IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

ASHLEY COUNTY MEDICAL CENTER, et al.,	)	
Plaintiffs	)	Civil Action No. 4-02-CV-00127 GTE
v.	)	
THE HONORABLE TOMMY G. THOMPSON, in his official capacity as Secretary of Health and Human Services,	)	
Defendant.	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

OF COUNSEL
Larry S. Gage, Esq.
Barbara D.A. Eyman, Esq.
POWELL, GOLDSTEIN, FRAZER & MURPHY, LLP
1001 Pennsylvania Avenue, N.W.
Sixth Floor
Washington, DC 20004
(202) 347-0066

WILLIAM C. CRENSHAW
POWELL, GOLDSTEIN, FRAZER & MURPHY, LLP
1001 Pennsylvania Avenue, N.W.
Sixth Floor
Washington, DC 20004
(202) 347-0066

DIANE MACKEY
FRIDAY, ELDREDGE & CLARK
2000 Regions Center
400 West Capitol Avenue
Little Rock, Arkansas 72201-3493
(501) 376-2011

Attorneys for Plaintiffs

TABLE OF CONTENTS

Plaintiffs, Ashley County Medical Center, et al., file the following Memorandum in Opposition to Defendant's Motion for Summary Judgment and in Support of Plaintiffs' Motion for Summary Judgment.

BACKGROUND

Plaintiffs, three individual hospitals, four national hospital associations and seven state hospital associations, filed this action, along with a Motion for Preliminary and Permanent Injunction, on March 7, 2002, seeking, among other things, to enjoin the scheduled March 19, 2002 effective date of a regulation promulgated by the U.S. Department of Health and Human Services ("HHS"), known as the "2002 UPL Rule." On March 12, 2002, Defendant, the Honorable Tommy Thompson, as Secretary of HHS ("Defendant" or the "Secretary"), agreed to defer the scheduled effective date of the 2002 UPL Rule to April 15, 2002.

The Court entered an Agreed Order Approving Joint Scheduling Report on March 26, 2002. Pursuant to the Scheduling Order, Defendant filed a Motion for Summary Judgment on March 27, 2002. This Memorandum is filed in Opposition to Defendant's Motion for Summary Judgment and in Support of Plaintiffs' Motion for Summary Judgment.[1] The Court has set a hearing on all pending matters and motions for April 10, 2002.

This case represents an issue of critical importance for "safety net" hospitals. A mere eight months after implementing a regulation in March 2001 (the "2001 UPL Rule") providing for a 150 percent upper payment limit ("UPL") that gave some degree of Medicaid

[1] Contemporaneously herewith, Plaintiffs have filed: (1) a Motion requesting the Court to treat their Motion for Permanent Injunctive Relief as a Motion for Summary Judgment; and (2) a Reply in Support of their Motion for Preliminary Injunctive Relief.

reimbursement protection to non-state public hospitals, HHS has sought to vitiate that protection. To make matters worse, HHS, in violation of the Administrative Procedure Act ("APA") has done so without any rational basis to support its policy change, and without considering the dire consequences such a radical shift would have on safety net hospitals and those they serve.

Defendant now attempts to justify this change of position by claiming the 2002 UPL Rule is intended to stop what Defendant mischaracterizes as abusive "kickbacks" in the guise of intergovernmental transfers. In reality, however, there is no factual support for this conclusion. The intergovernmental transfers criticized by Defendant are an integral part of the Medicaid program, designed to allow States to use local funds to assist in legitimately meeting the health care needs of the state's citizens. Intergovernmental transfers have existed as long as the entire nearly 40-year life of the Medicaid program. A regulation explicitly authorizing intergovernmental transfers has been essentially unchanged for over 16 years. Moreover, federal law expressly forbids HHS from restricting the very intergovernmental transfers about which HHS complains. Furthermore, this after-the-fact-attempted rationalization is inconsistent with the administrative record and can not stand.

HHS also issued the 2002 UPL Rule without complying with either the Regulatory Flexibility Act ("RFA") or the Congressional Review Act ("CRA"). While Defendant voluntarily deferred the original announced effective date due to HHS's failure to comply with the CRA, when Plaintiffs noted a further violation of the CRA, Defendant now claims that he has no obligation to comply with the law. Plaintiffs respectfully submit that Defendant, notwithstanding his protestations to the contrary, is not above the law.

Accordingly, the Court should deny Defendant's Motion for Summary Judgment and enter summary judgment in favor of Plaintiffs.

STATEMENT OF FACTS

In general, Plaintiffs rely on the Statement of Facts contained in their original Brief in Support of Plaintiffs' Motion for Preliminary and Permanent Injunction ("Plaintiffs' Brief"). Although not contradicting explicitly any of the facts laid out in Plaintiffs' original Statement of Facts, Defendant's 21-page Statement of the Case in his Memorandum in Support of his Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for a Permanent Injunction ("Defendant's Memorandum") distorts certain facts, so that it is incumbent on Plaintiffs to respond.

2001 UPL Rule

The description of the 2001 UPL Rule in Defendant's Memorandum stresses only the goal of promoting economy and efficiency, to the exclusion of any reference to the goal of *ensuring the survival of safety-net hospitals and continued access to care for Medicaid beneficiaries*. A clear example is Defendant's discussion of the October 10, 2000 proposed rule (that led to the 2001 UPL Rule). Defendant begins with the following quote:

> We are proposing a higher upper payment limit for services in non-State-owned or operated public hospitals operated by governmental entities other than the State itself because we believe that allowing higher Medicaid payments will fully reflect the value of public hospitals' services to Medicaid and the population it serves. Public hospitals are established to ensure access to needed care in underserved areas, and often provide a range of care not readily available in the community, including expensive specialized services, such as trauma and burn care and outpatient tuberculosis services. They also provide a significant proportion of the uncompensated care in the nation.

("Defendant's Memorandum" at 15-16) (quoting 65 Fed. Reg. 60151, 60153 (Oct. 10, 2000)). Defendant continues, "In the next breath, however, the Secretary emphasized that there was a significant downside to the policy of giving non-state public hospitals a higher UPL." (Defendant's Memorandum at 16.)

The quote that follows – the alleged "next breath" – actually skips right over the following crucial statement in the proposed 2001 UPL Rule on the goal of ensuring continued access to Medicaid beneficiaries and the ability of safety-net hospitals to fulfill their unique roles in their communities:

> The size and scale of public hospitals create extreme stresses and uncertainties, especially given their dependence on public funding sources. *We are concerned that these stresses may threaten the ability of these public hospitals to fulfill their mission and fully serve the Medicaid population.* As such we are proposing a higher UPL for these facilities.

65 Fed. Reg. at 60153 (Oct. 10, 2000) (emphasis added).

This incomplete characterization of the goals of the 2001 UPL Rule continues in Defendant's three-page discussion of the Final Rule, which again exclusively addresses the goal of monitoring and reducing improper enhanced payments. (Defendant's Memorandum at 16-19.) Left out of the Defendant's Memorandum is any reference to or recognition of the goal expressed in these unequivocal statements in the 2001 UPL Rule:

- We … were doing this [the 150 percent limit for non-state public hospitals] so that the new limits being applied to these providers *assured that they would remain in operation and continue to provide services to the Medicaid population*. 66 Fed. Reg. 3148, 3154 (Jan. 12, 2001) (emphasis added).

- Although we realize there is an ancillary benefit that may cover the costs of providing uncompensated care in these facilities, that was not the reason for our decision to set a higher UPL for these providers. We were more concerned with *assuring the continued existence and stability of these core providers* who serve the Medicaid population. Id. (emphasis added).

- Our discussions with a wide range of groups led us to believe that the only group of providers that both retained this money and would *suffer harm that would hinder their ability to serve the Medicaid population* were non-State government-operated hospitals. 66 Fed. Reg. at 3155 (emphasis added).

- Non-State government-operated hospitals serve a unique role that we do not believe would continue to be adequately funded if it were not reflected in Medicaid rates. Id.

- In light of financial pressures facing government-operated hospitals, we believe a higher limit is appropriate to ensure Medicaid eligible individuals will continue to have adequate access to the health care services they provide. 66 Fed. Reg. at 3160.

While the 2001 UPL Rule was clearly intended to curb abuses (such as in those supplemental payment programs described in the Final OIG Report), the protection of safety net hospitals and those they serve was also a critical component that can not be ignored.

Defendant's New Regulatory Rationale: "Abusive" Intergovernmental Transfers

Defendant mischaracterizes intergovernmental transfers as inherently "abusive" and "kickbacks." (See, e.g, Defendant's Memorandum at 15, 18, 21, 30, 33-35, and 41.) Intergovernmental transfers are not "kickbacks" nor are they "abusive." As its name implies, an intergovernmental transfer is simply a transfer of monies from one level of government to another. In the case of the Medicaid program, this typically means an intergovernmental transfer from a local government or a provider owned or operated by a local government to the State Medicaid agency.

Intergovernmental transfers are an essential method by which governmental entities contribute real money from their budgets to the non-federal share of Medicaid payments. Our federal system contains a complex patchwork of legal jurisdictions, including States, counties, and other local governmental structures, and intergovernmental transfers recognize this

patchwork of responsibility. For example, in many States essential health care responsibilities, such as the provision of health care services to those in need, are not a direct state responsibility, but rather a responsibility of the county or city (sometimes pursuant to the state constitution or state statute). A county or city thus has a significant interest in assuring that the Medicaid program covers the health care needs of its citizens. It is thus not at all surprising that local governments and governmental entities contribute to the non-federal share of Medicaid expenditures. Because of limited state budgets, these contributions are often essential to the existence of the state's Medicaid program.

Since the beginning of the Medicaid program, entities other than the State have been explicitly permitted to provide the "non-Federal share" of Medicaid expenditures. The original Section 1902(a)(2) of the Social Security Act created by Congress in 1965 reads as follows:

> [A State plan must] provide for financial participation by the *State* equal to not less than 40 per centum of the *non-Federal* share of the expenditures under the plan with respect to which payments under section 1903 are authorized by this title….

Pub. L. No. 89-97, § 121(a), 79 Stat. 371 (1965) (codified at 42 U.S.C § 1396a(a)(2))(emphasis added). This statutory language has never been changed. See 42 U.S.C.A. § 1396a(a)(2) (West Supp. 2001). Thus, the Medicaid statute always has allowed that at least 60 percent of the non-Federal share of Medicaid expenditures not be provided by the State.[2]

Medicaid law has never required that States use general revenue funds to provide the non-Federal share of Medicaid expenditures. Since 1985, there has been explicit regulatory authority permitting public funds to be "transferred from other public agencies … to the State or

local agency" for use in financing the non-federal share. 42 C.F.R. § 433.45 (emphasis added), as promulgated in 50 Fed. Reg. 46652, 46664 (Nov. 12, 1985) (now at 42 C.F.R. § 433.51).

Considering the fact that Federal law and regulations have explicitly permitted intergovernmental transfers, it is not surprising that many States utilize this mechanism in order to provide the non-Federal share of Medicaid expenditures, including supplemental payments to hospitals.[3] It is similarly unsurprising, despite Defendant's contrary statements, that States would actually submit state plan amendments pursuant to a new regulation changing the upper payment limits and permitting enhanced payments to non-state public hospitals.

Defendant attempts to confuse the Court by repeatedly referring to legal intergovernmental transfers as "kickbacks." (See, e.g., Defendant's Memorandum at 15 ("kickbacks/transfers"), 18 ("abusive intergovernmental kickbacks"), 34 ("kick money back"), 35 ("Kicking back enhancements"), and 41 ("kicking back")). In the most egregious example of this attempt, Defendant includes a string cite purportedly documenting "abusive intergovernmental transfers" in state plan amendments submitted under the 2001 UPL Rule. (Defendant's Memorandum at 19, 29, and 34.) The cited references, however, primarily document States' routine use of intergovernmental transfers to finance the non-Federal share of

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[2] Despite the frequent references in Defendant's Memorandum to the "State share," such a term appears nowhere in the Medicaid statute, which refers only to the "non-Federal share" of Medicaid expenditures.

[3] In fact, HHS stated in the preamble to the 2001 UPL Rule that one of the salient and essential characteristics of a non-state government owned or operated hospitals was the ability of such a hospital to make an intergovernmental transfer. 66 Fed. Reg. 3148, 3153 ("Specifically, for the purposes of this regulation, non-State government owned or operated facilities are government facilities, as defined by their ability to make direct or indirect intergovernmental transfer payments to the State ….").

supplemental hospital payments.[4] Kickbacks are illegal remunerations that are forbidden in Federal health care programs, including Medicaid. 42 U.S.C. § 1320a-7b(b). Intergovernmental transfers, by contrast, are legitimate and statutorily-authorized sources of financing the non-federal share of Medicaid expenditures. They are *not* kickbacks and Defendant's use of such sensational terminology should not sway the Court's judgment in this case.

Similarly, Defendant recharacterizes the 2002 UPL Rule as "the latest round in a recurring struggle by the federal government to protect the integrity of the Medicaid program by limiting the ability of States to use creative financing loopholes to artificially inflate the States' own apparent financial contributions to the program, and correspondingly, the actual federal payment." (Defendant's Memorandum at 6.) This rationale represents a significant change in emphasis from the characterization of the 2002 UPL Rule contained in the rule itself. On the first page of the final 2002 UPL Rule, HHS states that its rationale was based on the following: (1) the 100 percent limit is more than sufficient to ensure that the poor have adequate access to medical services, (2) the higher payments (under the higher limit) are not necessarily being used to further the mission of public hospitals or their role in serving Medicaid patients, (3) many of

[4] Of the 28 specific pages contained in the pin-point citations to the record made by Defendant (covering state plans submitted by 13 States), some pages contain no decipherable reference to intergovernmental transfers at all. (U.S. Department of Health and Human Service, Rulemaking Record for Final Rule Issued on January 18, 2002: Medicaid Program; modification of the Medicaid Upper Payment for non-state government-owned and operated hospitals (2002) (2002 "Administrative Record: or "A.R.") at 1095, 1316, 1355.) Some pages merely reference the use of intergovernmental transfers as a method for determining which hospitals are government-owned or operated, in accordance with the 2001 UPL Rule. 2002 A.R. at 743-44, 1317, 1357. Thirteen page references merely mention the existence of intergovernmental transfers or document a transfer to provide the non-Federal share needed. 2002 A.R. at 651, 816, 818, 827, 834, 1125, 1128, 1234, 1306-07, 1315, 1354, and 1361. Moreover, information on

the impacted hospitals qualify for disproportionate share hospital (DSH) payments, and (4) the desire to restore "payment equity" among hospital providers. 67 Fed. Reg. 2602, 2603 (Jan. 18, 2002). In contrast, when Defendant describes the "three basic reasons" for changing the rule in his brief, Defendant cites to the *last* page of the preamble before the regulatory impact analysis to assert that Defendant's primary reason was that "the existing rule provided too easy a 'means for States to effectively claim a higher Federal share than warranted' through intergovernmental transfers." (Defendant's Memorandum at 24.)

Despite the clear legality of intergovernmental transfers, Plaintiffs do not dispute that HHS does not like them now and has not liked them historically. This does not change the fact that intergovernmental transfers are legal.

In 1990 and 1991, during the first Bush Administration, HHS attempted to issue regulations that would have significantly limited the ability of States to use intergovernmental transfers. See 55 Fed. Reg. 4626 (Feb. 9, 1990) (proposed rule); 56 Fed. Reg. 46380 (Sept. 12, 1991) (interim final rule); 56 Fed. Reg 56132 (Oct. 31, 1991) (interim final rule). The result was a clear statutory statement by Congress in the Medicaid Voluntary Contributions and Provider-Specific Tax Amendments of 1991 that

> the Secretary *may not restrict States' use of funds where such funds are derived from State or local taxes* (or funds appropriated to State university teaching hospitals) *transferred from or certified by units of government* within a State as the *non-Federal share* of expenditures under this title, regardless of whether the unit of government is also a health care provider….

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intergovernmental transfers is most often provided in direct response to HHS questions, contrary to HHS's assertion that States "voluntarily tipped their hand." (Defendant's Memorandum at 34).

Pub. L. No. 102-234, § 2(a), 105 Stat. 1798 (1991) (codified at 42 U.S.C § 1396b(w)(6)(A)) (emphasis added). This language was a clear rebuke to HHS for its attempts to regulate intergovernmental transfers. Congress required the Secretary to withdraw the October 31, 1991 interim final rule and expressly prohibited him from attempting to regulate intergovernmental transfers in the future. Pub. L. No. 102-234, § 2(c)(3), 105 Stat. 1799; see also H.R. Conf. Rep. No. 102-409, at 15-18 (1991), *reprinted in* 1991 U.S.C.C.A.N. 1441, 1441-44.

Underscoring the text of the statutory directive, the legislative history makes clear that if the Secretary believes that states are abusing intergovernmental transfers, his recourse is to Congress alone, not through administrative action. An accompanying committee report noted the Secretary's concern about abusive intergovernmental transfers as justification for his regulations and responded as follows:

> The [House Energy and Commerce] Committee wishes to remind HCFA [(now the Centers for Medicare and Medicaid Services (CMS))] of the lack of statutory authority for such actions. Also, the moratorium in the Committee bill is permanent and applies to all public funds used as a source of the State share of Medicaid expenditures, including those from public entities or units of government that are also health care providers that participate in Medicaid. *If the Secretary believes that any change in current statutory policy is warranted, he should present his legislative recommendations to this Committee and to the Congress. Under current law, he is without authority to make any changes in current policy or practice through regulation or administrative procedures.* The committee bill makes this explicit.

H.R. Rep. No. 102-310, at 15-16 (1991) (emphasis added), *reprinted in* 1991 U.S.C.C.A.N. 1413, 1426-27. To the extent that the Secretary now claims that the purpose of the 2002 UPL

Rule was to regulate intergovernmental transfers, the Secretary must propose these changes to Congress, not through the regulatory process.[5]

Disproportionate Share Hospital (DSH) Payments

Defendant spends three pages of his Statement of the Case discussing alleged abuse in the Medicaid DSH program. This discussion is irrelevant to the issues before the Court. The 2002 UPL Rule has nothing to do with alleged past abuse of Medicaid DSH payments. To the extent that the DSH history is included to demonstrate States' abuse of intergovernmental transfers, Defendant must direct those arguments to Congress. Moreover, the history of the DSH program was nowhere cited as a factor in the promulgation of the 2002 UPL Rule. To the contrary, the primary reference made to DSH in the Rule is that it should be a "mitigating factor" with regard to the impact of the 2002 UPL Rule on public hospitals. 67 Fed. Reg. at 2602, 2609; see also 57 Fed. Reg. at 2603 ("Many of the public safety net hospitals affected by this rule qualify as DSH hospitals."). Defendant does not dispute Plaintiffs' statements that there are significant limitations in the extent to which Medicaid DSH can mitigate the 2002 UPL Rule's impact. (See Plaintiffs' Brief at 33-34.)

OIG Reports

Defendant continues to rely on reports issued by the HHS Office of the Inspector General (OIG), to justify the 2002 UPL Rule. To his credit, Defendant acknowledges that the audits

[5] This same point was made in comments on the proposed 2002 UPL Rule. See, e.g., Letter of Denise K. Martin of California Association of Public Hospitals and Health Systems to Thomas A. Scully of Dec. 20, 2001 at 6, 2002 A.R. 475, 480; Letter of David E. Janssen and Fred Leaf of

summarized in the September 2001 final report, Office of the Inspector General, Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers, Report No. A-03-00-00216 (Sept. 11, 2001) (the "OIG Final Report"), 2002 A.R. at 19, consisted of "audits that had been conducted prior to March 2001 when the 150-percent rule took effect." (Defendant's Memorandum at 20.) However, Defendant now claims that a second part of the OIG Final Report "analyzed whether the trends identified … were likely to be significantly changed by the 150-percent rule." Id.

The OIG Final Report did not in any sense "analyze[] whether the trends identified … were likely to be significantly changed by the 150-percent rule," nor was this the report's stated objective. The report's text states that the objectives of the OIG review "were to analyze the States' use of IGTs [intergovernmental transfers] to finance enhanced payments to county or local government-owned nursing facilities and hospitals as part of their compliance with Medicaid upper payment limit regulations and to evaluate the financial impact of these transfers on the Medicaid program." (OIG Final Report at i.) It is true that after specifically commending CMS "for taking action to revise the Medicaid upper payment limit regulations" in the 2001 UPL Rule (what Defendant calls the "150-percent rule"), the OIG recommended six specific items to CMS, reflecting OIG's belief that CMS's regulatory changes do not go far enough, including reconsideration of the 150 percent limit for non-State public hospitals.[6] (OIG Final Report at iii-

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County of Los Angeles, Chief Administrative Office to Thomas A. Scully of Dec. 19, 2001 at 4, 2002 A.R. 467, 470.

[6]The other five recommendations were (1) annual audits of the accuracy of State upper payment limit calculations and enhanced payments, (2) definitive guidance of calculating the upper payment limit and facility-specific upper payment limits based on cost report data, (3) requiring that States demonstrate that enhanced payments are made to facilities and used to furnish

iv.) The OIG did not recommend that the 2001 UPL Rule "be repealed," (Defendant's Memorandum at 20), nor was there an examination of whether "trends identified" were likely to be changed by the 150 percent limit.

In its Final Report, the OIG identified "22 other States, as of October 2000, making annual Medicaid enhanced payments." (OIG Final Report at 3.)[7] A chart in the Final Report sets forth annual enhanced payments and annual federal financial participation. The value of this chart claimed by OIG is in showing "the rapid proliferation of these programs" and the large dollar values associated with them prior to the 2001 UPL Rule. Defendant may think that this chart has predictive value relative to the impact of the 2001 UPL Rule. However, the 2001 UPL Rule was intended to restrict many of these programs, particularly in the context of abusive nursing home programs, while protecting programs to assist non-state public hospitals. The chart thus has little if any predictive value at all.

An examination of the Administrative Records for the 2001 UPL Rule and 2002 UPL Rule indicates that in addition to the OIG Final Report summarizing past audits, only one report by the OIG ***not*** included in the 2001 Administrative Record (at least in draft form) was included in the 2002 Administrative Record. This report, regarding enhanced payments to hospitals in North Carolina, found that "the supplemental payments were used to fund Medicaid deficits for inpatient and outpatient hospital costs." (Office of the Inspector General, Review of Medicaid

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Medicaid services to Medicaid beneficiaries, (4) require that the return of a Medicaid payment be declared a refund and an offset to FFP generated, and (5) seek to eliminate or reduce transition periods.

[7] Significantly, the OIG reviewed supplemental payment programs for hospitals in less than half of those 22 States; in 13 States, the OIG only assessed enhanced payments to nursing homes. OIG Final Report at Appendix B, p. 2, 2002 A.R. at 45.

Enhanced Payments to Hospitals and the Use of Intergovernmental Transfers in North Carolina, Report No. A-03-00-00140 (June 22, 2001), at 2, 2002 A.R. at 53, 55; see also id. at 5, 2002 A.R. at 58 ("Except for bank fees, the hospitals retained the supplemental payments and used the funds to pay for facility expenses.")). Thus, the only new data that CMS had from OIG in considering the 2002 UPL Rule involved an appropriate use of enhanced payments to benefit hospitals.[8]

In addition to the fact that OIG's audits all predate the implementation of the 2001 UPL Rule, the audits can not rationally be extrapolated to all States. The OIG audits examined only seven programs in six States, of which only three involved hospitals. Further, as Defendant admits, OIG's role is to "investigate and report on potential abuses." (Defendant's Memorandum at 35-36 n.8.) Given that the OIG presumably selected States based on an expectation of finding abuses, it is not rational to use the OIG's equivocal findings of abuse in three hospital programs predating the 2001 UPL Rule as a justification for elimination of the higher limit contained in the 2001 UPL Rule.

LEGAL ARGUMENT

Plaintiffs will address the following legal issues:

- The validity of the 2002 UPL Rule is ripe for determination and Plaintiffs have standing to challenge the rule's effectiveness
- Plaintiffs have stated the proper standard for administrative review and the 2002 UPL Rule fails because:

[8]The data supplied by the North Carolina audit confirms the conclusion of the OIG in its Final Report that "The hospital providers kept a large portion of the enhanced payments in contrast to the nursing home providers." (OIG Final Report at 4, 2002 A.R. at 4; see also Transmittal Letter from Michael Mangano to Thomas Scully of 9/11/01, at 2, 2002 A.R. at 16.)

- Defendant has not stated a rational basis for vacating the 2001 UPL Rule
- Defendant's post hoc rationalization for the 2002 UPL Rule -- preventing abusive intergovernmental transfers -- is legally insufficient
- Defendant failed to examine relevant data, relied on irrelevant data, failed to articulate a rational connection between the facts found and the choice made, and failed to consider an important aspect of the problem – harm to safety net hospitals
- The 2002 UPL Rule lacks a sufficient statement of basis and purpose
- Defendant ignored Congressional intent

- The 2002 UPL Rule fails to comply with the Regulatory Flexibility Act

- The Congressional Review Act prohibits the 2002 UPL Rule from being effective any earlier than May 14, 2002

I. The Validity of the 2002 UPL Rule is Ripe for Determination and Plaintiffs Have Standing to Challenge the Rule's Effectiveness.

Defendant argues that Plaintiffs do not have standing because they can not trace injury to the 2002 UPL Rule and that the case is not ripe because Plaintiffs' injuries are dependent on contingent future events. (Defendant's Memorandum at 25, citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) and Texas v. United States, 523 U.S. 296, 310 (1998)).

Defendant misconstrues both the law and the facts with respect to the issues of standing and ripeness in this case. Contrary to Defendant's position, Plaintiffs are the objects of the government action at issue in this case, and no contingent actions by third parties are required before the injuries will befall Plaintiffs as the result of the promulgation of the 2002 UPL Rule. The untenable nature of Defendant's position becomes apparent when taken to its logical conclusion, namely that no plaintiff, other than a state, could ever bring a challenge to a federal Medicaid regulation. In fact, the only court to be confronted with this argument has soundly rejected it. Nat'l Ass'n of Chain Drug Stores, Inc. ("NACDS") v. Bowen, 1989 WL 43948 (D.D.C. 1989).

In NACDS, HHS made a similar argument – that the plaintiff did not have standing, because "States, not defendants, determine the amount of reimbursement to providers of prescription drugs." Id. The court rejected HHS's reasoning, explaining that:

> While the challenged rule may not require States to change their reimbursement methodologies, the rule does establish upper limits for reimbursement, and these upper limits affect the compensation that providers receive. Further, the rule may affect a provider's decision whether to participate in Medicaid, and, thus, the accessibility of Medicaid services. This implicates important statutory objectives. Finally, if, as plaintiff alleges, HCFA failed to explain its decision to promulgate the proposed rule, this action by the agency affected important interests of NACDS and its members in participating in a program regulated by fair and reasonable regulations. For these reasons, the Court finds that plaintiff has standing in this case …

Id. at *4.

Moreover, none of the so-called contingencies presented by Defendant are in fact such. Could the States step in once this rule goes into effect to attempt to ameliorate the devastating financial consequences of this regulation on the survival of public hospitals? Certainly, but these ameliorating steps would be exactly that, steps to ameliorate the injury after-the-fact, that have no effect on standing or ripeness.

Defendant also mischaracterizes the facts surrounding Plaintiffs' claims. Contrary to Defendant's assertions, many of the State plan amendments included in the record refer to payments to public hospitals up to the federally determined upper payment limit. See 2002 A.R. at 566, 578, 587, 971, 1105, 1140, 1237, 1239, 1302. When the federally determined upper payment limit is decreased, as it is by the regulation at issue in this case, the payments to public hospitals will *automatically* decrease.[9] Thus, the action taken by HHS in promulgating the 2002

[9] In other States, payments to hospitals are based on a calculated percentage of a pool calculated based on the difference between the upper payment limit and existing Medicaid payments. See,

UPL Rule has a direct impact on Plaintiffs, without any intervening acts or the actions of third parties required, and Plaintiffs easily satisfy the injury-in-fact and immediacy showings necessary under the standing and ripeness doctrines.

Even outside the Medicaid context, Defendant's argument is untenable, as applied to the facts surrounding the promulgation of the 2002 UPL Rule, and its impact on Plaintiffs. The regulation implementing the new payment limit, not any intervening event, will result in Plaintiffs' injuries. The case defendant cites, Texas v. United States, is inapposite to the claims brought by the plaintiffs, because contrary to Defendant's assertions, Plaintiffs' claims are not contingent on future events.

This distinction was recognized by the court in U.S. House of Representatives v. U.S. Dep't of Commerce, 11 F. Supp. 2d 76 (D.D.C.), *appeal dismissed by* 525 U.S. 978 (1998):

> [i]n that case [Texas v. United States], if specific steps did not transpire, there would never be an injury…. By sharp contrast, in the instant case, the injury is not dependent upon future events X, Y, and Z taking place…[q]uite the opposite: '*contingent future events that may not occur as* anticipated, or indeed may not occur at all' *are necessary for statistical sampling not to be utilized* in the 2000 census for purposes of congressional apportionment."

Id. at 92 (*quoting* Texas v. United States, 523 U.S. at 299) (emphasis added). This same distinction applies to the promulgation of the 2002 UPL Rule. The injury to plaintiffs is not

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e.g., 2002 A.R. at 821, 832, 1295, 1315, 1319, 1326. For these States, payments to hospitals would also be immediately and automatically impacted, since the size of the pool would shrink as a result of the implementation of the 2002 UPL Rule.

contingent on future events. Rather, contingent future events would be necessary for the injury *not* to occur.[10]

II. Plaintiffs Have Stated the Proper Standard for Administrative Review, and the 2002 UPL Rule Fails to Comply With That Standard.

Defendant attempts to argue that Plaintiffs have mis-cited the applicable standard of review.[11] In fact, the very first paragraph of Plaintiffs' argument section, beginning on page 23 of Plaintiffs' Brief, sets forth the proper legal standard for an APA challenge to an informal rule, that is, 5 U.S.C. § 706(2)(A), and the test established by the Supreme Court in Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983). These are the exact same standards that Defendant relies on in his brief. (Defendant's Memorandum at 31 - 33.)

Under 5 U.S.C. § 706(2) of the APA, a reviewing court must "hold unlawful and set aside agency action … found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law …." As the Supreme Court explained in Motor Vehicle Manufacturers:

> The scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must [*a*] examine the relevant data and [*b*] articulate a satisfactory explanation for its action including [*c*] a "rational connection between the facts found and the choice made" …. Normally, an agency rule would be arbitrary and capricious if the agency has [*d*] relied on factors which Congress has not intended it to consider, [*e*] entirely failed to consider an important aspect of the problem, [*f*]

[10] It is also worth highlighting that the likelihood that the events Defendant points to will occur is minimal at best. Holding one or more hospitals harmless from the cuts would require States to inflict even deeper cuts on other providers, making their injury even more profound. Moreover, it is completely unrealistic to assert that States, in this time of extreme fiscal pressure on their budgets, would be able to assume the financial responsibility being renounced by the federal government through this rule.

[11] Defendant wrongly states that Plaintiffs rely on 5 U.S.C. § 706(E), (Defendant's Memorandum at 32); Plaintiffs never cite that APA provision, and do not rely on it.

> offered an explanation for its decision that runs counter to the evidence before the agency; or [*g*] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

463 U.S. at 42 (internal citations omitted; bracketed letters identifying the separate factors that must be evaluated by a reviewing court added).

Plaintiff's entire brief follows the legal tests identified above.[12]

In his brief, Defendant spells out the legal test set forth in Motor Vehicle Manufacturers, (Defendant's Memorandum at 33), but fails to follow it, even though he concedes that it controls this case. Instead, Defendant relies on a short-hand test that merely requires that he have a "rational basis" for his rulemaking. Significantly, Defendant never cites to *any* caselaw whatsoever to support the "rational basis" test as he applies it to the facts of the 2002 UPL rulemaking, (see Defendant's Memorandum at 33-43), while completely ignoring the Motor Vehicle Manufacturers test, and Plaintiffs' arguments under that test.[13]

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[12] The headers in Plaintiffs' Brief clearly reflect these multiple factors of the legal test set forth in Motor Vehicle Manufacturers: "HHS Relied on Inaccurate and Irrelevant Data," (Plaintiffs' Brief at 24); "HHS Ignored Relevant Evidence That Was Counter to Its Predetermined Policy Choice," (Plaintiffs' Brief at 26); "HHS Failed to Consider the Substantial Evidence of Likely Harm to Safety Net Hospitals and their Patients Caused by the Regulation" (Plaintiffs' Brief at 28); "HHS Failed to Articulate a Rational Connection Between the Policy Decision Contained in the January 2002 UPL Rule and Claimed Mitigating Factors," (Plaintiffs' Brief at 32.) In essence, Defendant took out of context Plaintiffs' argument concerning Defendant's failure to consider substantial evidence of likely harm to public hospitals in order to argue Plaintiffs relied on an incorrect legal standard.

[13] In several places in his brief, Defendant fails to recognize the rulemaking process requirements of the APA, and the multiple factors a reviewing court must evaluate. (See, e.g., Defendant's Memorandum at 38.) ("The need to limit the opportunity for abusive intergovernmental transfers was sufficient, standing alone, to provide a rational basis for Defendant's decision to lower the upper payment limit …."); (Defendant's Memorandum at 43) ("The equity rationale, standing alone, is sufficient to sustain the 100-percent rule against a claim that it is arbitrary and capricious, in violation of the APA.")).

Without analyzing the holding of the case, or citing any cases to the contrary, Defendant also questions the validity of Crowley's Yacht Yard v. Pena, 863 F. Supp. 18 (D.D.C. 1994). In fact, Crowley's is good law in the D.C. Circuit, and has been for eight years, even as dozens of challenges to agency regulations afforded that court with opportunities to call the holding into question. In any event, Motor Vehicle Manufacturers and other APA case law amply support Plaintiffs' arguments.

Applying the proper standard of review leads inevitably to the conclusion that the 2002 UPL Rule fails for at least five independent reasons:

(a) Defendant has not stated a rational basis for vacating the 2001 UPL Rule;
(b) Defendant's post hoc rationalization for the 2002 UPL -- preventing abusive intergovernmental transfers -- is legally insufficient;
(c) Defendant failed to examine relevant data, relied on irrelevant data, failed to articulate a rational connection between the facts found and the choice made, and failed to consider an important aspect of the problem – harm to safety net hospitals;
(d) The 2002 UPL Rule lacks a sufficient statement of basis and purpose; and
(e) Defendant ignored Congressional intent.

A. Defendant Has Not Stated a Rational Basis for Vacating the 2001 UPL Rule.

Defendant appears to assume throughout his brief that because the 2001 UPL Rule had been adopted by a predecessor administration just one year earlier, he is free to reject the policy out of hand. "Surely, it was not unreasonable for the current Secretary to take a second look at the question and respectfully reach a different conclusion than his predecessor about the wisdom of enhanced payments for only one category of safety-net hospitals." (Defendant's Memorandum at 39.) The underlying assumption is that the agency has virtually unlimited discretion to replace an existing regulation without following the strictures of the APA, including the requirement that the agency provide a coherent justification for the change.

Followed to its logical conclusion, this assertion would render the procedural requirements of the APA a nullity. Moreover, this statement is made without citation of authority and is not supported in the law. Indeed, when changing a regulation, the agency has the burden of demonstrating by reasoned analysis that the change is justified. "The rescission or modification of rules is subject to [the arbitrary and capricious] standard, and 'an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when the agency does not act in the first instance.'" Sierra Club v. Clark, 755 F.2d 608, 619 (8th Cir. 1985) (quoting Motor Vehicle Manufacturers Association of the U.S. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 42 (1983) (citation omitted)).

This principle has been recognized repeatedly by courts in a variety of contexts, and is not open to serious question. "It is axiomatic that an agency choosing to alter its regulatory course 'must supply a reasoned analysis indicating that its prior policies and standards are being deliberately changed, not casually ignored.'" Action for Children's Television v. F.C.C., 821 F.2d 741, 745 (D.C. Cir. 1987) (citation omitted). Further, the lawfulness of the regulation must be judged on the justifications offered by the agency in the record. If the agency has not supplied a reasoned basis for its action, courts may not supply one. Motor Vehicle Manufacturers Association of the U.S. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983); Action for Children's Television, 821 F.2d at 745 ("Under basic principles of separation of powers, buttressed in no small measure by common sense, we are not to do the agency's work for it."). As Plaintiffs' Brief demonstrates, Defendant has not met this burden. A change in administrations is not license to ignore the APA.

B. Defendant's Post Hoc Rationalization for the 2002 UPL Rule -- Preventing Abusive Intergovernmental Transfers -- is Legally Insufficient.

Defendant's new apparent primary rationale for the 2002 UPL Rule is the "Secretary's concern about the potential for intergovernmental transfers under the new 150-percent rule." (Defendant's Memorandum at 33.) This rationale can not support the elimination of the 150 percent limit contained in the 2002 UPL Rule for three reasons. First, to the extent this new rationale differs from the rationales expressed in the statement of basis and purpose in the 2002 UPL Rule itself, it is a post hoc rationalization that should not be accorded any weight. Second, even if this rationale were not a post hoc rationalization, Defendant is expressly forbidden by statute from restricting intergovernmental transfers. Third, Defendant points to no evidence in the record to support his allegation that intergovernmental transfers in regard to the higher upper payment limit were in fact abusive or that the lower limit would prevent such abuses.

1. Defendant's New Regulatory Rationale of Preventing Abusive Intergovernmental Transfers is a Post Hoc Rationalization.

Defendant in his brief characterizes the rulemaking regarding the 2002 UPL Rule as an effort "to protect the integrity of the Medicaid program by limiting the ability of States to use creative financing loopholes …," (Defendant's Memorandum at 6), and which reflects "the Secretary's concern about the potential for abusive intergovernmental transfers." (Defendant's Memorandum at 33.) This characterization is significantly different from that which was contained in the statement of basis and purpose of the 2002 UPL Rule.

In the rule itself, HHS stated that the changes contained therein were based on the following: (1) the 100 percent limit is more than sufficient to ensure adequate access, (2) the higher payments (under the higher limit) are not necessarily being used to further the mission of

public hospitals or their role in serving Medicaid payments, (3) many of the impacted hospitals qualify for disproportionate share hospital (DSH) payments, and (4) restoring "payment equity" among hospital providers. 67 Fed. Reg. at 2603. The closest that HHS comes to discussing alleged "abusive intergovernmental transfers" is in its statement that higher payments (under the higher limit) are not necessarily being used to further the mission of public hospitals or their role in serving Medicaid payments. HHS states here that the "OIG has issued several reports demonstrating that a portion of the enhanced payments made as part of the UPL process are being transferred directly back to the State via intergovernmental transfers and used for other purposes." Id. The rule indicates that the reason for lowering the upper payment limit for non-state public hospitals is not the "abusive intergovernmental transfers" *per se*, but the fact that the higher upper limit is not serving its intended purposes. HHS can not now decide that the true purpose of the regulation was to eliminate abusive intergovernmental transfers and therefore it was not obligated to actually determine whether the higher upper limit was serving its intended purposes. In fact, Defendant explicitly disclaimed in the preamble to the 2002 UPL Rule that his intention was to regulate intergovernmental transfers. 67 Fed. Reg. at 2606 ("We are not restricting the States' use of funds transferred or certified from units of government.").

The Supreme Court has spoken clearly with regard to post hoc rationalizations in the case that both parties recognize sets the standard in this case. In Motor Vehicle Manufacturers, the Court addressed rationales provided by the Department of Transportation that were not contained in the original agency rulemaking by simply stating as follows:

> The short—and sufficient—answer to petitioners' submission is that the courts may not accept appellate counsel's post hoc rationalizations for agency action. Burlington Truck Lines v. United States, supra, 371 U.S., at 168, 83 S.Ct., at 245. It is well-established that

> an agency's action must be upheld, if at all, on the basis articulated by the agency itself. Ibid.; SEC v. Chenery, 332 U.S. 194, 196, 67 S.Ct. 1575, 1577, 91 L.Ed. 1995 (1947); American Textile Manufacturers Inst. v. Donovan, 452 U.S. 490, 539, 101 S.Ct. 2478, 2505, 69 L.Ed.2d 185 (1981).

463 U.S. at 50. The Court's reasoning applies equally in the instant case.

2. Defendant is Prohibited From Regulating Intergovernmental Transfers.

Even if Defendant's new rationale of preventing "abusive intergovernmental transfers" were not a post hoc rationalization for the rulemaking contained in the 2002 UPL Rule, Defendant could not have issued the 2002 UPL Rule to restrict intergovernmental transfers because Defendant is expressly prohibited by the Medicaid statute from doing so. 42 U.S.C. § 1396b(w)(6)(A) ("The Secretary may not restrict States' use of funds where such funds are derived from State or local taxes … transferred from or certified by units of government."). To the extent that Defendant now admits that his purpose was to attempt to restrict intergovernmental transfers, Defendant's regulation was not permissible and should be invalidated. If this Court believes that HHS intended to restrict intergovernmental transfers through the 2002 UPL Rule, this reason alone is sufficient to invalidate the rule. Congress has explicitly prohibited Defendant from restricting intergovernmental transfers, 42 U.S.C. § 1396b(w)(6)(A), and Defendant may not circumvent that prohibition.

3. Defendant Has Provided No Evidence in the Record of "Abusive Intergovernmental Transfers."

Despite Defendant's exhortations about the purpose of the 2002 UPL Rule in terms of the potential for "abusive intergovernmental transfers," Defendant has provided no definition of which intergovernmental transfers are indeed abusive and how the 2002 UPL Rule actually impacts the potential for "abusive intergovernmental transfers." As stated above in the

Statement of Facts, intergovernmental transfers are legal and have been legal since the beginning of the Medicaid program. See 42 U.S.C. § 1396a(a)(2); 42 C.F.R. § 433.51. Defendant can not logically point to every instance of an intergovernmental transfer in the Administrative Record as evidence of "abusive intergovernmental transfers." Nevertheless, this is what Defendant has done. See 67 Fed. Reg. at 2607 ("The majority of the State plan proposals submitted since the effective date of the January 12, 2001 rule required hospitals to either fund the State's share of the costs of the 150 percent UPL payment or transfer part of the UPL payment back to the State or local government."); (see also Defendant's Memorandum at 29) (citing same language and string cite to state plan amendments in the administrative record). Since intergovernmental transfers are legal under the Medicaid statute, merely noting the existence of such transfers in state plan amendments can not be sufficient to declare them "abusive" or a rational basis on which to eliminate the protection afforded to public hospitals in the 2001 UPL Rule.

Further, Defendant has provided no rational relationship between the change contained in the 2002 UPL Rule – elimination of the higher payment limit for non-state public hospitals -- and his new rationale for the rule – preventing "abusive intergovernmental transfers." Even with a lower payment limit, there is nothing in the 2002 UPL Rule that prevents States from requesting and receiving intergovernmental transfers from non-state public entities. States could theoretically require transfers from non-state public hospitals of the same magnitude currently requested even in the absence of the 150 percent limit. Defendant has provided no evidence that lowering the 150 percent limit for non-state public hospitals to 100 percent will in any way dissuade any intergovernmental transfers, particularly those he has characterized as "abusive." Rather the only result of the 2002 UPL Rule is that States will be significantly restricted in their

ability to pay non-state public hospitals, a result that will significantly harm these safety net hospitals.

C. Defendant Failed to Examine Relevant Data, Relied on Irrelevant Data, Failed to Articulate a Rational Connection Between the Facts Found and the Choice Made, and Failed to Consider an Important Aspect of the Problem – Harm to Safety Net Hospitals

Plaintiffs acknowledge that Defendant is entitled to a certain amount of deference under Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984). This deference, however, is not unlimited. See Motor Vehicle Manufacturers supra, 463 U.S. at 42. As discussed below, in several respects Defendant has acted in an arbitrary and capricious manner that warrants this Court setting aside the 2002 UPL Rule.

1. Defendant Failed to Examine Relevant Data on the 2001 UPL Rule Before Rescinding the Higher Limit for Public Hospitals

In its rulemaking process on the 2002 UPL Rule, Defendant failed to examine relevant data that had been submitted to the agency before rescinding the higher limit for public hospitals. Most importantly, and as stated in detail in Plaintiffs' Brief and below, Defendant failed to consider the harm to safety net hospitals and their patients that would result from the 2002 UPL Rule (Plaintiffs' Brief at 28-32), despite specifically requesting comments on the impact the rule would have on hospitals. 66 Fed. Reg. 58694, 59696 (Nov. 23, 2001). In addition, Defendant by his own admission has failed to consider a significant number of comments. Furthermore, Defendant failed to even collect data that he had indicated would be important in the 2001 UPL Rule.

In promulgating the 2002 UPL Rule Defendant was required to consider the "written data, views, or arguments" submitted in timely comments on the proposed rule. 5 U.S.C. §

553(c). "Section 553 requires consideration of *whatever* data and views are submitted. Such consideration has been considered to demonstrate an 'open mind.'" Mortgage Investors Corp. of Ohio v. Gober, 220 F.3d 1375, 1379 (Fed. Cir. 2000) (citing Advocates for Highway & Auto Safety v. Federal Highway Admin., 28 F.3d 1288, 1293 (D.C. Cir. 1994))(emphasis added). "While changes and revision are indicative of an open mind . . . an agency's failure to make any does not mean its mind is closed. Either way, it is the *agency's burden* to persuade the court that it has accorded the comments a *full and fair hearing*." Advocates for Highway & Auto Safety, 28 F.3d at 1392 (citation omitted) (emphasis added).

Defendant is hard pressed to argue that he considered the "written data, views, or arguments" submitted in timely comments on the proposed rule because by his own admission he failed to consider at least 13 comments submitted. Defendant does not contest that these comments were timely. Declaration of Michelle R. Shortt, Attachments ("Shortt Decl."); Declaration of Timothy C. Miller, Attachments ("Miller Decl."). All 13 letters were internally misplaced, but were received by Defendant's Division of Regulations and Issuances before the date the 2002 UPL Rule was originally to become effective (the three letters attached to the Shortt Declaration may have been received prior to the January 18, 2002 publication date). (Shortt Decl. ¶ 6.) Defendant has apparently not taken any measures to consider the timely received comments, except to dismiss them for purposes of this litigation as redundant. (Defendant's Memorandum at 45, n.13.) Specifically, Defendant neither revised the draft final 2002 UPL Rule to reflect the first three letters recovered (Shortt Decl. ¶ 6), nor did Defendant even reflect in the Federal Register notice announcing a delay in the rule's effective date that the additional timely comments had been received and considered. See 67 Fed. Reg. 12479. Thus,

Defendant failed to consider all of the data and views submitted, Mortgage Investors Corp., 220 F.3d at 1379, representing one more clear example of Defendant's pattern of non-compliance with the procedural requirements of the APA in issuing the 2002 UPL Rule.[14]

Defendant also failed to consider data that had been considered essential in the 2001 UPL Rule. The 2001 UPL Rule required States to report to CMS all UPL payments to hospitals in excess of 100 percent UPL, together with each hospital's calculation of the amount that would constitute 100 percent UPL. 42 C.F.R. §§ 447.272(f), 447.321(f). These State reports on implementation of the 2001 UPL Rule would have provided relevant facts to evaluate the 2001 UPL Rule, but CMS neglected to seek permission to gather the data required by its own regulation until just before proposing to rescind the regulation. Thus, Defendant lacked the most relevant facts possible with which to evaluate the need to rescind the 2001 UPL Rule.

Defendant's attempt to claim that this data would not be relevant in any event is unpersuasive. If Defendant believed the data to be collected pursuant to the 2001 UPL Rule

[14] Defendant's claim that his failure to consider all timely comment letters is "harmless error," Defendant's Memorandum at 45 n.13, is baseless. The ignored comment letters contain data and views, including evidence of harm to hospitals, that are not reflected in the other timely comment letters. One example is the 13-page letter from Plaintiff California Children's Hospital Association (CCHA). (Miller Decl., Attachment.) Among the *unique* data and views contained in that letter are the following: (1) The 2002 UPL Rule could mean a loss of $40-$80 million annually to California's children's hospitals (Id. at 1); (2) Financial cuts of that magnitude effectively mean loss of funding for more than 35,000 inpatient days of care or 800,000 clinic visits for children in California (Id. at 4); (3) The proposed cuts come at a time of increased mandatory hospital spending, including costly requirements that hospitals meet new guidelines for structural resistance to earthquakes (Id.); (4) The combined costs of these other strains and the new burden of the 2002 UPL Rule could result in a collapse of the State's pediatric medical infrastructure (Id.); (5) The estimated cost to California children's hospitals of the 2002 UPL Rule during California's transition period is $238 million (Id. at 6.); and (6) The 2002 UPL Rule could lead non-State government hospitals to pull out of the state's IGT program, which would cause the collapse of the program that funds all eligible safety net hospitals (Id. at 7).

were insufficient, Defendant should have sought to collect and analyze relevant data. Defendant was responsible for collecting and analyzing relevant data as part of the rule-making process and cannot rely on its failure to do so as a justification for the lack of data.

2. HHS Relied Most Heavily on Irrelevant Data in the OIG Final Report to Support Rescinding the 2001 UPL Rule

As discussed above, Defendant insists that the OIG Final Report provides a relevant factual basis for rescinding the higher limit in 2001 UPL Rule, notwithstanding the fact that (a) *all data* included in the OIG Report predates the 2001 UPL Rule itself; and (b) the OIG Report is based upon audits of UPL payments to hospitals in only *three* States. (OIG Final Report at 3.) Defendant argues that the OIG Final Report is relevant because it "confirmed" and "predicted" alleged intergovernmental transfer abuses. (Defendant's Memorandum at 35.) Of course, any confirmations or predictions made on the basis of the OIG Final Report are simply not grounded on States' behavior in implementing the 2001 UPL Rule.

3. To the Extent HHS Examined Relevant Facts in Submitted State Plan Amendments, it Failed to Articulate a Rational Connection Between the Facts Found and the Choice Made.

To the extent that the state plan amendments submitted under the 2001 UPL Rule constitute relevant evidence for the purposes of evaluating the 2001 UPL Rule, Defendant has failed to articulate the required rational connection between the facts of those submitted state plan amendments and the policy of rescinding the 2001 UPL Rule. See Motor Vehicle Manufacturers, 463 U.S. at 42.

As explained above, of the 23 citations of submitted state plan amendments included in Defendant's string cite purportedly documenting abusive intergovernmental transfers

(Defendants' Memorandum at 19, 29 and 34), the vast majority of the cited state plan amendments mention intergovernmental transfers only in the context of financing the *non-Federal share* of Medicaid payments, if at all. Moreover, Defendant fails to articulate a rational connection between these alleged abusive intergovernmental transfer payments, and rescinding the 2001 UPL Rule. Repealing that Rule will only reduce Medicaid supplemental payments to hospitals, but will leave intergovernmental transfers, which are legal, untouched.

Defendant also provides no rational connection between the record and two other stated rationales for the 2002 UPL Rule, the argument that the 100 percent payment level is sufficient and the "payment equity" argument. Defendant supports both of these rationales primarily by stating that sufficiency is a "judgment call in which people can disagree," Defendant's Memorandum at 38 and discounting the analysis provided in the 2001 UPL Rule, without providing any substantial new analysis. Defendant cites his previously stated concern about intergovernmental transfers, and claims that the mere existence of a transfer denies any benefit to the hospital. (Defendant's Memorandum at 41 ("It cannot simultaneously be true that (a) enhanced funds are needed to keep the hospital financially afloat if (b) enhancement programs contemplate that some or all of the money will be transferred right back to the States or to some other governmental entity")). Defendant points to no instance where "all of the money" will be transferred, and logically it can not make sense that only some transfer results in no value to a hospital, which appears to be Defendant's position. The 2001 UPL Rule recognized that non-state public hospitals need additional financial support given the unique role they serve. 66 Fed. Reg. 3148, 3154-3155, and 3160 (see quotes on p. 5 infra). Unsubstantiated statements by the

Secretary cannot be sufficient basis for removal of the 150 percent limit, particularly in the face of contrary evidence provided in numerous comment letters.

4. By Ignoring Extensive Evidence in the Rulemaking Record that Safety Net Hospitals' Survival and Access to Health Care for Medicaid Beneficiaries Would be Threatened Without the 2001 UPL Rule, HHS Failed to Consider an Important Aspect of the Problem Addressed in the 2002 UPL Rule

Defendant contends that whether the 2002 UPL Rule will ensure adequate access to health care for Medicaid beneficiaries is a judgment call that Defendant must make. (Defendant's Memorandum at 38.) Plaintiffs agree, but insist that Defendant may not make that judgment call until he has *examined the relevant facts*, as discussed above, and *considered important aspects of the problem*. Motor Vehicle Manufacturers, 463 U.S. at 42. Plaintiffs discussed at length in their opening brief Defendant's failure to weigh the costs to hospitals of the 2002 UPL Rule, including widespread hospital predictions in comment letters that their ability to meet the health care needs of Medicaid beneficiaries would be significantly threatened. (Plaintiffs' Brief at 26-32.) Defendant does not respond to these arguments with evidence to the contrary, but rather continues to disregard this crucial aspect of the need for a 150 percent UPL to ensure continued access to health care for this nation's poor and uninsured, as addressed in the 2001 UPL Rule.

Defendant's offered explanations why access to health care for poor people will not be threatened by rescinding the higher limit in 2001 UPL Rule are insufficient on their face. First, Defendant asserts *state* and *private* hospitals manage to operate under the lower limits. (Defendant's Memorandum at 39.) This explanation disregards the critical problem addressed in the 2001 UPL Rule that non-State government-owned or operated hospitals require greater

Medicaid payments than other categories of hospitals to meet the health care needs of the populations they serve. As the 2001 UPL Rule explained,

> The size and scale of public hospitals create extreme stresses and uncertainties, especially given their dependence on public funding sources. We are concerned that these stresses may threaten the ability of these public hospitals to fulfill their mission and fully serve the Medicaid population. As such we are proposing a higher UPL for these facilities.

65 Fed. Reg. 60153 (emphasis added).

Defendant next contends that States are still free, under aggregate limits, to provide greater support for some non-State government-owned or operated hospitals within the lower UPL cap, at the expense of others "(perhaps in more affluent parts of the State)." (Defendant's Memorandum at 40.) While the 2001 UPL Rule articulated extensively the reasons why non-State government-owned and operated hospitals require, as a category, enhanced payments, Defendant neither in the 2002 UPL Rule, nor in his brief, articulates a reason why some local government hospitals with a mission of serving Medicaid and uninsured patients should receive enhanced Medicaid payments and others should not.

Finally, Defendant continues to point to DSH payments as a mitigating factor that will ensure continued access to health care in safety net hospitals for Medicaid beneficiaries, ignoring the fact that many non-State government-owned or operated hospitals do not qualify as DSH hospitals. (Defendant's Memorandum at 41-42.) For all of these reasons, Defendant clearly failed to consider this important aspect of the problem of UPL supplemental payments, and thus

engaged in arbitrary and capricious rulemaking.[15] See Motor Vehicle Manufacturers, 463 U.S. at 42.

D. The 2002 UPL Rule Lacks a Sufficient Statement of Basis and Purpose.

Defendant fails to recognize that the requirement of a sufficient statement of basis and purpose is more than an administrative technicality. The APA, 5 U.S.C. § 553(c), requires that agencies include in each final rule a concise general statement of basis and purpose: "[I]f the judicial review which Congress has thought it important to provide is to be meaningful, the 'concise general statement of … basis and purpose' mandated by [the APA] will enable us to see what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did." Boswell Memorial Hospital v. Heckler, 749 F.2d 788, 794 (D.C. Cir. 1984) (citations omitted). Specifically, the statement of basis and purpose "must respond to the major comments received, explain how they affected the new regulation, and, where an old regulation is replaced, explain why the old regulation is no longer desirable." Crowley's, 863 F. Supp. at 20 (quoting Action on Smoking & Health v. Civil Aeronautics Bd., 699 F.2d 1209, 1216 (D.C. Cir. 1983) (other citations omitted)).

Defendant has chosen not to even discuss Plaintiffs' argument that the 2002 UPL Rule's statement of basis and purpose is inadequate due to the complete absence of any assessment of evidence in the administrative record of harm from the rule to hospitals that would jeopardize access to health care for Medicaid patients. (See Defendant's Memorandum at 44-45.) In

[15] Defendant's other argument, that hospitals could not truly need supplemental payments at a higher level if they return a portion of that payment to the state, (Defendant's Memorandum at 40), ignores the reality that these supplemental payments would be unlikely without the legal intergovernmental transfer payments.

particular, the statement of basis and purpose does not address the substantive, quantitative assessments of likely harm to hospitals submitted by numerous commenters at HHS's explicit request, 66 Fed. Reg. at 58696, nor does it explain how those assessments of harm affected the new regulation. In the facts section of his brief, Defendant dismisses those predictions of harm as "purely speculative." (Defendant's Memorandum at 27.) As Plaintiffs explain above, the harm to hospitals from the 2002 UPL Rule will be direct and real, not speculative. These significant comments raising concerns about the viability of non-State public hospitals and their continued ability to serve their safety net mission -- a crucial aspect of the problem addressed in the 2002 UPL Rule -- is exactly the type of evidence that must be raised and responded to under APA law.[16] See Crowley's, 863 F. Supp. at 20.

Nor does Defendant respond to Plaintiffs' argument that the statement of basis and purpose is deficient due to Defendant's willful mischaracterization of the comment letters. Specifically, the statement of basis and purpose employs the identical term, "several," to describe the numbers of comment letters for and against the proposed 2002 UPL Rule, when in fact the numbers of comments were apparently two in favor and approximately 240 opposed. Defendant merely asserts in his brief that it "matters little that most of the commenters … objected to the upper payment limits."

[16] Defendant has similarly ignored Plaintiffs' argument that HHS failed to respond to comment letters citing the December 2001 Conference Report language directing the agency not to change the 2001 UPL Rule until it has assessed its impact. In the facts section of his brief, Defendant purports to have addressed these comments in the preamble to the final rule, in the statement, "Whether or not any particular individuals had an agreement in the past about how this requirement should apply is not at issue." (Defendant's Memorandum at 30.) The context of this response, however, plainly concerned Congressional action leading up to the 2001 UPL Rule - not the December 2001 Conference Report. See 67 Fed. Reg. at 2605.

Defendant's dismissive response also ignores the prevailing caselaw in this Circuit that an agency acts arbitrarily and capriciously when it fails to raise and respond in its statement of basis and purpose to significant criticisms of studies relied on to support a rule. See Menorah Medical Ctr. v. Heckler, 768 F.2d 292, 295 (8th Cir. 1985) (citing St. James Hospital v. Heckler, 760 F.2d 1460, 1469-70 (7th Cir. 1985). In the statement of basis and purpose of the 2002 UPL Rule, HHS stated, "[w]e believe that the OIG reports confirmed our subsequent analysis …." 67 Fed. Reg. at 2609. Now, in his brief, Defendant reverses this chronological order of reliance, by asserting that his subsequent analysis confirms the OIG report. (Defendant's Memorandum at 24.) Nowhere does Defendant address significant criticism that all of the data utilized in the OIG Report predates the 2001 UPL Rule.[17]

Clearly the statement of basis and purpose of the 2002 UPL Rule has not enabled this court or the public to see "what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did." Boswell, 749 F.2d at 794.

E. Defendant Ignored Congressional Intent.

Defendant misconstrues Plaintiffs' argument that HHS ignored congressional direction while rushing into a rulemaking process that could harm safety net hospitals as a substantive objection to HHS's authority to promulgate regulations regarding the upper payment limits that

[17] Defendant also mischaracterizes the record by contending that he did not "discuss in detail the Medicaid state plan of each and every state," (Defendant's Memorandum at 44), when the statement of basis and purpose did not provide any detail about the state plan of any identifiable state at all. 67 Fed. Reg. at 2605. Indeed, until receiving the rulemaking record as part of this litigation, the public had no access to the state plan amendment materials submitted under the 2001 UPL Rule, which, in any case, reveal that while there is significant evidence that States use intergovernmental transfers, there is not significant evidence that States abuse intergovernmental transfers.

apply to hospitals.[18] Plaintiffs' discussion of congressional intent expressed in the 2002 Labor-HHS appropriations process was one of several points describing the many ways in which HHS's 2002 UPL Rule was arbitrary and capricious. Congress has stated that HHS should draft new rules regarding the upper payment limit only "after the administration has had an opportunity to assess the implementation of the new regulations and only in conjunction with the States and their Medicaid programs [and expressed] concern[] that eliminating the higher payment limit category compromise struck last year would be disastrous for all safety net hospitals, both public and private, that participate in the Medicaid program. " S. Rep. No. 107-84 at 215 (2001), *concurred in by the entire Congress in* H.R. Conf. Rep. No 107-342, at 103 (2001). This language was intended to avoid precisely the "rush to rulemaking" that HHS was undertaking and concluded immediately thereafter. Defendant's claim that Defendant followed these congressional prescriptions is not credible. (Defendant's Memorandum at 30: "Thus, the Secretary did exactly what the congressional committees suggested: he waited for evidence that States would try to take advantage of the 150-percent rule to inflate FFP through abusive intergovernmental transfers before he undertook to amend the regulations.")[19]

[18] Defendant also misstates this argument as Plaintiffs' "first substantive objection." (Defendant's Memorandum at 28.)

[19] The sequence of events with regard to the congressional directives and the 2002 UPL Rule rulemaking is instructive. The Senate approved the report language on October 11, 2001, before HHS published its proposed rule on November 23, 2001. Congress reaffirmed this language by approving the conference report referencing the Senate report language on December 19 and 20, before the December 24, 2001 close of the comment period. HHS issued the final regulations only a few weeks days later on January 18, 2001. Congress had explicitly requested that Defendant not rush to judgment and act in a manner that would be disastrous for all safety net hospitals. Defendant ignored that request and, despite notification by multiple commenters of Congress's expressions of legislative intent, did not even feel the need to respond in the 2002 UPL Rule.

III. The 2002 UPL Rule Fails to Comply with the Regulatory Flexibility Act.

As Defendant concedes in his brief, a final regulatory flexibility analysis must be completed by an agency when a final rule is promulgated. 5 U.S.C. § 604, (Defendant's Memorandum at 46.) The final regulatory flexibility analysis must include "a description of the *steps the agency has taken to minimize the significant economic impact on small entities*." 5 U.S.C. § 604(a)(5) (emphasis added).

The mitigating factors that Defendant outlines in its brief, are just that – pre-existing factors. Defendant argues, for example (erroneously as discussed previously), that the existence of the DSH program and the transition period mitigate the impact of the promulgation of the 2002 UPL Rule. (See Defendant's Memorandum at 47-48.) Defendant fails to recognize the distinction between the mitigating factors that it points to, and the description of mitigating "steps" required by the Regulatory Flexibility Act. 5 U.S.C. § 604(a)(5). The factors that Defendant points to are part of the status quo.

Nowhere does Defendant discuss any affirmative steps that the agency has taken or intends to take to mitigate the injury that the 2002 UPL Rule will cause to public hospitals. See National Ass'n of Psychiatric Health Systems v. Shalala, 120 F. Supp. 2d 33, 44 (D.D.C. 2000) (finding that one of the defects that stemmed from the agency's failure to perform an RFA was that "[t]here is not discussion of what, if any, steps the agency took to minimize the significant economic impact on small businesses."). Completion of the regulatory flexibility analysis must involve more than a rubber stamp by the agency. Attesting to the completion of this analysis, without fulfilling its requirements is nothing more than mere lip service. See Associated

Fisheries of Maine, Inc. v. Daley, 127 F. 3d 104, 117 (1st Cir. 1997) (approving the RFA that was conducted because "the record reveals that the Secretary explicitly considered numerous alternatives, exhibited a fair degree of sensitivity concerning the need to alleviate the regulatory burden on small entities . . . adopted some salutary measures designed to ease that burden and satisfactorily explained his reasons for rejecting others.").

IV. The Congressional Review Act Prohibits the 2002 UPL Rule From Being Effective Any Earlier Than May 14, 2002.

The requirements of the Congressional Review Act (CRA) are very clear. For all rules, "the Federal agency promulgating such rule shall submit [a report] to each House of Congress and to the Comptroller General." 5 U.S.C. § 801(a)(1)(A). Further, a major rule relating to such a report shall take effect on the latest of "the later of the date occurring 60 days after the date on which (i) the Congress receives the report submitted under paragraph (1); or (ii) the rule is published in the Federal Register." 5 U.S.C. § 801(a)(3)(A). The language is unequivocal. The 2002 UPL Rule, as a major rule, can not take effect until at least 60 days after the Congress receives the report, and the report must be submitted to both Houses of Congress. In this case that date is May 14, 2002, as established by notices published in the Congressional Record. 148 Cong. Rec. S2007 (daily ed. March 18, 2002).

Defendant should not be permitted to dodge his legal responsibilities by asserting defenses based on incomplete statements by the General Accounting Office, notions of constructive notice, and claims of judicial non-reviewability. At the very least, the clear CRA violations provide this Court with additional evidence of the slipshod rulemaking process HHS conducted with regard to the 2002 UPL Rule.

A. Statements by the General Accounting Office and Constructive Notice Do Not Substitute for Compliance with the Congressional Review Act.

The CRA requires that the agency provide the Comptroller General with a copy of the required report regarding each rule, as well as additional information regarding cost-benefit analysis and the Regulatory Flexibility Act. 5 U.S.C. § 801(a)(1). The Comptroller General has 15 days to provide a report to Congress assessing agency compliance with the procedural steps required by the CRA. 5 U.S.C. § 801(a)(2).

On February 15, 2002, the Comptroller General issued his report with regard to the 2002 UPL Rule, which he received on February 4. (Letter from Kathleen Wannisky, to GAO-02-421R, B-289880 of 2/15/2002 (the "GAO Letter")). The GAO Letter states that Congress received the report concerning the 2002 UPL Rule on February 14, 2002. On February 27, 2002, the Congressional Record, which provides the official record of the public proceedings of each House of Congress as reported by the Official Reporters, 44 U.S.C. § 903, reported that the House had received Executive Communication number 5654, transmitting HHS's report regarding its 2002 UPL Rule, on February 20, 2002. 148 Cong. Rec. H633 (daily ed. Feb. 27, 2002). On March 18, 2002, the Congressional Record, reported that the Senate had received Executive Communication EC-5776, transmitting HHS's report regarding its 2002 UPL Rule, on March 15, 2002. 148 Cong. Rec. S2007 (daily ed. March 18, 2002). Given that both Congressional Record notices post-date the February 15 report by the Comptroller General, it is not surprising that the Comptroller General's report does not reference the Congressional Record in terms of the dates of receipt by Congress. What is significant, however, is that the

Comptroller General concluded that the "final rule does not have the required 60-day delay in the effective date to allow for congressional review." (GAO Letter at 1-2.)

Defendant would like this Court to accord more weight to the Comptroller General's second-hand description of when Congress received the rule than to the official record of the public proceedings of each House of Congress, claiming the GAO Letter is conclusive evidence of the receipt of the rule by Congress. (Defendant's Memorandum at 52-53.) Plaintiffs' Brief, which was filed prior to the Senate's receipt of the HHS report on March 15, 2002, clearly stated that "No record of Senate receipt of the report has yet been reported." (Plaintiffs' Brief at 44.) In fact, the Congressional Record now reflects that the Senate received the 2002 UPL Report on March 15, 2002. 148 Cong. Rec. S2007.

Defendant also claims that the Senate had constructive notice of the regulation because a Senator proposed legislation to address the 2002 UPL Rule on February 4, 2002 and that the "purpose of the CRA has been met." (See Defendant's Memorandum at 52 ("The only conceivable interest of plaintiffs . . . was already facilitated by the publication of the final rule in the Federal Register on January 12, 2002")). The CRA does not allow for constructive notice. If it did, then the Act's explicit language requiring a major rule be effective no earlier than the ***later*** of publication or receipt by Congress would have no meaning. Publication in the Federal Register would always provide constructive notice. Defendant's interpretation would not accord sufficient weight to the requirement that both houses of Congress receive the report. See, e.g., Duncan v. Walker, 533 U.S. 167, 174 (2001) ("We are … 'reluctan[t] to treat statutory terms as surplusage' in any setting.") (citing Babbitt v. Sweet Home Chaper, Cmtys. For Great Ore., 515 U.S. 687, 698 (1995) (other citation omitted)); See also Jasa v. Millard Pub. Sch. Dist. No. 17,

206 F.3d 813, 815 (8th Cir. 2000) (recognizing the "principle of statutory construction that avoids creating mere surplusage").

B. The Congressional Review Act Does Not Preclude Judicial Review of When the 2002 UPL Rule Can Be Effective.

The Administrative Procedure Act allows challenges to certain final agency actions, even absent private right of action under a specific statute. See Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 883 (1990) (stating the Court has "long since rejected" the view that only statutes with private right of action may be enforced under the APA). The APA states that "[a] person suffering a legal wrong because of an agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. To make a claim against an agency, "the person claiming a right to review must identify some agency action," and "the party seeking review must show that he has suffered a legal wrong or been adversely affected by that action within the meaning of a relevant statute." Preferred Risk Mut. Ins. Co. v. United States, 86 F.3d 789, 792 (8th Cir. 1996) (citing Nat'l Wildlife Federation, 497 U.S. at 882-83). That the CRA includes no explicit private cause of action is immaterial to an aggrieved party's ability to challenge an agency's final action in violation of the CRA.

While it is true that the CRA states that "No determination, finding, action, or omission under this chapter shall be subject to judicial review," 5 U.S.C. § 805, this language is ambiguous as to whether it intends to bar review of congressional actions or agency actions. When a statute is ambiguous, it is sensible to resort to legislative history. In this case, the legislative history of the CRA supports the conclusion that the language is intended to bar

congressional action, not agency action. In language deliberately inserted by co-sponsors of the CRA legislation into the Congressional Record, the co-sponsors stated as follows:

> nor may a court review whether Congress complied with the congressional review procedures in this chapter. This latter limitation on the scope of judicial review was drafted in recognition of the constitutional right of each House of Congress to 'determine the Rules of its Proceedings,' U.S. Const., art I, § 5, cl. 2, which includes being the final arbiter of compliance with such Rules.

142 Cong. Rec. S3686 (1996) (statement for the record by Sens. Nickles, Reid, and Stevens); see also 142 Cong. Rec. E577 (1996). The cosponsors further stated that

> The limitation on judicial review in no way prohibits a court from determining whether a rule is in effect. For example, the authors expect that courts might recognize that a rule has no legal effect due to the operation of subsections 801(a)(1)(A) or 801(a)(3).

142 Cong. Rec. S3686; see 142 Cong. Rec. E577 (submission for the record by Rep. Hyde). These arguments have led one commentator to conclude that judicial review is appropriate where an agency fails to comply with CRA requirements. See Morton Rosenberg, "Whatever Happened to Congressional Review of Agency Rulemaking?", 51 Admin. L. Rev. 1051, 1069-1074 (1999).

Plaintiffs recognize the limitations of legislative history, particularly of statements following enactment of legislation. However, the above quoted statements by the sponsors of the legislation were inserted into the record specifically because of the absence of any other legislative history regarding the CRA. 142 Cong. Rec. S3683 (Statement of Sen. Nickles that because the CRA "was the product of negotiation with the Senate and did not go through the committee process, no other [relevant] expression of its legislative history exists . . . This joint statement is intended to provide guidance to the agencies, the courts, and other interested parties when interpreting the act's terms."). In appropriate cases, courts have accorded weight to

pronouncements by sponsors of legislation. See, e.g., Crosby v. National Foreign Trade Council, 530 U.S. 363, 375 n.9 (2000) (examining statements by sponsors of legislation).

Furthermore, and in the alternative, it is not necessary for this court to review a "determination, finding, action, or omission" under the CRA. 5 U.S.C. § 805. This court merely needs to assess when and whether the 2002 UPL Rule may be effective consistent with Section 801 of the CRA. The plain language of the statute does not prohibit this assessment.

Finally, adopting Defendant's position that judicial review is prohibited would essentially make the CRA meaningless. The statute would ascribe responsibilities without any remedy for violations. Such a conclusion would be an absurd result and statutes are to be interpreted to avoid absurd results. Hughey v. JMS Development Corp., 78 F.3d 1523, 1529 (11th Cir. 1996) ("Courts will not foolishly bind themselves to the plain language of a statute where doing so would 'compel an odd result'") (citation omitted). See also Marbury v. Madison, 5 U.S. 137, 163 (1803) ("It is a settled and invariable principle, that every right, when withheld, must have a remedy, and every injury, its proper redress.") (citing 3 Bl. Com. 23).

C. Plaintiffs' Allegations Fall Within the CRA's 'Zone of Interests'

Contrary to Defendant's assertions, Plaintiffs have been harmed by the failure of HHS to follow the rulemaking dictates of the Congressional Review Act. Because hospitals affected by an agency's rulemaking fall within the CRA's "zone of interests," Plaintiffs have standing to challenge the improperly implemented Medicaid UPL rule under that statute.

The APA provides a remedy for those who suffer "a legal wrong because of an agency action," or who are "adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. The Eighth Circuit has stated that, under this provision, a

plaintiff must "identify a substantive statute or regulation that the agency has transgressed." Preferred Risk Mut. Ins. Co., 86 F.3d at 792. The substantive statute at issue here is the CRA. As part of showing that the agency has committed a legal wrong on the plaintiff, the Eighth Circuit has stated: "The complained injury must fall within the 'zone of interest' sought to be protected by the statutory provision whose violation forms the basis for his complaint." Id. at 793, n.6 (citing Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 396-97 (1987)).

This test for prudential standing has been broadly applied. A plaintiff satisfies the test when his injury "arguably [falls] within the zone of interests to be protected or regulated by the statute . . . in question." FEC v. Akins, 524 U.S. 11, 20 (1998) (citing Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co., 522 U.S. 479, 488 (1998), quoting Ass'n of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153 (1970)). See also Bennett v. Spear, 520 U.S. 154, 163 (1997). The zone of interests test "is not meant to be especially demanding." Clarke, 479 U.S. at 399. The test merely "denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it can not be reasonably be assumed that Congress intended to permit the suit." Id.

The CRA's provisions impose procedural requirements for agency rulemaking, including reporting requirements to the House and Senate. Defendant interprets the CRA's purpose in an extremely narrow fashion, as intended to "vindicate[] the prerogatives of Congress alone." (Defendant's Memorandum at 52.) On the contrary, the purposes implicit in the statute ensure that agencies follow certain procedural reporting requirements to allow legislative review of rules that have at least a $100 million effect on the economy. Those affected by improperly implemented major rules certainly fall within the CRA's zone of interest. Because they are

directly affected by the rule at issue, Plaintiffs are not "marginally related" to the procedural requirements imposed on agency rulemaking by the CRA, nor is their request for HHS compliance with the CRA "inconsistent with the purposes implicit in the statute." Clarke, 479 U.S. at 399. Quite the opposite: Plaintiffs injured by the rule seek to enforce the mandates of the CRA. They have standing to do so.

CONCLUSION

For the reasons stated above, the Court should enter summary judgment in favor of Plaintiffs and deny summary judgment for Defendant.

Respectfully submitted,

WILLIAM C. CRENSHAW
POWELL, GOLDSTEIN, FRAZER & MURPHY, LLP
1001 Pennsylvania Avenue, N.W.
Sixth Floor
Washington, DC 20004
(202) 347-0066

DIANE MACKEY
FRIDAY, ELDREDGE & CLARK
2000 Regions Center
400 West Capitol Avenue
Little Rock, Arkansas 72201-3493
(501) 376-2011

Attorneys for Plaintiffs

BY:_____
DIANE MACKEY #78101

OF COUNSEL:
Larry S. Gage, Esq.
Barbara D.A. Eyman, Esq.
POWELL, GOLDSTEIN, FRAZER & MURPHY, LLP
1001 Pennsylvania Avenue, N.W.
Sixth Floor
Washington, DC 20004
(202) 347-0066

Certificate of Service

The undersigned hereby certifies that a true and correct copy of the above and foregoing has been served on the following parties by mail, properly addressed and postage prepaid this ____ day of April, 2002:

PETER ROBBINS (and by hand delivery)
Department of Justice
901 E Street, NW.
Room 962
Washington, D.C. 20530
Attorney for Defendant

GWEN HODGE
Assistant United States Attorney
425 West Capitol Avenue
Suite 55
Little Rock, Arkansas 72201
(502) 342-5337
Attorney for Defendant

_____