, CMS affirms that “[a] hospital’s claims for covered outpatient drugs are not subject to the NDC reporting requirement if the hospital meets the criteria of Section 1927(j)(2).”¹⁴ Thus, the government has acknowledged the statutory and common sense inter-connectedness of

⁹ *Id.*

¹⁰ CMS Clarification, *supra* note 4.

¹¹ Defendants’ Motion to Dismiss at 2, *Univ. Med. Ctr. of S. Nev. v. Leavitt*, No. 08-1456 (CKK) (D.D.C. Nov. 17, 2008) (“Defendants’ Motion to Dismiss”). *See also* 42 U.S.C. § 1396r-8 (codifying the Medicaid Drug Rebate Program).

¹² *See* Plaintiffs’ Opposition to Defendants’ Motion to Dismiss, *supra* note 5, at 14.

¹³ Defendants’ Reply Brief, *supra* note 8, at 8.

¹⁴ CMS clarification, *supra* note 4.

the reporting and rebate requirements, and affirmed that, where a hospital is exempt from rebate requirements, states are not required to implement or enforce the NDC reporting requirement.

C. Interpretation of Purchasing Costs in Section 1927(j)(2)

Finally, CMS has altered its position with respect to its interpretation of the term “purchasing costs” as referenced in Section 1927(j)(2). As noted above, Section 1927(j)(2) exempts from Medicaid rebate requirements those Medicaid-participating hospitals that dispense covered outpatient drugs using formulary systems, and which bill states at no more than the hospital’s “purchasing costs” as “determined under the state plan.”¹⁵ Drugs administered by medical professionals in hospital outpatient clinic settings are nearly always subject to hospital formulary systems, so the 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 those for which the hospital “bills [Medicaid] no more than the hospital’s purchasing costs for covered outpatient drugs (as determined under the State plan).”¹⁶

Importantly, and as will be discussed in greater detail in Section III of this document, a hospital’s “purchasing costs” within the meaning of Section 1927(j)(2) cannot be construed to mean the actual acquisition costs of obtaining the drugs administered in outpatient settings. This is so because the plain language of the exemption makes clear that the “purchasing costs” referred to in subsection (j)(2) are those determined under the provisions of a state’s Medicaid plan as the maximum proper billing and reimbursement rates for hospital outpatient drugs administered to Medicaid beneficiaries. Any other construction renders the statutory language meaningless and completely superfluous.

CMS’ use of terminology and construction of the term “purchasing costs” has varied over time. Initially, in its response to comments in the preamble to its final regulation, CMS used the terms “purchasing costs” and “acquisition costs” interchangeably, thus creating confusion for both states and hospitals:

Comment: Several commenters wrote that the DRA does not change the existing statute at section 1927(j)(2) of the Act that exempts from Medicaid drug rebates drugs administered to patients in hospital outpatient clinics and departments.

Response: We agree that the DRA did not change the exclusion of drugs from Medicaid rebates when dispensed in an outpatient hospital setting as long as Medicaid is billed at the hospital’s *purchasing costs*. However, hospitals commonly bill Medicaid without regard to their costs and accept the full reimbursement provided under the Medicaid State plan. When this is the case, drug manufacturers are responsible for paying rebates with respect to those drugs that qualify as covered outpatient drugs under section 1927(k)(3) of the Act.¹⁷ ...

¹⁵ Social Security Act § 1927(j)(2), 42 U.S.C. § 1396r-8(j)(2).

¹⁶ *Id.*

¹⁷ 72 Fed. Reg. at 39,219.

...
Physician administered drugs will be excluded from the Medicaid Drug Rebate Program requirements only when hospital outpatient departments have dispensed these drugs using drug formulary systems, and have billed Medicaid at **acquisition costs**, consistent with section 1927(j)(2) of the Act.¹⁸

Moreover, in subsequent unpublished telephone and personal conversations with state Medicaid agency personnel and in presentations at conferences such as the 2008 340B Coalition Summer Conference in Washington, D.C., CMS took the position that hospitals could be exempt from the mandated NDC reporting requirements only if they billed state Medicaid programs at **actual acquisition cost**.¹⁹ In addition, in the agency's brief in support of its motion to dismiss, CMS argued that the statutory language "'purchasing costs,' [as determined under the state plan,] is simply the amount that the 'hospital' paid to 'purchase' the covered outpatient drug in question."²⁰ Under this analysis, the phrase "as determined under the state plan" is rendered meaningless.

In recent months, however, CMS has retreated from these earlier constructions. In its reply brief of January 2009 the agency acknowledged that the Secretary, not CMS, has the authority to interpret the requirements of the Medicaid Act, and that the Secretary has **not sought to define** the term "purchasing costs" as set forth in Section 1927(j)(2).²¹ Thus, CMS has admitted that the agency's earlier, varied musings regarding the definition of "purchasing costs" are without legal force.

III. CMS' Pre-Litigation Position on NDC Reporting Was Untenable

CMS changed its position on the key issues described above because its pre-litigation analysis of the relevant law was misinformed. Recall CMS's statement in the preamble that **any** provider who bills Medicaid must use NDC codes for physician administered drugs, and that the statute "**does not differentiate between providers** in requiring that states collect [NDC information]."²² Pursuant to this line of reasoning, even hospitals that fall within the exemption of Section 1927(j)(2) are subject to the NDC reporting requirement. Below, we discuss some of the reasons why this position is untenable.

A. States' Obligation to Collect Rebates and NDCs Must Be Read in Conjunction with the 1927(j)(2) Exemption

Section 6002 of the DRA, entitled "Collection and Submission of Utilization Data for Certain Physician Administered Drugs," amended Section 1927(a) of the SSA to require states receiving federal matching payments for Medicaid outpatient drug coverage to provide for the

¹⁸ *Id.*

¹⁹ "Physician administered Drugs, 'The CMS Perspective,'" Joseph L. Fine, Technical Director, Pharmacy Division, CMS, July 15, 2008, slide 14. For 340B participating hospitals, this would mean the actual 340B price of the covered outpatient drugs.

²⁰ Defendants' Motion to Dismiss, *supra* note 11, at 40.

²¹ Defendants' Reply Brief, *supra* note 8, at 17-19.

²² 72 Fed. Reg. at 39,219.

submission of “utilization data and coding (such as J-codes and National Drug Code numbers)” for drugs that are “physician administered (as determined by the Secretary),” as “necessary to identify the manufacturer in order to secure rebates under [Section 1927].”²³

On the face of the statute, certain points are clear. First, the heading of Section 6002 plainly indicates that Congress did not intend the provision to apply to all “physician administered drugs,” but rather to a subset described in the DRA as “certain” physician administered drugs. Second, the Secretary of Health and Human Services (“HHS”) is accorded some discretion in determining the scope of applicability of the provision, and interpreting the term “physician administered.” Third, Section 6002 expressly amends Section 1927(a) of the SSA, but does not purport to amend or repeal any other, pre-existing provision of the Medicaid statute. In particular, the DRA provision makes no reference to, and does 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 Medicaid rebate requirements.²⁴

Congress’ intent to leave intact the rebate exemptions previously articulated in Section 1927(j) is made all the more clear in the conference report accompanying the bill that was enacted as the DRA. 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 this law expressly exempted drugs provided through managed care organizations and in certain outpatient hospital settings from manufacturer rebate requirements.²⁵ The joint House and Senate conferees acknowledged, in other words, the exemptions from rebate requirements that are established in Section 1927(j) of the Medicaid statute. The conferees went on in their report 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.**”²⁶ Thus, in the remainder of the discussion in the conference report, it is clear that the references to “physician administered outpatient drugs” (to which Congress intended the new law to apply) pertain to drugs that had generally not been subjected to rebate requirements by the states, despite the absence of any applicable statutory exemption. There is no suggestion of an intent to apply the NDC reporting requirement to drugs that the conference committee expressly acknowledged are statutorily exempt from rebates.

Because the legislators responsible for enacting the DRA were fully aware of the preexisting statutory exemptions from rebate requirements in the Medicaid law, their failure to amend or even mention those provisions in Section 6002 cannot reasonably be construed as an oversight. Simply put, if Congress had wanted to repeal or amend these provisions, it most certainly would have stated this intention. Accordingly, for purposes of determining the impact of Section 6002 on hospital clinic administered drugs, the relevant inquiry is whether those drugs fall

²³ Deficit Reduction Act of 2005 § 6002, 42 U.S.C. § 1396r-8(a) (adding Section 1927(a)(7) to the Social Security Act).

²⁴ Subsection (j)(1) exempts from rebates covered outpatient drugs dispensed by health maintenance organizations (including Medicaid managed care organizations).

²⁵ See H.R. Rep. No. 109-362, at 262 (2005) (Conf. Rep.).

²⁶ *Id.*

within the Section 1927(j)(2) exception from rebate requirements. Any drugs that fall within the scope of that exception were very clearly intended to be excluded from the definition of “physician administered drugs” under the DRA, and continue to be exempt from Medicaid rebates.

In summary, Section 1927 of the SSA, as amended and taken as a whole, unambiguously exempts drugs administered on an outpatient basis in hospital clinics and departments from the Medicaid rebate requirements otherwise established by that same provision of law. The long-standing statutory exemption set forth at Section 1927(j)(2) was left intact and unaffected by Section 6002 of the DRA, and Section 6002’s reference to drugs that are “physician administered” therefore cannot properly be interpreted to include hospital clinic administered drugs. Thus, CMS’ NDC reporting requirement, which was implemented pursuant to Section 6002 of the DRA, must be interpreted and applied in a manner that is consistent with the statutory exemption at Section 1927(j)(2).

B. Application of the 1927(j)(2) Exemption is a Matter of State Policy Because “Purchasing Costs” Are Determined Under the State Plan

As was discussed in Section II above, a hospital’s “purchasing costs” within the meaning of subsection (j)(2) cannot fairly be construed to mean the actual acquisition costs of obtaining the pharmaceutical products administered in outpatient settings, which may be lower (or in some instances higher) than the purchasing cost established under a Medicaid state plan. This is so, again, because the plain language of the exemption makes clear that the drug “purchasing costs” referred to in Section 1927 (j)(2) are those determined *under the provisions of a state’s Medicaid plan* as the maximum proper billing and reimbursement rates for hospital outpatient drugs administered to Medicaid beneficiaries.

It is one of the fundamental canons of statutory construction that, if possible, no clause, sentence, or word of a statute is to be construed as “superfluous, void or insignificant” or without operative effect.²⁷ The importance of this principle in interpreting the law has been “endlessly reiterated” in judicial precedent,²⁸ and has been emphasized in decisions of the United States Supreme Court spanning more than a century.²⁹ These decisions leave no question as to the continued vitality of this the principle and its applicability to the present question of statutory construction.³⁰ Since the parenthetical descriptor “as determined under the State plan” can, and

²⁷ See, e.g., *Cooper Industries, Inc. v. Aviall Services, Inc.*, 543 U.S. 157, 167 (2004); *TRW Inc. v. Andrews*, 534 U.S. 19 (2001); *Duncan v. Walker*, 533 U.S. 167, 174 (2001).

²⁸ *Qi-Zhuo v. Meissner*, 70 F.3d 136, 139 (D.C. Cir. 1995).

²⁹ See *Bennett v. Spear*, 520 U.S. 154, 173 (1997); *Bailey v. United States*, 516 U.S. 137, 145-46 (1995); *Ratzlaf v. United States*, 510 U.S. 135, 141 (1994); *United States v. Nordic Village, Inc.*, 503 U.S. 30, 36 (1992); *Federal Election Comm’n v. National Conservative Political Action Comm.*, 470 U.S. 480, 486 (1985); *United States v. Menasche*, 348 U.S. 528, 538-39 (1955); *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883); *Washington Market Co. v. Hoffman*, 101 U.S. 112, 115-16 (1879).

³⁰ The rule against surplusage is, to be sure, not entirely absolute, and can in some instances be overcome by a canon permitting words to be interpreted as surplusage if they appear to have been inserted by the legislature “inadvertently” or if their only possible meaning would be “repugnant to the rest of the statute.” See *Lamie v. United States Trustee*, 540 U.S. 526, 535 (2004) (citing *Chickasaw Nation v. United States*, 534 U.S. 84, 94 (2001)). Here, however, neither the nature of the clause in question nor its legislative history suggest any inadvertence on the part of Congress, and giving effect to the statutory reference to determination under state plans is in no way repugnant to the statutory scheme.

therefore must, be construed to have meaning and operative effect, it follows that “purchasing costs” within the meaning of the statute do not refer to actual purchase prices, but to costs defined by applicable Medicaid state plan provisions.

Moreover, the legislative history of Section 1927 (j)(2) buttresses the conclusion that the exemption applies to outpatient drugs billed by hospitals to Medicaid at allowable levels specified under applicable Medicaid state plans. The provision that became (j) originated in the Senate, and as initially drafted contained no reference to costs determined under state plans. The Senate bill language relevant to the hospital drug exception provided as follows:

The State plan shall provide that hospitals providing medical assistance under such plan that such hospitals which [*sic*] bill the plan no more than the hospital’s acquisition costs for covered outpatient drugs are not subject to the requirements of this section.³¹

The substance of the rebate exemption provision, as described on the floor of the Senate at the beginning of debate on the reconciliation bill, was that “[h]ospitals and HMOs with certain drug purchasing arrangements and that meet other requirements . . . would be exempt.”³² The Joint House and Senate Committee of Conference, in reporting out the final bill that became the Omnibus Budget Reconciliation Act of 1990, similarly described the Senate provision in the following terms:

States are required to exempt hospitals from these requirements provided the hospitals bill Medicaid no more than the hospital’s acquisition costs for covered outpatient drugs.³³

The House bill contained no corresponding provision, and in fact the section-by-section analysis in the conference report indicates that the conference agreement did not include this exemption provision at all.³⁴ Subsequently, although published legislative history fails to reflect precisely how or why the provision was ultimately altered, the final bill reported out by the conference committee and eventually enacted into law included a revised version of the Senate’s exemption provision. The final language of the law contained a significant change from the earlier Senate provision, namely, substitution of the current reference to a “hospital’s purchasing costs for covered outpatient drugs (as determined under the State plan)” in place of the previous Senate bill’s reference to a “hospital’s acquisition costs for covered outpatient drugs.” In light of this modification of the Senate bill language, it must be assumed that the legislature intended the statutory text to describe something other than hospitals’ actual costs of acquiring drugs when it used the term “purchasing costs,” and specifically intended to refer to cost levels defined under state plan provisions.

Thus, under the plain language of the exemption provision at Section 1927(j)(2) and long-held principles of statutory construction, “purchasing costs” are determined by states under their

³¹ S. Res. 2309, 101st Cong. § 6201 (1990).

³² 136 Cong. Rec. S15629 (daily ed. Oct. 18, 1990).

³³ H.R. Rep. No. 101- 964, pt. B at 427 (1990).

³⁴ *Id.* at 428.

respective state plans. In addition, CMS has acknowledged that the Secretary of HHS, not CMS, has the authority to interpret the requirements of the Medicaid Act, and the Secretary has not sought to define the term “purchasing costs” as set forth in Section 1927(j)(2).³⁵ The application of the Section 1927(j)(2) exemption therefore remains a matter of state policy. If states interpret their state plans to treat all or a subset of hospital physician administered drugs as being billed at the drug’s “purchasing cost,” then the drugs are no longer rebatable under Medicaid. This, in turn, means that they are no longer subject to NDC reporting. States can achieve this result by construing “purchasing costs” to include expenses beyond simply the actual acquisition cost of the drug. They can include, for example, hospital salary and overhead costs associated with operating a purchasing department, hospital drug delivery and storage costs, etc.

Pursuant to federal regulation, a state Medicaid plan must provide that it will be amended whenever necessary to reflect certain “material changes.”³⁶ Although state plan amendments generally require CMS approval, at least one jurisdiction has held that a state’s interpretation of its state plan will generally *not* constitute a “change” so as to evoke the requirement of federal approval, unless the clear effect of the interpretation is actually to alter the written terms of the plan.³⁷ Under this reasoning, so long as states are not interpreting the term “purchasing costs” in a manner that conflicts with existing state plan language, it is unlikely that a state plan amendment would be warranted.

IV. States Can Exercise Their Authority Under Section 1927(j)(2) to Exempt Hospital Clinic Drugs from both Medicaid Rebate and NDC Reporting Requirements Without Risking the Loss of Federal Matching Funds

When CMS issued regulations implementing the NDC reporting provisions, it not only failed to explain the opportunity for states to exempt hospital physician administered drugs from such requirements under 1927(j)(2), it warned that federal matching funds would not be available to states that failed to collect NDC information for such drugs. The final CMS regulation provided that “no [federal matching payments would be] available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.”³⁸

Despite this mandate, many state Medicaid programs have resisted implementation of the NDC reporting requirement because of the inherent difficulties in creating and funding the infrastructure by which to collect NDC information for physician administered drugs. Hospitals, too, continue to struggle with the extraordinary amount of time and resources necessary to comply with NDC reporting requirements: few hospitals have electronic billing systems and pharmacy purchasing programs that are sufficiently linked to allow the hospital to capture and report NDCs when billing Medicaid, absent a significant overhaul of the hospital’s underlying information technologies. In addition, less than 10 percent of hospitals have bedside bar-coding capabilities, so most rely on their clinical and administrative staff to research, retrieve and report the relevant

³⁵ Defendants’ Reply Brief, *supra* note 8, at 17-19.

³⁶ 42 C.F.R. § 430.12.

³⁷ *Concourse Rehabilitation and Nursing Center, Inc., v. DeBuono*, 179 F.3d 38, 46 (2d. Cir. 1999).

³⁸ 42 C.F.R. § 447.520.

product codes.³⁹ The lack of bar-coding at bedside, the difficulty in identifying the NDCs of drugs mixed in cocktails to treat cancer or HIV, the mix of different equivalent generics in administration, and the variety of package sizes (and NDCs) for the same drug product could all result in the misreporting of NDC numbers. This inadvertent misreporting could, in turn, cause states to mistakenly accuse hospitals of fraudulent billing practices. Faced with this potential liability, some hospitals have chosen not to bill at all for physician administered drugs, and are suffering significant financial losses as a result.

For these and other reasons, nearly two-thirds of states sought to delay compliance with the new NDC reporting law, suggesting that they were either unprepared or unwilling to implement the new law. While the DRA authorized CMS to grant extensions to states that were having difficulty complying with the NDC reporting requirement, no extensions were granted beyond June 30, 2008. The rule therefore went into effect the following day, notwithstanding the continuing concerns of many states.

With the resolution of the SNHPA/UMC litigation and the issuance of the CMS clarification, states can rest assured that they will not be denied federal matching funds if they choose not to collect NDC information from hospitals meeting exemption criteria. In its clarification, CMS specifically asserts that states are **“not required to collect NDCs under the DRA”** for hospital claims for covered outpatient drugs, where a hospital meets the criteria of Section 1927(j)(2).⁴⁰ Accordingly, states that choose to exempt such hospitals from having to submit NDCs **will not lose their federal matching funds under Medicaid**. Nor will matching funds be denied a state that chooses not to collect manufacturer rebates on these drugs, because CMS has expressly recognized that hospitals meeting the criteria of Section 1927(j)(2) are exempt from federal Medicaid rebate requirements.

With the Section 1927(j)(2) exemption now clearly recognized by the federal government, the onus is on states to exercise their rights under 1927(j)(2) to spare themselves – and their hospitals – from the financial, administrative, and logistical burden of collecting NDC numbers from hospitals for the purpose of requesting manufacturer rebates. In other words, while the resolution of the litigation and the issuance of the clarification “open the door” for states to free themselves and hospitals from burdensome NDC collection/submission requirements, states must now choose to “go through” that door, by recognizing NDC reporting and rebate exemptions for hospitals that meet the criteria of Section 1927(j)(2). Toward that end, hospitals, manufacturers, and state legislators should avail themselves of the opportunity created by the CMS clarification, and urge state Medicaid programs to exercise their authority to exempt some or all hospital physician administered drugs from both NDC reporting and manufacturer rebates.

³⁹ ASHP Survey Results: Provision of NDC Numbers on Outpatient Medicaid Claims (Feb. 2007).

⁴⁰ CMS clarification, *supra* note 4.