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

ASHLEY COUNTY MEDICAL CENTER,	)	
	)	
	)	
et al.	)	
	)	
Plaintiffs,	)	**Civil Action No.**
	)	
v.	)	
	)	
THE HONORABLE TOMMY G. THOMPSON, in his official capacity as Secretary, United States Department of Health and Human Services,	)	
	)	
Defendant.	)	
	)	

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY AND PERMANENT INJUNCTION

TABLE OF CONTENTS

Plaintiffs Ashley County Medical Center ("Ashley"), Delta Memorial Hospital ("Delta"), Alameda Medical Center ("Alameda"), Arkansas Hospital Association ("ArHA"), American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), National Association of Children's Hospitals ("N.A.C.H."), National Association of Public Hospitals and Health Systems ("NAPH"), California Association of Public Hospitals and Health Systems ("CAPH"), California Children's Hospital Association ("CCHA"), California Healthcare Association ("CHA"), Florida Hospital Association ("FHA"), Georgia Hospital Association ("GHA"), and Healthcare Association of New York State ("HANYS"), submit this Brief in support of their Motion for Preliminary and Permanent Injunction (the "Motion") filed herewith. The Motion seeks, pursuant to Rule 65 of the Federal Rules of Civil Procedure, preliminary and permanent injunctive relief enjoining the implementation of a new Medicaid regulation issued by the U.S. Department of Health and Human Services ("HHS" or "Agency") and due to become effective on March 19, 2002 (the "2002 Upper Payment Limit Rule" or the "2002 UPL Rule").

Medicaid supplemental UPL payments are a critical source of support for "safety net hospitals," i.e., those that serve the poor. Many of these hospitals are in severe financial distress due to the significant amounts of health care they provide to poor and uninsured patients for which they receive little or no reimbursement. Often safety net hospitals are the only source of health care for these patients. A rash federal regulation that drastically reduces supplemental payments to these hospitals will have a profound impact on Medicaid and low income patients, jeopardizing their access to life saving and prolonging health care.

The 2002 UPL Rule significantly lowered the limit on such payments for public hospitals that had been adopted by HHS in a regulation just nine months before (the "2001 UPL Rule").

As described in detail below, HHS offered no legally sufficient reason for this change of mind, and violated numerous administrative requirements in doing so.

As described in more detail in the Declarations and comment letters included as exhibits in the Exhibit Volume,[1] if implemented as planned, the 2002 UPL Rule will force many financially strapped safety net hospitals to reduce or eliminate inpatient and outpatient services in some of the nation's poorest communities. Many such hospitals will also be forced to reduce community-wide emergency and public health services and will otherwise be unable to respond effectively to future emergencies. The cutbacks in services will directly affect their mostly poor patients, who will be forced to forego or postpone seeking care, travel great distances for treatment, or rely on already overburdened emergency rooms for care that is more appropriately (and efficiently) provided in other settings. The impact on their health status will be direct and in some cases, tragic.

Plaintiffs respectfully submit that the Court should enjoin the implementation of the 2002 UPL Rule, which HHS has announced will take effect March 19, 2002.

The 2002 UPL Rule is legally deficient in numerous ways. HHS has acted in an arbitrary and capricious manner in implementing the rule without adequate support and while ignoring relevant data. HHS has not complied with the procedural requirements of the Administrative Procedure Act ("APA") and Regulatory Flexibility Act. As demonstrated below, Plaintiffs satisfy all of the requirements for preliminary and permanent injunctive relief, and accordingly the Court should enjoin the implementation of this ill-considered and legally deficient rule.

[1] Each Plaintiff has submitted a Declaration describing, among other things, the harm it, or its constituent members, will suffer as a result of the 2002 UPL Rule. In addition, the following hospitals who are not plaintiffs but who are members of plaintiff associations, also have submitted Declarations: Hennepin County Medical Center, Natividad Medical Center, The New York City Health and Hospitals Corporation and San Francisco General Hospital Medical Center. The Declarations are contained in the Exhibit Volume submitted herewith.

In addition, if the agency does not do so promptly, this Court should delay the scheduled March 19 implementation of the 2002 UPL Rule because HHS failed to comply with the notice requirement in the Congressional Review Act. Pursuant to 5 U.S.C. § 801(a)(3)(A), a major regulation such as the one at issue here cannot become effective until 60 days after the rule and a report on its impact has been delivered to Congress. Here, as discussed below, although the 2002 UPL Rule was published as a final rule in the Federal Register on January 18, 2002, it was not received by Congress until approximately February 20, 2002, effectively delaying the implementation date until at least mid-April. Thus, the rule's current effective date of March 19, 2002 is legally defective and should not be permitted to stand.

STATEMENT OF FACTS

Parties

As described in more detail in the Complaint, Plaintiffs represent a broad national cross-section of individual hospitals and hospital associations whose interests are adversely affected by the 2002 UPL Rule. The hospitals are publicly owned hospitals located in Arkansas (Ashley and Delta) and California (Alameda) (collectively, the "Hospital Plaintiffs"). The associations include four national hospital associations (AAMC, AHA, N.A.C.H. and NAPH), as well as several state hospital associations (ArHA, CAPH, CCHA, CHA, FHA, GHA, HANYS) (collectively, the "Association Plaintiffs").

Defendant the Honorable Tommy G. Thompson is the Secretary of the United States Department of Health and Human Services (the "HHS Secretary" or the "Secretary") whose responsibility is, *inter alia*, to implement the provisions of Title XIX of the Social Security Act, as amended, 42 U.S.C. § 1396, et seq. (the "Medicaid Statute"). In accordance with 42 U.S.C. §§ 1396(a)(30)(A), 1396(a)(4) and 1302 pursuant to an informal rule-making process, HHS

issued the 2002 UPL Rule in a regulation proposed on November 23, 2001, finalized on January 18, 2002 and scheduled to become effective March 19, 2002. To be lawful, this regulation must comply with the procedural requirements of the Congressional Review Act, 5 U.S.C. § 801 *et seq*. and the strictures of the APA, 5 U.S.C. § 551 *et seq*.

The Medicaid Program

Medicaid is an entitlement program, jointly operated and financed by the federal and state governments, that pays for comprehensive health care services to eligible low-income persons. Medicaid is the largest program providing medical services to America's poorest people. Within broad national guidelines set by the federal government, each state establishes eligibility standards, determines the type, amount, duration, and scope of services, sets payment rates for services, and administers the program. The program varies considerably by state, but there are certain minimum federal standards that all states must meet. 42 U.S.C. § 1396 *et seq*.

Each state is required to establish and receive HHS approval for a medical assistance plan (the "State Plan"), which must describe eligibility, benefits, reimbursement methodologies and certain other details of the state's Medicaid program. With regard to reimbursement, the State Plan must describe the methodology used to pay providers, but it need not list amounts to be paid to specific individual providers. The State Plan may be amended as frequently as the state desires. HHS reviews and has approval authority over the original plan and each subsequent amendment to ensure conformance with federal requirements outlined in the Medicaid Statute and accompanying regulations. 42 U.S.C. § 1396a; 42 C.F.R. ¶¶ 430.10 – 430.20.

Medicaid's Importance to Safety Net Hospitals

As the nation's largest public health insurance program for the poor, Medicaid has become the single most important payer for most safety net hospitals. Medicaid's

reimbursement rates, however, are typically lower than the costs incurred by such hospitals in providing care to Medicaid enrollees, and significantly lower than rates paid for similar services by other third party payers (Medicare and private insurance). Because many hospitals with large Medicaid populations also serve a substantial number of uninsured patients, these hospitals tend to face much more extreme financial stresses than average hospitals. (Declaration of Christine Capito Burch, Executive Director, NAPH (hereinafter "Burch Decl.") ¶ 7, Ex.1.)

The term "safety net hospitals," while not specifically referenced in the Medicaid statute, is generally understood to refer to those institutions that make their services available to all persons, regardless of ability to pay, insurance status or health status. In many cases, safety net hospitals are the only source of hospital care for the poor, who would otherwise have nowhere else to turn. These institutions also typically provide costly specialized services relied upon by the entire community regardless of insurance status, such as high level trauma care, burn care, neonatal intensive care and emergency psychiatric services. Safety net hospitals include both public and private institutions, children's hospitals, teaching hospitals, small rural sole-community providers and large urban health systems. (Burch Decl. ¶ 5, Ex.1.)

Plaintiff hospitals, the members of Plaintiff hospital associations and hospitals that have submitted declarations in support of the Motion reflect the diversity of America's safety net hospital infrastructure.

Because these safety net providers typically form the core of the provider network on which state Medicaid programs rely to serve their populations, both the federal government and the states have a vital interest in ensuring their viability. The Medicaid program has therefore developed certain mechanisms to provide targeted supplemental safety net support. For example, one program, the Medicaid Disproportionate Share Hospital ("DSH") program, allows

states to provide supplemental support to those hospitals that serve a disproportionate share of Medicaid and uninsured patients to help cover the unreimbursed costs of care. 42 U.S.C. § 1396r-4(g). The DSH program is subject, however, to state-by-state caps that vary wildly and hospital-specific caps that are sometimes insufficient.[2]

Because of the insufficiency of many state DSH programs to fully support critical safety net hospitals, some states have established supplemental payments outside of the DSH program to ensure the viability of these providers. These payments are subject to the upper payment limit at issue in this case. Arkansas, for example, faced with such arbitrary federal constraints on its ability to provide its safety net hospitals with DSH funding, has, over the last two years, established a series of non-DSH supplemental payments for its safety net hospitals. These payments include targeted adjustments for local public hospitals, private hospitals, pediatric hospitals, and state teaching hospitals. Though these payments are still modest by national standards, beginning in 2001, for the first time Arkansas' safety net hospitals were able to rely on the support that has long been available to their counterparts in other states (Declaration of James Teeter, President, ArHA (hereinafter "Teeter Decl.") ¶ 7, Ex. 2.) The 2002 UPL Rule will greatly restrict Arkansas' ability to provide these critical payments. Without these payments, many safety net hospitals in Arkansas and elsewhere simply would not survive. (Burch Decl. ¶ 15, Ex. 1.)

[2] For example, until recently, Arkansas had a statutory federal DSH allotment of $2 million out of a total of $9.3 *billion* nationwide. 42 U.S.C. § 1396r-4(f)(2). Arkansas' DSH allotment was recently increased to approximately $16 million, still far below the national average. 42 U.S.C. § 1396r-4(f)(5). Even with the recent increase, Arkansas' DSH allotment translates into approximately $33 per Medicaid recipient, as compared to a national average of $237 per Medicaid recipient. By contrast, a small state like New Hampshire is allowed to make DSH payments equivalent to $1,298 per Medicaid recipient. (Enrollment figures from HCFA-2082 reports by states, available at www.hcfa.gov/medicaid/msis/mcd99t01.pdf.)

Medicaid Financing

Medicaid expenditures are funded by a combination of federal and non-federal sources, with the proportion of federal funding varying from state to state based on a statutory formula. While state governments typically supply a majority of the non-federal share of Medicaid expenditures, since its enactment in 1965 the Medicaid statute has always permitted a portion of the non-federal share to be financed from other sources. These sources can include (with some restrictions) provider taxes, voluntary donations by non-provider individuals or organizations, and funds transferred to the state from other governmental entities (sometimes referred to as inter-governmental transfers or IGTs). 42 U.S.C. § 1396b(w). Up to 60 percent of the non-federal share of Medicaid spending in a state may be financed from such non-state sources. 42 U.S.C. § 1396a(a)(2).

In many areas of the country, cities, counties and other local governments, as well as public hospitals, contribute to the non-federal share of Medicaid expenditures pursuant to this longstanding statutory and regulatory authority. In Arkansas, public hospitals share in the financing of the non-federal portion of Medicaid expenditures, including the Medicaid supplemental payments described above. (Teeter Decl. ¶ 7, Ex. 2.) California's program is similarly reliant on local funding sources, which support the non-federal share of supplemental payments not only to public hospitals but to children's hospitals and other private safety net hospitals as well. (Declaration of Susan Maddox, President and CEO, CCHA (hereinafter "Maddox Decl.") ¶ 10, Ex. 3 Declaration of C. Duane Dauner, President, CHA (hereinafter "Dauner Decl.") ¶ 7, Ex. 4; Declaration of Denise K. Martin, President and CEO, CAPH (hereinafter "Martin Decl.") ¶ 10, Ex. 5). In other states, taxes on hospitals and other providers contribute to the non-federal share. Having evolved into its present form over decades, this web

of federal, state, local and private financing for the safety net is complex and often difficult to untangle. Yet without these sources of funding, it is safe to say that many Medicaid services and expenditures, including critical DSH and other supplemental payments to safety net providers, would not be possible. (Burch Decl. ¶ 8, Ex. 1.)

Medicaid Reimbursement Prior to 2001

Federal Medicaid law places very few restraints on states' ability to set payment rates for Medicaid providers. The Medicaid statute does not direct states to adopt any particular payment methodologies or dictate the rates or amounts paid to hospitals and other providers. It merely requires that payments be consistent with efficiency, economy and quality of care, and be sufficient to enlist enough providers to ensure that care is as available to Medicaid patients in an area as it is to the general population. 42 U.S.C. § 1396a(a)(30)(A).

Prior to 1981, the Medicaid statute generally required states to pay hospitals on the basis of Medicare principles. In 1981, however, Congress amended the statute to eliminate this requirement and to give states greater flexibility to establish new hospital payment methodologies. Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, § 2173, 95 Stat. 357. Subsequently, however, HHS by regulation required state payments to meet the efficiency criteria by setting broad upper payment limits (UPLs) on reimbursement, based on what Medicare would pay for similar services. These upper payment limits were applied in the aggregate to different types of Medicaid providers. For example, prior to 2001, a state needed only to provide assurances to HHS that its payments to all nursing homes or hospitals (except state-operated facilities) did not exceed what Medicare would pay in the aggregate for all such services.

These pre-2001 aggregate upper limits had provided states with considerable flexibility to establish supplemental payment programs for nursing homes, hospitals and other providers. In early 2000, reports began surfacing in the press and elsewhere of some states establishing programs that used this flexibility to pay nursing homes hundreds of millions of dollars in supplemental payments, substantially all of which was immediately returned to the state. Because a Medicaid payment had technically been made to the nursing home, however, states could claim federal Medicaid matching funds even though those funds did not remain with the facility. (Burch Decl. ¶11, Ex. 1.)

However, some states had legitimately used the flexibility presented by the pre-2001 UPL regulations to adopt critically-needed, targeted supplemental payments for essential safety net hospitals (See, e.g., Martin Decl. ¶ 9, Ex. 5; Maddox Decl. ¶ 9, Ex. 3; Dauner Decl. ¶ 5, Ex. 4.) These payments were permitted under the regulation because base Medicaid rates were generally so low that there was a significant gap between those rates and the UPL. Thus even with the supplemental payments, aggregate payments did not exceed the UPL. And while at times the non-federal share of these supplemental payments also was funded through IGTs, the nursing home issues described above simply did not exist with the hospital-based programs. Not only did hospitals retain these funds for important safety net services, Office of Inspector General, U.S. Dept. of Health and Human Services, Report No. A-03-00-00216 (2001) (hereinafter, "the OIG Report"), in some cases IGTs made by local governmental entities were also used to fund other health services for the poor. (See, e.g., Martin Decl. ¶ 10, Ex. 5; Maddox Decl. ¶ 8, Ex. 3.) These include expanded coverage, non-hospital primary care services, and critical Medicaid services provided by certain private safety net providers, such as children's hospitals. In a few states, including most notably California, these legitimate programs had

existed for years, and had become an integral and irreplaceable piece of the complex financing on which safety net hospitals rely (Martin Decl. ¶ 8, Ex. 5; Maddox Decl. ¶ 8, Ex.3; Dauner Decl. ¶ 5, Ex.4.)

January 12, 2001 UPL Rule

In a regulation proposed on October 10, 2000, finalized January 12, 2001 and effective March 13, 2001 (the "2001 UPL Rule"), HHS revised the broad upper payment limits in an attempt to curb the abuses that had been reported in some state nursing home programs. 66 Fed. Reg. 3148 (2001)[3] (codified at 42 C.F.R. §§ 447.272, 447.321).

Citing reviews by the Office of the Inspector General ("OIG") on supplemental payment programs in six states, HHS concluded that:

> [e]nhanced payments to public nursing facilities were not being retained by the facilities to provide services to Medicaid beneficiaries. Instead, the majority of the enhanced payment was returned by the providers to the States through intergovernmental transfers (IGT). The States then used the funds for other purposes, some of which were unrelated to the Medicaid program. … *Unlike the nursing facilities, public hospital providers retained the majority of the Medicaid enhanced payments.*

66 Fed. Reg. 3150 (January 12, 2001) (emphasis added).

To address the problems raised by the OIG, HHS proposed the 2001 UPL Rule revising the prior UPL regulation to establish three categories of facilities - state, non-state public and private facilities - and requiring payments to providers within each category not to exceed the aggregate UPL. Thus, for example, states would no longer be able make payments to their public nursing homes equal to the difference between Medicaid and Medicare rates for *all* (non-state) nursing homes. Under the new rule, payments to public nursing homes were limited to the aggregate amount that Medicare would pay only to those public providers. As a result, the maximum amount that could be paid public (or private) providers was greatly reduced.

In adopting these new category-specific UPLs, however, HHS was concerned about the potential negative impact of reducing state flexibility to make supplemental payments to public hospitals. HHS was also concerned about the potential disruption to the safety net infrastructure in states that had long-established hospital UPL programs. For these reasons, HHS established a higher UPL for the category of non-state governmental hospitals. For these hospitals, the aggregate limit was set at 150 percent (rather than 100 percent) of what Medicare would pay.

HHS took this step in recognition of the critical and uniquely challenging role of such hospitals in providing access to health care services to low-income Medicaid and uninsured individuals. HHS explained the establishment of the higher public hospital limit as follows:

> [W]e believe that allowing higher Medicaid payments will fully reflect the value of public hospitals' services to Medicaid and the populations 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.
>
> 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. 60151, 60153 (Oct. 10, 2000).

In doing so, HHS acknowledged that some states such as California had legitimately adopted supplemental payment programs for safety net hospitals that relied on the payment flexibility in the pre-2001 regulation to target support to particular providers. The higher public hospital limit was important because it both partially mitigated the cuts that the 2001 UPL Rule would impose on states (like California) with long-standing hospital supplemental payment programs, and also permitted states that had not adopted supplemental payment programs for

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[3] Copies of the proposed and final UPL Rules referenced herein are included in the Exhibit Volume.

hospitals (like Arkansas) to do so in a meaningful manner. HHS considered more restrictive approaches to address the reported abuses of Medicaid payment flexibility, but rejected them in favor of the compromise represented by the 150 percent limit.

In adopting the higher public hospital limit, HHS also established specific reporting requirements to determine whether the 150 percent level was appropriate and to ensure that the higher payments actually benefit local public hospitals:

> We were aware in publishing the proposed rule that proper payment data were difficult to obtain . . . It was not clear what level of funding would be needed to both meet these needs [of public hospitals] and, at the same time, curtail the practice of transferring enhanced payments back to State treasuries. Given limited data, we proposed a UPL for these facilities of 150 percent of a reasonable estimate of Medicare payment principles. We are instituting reporting requirements . . . that will allow us to monitor and track the distribution of these funds.

66 Fed. Reg. 3155. HHS further expressed its belief that the reporting requirements "will be a necessary administrative tool to ensure the proper administration of the Medicaid program." 66 Fed. Reg. 3158.

By mandating these reporting requirements, HHS recognized the need for gathering additional data to assess the UPL program. Nevertheless, HHS waited until shortly before it proposed the elimination of the 150 percent limit to seek approval to collect the required information. Approval to obtain needed data was obtained from OMB on November 20, 2001, OMB number (0938-0855), but it is unclear whether HHS ever moved forward to actually request data from states. In any case, it would have been impossible for HHS to collect any data in time to base its decision to issue the 2002 UPL Rule on a reasoned analysis of state experiences under the higher limit.

Nor did HHS in late 2001 take into account the fact that the 2001 UPL Rule was specifically endorsed by Congress before the final rule was issued. Section 705 of the Medicare,

Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000, signed on December 21, 2000, required that HHS publish a final regulation based on the proposed rule announced in October 2000 and further dictated requirements for the regulation. H.R. 5661, 106th Congress § 705(a); Pub. L. No. 106-554, § 1(a)(6), 114 Stat. 2763, App. F (2000).

In reliance on this new regulation, several states began developing supplemental payment programs for public and private safety net providers. In the summer of 2001, Arkansas and Mississippi were the first two states to receive approval for State Plan Amendments implementing such programs. (Teeter Decl. ¶ 7, Ex. 2; Comment No. 18, Letter from Sam Cameron of Mississippi Hospital Association to CMS of 12/17/01 (hereinafter "Cameron letter") at 2, Ex. 6.) Thomas Scully, the Administrator of the Centers for Medicare and Medicaid Services ("CMS", the agency within HHS responsible for overseeing the Medicaid program), praised the Arkansas and Mississippi programs as appropriate and legitimate uses of the 150 percent limit. (Burch Decl. ¶12, Ex. 1; Teeter Decl. ¶ 9, Ex. 2.) By November 2001, 28 states had pending or approved State Plans relying on reimbursement at the 150 percent rate. 66 Fed. Reg. 58696.

November 23, 2001 Notice of Proposed Rule Making

Just eight months after the effective date of the 2001 UPL Rule, HHS moved to rescind a significant part of it. On November 23, 2001 HHS published a Notice of Proposed Rule Making, Modification of Upper Payment Limit for Non-State Government-Owned or Operated Hospitals, 66 Fed. Reg. 58694 (2001) ("NPRM"), proposing to eliminate the 150 percent UPL created in the 2001 UPL Rule.

HHS acknowledged that it had previously "believed that there was a need for a higher UPL to apply to payments to these public hospitals because of their important role in serving the Medicaid population." Id. The Agency explained its change of heart as follows: "Since the public hospitals are not retaining the funds available as a result of this higher UPL, those funds are neither furthering their special mission nor ensuring continued access to these facilities for the Medicaid population." Id.

The sole basis offered by HHS to support this broad conclusion was a series of reviews conducted during 2000 of state supplemental payment programs by the OIG (consolidated in a September 11, 2001 OIG Final Report (Office of Inspector General, U.S. Dept. of Health and Human Services, Report No. A-03-00-00216 (2001)) claiming that a portion of the supplemental payments in those states were transferred back to the state. These previously conducted OIG reviews are the same reports that HHS had relied on one year earlier to reach the opposite conclusion that "[u]nlike the nursing facilities, public hospital providers retained the majority of the Medicaid enhanced payments." 66 Fed. Reg. 3150.

The OIG Report

The OIG Report focuses on problems in implementing supplemental Medicaid payments in six states, and of those, it assesses hospital programs in only three states. The other reviews in three states were of programs providing enhanced payments to nursing homes. The OIG found that in the limited study it conducted of nursing homes, substantially all of the federal Medicaid funds generated by enhanced payments to these facilities were returned to the state and did not actually benefit the institutions that were the nominal recipients.

The OIG came to a different conclusion with respect to supplemental payments to hospitals, which it highlighted in its report findings and pointed out to CMS Administrator

Scully in its transmittal letter: "In contrast to the nursing facilities, hospital providers kept a large portion of the enhanced payments." (Letter from Michael Mangano, HHS Office of Inspector General to Thomas Scully, CMS of 09/11/01 at 2, Ex. 7.)

Despite the concession that hospitals are directly benefiting from supplemental payment programs, the OIG nevertheless recommends the elimination of the 150 percent higher limit. Yet neither this recommendation nor the reviews that led to it is based on actual state experience under the 150 percent regulation. Rather, the OIG only analyzed programs established under the old, pre-2001 UPL regulations. The OIG Report does not look at whether states have appropriately used the flexibility provided with the higher limit; it does not examine whether a changed political environment arising from reported problems with nursing home payments may have led states to design more appropriate programs; and it does not analyze whether the changes adopted in 2001 sufficiently curbed the questionable practices that led to their promulgation. (Burch Decl. ¶ 15, Ex. 1.) The OIG Report did not do any of these things because it could not do any of these things - it was looking at state experiences under a repealed regulatory scheme.

Public Comments

HHS recognized that the proposed rule could have a significant impact on hospitals, and explicitly invited "public comments on the possible effects that this proposed rule would have on small entities in general and on small rural hospitals in particular." 66 Fed. Reg. at 58696. The comment period it established, however, was as short as legally permissible, with comments due 30 days after publication of the proposed rule, or Christmas Eve, December 24, 2001.

At least 220 commenters submitted letters to HHS responding to the proposed rule, including Plaintiffs and/or the hospital associations that represent the Hospital Plaintiffs. These letters clearly predict the drastic and severe impact on public hospitals from the proposed new

rule. See, e.g., Comment No. 48, Letter from Mitchell Katz of City and County of San Francisco Dept. of Public Health to Thomas Scully of 12/20/01, (hereinafter "Katz letter"), Ex 8; Comment No. 67, Letter from Paul Cunningham of Arkansas Hospital Association to Thomas Scully of 12/15/01 (hereinafter "Cunningham letter"), Ex. 9.) They criticized the validity of the only empirical evidence HHS supplied to support the rule change, the fact that the proposed rule ran counter to Congressional intent, the failure to comply with the requirements of the Administrative Procedure Act, and many other aspects undermining the proposed elimination of the enhanced Medicaid supplemental payment. See, e.g., Comment No. 44, Letter from Kurt Stuenkel of Georgia Safety Net Coalition to CMS of 12/21/01 at 2, Ex. 10; Comment No. 40, Letter from Lynne Fagnani of NAPH to Thomas Scully of 12/21/01 at 2, 3 6, Ex. 11.) Several commenters pointed out the flaws in the OIG Report and HHS's reliance on it as a basis for modifying the regulation. See, e.g., Comment No. 50, Letter from Denise Martin of CAPH to Thomas Scully of 12/20/01 (hereinafter "Martin letter") at 7-8, Ex. 12; Comment No. 68, Letter from Nancy Galvagni of Kentucky Hospital Association to Thomas Scully of 12/19/01 (hereinafter "Galvagni letter") at 2, Ex.13.) None of the criticisms was answered in the final rule.

At least three of the letters that were submitted to HHS in a timely manner were inexplicably excluded from the official rulemaking record. (Declaration of Jordan J. Cohen, M.D., President, AAMC (hereinafter "Cohen Decl.") ¶ 10, Ex. 14; Declaration of Lawrence A. McAndrews, President and CEO, N.A.C.H. (hereinafter "McAndrews Decl.") ¶ 10, Ex. 15; Maddox Decl. ¶ 18, Ex. 3.) Each of these excluded letters objects to the proposed rule and highlights the harm it would cause if implemented. HHS officials have conceded that at least N.A.C.H.'s letter reached the Agency during the comment period, but was not considered during

the rulemaking process. (Declaration of Suzanne M. Hansen, Director of Medicaid and State Policy, N.A.C.H. (hereinafter "Hansen Decl.") ¶ 6, Ex. 16.)

Congressional Action

Both before and after HHS published the proposed regulation in November 2001 and before the final regulation was released in January 2002, Congress made its views clear. In appropriating FY 2002 program management funding to CMS to administer Medicaid, Congress directed HHS to wait until it had fully assessed the implementation of the 2001 UPL Rule before modifying it. HHS ignored this directive.

In October 2001, the Senate Appropriations Committee adopted the following language in its report accompanying the FY 2002 Labor-Health and Human Services-Education Appropriation Act, S. 1536:

> The Committee is pleased that the administration, in January and September 2001, supported this Medicaid upper payment limit agreement in the promulgation of Medicaid upper payment limit regulations. Further, the Committee reiterates its commitment to both the letter and spirit of this agreement, and directs the administration to maintain its course in complying with congressional intent. *Any subsequent modifications should be done only after the administration has had an opportunity to assess the implementation of the new regulations and only in consultation with the States and their Medicaid programs, as well as the other stakeholders. The Committee is extremely concerned 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 page 215 (2001) (emphasis added).

After HHS proposed the rule in November 2001, but before the comment period closed, the full Congress explicitly endorsed this language in passing the final Labor-HHS appropriations bill on December 20, 2001. The joint conference report accompanying that final legislation asserted that the "conferees strongly concur with Senate report language regarding the Medicaid upper payment limit agreement that was included in the Omnibus Consolidated and

Emergency Supplemental Appropriations Act for Fiscal Year 2001." H.R. Conf. Rep. 107-342, 103 (2001). President Bush signed this bill into law on January 10, 2002. Pub. L. No. 107-116 (2002).

NAPH quoted this language in its entirety in its comment letter to the proposed rule. AHA also pointed it out. Eight days after passage of the conference report, the final UPL regulation was issued, without acknowledgment of this clear reiteration of congressional support for the 150 percent compromise and its plea to HHS for more careful and deliberate analysis prior to making any changes.

January 18, 2002 Final Rule

On January 18, 2002, HHS published the final 2002 UPL Rule in the Federal Register. Thus, HHS took a mere 17 working days after the deadline for receipt of comments, and a period in which two major federal holidays fell, to "review" more than 200 comments. Final Rule, Modification of Upper Payment Limit for Non-State Government-Owned or Operated Hospitals, 67 Fed. Reg. 2602 (2002) (to be codified at 42 C.F.R. pt. 447). The 2002 UPL Rule "modified the Medicaid upper payment limit (UPL) provisions to remove the 150 percent UPL for inpatient hospital services and outpatient hospital services furnished by non-State government-owned or operated hospitals." Id. The regulation will reduce the higher 150 percent UPL for non-State government-owned or operated hospitals to 100 percent. HHS's intended effective date for the 2002 UPL Rule is March 19, 2002. Because it was not formally received by Congress until February, the GAO has informed the Agency that the requirement of a 60-day Congressional review period under the CRA has not been met and that the effective date must be postponed. HHS has yet to respond. (See Letter from Kathleen E. Wannisky of GAO to The Honorable

Max Baucus, U.S. House of Representatives and the Honorable W.J. "Billy" Tauzin, U.S. Senate of February 15, 2002, Ex. 17.)

In eliminating the 150 percent UPL, HHS relied on its asserted belief that the 100 percent UPL is "more than sufficient" to provide "adequate access to services" by Medicaid beneficiaries at public hospitals. 67 Fed. Reg. 2603. This "belief" on the part of the Agency is not supported by any concrete relevant data or other facts and not by the overwhelming evidence to the contrary contained in the 220 timely submitted comments. HHS failed to analyze the experience of the two states (Arkansas and Mississippi) that had received approval for and implemented safety net programs pursuant to the 150 percent limit, even though it received comments from hospital associations in both states documenting the benefits of their programs (Teeter Decl. ¶ 13, Ex. 2; Cunningham letter at 3, Ex. 9; Comment No. 18, Letter from Sam Cameron of Mississippi Hospital Association to CMS of 12/17/01, at 2, Ex. 6.) Rather, HHS relies almost exclusively on the same inapplicable OIG reports that had led to the establishment of the 150 percent limit in the first place.

Harm to Hospitals

The Hospital Plaintiffs and the members of the Association Plaintiffs are safety net hospitals that participate in the Medicaid program and qualify for supplemental Medicaid funds available pursuant to the January 12, 2001 UPL Rule. These hospitals rely on these payments in order to ensure access to essential health care services for Medicaid and other low-income patient populations they serve.

As reflected in the Declarations and comment letters, if the current 150 percent upper payment limit for non-state public hospitals is eliminated on March 19, 2002, the Hospital Plaintiffs and many members of the Association Plaintiffs will be required to make deep cuts in

essential services on which their underserved patient populations rely. Predicted cuts could include elimination of entire departments and closure of certain on- and off-campus facilities. In many of these hospitals' communities, there are simply no other providers able to step in and replace these lost services. As a result, many low-income Medicaid enrollees and uninsured people will effectively lose their access to essential health care services, while entire communities will lose essential community-wide services and be less prepared for future emergencies.

Some of the outcomes of the implementation of the rule, as documented in the attached declarations, include:

- elimination of community clinics, forcing people to use hospital emergency rooms for primary care services (Declaration of Benjamin Chu, President, HCC (hereinafter "Chu Decl.") ¶ 14, Ex. 18; Declaration of Mike Opat, Chair, Board of Hennepin County Commissioners (hereinafter "Opat Decl." ¶ 14, Ex. 19.)

- overburdened emergency rooms leading hospitals to divert critical patients to distant hospitals (Declaration of Mitchell Katz, Director of Public Health, City and County of San Francisco Department of Public Health (hereinafter "Katz Decl.") ¶ 14, Ex. 20.)

- reduction in services requiring patients to travel long distances to the nearest alternative provider (Declaration of Kurt Meyer, CEO, Delta (hereinafter "Meyer Decl."), ¶ 13, Ex. 21; Declaration of Russ D. Sword, CEO, Ashley (hereinafter "Sword Decl.") ¶ 14, Ex. 22.)

- significant reductions in linguistic services and outreach to non-English speaking patients (Declaration of David Small, CEO, Natividad (hereinafter "Small Decl.") ¶ 11, Ex. 23.)

- inability to retain physicians on staff who are qualified to provide specialized care (including critically needed care such as obstetrical/gynecological services for women) (Meyer Decl. ¶ 14, Ex. 21; Sword Decl. ¶ 13, Ex. 22.)

- reduction in hospital programs to handle acute psychiatric care (Declaration of Kenneth B. Cohen, CEO, Alameda (hereinafter "K. Cohen Decl.") ¶ 13, Ex. 24.)

The impact of the loss of the higher limit for non-state governmental hospitals, moreover, is not limited to public hospitals alone. Other safety net providers – including private children's

and teaching hospitals and public and private clinics – also will be harmed. (McAndrews Decl. ¶ 12, Ex. 15; Maddox Decl. ¶ 20, Ex. 3.) The importance of the 150 percent UPL rule to maintaining the delicate balance of safety net financing in many states cannot be overestimated.

The 2002 UPL Rule Should be Enjoined

The 2002 UPL Rule should be enjoined for numerous reasons. The 2002 UPL Rule was promulgated on the basis of irrelevant and inaccurate data, without properly considering or responding to the comments submitted to HHS, and without properly considering the effect on the nation's safety net hospitals. These shortcomings are also reflected in the rule's legally insufficient statement of basis and purpose. For these reasons, the Final Rule was not promulgated in compliance with the Administrative Procedure Act and constitutes arbitrary and capricious action by HHS. The 2002 UPL Rule also fails to perform analyses required by the Regulatory Flexibility Act and the Social Security Act.

Finally, there can be no dispute that HHS has violated the requirements of the Congressional Review Act. Accordingly, the 2002 UPL Rule has a premature effective date. On this basis alone, the Court should enter injunctive relief.

Plaintiffs do not have an adequate remedy at law. If the 2002 UPL Rule is implemented, as planned by HHS, on March 19, 2002, Plaintiffs' ability to continue to provide necessary medical care to Medicaid enrollees and other low income and vulnerable patients will be seriously and irreparably compromised. As those individuals lose access to medical care, the sick will get sicker, minor injuries will become life-threatening, hospital emergency rooms will overflow with patients, causing lengthy and dangerous ambulance diversions, and the quality of health care will suffer immeasurably. These are all consequences of the 2002 UPL Rule, should it go into effect.

As detailed below, Plaintiffs have a substantial likelihood of success on the merits, Plaintiffs will suffer irreparable harm, any harm to HHS is outweighed by the harm to Plaintiffs, and the injunction sought is in the public interest. Accordingly, Plaintiffs respectfully request a preliminary injunction and a permanent injunction to prevent the 2002 UPL Rule from being implemented. Plaintiffs further request that the Court entertain their Motion for a Preliminary and Permanent Injunction on an expedited basis so that this matter is determined before the rule's currently scheduled effective date of March 19, 2002.

LEGAL STANDARD FOR ISSUANCE OF INJUNCTIVE RELIEF

In evaluating a motion for preliminary injunction, a court reviews four factors: "(1) the probability of success on the merits; (2) the threat of irreparable harm to the movant; (3) the balance between this harm and the injury that granting the injunction will inflict on other interested parties; and (4) whether the issuance of an injunction is in the public interest." Entergy Arkansas, Inc. v. Nebraska, 210 F.3d 887, 898 (8th Cir. 2000). "[E]ach factor must be considered to determine whether the balance of equities weighs toward granting the injunction." United Indus. Corp. v. Clorox Co., 140 F.3d 1175, 1179 (8th Cir. 1998) (citation omitted).

These four factors, however, "are not a rigid formula," Bandag, Inc. v. Jack's Tire & Oil, Inc., 190 F.3d 924 (8th Cir. 1999), as "[n]o single factor in itself is dispositive." Clorox Co., 140 F.3d at 1179 (citation omitted). Whether the injunction should issue is subject to the broad discretion of the district court. "A district court has broad discretion when ruling on requests for preliminary injunctions." Clorox Co., 140 F.3d at 1179. In determining whether to grant a motion for preliminary injunction, the "court should flexibly weigh the case's particular circumstances to determine whether the balance of equities so favors the movant that justice

requires the court to intervene." Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc., 182 F.3d 598, 601 (8th Cir. 1999) (internal quotation omitted).

Courts apply effectively the same standard for entry of a permanent injunction, with the only difference being that movants must attain success on the merits. "The standard for granting a permanent injunction is essentially the same as for a preliminary injunction, except that to obtain a permanent injunction the movant must attain success on the merits." Bank One v. Guttau, 190 F.3d 844, 847 (8th Cir. 1999) (citation omitted). Here, given the nature of Plaintiffs' claims, Plaintiffs have requested, pursuant to Rule 65(a)(2) of the Federal Rules of Civil Procedure, that the preliminary hearing of this matter be consolidated with the trial on the merits. Accordingly, the Court should enter permanent, as well as preliminary, injunctive relief.

ARGUMENT

I. Plaintiffs Are Likely to Succeed on the Merits of Their Claims

A. The 2002 UPL Rule is Arbitrary and Capricious

The Administrative Procedure Act requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law …" 5 U.S.C. § 706(2).

> 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 examine the relevant data and articulate a *satisfactory explanation* for its action including a "rational connection between the facts found and the choice made"…Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 42 (1983) (internal citations omitted; emphasis added) (holding that National Highway

Traffic Safety Administration acted arbitrarily and capriciously in revoking a motor vehicle safety standard that new vehicles be equipped with passive restraints by failing to present an adequate basis and explanation for rescinding the passive restraint requirement).

As detailed below, HHS's promulgation of the 2002 UPL Rule constitutes arbitrary and capricious action under 5 U.S.C. § 706 of the APA and the cases interpreting it, and this Court should hold the rule unlawful.

1. HHS Relied on Inaccurate and Irrelevant Data

The APA requires an agency to examine and apply *relevant* data in rulemaking. Motor Vehicle Manufacturers, 463 U.S. at 43. A court's task:

> is to determine whether the agency has articulated a rational connection between its factual judgment and its ultimate policy choice, and whether the underlying factual judgments are supported by substantial evidence.

Crowley's Yacht Yard, Inc. v. Pena, 863 F. Supp. 18, 21 (D.D.C. 1994). See also City of Rochester v. Environmental Protection Agency, 496 F. Supp. 751 (D. Minn. 1980) ("[A]gencies must make findings that support their decisions, and those findings must, in turn, be supported by substantial evidence. A rational connection between the facts found and the remedy ordered must be articulated.") (citing Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)).

This principle was the basis on which numerous courts around the country overturned a rule issued by HHS on Medicare reimbursement of malpractice expenses. The final rule relied on faulty data reflected in a single study, and was therefore ruled to be arbitrary and capricious. See, e.g., Boswell Memorial Hospital v. Heckler, 749 F.2d 788 (D.C. Cir. 1984). See Menorah Medical Ctr. v. Heckler, 768 F.2d 292, 295-96 (8th Cir. 1985) (finding that failure to respond to significant criticisms regarding adequacy of data in study and accuracy of statistics it relied on

was arbitrary and capricious). In particular, the study drew conclusions that were not adequately supported in the data, and the data itself was based on too small of a sample. Lloyd Noland Hospital and Clinic v. Heckler, 762 F.2d 1561, 1568 (11th Cir. 1985).

Similarly, in Crowley's, the Department of Transportation based a rule regulating traffic flow on the Chicago River on a study of boat traffic gathered during a major festival in Chicago when traffic was excessive. The court noted that there was no other data in the administrative record that supported the conclusions of the discredited study and the agency's position, and therefore held that the rule was arbitrary and capricious. Crowley's, 863 F. Supp. at 21-22. The case law thus indicates that an agency may not support a regulation with a report that is based on data that is unrepresentative of the relevant facts or is too limited in size or scope to be generalized beyond the data included in the study.

HHS's reliance on the OIG Report is arbitrary and capricious for the same reasons that the regulations in these cases were struck down. Like the malpractice cases, the conclusions in the OIG Report are not supported in the data and not properly generalized to all states. See Boswell, 628 F. Supp. at 1125. Like the study leading to the Chicago River regulation in Crowley's, the data in the OIG Report was gathered at inappropriate times that are unrepresentative of the problem the regulation seeks to address. See Crowley's, 863 F. Supp. at 20-21. The OIG's conclusion that the 150 percent limit should be rescinded was based on a study of state supplemental programs under a different regulatory regime. It does not analyze state experiences under the 150 percent regulation. It does not examine whether the steps taken in the 2001 UPL regulation were sufficient to address any abuses. It does not consider the impact that the changed political environment and negative press attention may have had on

states establishing new safety net payments. In short, the OIG Report is irrelevant and inaccurate because it was conducted during the wrong time period.

Moreover, the OIG Report focuses on problems in implementing UPL supplemental payments in only six states, and of those, only three involved payments to hospitals. (OIG Report at 2.). The generalization of the OIG Report's findings to the entire nation is unfairly skewed because the OIG reviewed only states where there were believed to be problems, rather than a random sample of states with supplemental payment programs. It is not reasonable for HHS to conclude that the three states selected for the OIG audits were states with typical UPL programs.

Finally, as in the malpractice and Chicago River cases, the flawed OIG report is the sole information on which HHS is relying to rescind the 150 percent limit. It is arbitrary and capricious to rely on faulty data in a single study. See, e.g., Lloyd Noland Hospital and Clinic v. Heckler, 762 F.2d 1561, 1568 (11th Cir. 1985) ("It is ... an abuse of discretion to base a regulation on faulty data.") (citation omitted); Boswell, 749 F.2d 788, 803; Crowley's, 863 F. Supp. at 21-22.

For all these reasons, HHS acted arbitrarily and capriciously in relying on the flawed OIG Report as its sole empirical support for the 2002 UPL Rule, and this Court should not let the regulation stand.

2. HHS Ignored Relevant Evidence That Was Counter to Its Predetermined Policy Choice

An agency rule is arbitrary and capricious if the agency "entirely fail[s] to consider an important aspect of [a] problem." St. James Hospital v. Heckler, 760 F.2d 1460, 1465 (7th Cir. 1985) (quotation omitted); Motor Vehicle Manufacturers Ass'n., 463 U.S. at 43.

In this case, gaps in the Agency's evidentiary basis for rulemaking are startling. Two states (Arkansas and Mississippi) had implemented programs under the 150 percent UPL, which Thomas Scully, the HHS official responsible for the Medicaid program, had praised as appropriate and legitimate. (Teeter Decl.¶ 7, Ex. 2.) The hospital associations of both states had submitted comments on the proposed rule detailing the importance of the supplemental payments to hospitals and low income patients. (Cameron letter at 2, Ex. 6; Cunningham letter, Ex. 9.) HHS asserts that up to 31 states have supplemental payment programs using the higher limit. 67 Fed. Reg. 2609. Hospitals, hospital associations and states in many of these additional states also submitted similar comment letters. (See, e.g., Comment No. 22, Letter from Gary Redding of Georgia Department of Community Health to CMS of 12/17/01 (hereinafter, "Redding letter") at 2, Ex. 25; Comment No. 62, Letter from Gregg Knaupe of Texas Hospital Association to Thomas Scully of 12/20/01, Ex. 26.) HHS does not analyze either the implemented supplemental payment programs in Arkansas and Mississippi. An analysis of the experience in these states could have helped HHS to answer the questions that the OIG Report could not regarding the effectiveness of the 2001 UPL Rule in addressing the problems identified under the pre-2001 UPL regulations.

Most of HHS's criticism of the 150 percent public hospital limit – and the only detailed criticisms – are based on the OIG Report. In response to a comment, however, HHS does state that its actions also are based on "our own review of the new State plan amendments submitted after the January 2001 rule took effect." Id. at 2608. Yet there is no analysis in the proposed or final rules of those programs.

The lack of analysis is likely due to the fact that HHS did not have adequate data to analyze the programs because the Agency did not implement the reporting requirements that

were an important feature of the 2001 UPL Rule. Instead, HHS waited until shortly before the November 23 NPRM was issued to obtain approval to begin collecting the information, and it is unclear whether any requests have yet been sent to states to submit the data. Indeed, HHS admits that the 2002 UPL Rule "is not based on the reporting requirements." 67 Fed. Reg. 2602, 2607. Yet in January of 2001, HHS had clearly concluded that without such data it could not adequately assess the impact of the 150 percent UPL:

> The purpose of this [reporting] requirement was to ensure the higher payments are appropriate and are being fully retained by hospitals. We believe the separate identification of these payments will be a necessary administrative tool to ensure the proper administration of the Medicaid program. ... We disagree with the commenters that current reporting requirements are adequate. ... Not only do we feel it is appropriate for us to collect information on provider payments, but we believe that it is necessary to ensure Federal matching dollars are appropriately expended.

66 Fed. Reg. 3158. In other words, the data otherwise at HHS's disposal was not adequate to properly assess the implementation of the 150 percent limit. In order to conduct the appropriate analysis, HHS would need to collect the data through the state reports it never requested.

Rescinding an existing rule without reviewing any relevant data as to the rule's operation or effect constitutes arbitrary and capricious action by HHS. The agency must have a reasoned basis for reversing a previously enacted rule. "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 an agency does not act in the first instance." Motor Vehicle Manufacturers, 463 U.S. at 42. Here, there was no assessment whatsoever of the actual implementation of the regulation to be rescinded.

3. HHS Failed to Consider the Substantial Evidence of Likely Harm to Safety Net Hospitals and their Patients Caused by the Regulation

In the preamble to the 2002 UPL Rule, HHS asserts conclusively that

> The payments that States are permitted to make to hospitals consistent with the revised UPL are sufficient to pay the full reasonable costs to hospitals of serving the Medicaid population, and *will assure access* to those hospitals for Medicaid beneficiaries.

67 Fed. Reg. 2608 (emphasis added). This is an extraordinary statement to make when the evidence in the record so clearly indicates the contrary, and when HHS can point to no supporting data for its conclusion. The harm to hospitals will be severe and access for Medicaid patients sharply reduced, as documented over and over again in comment letters. For HHS to conclude in this brief passage appearing in a nine-page Federal Register notice that the regulation will have no appreciable impact is patently arbitrary and capricious.

Whether the 2002 UPL Rule will permit sufficient payments to hospitals to assure continued access to those hospitals for Medicaid beneficiaries is an important aspect of the Medicaid supplemental payment regulation. The Agency's assurance that the rule will preserve continued access to Medicaid-covered health care at safety net hospitals is also a factual judgment underlying the policy choice represented by the rule, and thus must be supported by substantial evidence. Crowley's, 863 F. Supp. at 21.

Comments submitted to HHS in response to the proposed rule placed before the Secretary provide ample and detailed quantitative and qualitative evidence of the likely harmful impact on individual safety net hospitals should this regulation become effective. The letters describe likely closures of hospitals and/or units of hospitals, reduction in hospital capacity (e.g. fewer beds), closure of emergency rooms, elimination of outpatient clinics and staff layoffs. Specifically:

- The survival of several public hospitals in Arkansas would be jeopardized, including hospitals that are the sole hospitals in entire counties, thus exacerbating a crisis in rural health care in that State, where 25 percent of the counties already lack even one hospital. (Cunningham letter at 1, Ex. 9.)

- Los Angeles County hospitals (the second largest public hospital system in the country) would be forced to reduce their capacity by approximately 197,465 inpatient

days of care, 378,055 ambulatory care visits and 114,681 emergency room visits annually. (Comment No. 31, Letter from Andrew L. Stern of Service Employees International Union to Thomas Scully of 12/20/01 (hereinafter, "Stern letter") at 3, Ex. 27.)

- The Oregon Health and Science University's mission of serving the poor would be jeopardized and its financial viability devastated. (Comment No. 57, Letter from Aaron Crane of Oregon Health & Science University Hospitals and Clinics to Thomas Scully of 12/14/01 (hereinafter, "Crane letter") at 2, Ex. 28.)

- San Francisco General Hospital Medical Center would lose: 22 acute care beds, 8,000 patient days of care, the services of neurosurgeons and other physicians and the ability to maintain and upgrade critical equipment. The loss of funding would require it to double the number of times it must divert ambulances away from its emergency room, jeopardizing the entire emergency care system in San Francisco. (Katz letter at 2, Ex. 8.)

- Kentucky safety net hospitals' ability to continue to serve the state's growing Medicaid population along with growing indigent care will be threatened. (Galvagni letter at 3, Ex. 13.)

- Highland County Hospital could be forced to close its emergency department and trauma center. (Martin letter at 9, Ex. 12.)

- Kern Medical Center may not be able to seek or maintain a trauma center designation. (Id. at 9-10, Ex. 12.)

- Natividad predicts that the new regulation will reduce its capacity to serve patients by 100,000 visits per year in its Family Practice, Pediatric, Women's Health and Specialty Services. (Comment No. 53, Letter from David R. Small of the Natividad Medical Center to Thomas Scully of CMS of 12/18/01 (hereinafter, "Small letter"), at 1, Ex. 29.)

Significantly, many commenters stressed that States use intertwined funding streams from various sources, including local governments and providers, to finance their safety net health care systems. Therefore, a reduction in supplemental payments pursuant to the reduction of the 150 percent UPL would cause significant harm not just to non-State government-owned and operated hospitals, but to all safety net facilities.

- In Montana, instead of support for 32 small rural hospitals, only three hospitals will receive support. (Comment No. 58, Letter from the Honorable Judy Martz, Governor of Montana to Thomas Scully of 12/21/01, at 2, Ex. 30.)

- In Georgia, the anticipated reduction in supplemental payments could jeopardize funding for up to 1,232 mentally retarded individuals and 4,000 elderly patients. Redding letter at 2, Ex. 25.)

- In Florida, elimination of the higher percent UPL would force the State to reduce reimbursement to all providers, harming not just the non-State government-owned or operated hospitals, but 70 public and private safety net hospitals statewide. (Comment No. 46, Letter from John Hillenmeyer of Florida Statutory Teaching Hospital Council to Thomas Scully of 12/20/01, at 2, Ex. 31.)

Finally, many commenters submitted for the Agency's consideration precise dollar amounts reflecting the likely negative impact on hospitals of reducing UPL payments from 150 percent to 100 percent.

- Forty-one Arkansas hospitals would lose $20 million annually. (Cunningham letter at 1, Ex. 9; Cameron letter at 2, Ex. 6.)

- In California, the Alameda County hospital system would lose $14 to $15 million per budget year; the Santa Clara Valley Medical Center would lose $28 million per year. (Comment No.5, Letter from Fred J. Zierten to Secretary Thompson of HHS, at 1, Ex. 32.).The University of California academic medical centers would lose $48 million per year. (Comment No. 25, Letter from William H. Gurtner of the University of California to CMS of 12/19/01, at 3, Ex. 33.) The Los Angeles County Public Health System would lose $125 million per year (Comment No. 27, Letter from Tyrone Freeman of SEIU to Thomas Scully of 12/20/01, at 1, Ex. 34.) California children's hospitals would lose $25 to $30 million per year. (Comment No. 30, Letter from Grantland Johnson of the State of California Health and Human Services Agency to CMS of 12/20/01, at 3, Ex. 35.) The San Francisco General Hospital Medical Center would lose $10 million per year. (Katz letter at 1, Ex. 8.)

- Missouri hospitals would lose $37 million that would have benefited 37 non-State government-owned hospitals. (Comment No. 13, Letter from Gregory A. Vadner of the Missouri Department of Social Services to CMS of 12/17/01, at 1, Ex. 36.)

- The Hennepin County Medical Center in Minnesota would lose $8 million per year. (Comment No. 23, Letter from Mike Opat, Chair of the Board of Hennepin County Commissioners to Thomas Scully of 12/20/01, at 1, Ex. 37.)

- Florida's Jackson Memorial Hospital would lose $34 million per year. (Stern letter at 1, Ex. 25.)

- The Oregon Health and Science University Hospital would lose over $12 million per year. (Crane letter at 2, Ex. 28.)

- Finally, the University Hospital of the University of Medicine and Dentistry of New Jersey would lose more than $59 million annually. (Comment No. 61, Letter from Deborah C. Bradley of the State of New Jersey Department of Human Services to Thomas Scully of 12/18/01, at 1, Ex. 38.)

The rulemaking record thus includes voluminous evidence supplied by commenters that this final rule will indeed gravely jeopardize continued access to care at safety net hospitals for Medicaid beneficiaries. HHS points to no evidence to suggest that these safety net hospitals will be able to absorb such severe financial losses and still ensure access to care for Medicaid patients. By asserting the contrary with no analysis or support, HHS has both failed to consider relevant evidence of likely harm to hospitals, an important aspect of the problem addressed in the regulation, and also failed to support its factual judgments with substantial evidence. Therefore, HHS has acted arbitrarily and capriciously in issuing this final rule. See St. James Hospital, 760 F.2d at 1465; see also Crowley's, 863 F. Supp. at 21.

4. HHS Failed to Articulate a Rational Connection Between the Policy Decision Contained in the January 2002 UPL Rule and Claimed Mitigating Factors

In dismissing the impact on hospitals, HHS also points to mitigating factors that it assumes supports its position. These factors include the availability of Disproportionate Share Hospital payments, the availability of transition periods under the 2001 UPL Rule, and the OIG Report's conclusions. 67 Fed. Reg. 2609. None of these factors mitigates the impact detailed in the comments and described above, and they therefore provide no rational basis to support HHS's conclusion that the regulation will not impact safety net hospitals and their patients.

Courts reviewing whether an agency has acted in an arbitrary and capricious manner must "determine whether the agency has articulated a rational connection between its factual

judgment and its ultimate policy choice, and whether the underlying factual judgments are supported by substantial evidence." Crowley's, 863 F. Supp. at 21. "[A]gencies must make findings that support their decisions, and those findings must, in turn, be supported by substantial evidence. A rational connection between the facts found and the remedy ordered must be articulated." City of Rochester v. U.S. EPA, 496 F. Supp. 751 (D. Minn. 1980) (citing Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)). Because the claimed mitigating factors are not supported by substantial evidence and the agency has not articulated a rational connection between these mitigating factors and its policy decision, HHS's 2002 UPL Rule is arbitrary and capricious.

HHS states that its rationale for the change contained in the 2002 UPL Rule is, in part, the fact that "[m]any of the public safety net hospitals affected by this rule qualify as DSH hospitals" and that recent legislation allows states the ability to make higher Medicaid DSH payments to public hospitals. 67 Fed. Reg. 2603. HHS repeats this rationale as a mitigating factor in its regulatory impact analysis. Id. at 2609. Although it is true that many hospitals impacted by this rule qualify for DSH payments, the existence of the DSH program does not and cannot serve as a mitigating factor for the 2002 UPL Rule. First, many small hospitals, including plaintiff Ashley, are not eligible for DSH payments because they do not have two obstetricians on staff. 42 U.S.C. § 1396r-4(d); (Sword Decl. ¶ 8, Ex. 22.) Second, the magnitude of DSH payments in some states such as Arkansas are severely limited by federal law. 42 U.S.C. § 1396r-4(f). Even if Ashley qualified for DSH, therefore, it would not be able to obtain significant support through it given the vast statewide need. HHS's mitigating factor for Arkansas and hospitals with similarly meager DSH allotments provides little comfort.

Third, even for those hospitals that do receive substantial DSH payments, HHS's contention that the availability of DSH will mitigate the harm is incorrect. The severe harm described in the comment letters was harm that would occur *even with full DSH payments.* California, for example, has a substantial DSH allotment which is fully utilized in payments to hospitals. These payments alone, however, are insufficient to meet the needs of safety net hospitals, and therefore the supplemental payments that are scheduled to be eliminated under the 2002 UPL Rule are critical. The existence of the DSH program does not mitigate the harm of the 2002 UPL Rule documented in the comments for California hospitals and other hospitals receiving significant DSH payments.

Finally, the fact that recent legislation increases hospital-specific DSH limits for a limited two-year time period also is not a rational mitigating factor. Despite the increase in the limit, states are still subject to state-by-state DSH allotments, so that an increase in the hospital-specific caps does not translate into higher DSH payments unless and until DSH allotments are increased. Moreover, California hospitals, which demonstrated extremely severe harm, are already subject to the higher hospital-specific DSH limit and therefore will not benefit from the recent legislation. (42 U.S.C. § 1396r-4; Pub. L. No. 105-33, § 4721 (e), 111 Stat. 514 (1997), as amended by Pub. L. No. 106-113, § 1000(a)(6), 113 Stat. 1501A-396 (1999)).

HHS also claims that the harm is mitigated because states "may qualify for one of the transition periods" contained in the January 2001 regulation. 67 Fed. Reg. 2609. Again, there is no rational basis for this statement. First, while eight states qualify for a transition period, most states, including Arkansas, are not eligible for a transition period.

Moreover, even those states that are subject to a transition are harmed. Those states that do qualify for transitions were made eligible pursuant to the January 2001 regulation. California,

for example, is subject to an eight year transition. But the 2002 UPL Rule has the effect of making that transition much more severe, so that supplemental payments to hospitals will phase down to a level that is $300 million less per year than it would have been in the absence of the latest rulemaking. As a result, the cuts in supplemental payments to California hospitals will be much steeper each year of the transition than under the 2001 UPL Rule. (Martin Decl. ¶ 15, Ex. 5; Maddox Decl. ¶ 15, Ex. 3; Dauner Decl. ¶ 12, Ex.4). Given the fact that the transition periods already existed under the 2001 UPL Rule, they cannot serve as a mitigating factor for the 2002 UPL Rule, which dramatically increased the amount of the required cutbacks.

Finally, HHS points to an assertion in the flawed OIG Report that the 150 percent UPL has not been adequately supported through an analysis of hospitals' financial operations. 67 Fed. Reg. 2609. But while the OIG Report contends that the need for the 150 percent UPL has not been adequately supported, it does not point to any valid evidence that the 150 percent UPL is *not* needed.

The OIG Report's statement about the lack of data is precisely the problem with the entire rulemaking process: HHS has not collected any relevant data and in the absence of such data there simply is no rational basis for eliminating the 150 percent limit. In establishing that limit in 2001, HHS was *reducing* state flexibility to make payments to public hospitals as compared to the previous rule. In cutting back on that flexibility, HHS expressed explicit concern about the impact of that reduction on public hospitals. 66 Fed. Reg. 3155. Acknowledging the lack of adequate data to set the public hospital UPL at precisely the right level, HHS opted to set it at the 150 percent level, which appeared to strike an appropriate balance between promoting fiscal integrity and protecting the health care safety net. Id. HHS was overtly reluctant to cut any deeper than that. In the 2002 UPL Rule, however, HHS points to

the lack of data as a "mitigating factor" reducing the harm. Again, there simply is no rational basis for this contention.

5. HHS Defied Congressional Intent in Issuing the January 2002 UPL Rule.

Agency rulemaking is valid only insomuch as it implements Congress' intent. Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 842 (1984) ("When a court reviews an agency's construction of a statute … [f]irst, always, is the question whether Congress has directly spoken to the precise question at issue.")

In the context of this rulemaking, Congress expressed explicit support for the compromise represented by the January 2001 Rule and directed HHS not to rescind it until "after the administration has had an opportunity to assess the implementation of the new regulations and only in consultation with the States and their Medicaid programs, as well as the other stakeholders." S. Rep. No. 107-84 at page 215 (2001) (language with which the full Congress "strongly concurred,") H.R. Conf. Rep. 107-342, 103 (2001).

The fact that Congress included this language in the annual appropriations report that provided administrative funding to HHS to carry out its duties in overseeing the Medicaid program is significant. Even more to the point, the language was included in the section of that report entitled "Centers for Medicare and Medicaid Services Program Management" in a subsection labeled "Federal administration." In appropriating administrative funding for CMS, Congress was telling CMS how it did and did not want the Agency to spend that money. Congress *did* want CMS to conduct a more thorough analysis of states' experiences under the 150 percent limit. It *did not* want CMS to rush the then-proposed regulation to premature implementation. Congress was concerned about the very same violations of basic procedural protections that led Plaintiffs to file this Complaint.

Standing on their own, the flaws in HHS's rulemaking process constitute arbitrary and capricious action in violation of the APA and Congress' intent in enacting the APA. But here the violation of congressional will is even more pointed, because Congress weighed in during the rulemaking process to warn HHS to proceed with due deliberation and care. HHS ignored both the fundamental precepts of the APA and Congress' direct instructions to evaluate the impact of the regulation. The disregard of explicit congressional will is further evidence that the 2002 UPL Rule is arbitrary and capricious.

B. The 2002 UPL Rule Fails to Comply With the Requirement of a Concise Statement of Basis and Purpose Mandated by the Administrative Procedure Act

All final rules must include a "concise general statement of their basis and purpose." 5 U.S.C. § 553(c). "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 (D.D.C. 1994) (quoting U.S. v. Nova Scotia Food Prods., Corp., 568 F.2d 240, 252 (2d Cir. 1977) and Action on Smoking & Health v. Civil Aeronautics Bd., 699 F.2d 1209, 1216 (D.C. Cir. 1983) (other citations omitted)).

A court reviewing a Basis and Purpose Statement must be able to "assure itself that all relevant factors have been considered by the agency." Home Box Office, Inc. v. F.C.C. 567 F.2d 9, 36 (D.C. Cir. 1977). "[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). In promulgating the 2002 UPL Rule, HHS has failed to meet this standard.

1. HHS Failed to Respond to Significant Comments on the Deficiencies of the OIG Report, or Explain How those Comments Affected the New Regulation

HHS's reliance on the flawed OIG Report as the sole empirical support for the 2002 regulation is arbitrary and capricious, as explained above. But in addition, HHS's failure to respond to the many comments pointing out those flaws is grounds for holding the Basis and Purpose Statement insufficient as a matter of law. In the Medicare Malpractice Rule cases, HHS's reliance on an inaccurate study was held arbitrary and capricious not only because of the flaws in the study, but also because the final rule's Basis and Purpose Statement did not reflect commenters' extensive criticisms of the study. Menorah Medical Ctr. v. Heckler, 768 F.2d 292, 296 n.7 (8th Cir. 1985) ("The failure to respond to significant criticisms of the rule ... violates the requirement of 5 U.S.C. § 553, that the agency supply an adequate basis-and-purpose statement for its rules.") (citation omitted); Boswell, 628 F. Supp. at 1125.

Plaintiffs NAPH, AHA, CAPH and several other commenters objected to HHS's reliance on the OIG Report to support the November 2001 proposed rule for all of the reasons set forth above. (See e.g., Comment No. 10, Letter from O. David Bevins of Kentucky River Medical Center to CMS of 12/05/01, at 1, Ex. 39; Redding letter at 2-3, Ex. 25; Stern Letter at 2, Ex. 27; Comment No. 41, Letter from Leighton Ku of Center on Budget and Policy Priorities to CMS of 12/20/01, at 2-3, Ex. 40; Comment No. 59, Letter from Edward A. Stolzenberg of Westchester Medical Center to Thomas Scully of 12/20/01 at 2, Ex. 41; and Galvagni letter at 2, Ex. 13.). The 2002 UPL Rule's Basis and Purpose Statement barely acknowledged these concerns:

> We received comments on the impact analysis stating that we did not adequately consider the impact on these entities and that in fact monies paid under the 150

> percent UPL were in fact retained by these facilities. *The commenters also noted that the OIG did not specifically look at the 150 percent UPL.* In addition, commenters noted that CMS did not effectively analyze the effects of the 150 percent UPL before issuing this new rule.

67 Fed. Reg. 2602, 2609. This one sentence could not possibly convey the multiple and varied criticisms leveled against the OIG Report and discussed above.

Nevertheless, HHS's response to the OIG Report critics is the conclusory (and chronologically convoluted) statement that "[w]e believe that the OIG Reports *confirmed* our *subsequent* analysis that States did not use these excess funds as part of the proper State Federal match.…" Id. (emphasis added). The commenters were not challenging the OIG Report's specific audit findings. They were challenging the relevance of those conclusions to the elimination of the 150 percent limit. HHS overlooked the major thrust of the criticisms of the OIG Report, reiterated in numerous comments, and instead maintained that the OIG Report is sufficient evidence in and of itself.

Because the Agency did not accurately reflect these significant comments challenging the only empirical evidence supporting the proposed rule, the Basis and Purpose Statement is arbitrary and capricious, and therefore deficient under the APA. See Menorah Medical Ctr., 768 F.2d at 296 n.7; Boswell, 749 F.2d at 797.

2. HHS Failed to Respond to Significant Comments Predicting Severe Harm to Hospitals

Similarly, HHS's lack of response to substantial comments detailing the significant harm the regulation would impose on safety net hospitals and their patients renders the Statement of Basis and Purpose legally insufficient. The D.C. Circuit has explained that "[t]he statement of basis and purpose must address, *with some precision*, the major comments received and, of course, explain why the old regulation is no longer desirable." Action on Smoking, 699 F.2d at 1216 (quoting Rodway v. U.S. Dep't of Agriculture, 514 F.2d 809, 817 (D.C. Cir. 1975)

(emphasis added). In Crowley's, the court identified three aspects of the Basis and Purpose Statement in the regulation at issue in that case that rendered it legally inadequate: (1) the agency's discussion of the major comments received was descriptive, rather than explanatory; (2) the Statement provided the agency's reasoning in conclusory fashion; and (3) the agency never explained how the comments received influenced the final rule. Crowley's, 863 F. Supp. at 20-21.

The Basis and Purpose Statement in the January 18, 2002 final rule includes only one paragraph raising in very broad terms the likely harm to hospitals from the proposed rule. 67 Fed. Reg. 2604. That paragraph lists some commenters' concerns about the effect of the rule on the health care safety net in certain unnamed States, on the likelihood that the rule would cause hospitals to cut services or close altogether, on diminished access to health care for the uninsured, a predicted health care crisis in one state, and concerns about the impact of the rule on children's hospitals.

The Agency's response to the comments is the following, in pertinent part:

> Although we previously believed a higher UPL was necessary to ensure the availability of safety net facilities, we have concluded that a 100 percent UPL will achieve that purpose because it is adequate to pay hospitals their reasonable costs of serving Medicaid patients.

Id. HHS goes on to repeat the same factors mitigating the harm discussed above (the availability of DSH and transition periods, as well as the OIG Report's conclusions).

As the court in Action on Smoking concluded,

> On its face, this explanation is palpably inadequate. The agency offers no reasoning to support its conclusion ... The APA guarantees the public an opportunity to comment on proposed rules. That opportunity "is meaningless unless the agency responds to significant points raised by the public."

Action on Smoking, 699 F.2d at 1217 (quoting Alabama Power Co. v. Costle, 636 F.2d 323, 384 (D.C. Cir. 1979)). As in Crowley's, the discussion of harm to hospitals and patients here is

descriptive not explanatory, it is conclusory and it does not explain how the comments influenced the final rule. The mitigating factors relied on to discredit predictions of harm, as demonstrated above, are illusory.

HHS's bold dismissal of the overwhelming comments that it had explicitly invited on hospital impact cannot be the foundation of a legitimate Basis and Purpose Statement, particularly when such impact goes to the very core of the effectiveness of the proposed regulation. (See 66 Fed. Reg. 58696) Because of the failure of the Basis and Purpose Statement to address the serious harm detailed in the comments, this Court should rule that the Statement is insufficient under the APA. See Action on Smoking, 699 F.2d at 1216. See also Crowley's, 863 F. Supp. at 20-21.

3. HHS Ignored Significant Comments Regarding the Unequivocal Expression of Congressional Intent that the 2001 UPL Rule Remain in Force Until It Has Been Properly Assessed

In their comment letters, Plaintiffs NAPH and AHA both quoted the directive from Congress, issued during the course of the rulemaking process, for HHS to slow down and assess the impact of the 150 percent regulation. The congressional intent was therefore placed squarely in front of the Agency, yet it failed even to mention these comments let alone respond to them. Congress' contemporaneous views on a rulemaking process already in progress must be considered a "major comment" and addressed in the Basis and Purpose Statement. HHS failed to do so, and the Statement is therefore deficient under the APA. Boswell, 749 F.2d at 794.

4. HHS Failed to Review All of the Timely Comments, and Failed to Accurately Characterize Many Significant Comments

HHS's apparent careless misplacement of at least three serious comment letters (Hansen Decl. ¶ 6, Ex. 16; Maddox Decl. ¶ 18, Ex. 3; McAndrews Decl.¶ 10, Ex. 15.) is further evidence of its failure to adequately respond to comments in its Basis and Purpose Statement. Moreover,

the characterization of the comments that *were* considered blatantly misrepresented the relative weight of the comments. HHS states that "[s]everal commenters expressed support for removing the 150 percent UPL," then "[s]everal commenters urged us to retain the 150 percent UPL." 67 Fed. Reg. 2604. In fact, the official rulemaking record includes 215 comment letters opposing elimination of the 150 percent UPL, and *only two* supporting its elimination. This mischaracterization of the content of the comment letters misleads the public and the reviewing court as to the nature of the evidence before the Agency – which is the reason for the requirement of a Basis and Purpose Statement in the first place.

Both the failure to consider timely submitted comments and the misrepresentation of the letters that were considered undermine the intent of the Basis and Purpose Statement and constitute arbitrary and capricious action in violation of the APA. HHS has failed to preserve in the Basis and Purpose Statement a record that will permit a reviewing court to "see the objections and why the agency reacted to them as it did." See Lloyd Noland, 762 F.2d at 1566.[4]

C. The 2002 UPL Rule Violates the Regulatory Flexibility Act and the Social Security Act

The Regulatory Flexibility Act ("RFA") requires agencies to assess the negative impact that a rule will have on small entities. 5 U.S.C. § 603(a). An agency must include an initial regulatory flexibility analysis in its proposed rule, and, if it determines that the rule will have a negative impact on small entities, it must include a Final Regulatory Flexibility Analysis (FRFA) in its final rule. 5 U.S.C. §§ 603, 604. Similarly, the Social Security Act provides that when

[4] The Agency's willful mischaracterization of the rulemaking record should not be condoned by this Court. See Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525, 530 (D.C. Cir. 1982) ("To allow an agency to play hunt the peanut with technical information, hiding or *disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport.*" (emphasis added)). See also Greater Boston Television Corp. v. FCC., 444 F.2d 841, 851 (D.C. Cir. 1971) ("Its supervisory function calls on the court to intervene not merely in case of procedural inadequacies ... but more broadly if the court becomes aware, especially from a combination of danger signals, that the agency has not really taken a 'hard look' at the salient problems." (emphasis added)).

HHS publishes a proposed rule under the Medicaid Statute that may have a significant impact on the operations of a substantial number of small rural hospitals, HHS must prepare a regulatory impact analysis. 42 U.S.C. § 1302(b)(1).

The FRFA, as set forth in 5 U.S.C. §604(a), must include, among other information,

> a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; … and a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes ….

National Ass'n of Psychiatric Health Sys., 120 F. Supp. 2d 33, 42 (D.D.C. 2000).

In the present case, HHS concedes in the rulemaking record that "[f]or the purposes of the RFA, all hospitals are considered to be small entities." 67 Fed. Reg. 2609. In its required analysis of the impact on small entities and rural hospitals, the Agency assesses only factors that allegedly will mitigate the harm to hospitals – not the harm itself. HHS did not obtain or analyze any reliable data in reaching its conclusion, and did not assess the detailed comments submitted by Plaintiffs and others concerning the degree of harm which the proposed regulation would impose.

In promulgating the 2002 UPL Rule, HHS stated that the change to be effected by the rule may "potentially have a significant impact on small entities, including rural hospitals." 67 Fed. Reg. 2609. The Agency concluded that the rule could have a significant impact on as many as 1,275 non-state government-owned or operated hospitals. Id. HHS's failure to substantively assess the impact on small entities and rural hospitals, which it acknowledges may be "significant," constitutes a violation of the RFA and the Social Security Act.

D. The Effective Date of the 2002 UPL Rule Fails to Comply with the Requirements of the Congressional Review Act

The Congressional Review Act ("CRA"), 5 U.S.C. § 801 *et seq*. was enacted in 1996 in order to ensure that Congress has sufficient time to review and consider major regulations. According to the CRA, a federal agency must submit a report including a copy of the rule and other information to each house of Congress and to the Comptroller General before a rule can be effective. 5 U.S.C. § 801(a)(1)(A). With regard to effective dates, the CRA provides that major rules such as the 2002 UPL Rule:

> shall take effect on the *latest of* –
>
> > (A) 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, if so published.

5 U.S.C. § 801(a)(3) (emphasis added).

The 2002 UPL Rule was published on January 18, 2002, with an effective date of March 19, 2002. The Congressional Record for February 27, 2002 reports that a letter from HHS transmitting the 2002 UPL Rule was received by the House of Representatives on February 20, 2002. 148 Cong. Rec. H633 (daily ed. Feb. 27, 2002) (No record of Senate receipt of the transmittal has yet been reported.) By the plain language of the CRA, therefore, the rule cannot be effective until at least mid-April, 2002 at the earliest, a full month later than HHS intends.

The Comptroller General, in its February 15, 2002 report to Congress required by the CRA, informed Congress and the Agency that the March 19 implementation date for the 2002 UPL Rule is impermissible due to the delay in transmitting the report to Congress.[5] A copy of this notice was sent to HHS. Nevertheless, to date HHS has failed to take any corrective action and has continued to move towards implementing the regulation on March 19, 2002. If the

agency does not act promptly to revise the implementation date in conformance with the requirements of the CRA, this Court should enjoin the March 19, 2002 effective date pursuant to the CRA.

Plaintiffs acknowledge that 5 U.S.C. § 805 limits judicial review of violations of the CRA. Legislative pronouncements concerning the statute make clear that this section was not intended to preclude a court from concluding that a regulation was not legally effective based on failure to comply with the applicable time deadlines:

> 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 (daily ed. Apr. 18, 1996) (Statement for the record by Sens. Nickles, Reid, and Stevens); see 142 Cong. Rec. E577 (daily ed. Apr. 19, 1996) (submission for the record by Rep. Hyde). See also Morton Rosenberg, Whatever Happened to Congressional Review of Agency Rulemaking?: A Brief Overview, Assessment and Proposal for Reform, 51 Admin. L. Rev. 1051, 1070-74 (1999) ("A reviewing court construing the language of the congressional review provision, the structure of the legislation, and its legislative history, is therefore likely to hold that a court is not precluded from preventing an agency from enforcing a covered rule that was not reported to Congress in compliance with the CRA.").

II. Plaintiffs Will Suffer Irreparable Harm if the Injunction is Not Issued

Unless this Court enters an injunction preventing implementation of the January 2002 Rule, Plaintiffs Ashley, Delta, and Alameda, along with the members of Plaintiffs, AAMC, AHA, CACH, N.A.C..H. and NAPH and the hospitals that have submitted declarations in

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[5] Letter from Kathleen E. Wannisky, United States General Accounting Office, to the Honorable Max Baucus, the Honorable Chuck Grassley, the Honorable W.J. "Billy" Tauzin, and the Honorable John Dingell, GAO-02-421R, B-289880 (Feb. 15, 2002) (available at http://www.gao.gov/decisions/majrule/d02421r.pdf).

support of this action – as well as the low-income Medicaid and uninsured patients these hospitals serve - will suffer permanent, irreparable harm.

In Arkansas, safety net hospitals were finally beginning to receive desperately needed supplemental Medicaid funding pursuant to the 150 percent UPL under a State Plan that was approved - and publicly endorsed - by CMS. (Teeter Decl. ¶ 8; Ex.2 ; Meyer Decl. ¶ 11; Ex. 21; Sword Decl. ¶ 11, Ex. 22.) Loss of those funds will be devastating, as the following examples of harm set forth in detail in attached declarations demonstrate:

- Ashley is the only hospital of any kind in its county, and provides medical attention – including the only available prenatal care to Medicaid beneficiaries – with a skeletal physician staff and operating deficits due to its safety net mission. The hospital must choose which of its limited services to eliminate in order to ensure its survival; the best option from a financial standpoint is the money-losing ob-gyn clinic, but that would force Medicaid patients to travel 45 minutes to an hour away for those critical services. (Sword Decl. ¶¶ 4, 7, 14, Ex. 22.)

- Delta is the only full service hospital in Desha County, Arkansas, and the only hospital within a 35 mile radius. Already financially-strapped, Delta will be required to cut either obstetric services, nuclear medicine, or inpatient or outpatient surgical services. Each of these options would require patients to travel up to 45 miles for substitute services, resulting in a significant impact on the health of our patients. Delta's ability to recruit physicians, already diminished, will be further harmed. (Meyer Decl. ¶¶ 5, 13, Ex. 21.)

Similar statements of irreparable harm are included in the attached declarations from Plaintiff and non-Plaintiff hospitals and associations. From the streets of New York City to the farms of Monterey County, California, the declarations attest to sharp reductions in services for poor people with very few other options should this regulation become effective. For example:

- Alameda already faces a day-to-day struggle for survival, due to factors beyond its control. Facing impending reductions in supplemental payments once California's transition period begins next year, Alameda must begin now to take steps to make up the resultant budgetary shortfall. In order to continue operations, it must eliminate entire departments providing outpatient services, primary and preventive care, and acute psychiatric services, and severely cut back those services it can salvage. (K. Cohen Decl." ¶¶ 10-13, Ex. 24.)

- New York City Health and Hospitals Corporation is already reeling from the routine challenges of serving as the public safety net health care system for New York's poor and underserved residents, and the extraordinary and unexpected challenges arising from the September 11th attacks. The loss of supplemental Medicaid funding could mean a significant reduction in its neighborhood based clinics, thereby continuing to challenge HHC's ability to serve low-income New Yorkers. (Chu Decl. ¶¶ 7, 12-14, Ex. 18.)

- San Francisco General Hospital Medical Center, the cornerstone of emergency medical services in the Bay area, will be forced to close at least 22 acute care beds, meaning 8,000 less days of inpatient care per year. Decreased capacity for all services will exacerbate its overburdened Emergency Department, doubling diversions and wreaking havoc on the entire system of emergency care in San Francisco. (Katz Decl. ¶ 14, Ex. 20.)

- Natividad Medical Center in Monterey County, California, already preparing to downsize its facilities based upon the cuts imposed by the January 2001 regulation, is now scrambling to determine how to make up for the additional losses associated with the 2002 UPL Rule. Its options are not attractive, including reducing its teaching program that provides a significant source of doctors available to immigrant and other low-income residents of this agricultural community, reducing or eliminating community clinics, closing inpatient beds and laying off up to 40 percent of its employees. Given the lack of other hospital providers within the region and the continuing increase of demand for services experienced by Natividad over the last several years, cutbacks of this magnitude cannot be implemented overnight. Thus, despite the one-year delay until California's transition period begins, Natividad must take steps now to begin to implement cutbacks. Such drastic moves will continue to harm the community for years to come. (Small Decl. ¶¶ 9-12, Ex. 23.)

- Hennepin County Medical Center, the only public hospital in the seven-county Minneapolis metropolitan area and the most important safety net hospital in Minnesota, operates at full capacity practically full time. Patients will now endure longer delays before they can receive medical attention, and the hospital will be left without funds for critically-needed equipment and facility replacement. (Opat Decl. ¶¶ 4-5, 14, Ex. 37.)

- AAMC estimates that some of its teaching hospital members may not survive at all, and a number may be forced to slash essential services to low-income and uninsured patients. (Cohen Decl. ¶ 11, Ex. 14.)

- AHA predicts that many of its members will be forced to endure deep cuts in services, and will be unable to deliver quality health care to their Medicaid and other low-income patients. (Declaration of Melinda Reid Hatton, Vice President, AHA, ¶ 11.)

- CAPH estimates that critical health services in California County will be significantly curtailed, and at least one public hospital may close. (Martin Decl. ¶ 10, Ex. 5.)

- CCHA warns that its children's hospitals will lose the funding to provide more than 35,000 inpatient days of care, or 800,000 clinic visits per year. (Maddox Decl. ¶ 20, Ex. 3.)

- N.A.C.H. states that many children's hospitals nationwide will be forced to make deep cuts in essential services, and may not survive at all. (McAndrews Decl. ¶ 12, Ex. 15.)

- NAPH predicts that some safety net hospitals will collapse under the constraints of these cuts. (Burch Decl. ¶ 21, Ex. 1.)

The irreparable harm described above by no means is exhaustive. Each safety net hospital that receives monies under the current rule faces a loss of funds. Given the precarious nature of safety net hospital financing, it is certain that overturning the current 150 percent UPL rule will have significant adverse consequences on an already overburdened health care system, at a time when rising unemployment, an economic downturn and an increase in the number of uninsured means that safety net hospitals are more desperately needed now than ever.

Moreover, the negative impact on many Medicaid recipients and low-income communities will be long-term. Patients who lose access to timely medical care may never recover. Community-based health care networks and outpatient facilities, once dismantled, are not easily or immediately rebuilt. This is especially true in poor, rural areas like Ashley and Desha Counties in Arkansas, which are already struggling to recruit medical staffs. The harm from this rule will be immediate and for many individuals and communities, permanent, even if the 2002 UPL Rule is reversed in the future.

Courts have held that eliminating the ability to provide medical care to such a significant degree constitutes irreparable harm. See Beverly Enterprises v. Mathews, 432 F. Supp. 1073,

1079 (D.D.C. 1976) (finding nursing home owner would suffer irreparable harm if injunctive relief did not restrain HHS from suspending Medicare reimbursements, stating that "it is clear that Plaintiff's ability to render effective medical services to those in need would be significantly hampered by the suspension of regular payments to which plaintiff would otherwise be entitled"). See also Columbia Hosp. For Women Foundation, Inc. v. Bank of Tokyo-Mitsubishi Ltd., 15 F. Supp. 2d 1, 5 (D.D.C. 1997) (finding that the hospital's argument that it would have to stop taking patients without injunctive relief constituted irreparable injury, although denying the hospital's request for injunctive relief based on the balance of harms). This court should also find that Plaintiff hospitals and the members of Plaintiff associations would face irreparable harm from the 2002 UPL Rule.

III. The Balance of Harms Tips Strongly in Favor of Plaintiffs

The balance of harms in this case strongly favors Plaintiffs. As described above, the Hospital Plaintiffs, all of the safety net hospitals represented by Association Plaintiffs in this case, and their low-income Medicaid and uninsured patients will suffer immediate, irreparable harm should the Court permit the 2002 UPL Rule to go into effect. By contrast, HHS will not suffer substantial harm if this Court preserves the status quo by granting this motion.

An order of this Court finding that the 2002 UPL Rule is not valid and indirectly requiring expenditure of additional funds by the federal government does not constitute the type of harm that is to be balanced against Plaintiffs' irreparable harm. By ordering HHS to comply with the 2001 UPL Rule as the last duly-enacted rule governing Medicaid upper payment limits, this Court would be ordering nothing more than for HHS to abide by the law. Any financial obligation incurred by the federal government as a result of its compliance with the law is not "harm" to be balanced against the harm to the Plaintiffs under the preliminary injunction

standard, and cannot justify imposition of irreparable harm to safety net hospitals and their needy patients described above. As the Fourth Circuit noted in affirming a preliminary injunction issued to redress deficiencies in administration of a state foster care program by city and state officials,

> [d]efendants' real harm is the expenditure of money. Admittedly the supply of money is finite, but balanced against that is the emotional, psychological and physical damage to children .... [W]e see no basis on which to fault the district court on how it balanced the equities [in concluding] that irreparable damage to plaintiffs ... outweighed the injury to defendants if relief was granted.

L.J. v. Massinga, 838 F.2d 118, 121-22 (4th Cir. 1987), abrogated on unrelated grounds by Suter v. Artist M., 503 U.S. 347 (1992). See also Gorrie v. Heckler, 606 F. Supp. 368, 374 (D. Minn. 1985) (granting preliminary injunction having the effect of increasing payments under the Aid to Families with Dependent Children program, noting that "public interest in preserving the family structure outweighs the public concern for saving the indeterminate amount of money at issue here.")

IV. Issuance of an Injunction is Plainly in the Public Interest

The public interest supports entry of an injunction prohibiting implementation of the 2002 UPL Rule. Protecting the health of the nation's indigent patients and preserving the fiscal viability of the hospitals which serve them defines the public interest in this case. See Beverly Enterprises v. Mathews, 432 F. Supp. 1073, 1079 (D.D.C. 1976) (pointing to the Medicare statutory and regulatory scheme that requires providers of healthcare services to be reimbursed at least monthly, stating that "[t]hus, both Congress and the Secretary have recognized ... the compelling public interest in providing timely and uninterrupted health care funding").

V. The Court Should Exercise Its Discretion to Waive a Security Bond

Under Rule 65(c), of the Federal Rules of Civil Procedure, this Court has authority to waive the posting of a bond in connection with the issuance of a preliminary injunction or temporary restraining order. Waiver of a bond is particularly appropriate in a case that is brought in the public interest. See, e.g., Bass v. Richardson, 338 F. Supp. 478, 491 (S.D.N.Y. 1971) (waiving the bond requirement in case where plaintiffs sued to correct abuses in a national health program that Congress intended to be vigorously and properly administered).

This case, brought in the public interest to protect access to essential healthcare services for the nation's low-income populations, fully justifies waiver of a bond under Rule 65(c). The appropriateness of such a waiver in a similar case was made abundantly clear by the Court of Appeals for the Third Circuit:

> In this case, Sacred Heart [Hospital] has sued to enforce the rights granted to it under the federal Medicaid statute, and in so doing has pursued a course of litigation clearly in the public interest, i.e., it seeks to preserve its role as a community hospital serving a disproportionate share of low income patients.

Temple University v. White, 941 F.2d 201, 220 (3rd Cir. 1991) (upholding district court's waiver of Rule 65 bond where hospital challenged states Medicaid reimbursement methods).

In this case, clearly brought in the public interest, waiver of the bond is particularly appropriate. The Court should exercise its discretion to decline to require plaintiffs to post a bond.

VI. The Court Should Consolidate the Preliminary Injunction Hearing With the Trial on the Merits and Enter Permanent Injunctive Relief

As noted above, the standard for a permanent injunction is similar to that of a preliminary injunction, except that Plaintiffs must attain success on the merits. Bank One v. Guttau, 190 F.3d 844, 847 (8th Cir. 1999) (citation omitted). Plaintiffs meet the requirements for both

preliminary and permanent injunctive relief. The Court should consolidate the preliminary injunction hearing with the trial on the merits and grant the requested relief.

VII. Timing of Requested Relief

Given the clear mandate of the CRA, Plaintiffs expect that the Agency will acknowledge that the 2002 UPL Rule cannot legally be effective on March 19, 2002 and publish a notice in the Federal Register revising the date. In the absence of such action, the Court should enter a preliminary injunction, and Plaintiffs respectfully request a hearing on an expedited basis on their request for injunctive relief, and specifically request that ruling be made prior to the 2002 UPL Rule's currently scheduled implementation date of March 19, 2002. If HHS defers the implementation date to a later date, Plaintiffs respectfully request a hearing on an expedited basis so that this matter is resolved prior to the new deferred implementation date.

CONCLUSION

As established above, Plaintiffs have a strong likelihood of success on the merits. Plaintiffs have demonstrated that HHS failed to comply with the Administrative Procedure Act because the Agency arbitrarily and capriciously issued the 2002 UPL Rule rescinding the 2001 UPL Rule without considering relevant evidence, including evidence on the negative impact the Rule will have on safety net hospitals, while it relied instead on an irrelevant, outdated OIG report for its sole empirical evidence in support of the regulatory change. Moreover, Plaintiffs have established that HHS failed to provide an adequate statement of basis and purpose in the 2002 UPL Rule, by failing to consider adequately all timely comments submitted on the proposed regulation. HHS also has failed to conduct the required analysis of impact to small entities and rural hospitals in violation of the Regulatory Flexibility Act and the Social Security Act. Finally, Plaintiffs have demonstrated that HHS cannot implement the January 2002 Rule on

March 19th as announced, because the Agency will not have provided Congress the 60-day review period mandated by the Congressional Review Act.

Plaintiffs have established that they and their members will suffer substantial, irreparable harm should the 2002 UPL Rule take effect. Plaintiffs have further demonstrated that these immense costs to safety net hospitals outweigh the costs to HHS of preserving the status quo. Finally, Plaintiffs have established that ensuring continued access to appropriate health care for this nation's low-income Medicaid and uninsured persons, whether in small, rural safety net hospitals like Ashley and Delta, or in their large urban counterparts, like Alameda, unquestionably serves the public interest. Because Plaintiffs have satisfied all of the requirements for a preliminary and permanent injunction, this Court should grant Plaintiffs' Motion.

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 #_____

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