UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNIVERSITY MEDICAL CENTER
OF SOUTHERN NEVADA
1800 West Charleston Blvd.
Las Vegas, NV 89102

SAFETY NET HOSPITALS FOR
PHARMACEUTICAL ACCESS
1501 M Street, NW
Suite 700
Washington, DC 20005

Plaintiffs,

vs.

MICHAEL O. LEAVITT, in his official
Capacity as Secretary, United States Department
of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201

KERRY WEEMS, in his official capacity as
Acting Administrator, Centers for Medicare &
Medicaid Services, and

CENTERS FOR MEDICARE & MEDICAID
SERVICES
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case: 1:08-cv-01456
Assigned To : Kollar-Kotelly, Colleen
Assign. Date : 8/21/2008
Description: Admn Agency Review

Civil Action No.:

COMPLAINT

Plaintiffs, University Medical Center of Southern Nevada ("UMC") and Safety Net Hospitals for Pharmaceutical Access ("SNHPA"), collectively the Plaintiffs ("the Plaintiffs") by and through their undersigned counsel, sue Defendants, Michael O. Leavitt, Secretary of the Department of Health and Human Services ("the Secretary"), the United States Department of Health and Human Services, Kerry Weems, in his official capacity as Acting Administrator, Centers for Medicare & Medicaid Services ("the Administrator"), and the Centers for Medicare & Medicaid Services ("CMS"), collectively the Defendants ("the Defendants"), and allege as follows:

I. INTRODUCTION

1. This is an action for declaratory and other relief in which plaintiffs seek to bar the enforcement of the interpretation by Defendants of a regulation requiring plaintiffs to collect certain drug utilization and coding data from physicians' offices when they bill Medicaid for "physician administered drugs" furnished to patients on an outpatient basis in order to facilitate the collection by the States of rebates from the drugs' manufacturers. The regulation implements section 6002 of the Deficit Reduction Act of 2005 ("DRA"), Pub. L. No. 109-71 (2005). That section provides: "In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary),...the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify

as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title."

2. The Defendants have interpreted the regulation in a manner that directly conflicts with Section 1927(j)(2) of the Social Security Act, 42 U.S.C. § 1396r-8(j)(2). That provision explicitly exempts from the rebate provision requirements a "hospital (providing medical assistance under [a Medicaid State] 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)... ."

3. Plaintiffs fall within the exemption provided in Section 1927(j)(2). Despite this, however, the Defendants have mandated that States require plaintiffs to provide the coding data in order to facilitate the collection of rebates on drugs that are exempt from the rebate requirements.

4. In order to provide the drug utilization and coding data mandated by Defendants' interpretation of its regulation, plaintiffs are being required to manually input the data at the time the patients are being treated. The time involved is substantial. In many cases, particularly where drugs are being compounded or where a vial is used for multiple doses, it is impossible to provide accurate data due to the nature of the drugs being administered. In addition, plaintiffs are being forced to overhaul their software to accommodate the required codes.

5. Since the only purpose of the requirement that plaintiffs furnish the drug utilization and coding data is to facilitate the collection of rebates and since the drugs administered by plaintiffs are exempt from the rebate requirements, the imposition of this

requirement on plaintiffs is arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

II. JURISDICTION AND VENUE

6. This action arises under the federal Medicaid Statute, Title XIX of the Social Security Act, 42 U.S.C. § 1396, *et. seq.* (the Medicaid program), the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551, 701, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201.

7. This Court has jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 2201, and 28 U.S.C. § 1361.

8. Pursuant to 28 U.S.C. § 1391(e), venue for Plaintiff's Complaint is proper in the United States District Court for the District of Columbia, where the Defendant federal official is located.

III. PARTIES

9. Plaintiff UMC is an approximately 577 bed, not-for-profit, acute care hospital located in Las Vegas, Nevada, that participates as a provider in the federal Medicare program, and qualifies as "disproportionate share hospital" (DSH) under Medicare standards set forth at Section 1886(d)(5)(F) of the Social Security Act, 42 U.S.C. § 1395ww(d)(5)(F). Plaintiff also qualifies, and has since July 1994 been enrolled, as a covered entity under the federal drug discount program established under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

10. Safety Net Hospitals for Pharmaceutical Access (SNHPA) is a non-profit corporation, organized and existing under the laws of the District of Columbia. SNHPA is

headquartered in Washington, DC. SNHPA is a national association of over 400 public and private non-profit hospitals and health systems throughout the U.S. that participate in the Public Health Service 340B drug discount program. Plaintiff UMC is a member of SNHPA. SNHPA, which was originally named the Public Hospital Pharmacy Coalition ("PHPC"), was formed in 1993 to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. When Congress was creating the 340B program in 1992, PHPC representatives took the lead role in ensuring that hospitals were included in the program and the organization has been representing the interests of 340B hospitals ever since. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety-net providers. SNHPA is dedicated to educating its members and others about the 340B program and creating new opportunities for members to save on pharmaceuticals and improve access to pharmaceutical care. SNHPA brings this lawsuit on behalf of its members.

At least one of SNHPA's members possesses standing in its own right to bring this lawsuit. UMC is a member of SNHPA. The claims asserted and the relief demanded in this Complaint do not necessitate the participation of any of SNHPA's individual members.

11. Defendant, the Honorable Michael O. Leavitt, is the Secretary of the United States Department of Health and Human Services ("DHHS"), the federal department responsible for administration of the 340B program and the implementation of the Medicaid statute. Secretary Leavitt is only being sued in his official capacity.

12. Defendant, the United States Department of Health and Human Services

("HHS") is responsible for implementing the provisions of the Medicaid Statute. HHS published a final regulation on July 17, 2007. That rule, codified at 42 C.F.R. § 447.520 (2007), establishes the new data reporting and collection requirements for outpatient drugs that are "physician administered."

13. Defendant, the Honorable Kerry N. Weems, is the Acting Administrator of CMS, the component of HHS charged with administering the Medicaid program. The Acting Administrator is only being sued in his official capacity.

14. Defendant, CMS, is the component of HHS that administers the Medicaid program.

IV. THE MEDICAID DRUG REBATE AND 340B PROGRAMS

15. The federal Medicaid statute, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, establishes a joint federal-state program, known as the Medicaid program, to provide medical assistance to individuals whose income and resources are insufficient to meet the cost of necessary medical services. "Medical assistance" means "payment of part or all of the cost" of covered services, including inpatient hospital services. 42 U.S.C. §§ 1396d(a), 1396d(a)(1). In order to receive federal "matching" payments for their Medicaid expenditures (referred to as Federal Financial Participation or "FFP"), States that participate in the Medicaid program must comply with the governing federal statute and implementing regulations, and must operate their Medicaid programs in accordance with a federally-approved Medicaid State Plan, meeting specifically defined statutory criteria. 42 U.S.C. § 1396a.

16. The Secretary has delegated federal responsibility for administration of the Medicaid program, including authority to promulgate Medicaid regulations, to approve or

disapprove Medicaid State Plans, and to otherwise effectuate and enforce the provisions and purposes of the Medicaid statute, to the Centers for Medicare & Medicaid Services ("CMS," previously known as the Health Care Financing Administration, or "HCFA"), a component of HHS.

17. Medicaid was established primarily to provide medical assistance to indigent populations eligible for receipt of federally funded or federally supported cash assistance programs, including the Aid for Families with Dependent Children (AFDC) program established by Title IV of the Social Security Act (which has since been eliminated and replaced with the Temporary Assistance for Needy Families ("TANF") program) and the Supplemental Security Income (SSI) program established under Title XVI of the Act, sometimes referred to as the "categorical" assistance programs. Under the Medicaid statute, states participating in Medicaid are required to provide medical assistance to "categorically eligible" individuals, which includes those who are eligible for and receive TANF or SSI, 42 U.S.C. § 1396a(a)(10)(A).

18. Each State has substantial discretion to determine what categories of individuals beyond the "categorically eligible" may receive Medicaid assistance in the State, but generally (i.e., absent a specific waiver of statutory requirements by the Secretary of HHS) is limited to furnishing Medicaid to persons who are at least "categorically related" to the mandatory covered groups (e.g., persons who, like "categorically eligible" SSI recipients, are aged, blind or disabled, or who are members of families with dependant children, even if not eligible to receive SSI or TANF benefits due to failure to meet financial need or other program criteria).

19. A State is not required to cover outpatient prescription drugs in its Medicaid

program; but if it chooses to do so, its outpatient drug program is subject to the provisions of Section 1927 of the Act, 42 U.S.C. § 1396r-8. That provision of law establishes, among other limitations on States' Medicaid prescription drug programs, a requirement that manufacturers of drugs covered by Medicaid or by Part B of the Medicare program must enter into agreements with the Secretary obligating the manufacturers to pay State Medicaid agencies rebates on drugs that are dispensed or administered to Medicaid beneficiaries and subsequently billed by a hospital or other health care provider to Medicaid.

20. Section 1927 also includes certain express exemptions from the rebate requirements otherwise applicable to outpatient drugs billed to Medicaid. In particular, subsection 1927(j) of the Act, 42 U.S.C. § 1396r-8(j), describes two categories of drugs that are "not subject to the requirements" of the Medicaid rebate program. Subsection (j)(1) exempts from rebates covered outpatient drugs "dispensed by health maintenance organizations" (including Medicaid managed care organizations). Subsection (j)(2) similarly exempts from requirements of the rebate provisions a " hospital (providing medical assistance under [a Medicaid State] 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)... ."

21. Although Section 1927, including the exemption provision in subsection (j)(2), has been in effect for almost fifteen years, the Secretary failed to promulgate regulations implementing that section of law until July 2007, when regulations were issued to implement certain amendments to the statute enacted through the DRA. No regulations have ever been promulgated specifically implementing or interpreting subsection (j)(2).

During the past 15 years, however, States have generally not collected rebates from manufacturers on outpatient drugs administered to Medicaid patients in hospital outpatient clinic settings, thus in effect applying the 1927(j)(2) exemption from rebates to drugs administered in those settings.

22. Indeed such drugs have ordinarily been billed to Medicaid in a manner that makes rebate collection difficult or impossible. Specifically, hospitals have generally billed Medicaid for outpatient clinic drugs through the use of the so-called "J-codes" used in Medicare billing. Although these codes break out drugs from other costs of medical care, they do not identify the drugs with the associated National Drug Code ("NDC") numbers otherwise used in Medicaid billings that transmit sufficiently detailed information respecting manufacturer, form, dosage, and packaging of medications to facilitate a State's determination of rebate charges.

23. This practice was, and is, firmly supported by the (j)(2) rebate exemption, since the description of hospital drugs contained in that section was, and still remains, almost uniformly applicable to hospital outpatient clinical settings.

24. In 1997, CMS issued a guidance document (Medicaid Drug Rebate Program Release No. 29, June 2, 1997) that addressed, among other things, whether rebates are due on drugs purchased by hospitals. According to the CMS guidance, such 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." Since physician administered drugs are rarely used in a hospital outpatient pharmacy, CMS in essence recognized that hospital physician administered drugs were excluded from the rebate program.

25. Virtually all hospitals that dispense or administer drugs in an outpatient clinic setting to Medicaid beneficiaries meet the statutory exemption in 1927(j)(2) as they: (1) use formulary systems in their outpatient clinics and departments; and (2) generally bill Medicaid for the "purchasing costs" of such drugs in accordance with the State plan as implemented by the State's provider manuals

26. The federal 340B drug discount program was established in 1992 through enactment of Section 602 of the Veterans Health Care Act of 1992, Pub.L. No. 102-585. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b, which (in conjunction with certain related provisions of the Medicaid statute) requires manufacturers of outpatient drugs covered by the Medicaid program to execute agreements with the Secretary of Health and Human Services obligating the manufacturers to sell their outpatient drugs to certain, eligible "safety net" health care providers at deeply discounted prices, determined according to a statutory formula. *See* 42 U.S.C. § 256b. *See also* 42 U.S.C. § 1396r-8(a)(5).

27. The 340B statute identifies twelve different categories of health care providers that may qualify as covered entities under the 340B program, including certain so-called Medicare "disproportionate share hospitals" ("DSH"), as well as various other facilities and entities that are recipients of federal grant funds under the PHS Act. *See* 42 U.S.C. § 256b(a)(4).

28. A hospital qualified to receive manufacturer discounts on covered outpatient drugs as a covered entity under the 340B statute must meet several statutory criteria. First, it must serve a sufficient number of low-income patients to qualify as a DSH under Medicare program standards established by Section 1886(d)(5)(F) of the Social

Security Act, 42 U.S.C. § 1395ww(d)(5)(F). Second, it must be owned or operated by a state or local government, be a public or private non-profit hospital that has formally been granted governmental powers by a state or local government, or be a private non-profit hospital under contract with a state or local government to provide health care services to low income individuals who are not beneficiaries of either Medicare or Medicaid benefits or assistance. 42 U.S.C. § 256b(a)(4)(L). Third, the hospital must have a "disproportionate share adjustment percentage" (as calculated under the Medicare statute at 42 U.S.C. § 1395ww(d)(5)(F)) that is greater than 11.75%. In addition, the hospital is prohibited from buying covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. Id. UMC meets these criteria.

29. The purpose of Congress in enacting 340B was to assist these facilities – which by their nature provide a great deal of uncompensated or free care to indigent persons – to stretch their limited resources so as to be better able to provide such care. Thus, Congress specifically intended for 340B covered entities to be able to purchase outpatient drugs at low, 340B prices.

30. The Secretary has delegated responsibility for administering the 340B program to the Health Resources and Services Administration ("HRSA"), and within that organization, the Office of Pharmacy Affairs ("OPA").

31. OPA administers the 340B program by, among other functions, determining what covered entities have met applicable 340B criteria, and disseminating information to manufacturers concerning which entities are entitled to 340B discounts. DSH hospitals wishing to benefit from the 340B program must make certain submissions to OPA to establish their compliance with statutory standards. Upon enrolling a covered entity in the

program, OPA lists the entity as an eligible entity on the OPA website, to which manufacturers and wholesalers have access for the purpose of verifying the entity's eligibility.

32. The Secretary has not issued any regulations to implement the 340B statute. Rather, the program has been operated since 1992 primarily on the basis of a series of policy guidance documents published in the Federal Register at various times over the last sixteen years.

33. One important principle that applies to the 340B program is a prohibition against so-called "double discounts" being imposed on manufacturers. As described in the preceding paragraphs, under agreements executed with the Secretary of HHS, manufacturers are obligated to furnish discounts on the prices charged for outpatient drugs purchased by qualifying 340B covered entities, while being required to pay rebates to State Medicaid agencies on outpatient drugs billed to Medicaid that are not purchased through the 340B program. If a Medicaid rebate is charged and paid on a drug that was purchased by a 340B covered entity under the 340B program, and subsequently used to treat a Medicaid patient, a "double-discount" problem can arise, because in this scenario the manufacturer would effectively be paying a discount twice on the same drug – once in the form of a rebate paid to the State Medicaid agency, and once as a 340B discount to a covered entity.

V. "PHYSICIAN ADMINISTERED" DRUGS AND THE DRA

34. In January 2006, Congress enacted the DRA, legislation that included, among its many provisions for federal cost-cutting measures, several important amendments to the Medicaid statute. Section 6002 of the DRA requires states to collect

utilization and coding data – such as National Drug Code ("NDC") numbers and "J-Codes" – for drugs that are "physician administered" to enable states to identify and collect rebates on those drugs.

35. NDC numbers are numerical codes that specifically identify drugs and include such information as the drug's manufacturer, dosage, form, and packaging. State Medicaid agencies need the specific information contained in NDC numbers in order to bill manufacturers for the rebates due on drugs that have been used to treat Medicaid beneficiaries and paid for by the Medicaid program, where those drugs are subject to the rebate requirements of the law.

36. The provision that became Section 6002 of the DRA had been introduced in Congress on the heels of an April 2004 HHS Office of the Inspector General ("OIG") report that found that millions of dollars were being lost to the Medicaid program due to the failure of states to collect rebates on "physician administered drugs," expressly defined in the OIG's report as "drugs that a medical professional administers to a patient ***in a physician's office***." Medicaid Rates for Physician Administered Drugs, OEI-03-02-00660 (April 2004) (emphasis added).

37. In reciting the content of current law, the Conference Report accompanying the DRA had explicitly recognized the statutory exemptions for (1) health maintenance organizations and (2) hospital outpatient clinics described in Section 1927(j) of the Social Security Act. The report specifically distinguished drugs subject to those statutory exemptions from "certain drugs administered by physicians... [that] have often been excluded from the drug rebate program although there is no specific statutory exclusion."

38. As this legislative history underscores, the DRA did not remove, amend, or

alter in any way the exemption from the Drug Rebate Program under Section 1927(j)(2) that applies to most hospital outpatient clinics. On the contrary, the report specifically recognized the hospital outpatient clinic exemption as it was distinguishing physician administered drugs for which there was no similar statutory exemption and for which the DRA now requires that NDC information be collected.

VI. OVERBROAD APPLICATION OF THE LAW BY CMS

39. On July 17, 2007, CMS promulgated a final regulation to implement Section 6002 of the DRA. That rule, codified at 42 C.F.R. § 447.520 (2007), establishes (consistent with the language Congress employed in the DRA) new NDC reporting and collection requirements for outpatient drugs that are "physician administered."

40. CMS received many comments regarding the requirement that State Medicaid Agencies provide for the submission of NDCs on claims for physician-administered drugs.

41. Several commenters noted that CMS had failed to define "outpatient drugs that are physician-administered." One commenter claimed that CMS was incorrectly interpreting the law by including drugs administered in the outpatient hospital setting.

42. CMS responded to these comments by acknowledging that it had "chosen not to define what is meant by a covered outpatient drug that is administered by a physician." CMS asserted its belief that the DRA amendments to section 1927 of the Act were intended "to emphasize that where covered outpatient drugs are administered by a physician and separately billed to Medicaid, **States are required to collect rebates from manufacturers for these drugs. The law requires that States obtain information on**

the claims forms that will allow them to bill manufacturers for rebates for specific covered outpatient drugs... ." (emphasis added).

43. In response to a comment about whether "contrast agents typically used during hospital-based radiological procedures" are excluded from Medicaid rebates, CMS responded affirmatively, noting that "[o]nly physician-administered drugs that are separately billed to Medicaid as covered outpatient drugs will be considered physician-administered drugs for the purposes of [the] rule."

44. CMS reiterated this view in response to a comment about drugs administered in an emergency room. According to CMS, "[d]rugs administered incident to an emergency room service that are billed separately as covered outpatient drugs...are covered under the Medicaid Drug Rebate Program and must be billed using the NDC in order for States to collect the Federal match."

45. Some commenters expressed the belief that CMS had gone beyond the intent of Congress when it passed the DRA "by including outpatient hospitals and clinics in the requirement for States to collect NDC-level information on pharmacy claims." CMS responded that it based its "interpretation on the language in the statute **which does not differentiate between providers in requiring that States collect information sufficient to bill for rebates for covered outpatient drugs** under section 1927(k)(3) of the Act. **To the extent that providers bill for covered outpatient physician-administered drugs separately; that is, the cost of the drug administered is a separate line item from the service provided, we believe that, in accordance with the statute, States should be seeking rebates with respect to such drugs.**" (emphasis added).

46. The interpretations offered by CMS cited in paragraphs 42, 43, 44, and 45

above make it clear that CMS regards "the physician administered drug" provision to apply in hospital outpatient clinic settings, and intends to require State Medicaid agencies to implement this construction of the law.

47. CMS, however, offered a conflicting view of this requirement in response to several other comments. In response to a comment that the DRA did 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, CMS stated that it agreed "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.**" (emphasis added). CMS then offered a variant of this response to a comment that 340B hospitals should not need to forego receiving discounts on drugs as a result of Medicaid collecting rebates on them. CMS asserted that the DRA provision does not apply to 340B hospitals that receive discounted drugs when those hospitals bill Medicaid "**at the acquisition cost [of the drug] as determined under the State plan.**" (emphasis added). In this second response, CMS substituted the phrase "acquisition cost as determined under the State plan" for the phrase "hospital's purchasing costs" contained in the earlier response and in the statutory exemption.

48. The interpretations set forth by CMS in paragraphs 42, 43, 44, and 45 directly conflict with the interpretations set forth by CMS in paragraph 47. These conflicting interpretations are evidence of the arbitrary and capricious nature of the action of CMS.

49. The arbitrary and capricious nature of CMS's interpretation can also be seen in a letter dated June 5, 2008 from Herb B. Kuhn, Deputy Administrator and Acting

Director of the Center for Medicaid and State Operations to William von Oehsen, President of SNHPA. This letter was in response to a letter dated October 16, 2007 written by Mr. von Oehsen to Secretary Leavitt regarding the potential impact of the Deficit Reduction Act's requirement that state Medicaid agencies collect NDC numbers to facilitate the payment of rebates on physician administered outpatient drugs. In his letter Mr. Kuhn states that drugs dispensed under the 340B program "are not subject to Medicaid rebates as long as those drugs are purchased under the 340B program and they are billed to Medicaid **at the acquisition cost**." (emphasis added). Mr. Kuhn acknowledges in his letter that section 1927(j)(2) exempts drugs from rebates when they are billed at the hospital's purchasing cost as determined under the State plan. However, he then proceeds to rewrite the plain statutory language by claiming that "[t]he State plan describes the estimated acquisition cost. This does not represent the hospital purchasing cost." Mr. Kuhn ignored the fact that Congress chose to use a term, i.e. purchasing cost, that is not defined by statute or regulation. Instead, Congress left it up to the states, not CMS, to determine purchasing costs. In effect, CMS is usurping state authority.

50. Limiting a 340B hospital to billing at the hospital's actual acquisition cost imposes a financial burden on the hospital. Estimated acquisition costs or purchasing costs allow the hospital to bill for all of the costs associated with purchasing a drug, not just the acquisition cost of the drug. For example, estimated acquisition costs or purchasing costs include costs such as wholesaler fees, the labor costs attributable to placing orders and other in-house purchasing activities, maintenance costs such as the cost of refrigeration and storage, and the costs of transporting the drug from the warehousing facility to the hospital, all of which cost more than the actual acquisition cost of the drug purchased. By seeking

to require hospital to bill at their actual acquisition costs, CMS is usurping state authority to develop billing and payment standards that account for these additional costs.

51. State Medicaid agencies are proceeding to implement what they understand to be a federal mandate to collect NDC numbers, and ultimately rebates, on all single-source drugs and the 20 most frequently used multiple-source drugs administered by medical professionals to patients in hospital outpatient departments and clinics.

52. However, as a result of the conflicting interpretations offered by CMS, State Medicaid agencies are implementing the requirements to collect NDC numbers in an inconsistent manner. These inconsistencies further underscore the arbitrary and capricious nature of the action of CMS.

53. For example, the State of Nevada is requiring hospitals such as plaintiff UMC to collect NDC numbers in all circumstances and is denying any claim that does not include the NDC number, regardless of the amount billed to Medicaid. The State of Iowa on the other hand does not require the reporting of NDC numbers if the hospital only bills Medicaid its acquisition costs.

54. The result of this overbroad application of the "physician administered drug" rule has imposed enormous new burdens on all hospitals with outpatient clinics and will be devastating to many "safety net" hospitals that, like Plaintiff UMC, serve low income communities and a high percentage of indigent and uninsured patients. For example, UMC estimates that the requirement that it furnish NDC numbers and its inability to comply with this requirement will cost it $5.1 million in unreimbursed drugs costs for 2008.

55. Few hospitals have electronic billing systems with the capacity to associate

NDC numbers with patient accounts for purposes of Medicaid billings, and in the long-term application of the physician administered drug rule to the hospital outpatient clinic setting will require hospitals to overhaul their electronic billing systems, at substantial cost and significant strain on administrative resources. In the short term, compliance with new NDC reporting requirements will require vast expenditures of administrative and clinical staff time on the difficult and time-consuming task of determining correct NDC numbers for drugs administered in the hospital clinic setting and manually recording, compiling and reporting those numbers on Medicaid billing submissions, with an attendant diversion of these staff resources from patient care-related functions.

56. It is unclear, in fact, how this task can be accomplished with any degree of accuracy in hospital clinics, where patients are frequently administered a drug in a quantity that is only part of a vial, package, or other drug container with which a specific NDC number indicating a specific package size or volume is associated, and where many patients receive injections or infusions of drug "cocktails," compounds of many different drugs in quantities and forms that are not easily associated with a specific NDC.

57. The imposition of the requirement to collect NDC numbers on hospitals and clinics that are exempt from the rebate requirements is arbitrary and capricious. The sole purpose of collecting the NDC numbers under the DRA is to enable the State Medicaid agencies to obtain rebates. Since hospitals such as the plaintiffs are exempt from the rebate requirement, there is no rational basis to require them to collect NDC numbers.

58. CMS has also seriously miscalculated the administrative impact of the requirement to collect NDC numbers. In the preamble to the Rule, CMS estimates that it would take fifteen seconds for an entity to include the NDC on claims submitted to the

State. CMS estimated that the cost per claim of this administrative effort, based on average annual wage and benefits, would be less than nine cents. 72 Fed. Reg. 39,142, 39,228 (July 17, 2007).

59. This assessment by CMS seriously underestimates the administrative burden of the requirement to collect NDC numbers. A survey by the American Society of Hospital Pharmacists ("ASHP") of its members concluded that the estimated cost per claim to include the NDC number would be $10.80.

60. The negative impact of overbroad application of the physician administered drug rule will be financially disastrous for hospitals, like Plaintiff UMC and other members of SNHPA, that serve a high Medicaid population as well as a significant number of other indigent patients. These hospitals depend on the benefit they receive from participating in the 340B drug discount program to enable them to provide medical services to individuals who are uninsured and unable to pay the costs of their own health care. For such hospitals, the CMS physician administered drug rule – if broadly applied as CMS now intends – means not only the administrative and financial burden of reconfiguring and overhauling their computerized billing systems, but also the loss of much of the financial benefit that permits them to provide access to crucial pharmaceuticals for the most needy.

61. The circumstances of Plaintiff UMC are typical of many 340B hospitals, and the adverse impact CMS' overbroad application of its rule will have on Plaintiff is representative of the harm that will be imposed on many similarly situated 340B hospitals.

COUNT I

VIOLATION OF THE MEDICAID STATUTE

62. Plaintiff realleges and incorporates by reference paragraphs 1-61 of the Complaint as if fully set forth below.

63. Defendant's broad application of the regulation at 42 C.F.R. § 447.520 to hospital outpatient clinic settings violates the Medicaid statute by failing to give effect to the exemption of hospital outpatient drugs from rebates, established by Section 1927(j)(2) of the Act, 42 U.S.C. § 1396r-8(j)(2).

COUNT II

ARBITRARY AND CAPRICOUS AGENCY ACTION

64. Plaintiff realleges and incorporates by reference paragraphs 1-61 of the Complaint as if fully set forth below.

65. Defendant's interpretations of the statutory provision at Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA, and of the regulation at 42 C.F.R. § 447.520, and his application of those provisions generally to drugs administered in hospital outpatient clinics and departments, is arbitrary and capricious and an abuse of discretion, in violation of the standards for agency action established by the Administrative Procedure Act at 5 U.S.C. § 706.

WHEREFORE, Plaintiff requests the following relief:

(1) A declaration by the Court that drugs administered to Medicaid patients in hospital outpatient clinics and departments are exempt from Medicaid rebate requirements when the hospital dispenses those drugs using formulary systems and complies with applicable Title XIX State Plan limitations on Medicaid reimbursement that are consistent

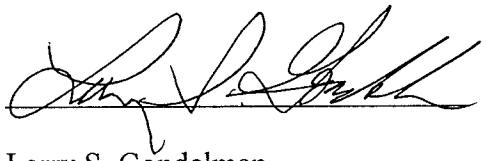
with federal regulations at 42 C.F.R. §§ 447.512, 447.514, and 447.518.

(2) A declaration that application of the NDC collection and reporting requirements at 42 C.F.R § 447.520 to hospital outpatient clinics and departments (except where a hospital does not use formulary systems or seeks reimbursement for covered outpatient drugs administered in those settings at a rate of payment in excess of the applicable cost limit established by the applicable Medicaid State Plan) is arbitrary and capricious, an abuse of discretion, and contrary to law;

(3) A permanent injunction prohibiting Defendants from requiring or encouraging State Medicaid agencies to collect NDC information from hospitals with respect to outpatient drugs administered to Medicaid patients in hospitals' outpatient clinics and departments, (except for hospitals that do not use formulary systems or that seek Medicaid reimbursement for covered outpatient drugs administered in those settings at a rate of payment in excess of the applicable cost limits established by the applicable Medicaid State Plan).

(4) An injunction requiring Defendants to publish or otherwise disseminate appropriate letters, instructions, guidelines, or other policy issuances to States and providers clarifying that hospital outpatient clinic drugs fall within the scope of 42 U.S.C. § 1396r-8(j)(2), and as such do not fall within the scope of Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA, unless such hospital does not utilize formulary systems, or seeks Medicaid reimbursement for such drugs in excess of estimated acquisition cost levels or other applicable cost limits determined under the applicable Medicaid State Plan.

(5) An order awarding Plaintiffs their costs and attorneys' fees for this action, and granting such other relief as the Court deems just and proper.



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Dated: August 21, 2008