IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALAMEDA COUNTY MEDICAL CENTER, *et al.* **Plaintiffs,** v. **THE HONORABLE MICHAEL O. LEAVITT, in his official capacity as Secretary, United States Department of Health and Human Services,** *et al.* **Defendants.**	**Civil Action No.**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

Plaintiffs submit this Memorandum in support of their Motion for Preliminary Injunction, which seeks to enjoin enforcement of the Medicaid rule ("the Rule") purportedly finalized by the Department of Health and Human Services ("HHS").[1] The Congressional opposition to this Rule has been clear and emphatic, culminating in a legislative moratorium barring its implementation that took effect May 25, 2007. HHS nevertheless issued the Rule over the objections of Congress and in violation of the moratorium.

Not only would the Rule have a devastating impact on the Medicaid program, but it would directly contravene the Medicaid Statute as it has evolved over the last forty years. The policies in the Rule would fundamentally alter the federal-state partnership that is at the core of the Medicaid program. In particular,

- The Rule re-establishes a cost-based limit on Medicaid payments, which Congress repealed as inefficient and administratively burdensome, and imposes this cost limit on payments to governmental providers, but not other providers, in violation of Sections 1902(a)(30)(A) and 1902(a)(13)(A) of the Social Security Act as amended;
- By imposing a provider-specific cost limit, the Rule overrides the Congressional mandate for regulations that recognize aggregate limits based on Medicare payment principles, as contained in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000; and
- The Rule restricts the permissible sources of the State's contribution to Medicaid expenditures to units of government with direct access to tax revenues, a condition that Congress has never imposed on States and that contravenes decades of Medicaid payment policies, in violation of Section 1902(a)(2), 1903(w)(7)(G) of the Social Security Act.

Not only has HHS ignored clear Congressional direction, it has discarded its own longstanding interpretations of the Medicaid Statute in favor of arbitrary and capricious policies not rationally related to the agency's stated objectives.

[1] 72 Fed. Reg. 29748 (May 29, 2007).

If not enjoined before the moratorium expires on May 25, 2008, the Rule will dangerously undermine the stability of Medicaid's safety net providers, which include Plaintiff Alameda County Medical Center ("Alameda") and many member hospitals of Plaintiffs the National Association of Public Hospitals and Health Systems ("NAPH"), the American Hospital Association ("AHA"), and the Association of American Medical Colleges ("AAMC") (together, "Associations"). The Rule's dramatic constriction of the federal financial commitment to State Medicaid programs will force many financially-strapped providers to reduce or eliminate critical inpatient and outpatient services, reduce essential community-wide services, lay off staff, and abandon capital improvement projects. These hospitals and other providers will be unable to recover funding lost due to the Rule, and there is no indication that this financial harm will be mitigated by alternate funding sources. Ultimately, the loss of federal funds will jeopardize the adequacy and quality of care for the Medicaid population and the entire health care safety net system. It is just these harms that Congress sought to avoid by acting to prevent this Rule through a moratorium, and Congressional will dictates that the Rule now be enjoined to prevent its impending, devastating impact.

STATEMENT OF FACTS

The Medicaid Program

Medicaid is a joint federal-state program providing coverage of comprehensive health care services for eligible low-income persons. 42 U.S.C. §§ 1396a-1396b. Each State is given significant discretion to administer its Medicaid program, subject to a federally-approved State Medicaid Plan and to broad national guidelines established by the SSA and applicable Medicaid regulations. *See* 42 U.S.C. § 1396a; 42 C.F.R. § 430.10. Defendant Michael O. Leavitt is the Secretary of Defendant HHS (the "Secretary"), and is responsible to implement Title XIX of the Social Security Act ("SSA" or "the Act"), as amended, 42 U.S.C. §§ 1396-1396v, which

establishes the Medicaid program ("Medicaid Statute"). Defendant Kerry Weems is the Acting Administrator of Defendant Centers for Medicare and Medicaid Services ("CMS"), the agency within HHS that administers the Medicaid program.

Federal-State Partnership in Medicaid Financing

Medicaid is predicated on a partnership in which the federal government shares with each State the expenses of its Medicaid program at Congressionally-determined matching rates. These rates of federal financial participation ("FFP") vary among States and are expressed as a Federal Medical Assistance Percentage ("FMAP"). *See* 42 C.F.R. § 433.10. Since the inception of the Medicaid program, federal law has permitted States to fund their share of Medicaid expenditures from "local sources" other than State general revenues. Pub. L. 89-97, § 121(a), 79 Stat. 286 (1965); 42 U.S.C. § 1396a(a)(2).

Medicaid Requirements for Payments to Providers

In the early years of the program, federal Medicaid law imposed provider-specific limits on the amount States could pay providers. Payments could not exceed a provider's charges for the services provided. Pub. L. No. 90-248, § 237(b), 81 Stat. 821 (1968) (creating § 1902(a)(30)(A) of the SSA). Payments to hospitals could not exceed the provider's costs, as calculated under Medicare reimbursement principles. Pub. L. No. 92-603, § 232, 86 Stat. 1329 (1972). Over time, Congress specifically rejected these provider-specific payment limits in favor of providing States flexibility to adopt incentives to contain costs, reward efficiency, permit bonuses, and reduce administrative burdens. Pub. L. No. 96-499, § 962(a), 94 Stat. 2599 (1980); Pub. L. No. 97-35, § 2174, 95 Stat. 357 (1981). Under current law, the primary substantive standard governing provider payments requires State payment methodologies to be consistent with "efficiency, economy and quality of care." 42 U.S.C. § 1396a(a)(30)(A). A second

provision provides for States to use a public process for rate-setting. *Id.* § 1396a(a)(13)(A). These two provisions are at issue in this challenge.

CMS (previously named the Health Care Financing Administration or "HCFA") has interpreted this "efficiency, economy and quality of care" standard in regulations imposing relatively flexible "upper payment limits" ("UPLs") on overall payments, based on what Medicare would pay for similar services. *See* 42 C.F.R. §§ 447.272(b), 447.321(b) (2006).[2] The UPLs are not applied on a provider-specific basis, but rather in the aggregate to different categories of providers.[3] As a result, Medicaid payments to an individual provider may exceed both costs and what Medicare would have paid that provider, so long as aggregate payments to each category of provider do not exceed the aggregate UPL.

CMS has refined the UPL rules several times over the years.[4] Through each of these refinements, CMS consistently has rejected proposals to apply the UPL on a provider-specific rather than aggregate basis, and has maintained a UPL based on Medicare rates—acknowledging the Congressional mandate for State flexibility to tailor payment systems to their own needs.[5] Eventually, Congress directed CMS to finalize regulations using aggregate, rather than provider-specific, payment limits based on Medicare principles not costs. *See* The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA").[6]

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[2] Despite the Moratorium, the Rule appears in the Code of Federal Regulations, 42 C.F.R. §§ 433.50, 433.51, 447.206, 447.207, 447.271, 447.272, 447.321, 457.220, 457.628 (2007). The currently effective version of these regulations can be found in the 2006 Code of Federal Regulations.

[3] The categories are State government-owned or operated facilities, non-State government-owned or operated facilities, and privately-owned or operated facilities. 42 C.F.R. §§ 447.272(a); 447.321(a).

[4] *See* 67 Fed. Reg. 2602 (Jan. 18, 2002); 66 Fed. Reg. 3148 (Jan. 12, 2001); 52 Fed. Reg. 28141 (Jul. 28, 1987); 48 Fed. Reg. 56046 (Dec. 19, 1983).

[5] *See, e.g.*, 67 Fed. Reg. at 2607; 66 Fed. Reg. at 3152, 3174; 52 Fed. Reg. at 28145; 48 Fed. Reg. at 56054-55.

[6] H.R. 5661, 106th Cong. (1999), enacted into law by reference in Pub. L. No. 106-554, § 1(a)(6), 114 Stat. 2763 (2000). BIPA required that HHS "[I]ssue . . . a final regulation based on the proposed rule announced on October 5, 2000 that . . . modifies the upper payment limit test . . . by applying an aggregate upper payment limit to payments made to government facilities that are not State-owned or operated facilities."

Medicaid Payments for Safety Net Providers

As described in the attached Declarations,[7] Alameda and many members of the Plaintiff Associations are governmental "safety net" hospitals that form the core of the provider network on which State Medicaid programs rely to serve their Medicaid populations. These hospitals serve all members of their communities, regardless of ability to pay, often providing the only access to health care for many of their patients.[8] Many provide highly sophisticated specialty and tertiary care services (trauma units, burn care units, neonatal intensive care, psychiatric emergency services, to name a few) relied on by entire communities.[9] Plaintiff Alameda and Declarants OHSU, Thomason, UCH, UUHC, and many other Association members are teaching hospitals training the next generation of the nation's physicians.[10]

Medicare's payment systems for hospitals, upon which Medicaid upper payment limits are based, provide above-cost supplemental payments and adjustments for certain types of hospitals, in recognition of their unique role in the health care system.[11] Consistent with the

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[7] Plaintiffs have submitted the following Declarations in support of this Motion: Ex. 29, Declaration of Wright Lassiter, CEO, Alameda (hereinafter "Lassiter Decl."); Ex. 30, Declaration of Patrick Wardell, CEO, Hurley Medical Center ("Hurley") (hereinafter "Wardell Decl."); Ex. 31, Declaration of James R. Nathan, CEO, Lee Memorial (hereinafter "Nathan Decl."); Ex. 32, Declaration of Peter Rapp, Executive Director, OHSU Hospitals and Clinics (hereinafter "Rapp Decl."); Ex. 33, Declaration of James N. Valenti, CEO, Thomason General Hospital ("Thomason") (hereinafter "Valenti Declaration"); Ex. 34, Declaration of Bruce Schroffel, CEO, UCH (hereinafter "Schroffel Decl."); Ex. 35, Declaration of David Entwistle, CEO, University of Utah Hospitals and Clinics ("UUHC") (hereinafter "Entwistle Declaration"); Ex. 25, Declaration of Christine Capito Burch, Executive Director, NAPH (hereinafter "Burch Dec."); Ex. 26, Declaration of Melinda Reid Hatton, General Counsel, AHA (hereinafter "Hatton Decl."); Ex. 27, Declaration of Ivy Baer, Regulatory Counsel, AAMC (hereinafter "Baer Decl."); and Ex. 28, Declaration of Lawrence A. McAndrews, CEO, N.A.C.H. (hereinafter "McAndrews Decl.").

[8] *See, e.g.*, Ex. 29, Lassiter Decl. ¶¶ 5-7, 9; Ex. 34, Schroffel Decl. ¶¶ 7, 9; Ex. 31, Nathan Decl. ¶ 6; Ex. 35, Entwistle Decl. ¶ 9; Ex. 33, Valenti Dec. ¶¶ 7,11; Ex. 30, Wardell Decl. ¶ 9; Ex. 32, Rapp Decl. ¶¶ 5, 9.

[9] Ex. 29, Lassiter Decl. ¶¶ 5-8; Ex. 31, Nathan Decl. ¶¶ 7-8; Ex. 34, Schroffel Decl. ¶¶ 7-8; Ex. 35, Entwistle Decl. ¶ 8; Ex. 33, Valenti Decl. ¶¶ 6-10; Ex. 30, Wardell Decl. ¶ 8; Ex. 32, Rapp Decl. ¶ 7.

[10] Ex. 29, Lassiter Decl. ¶ 6; Ex. 32, Rapp Decl. ¶ 6; Ex. 33, Valenti Decl. ¶ 8; Ex. 34, Schroffel Decl. ¶¶ 6-7; Ex. 35, Entwistle Decl. ¶¶ 6-7.

[11] For example, Medicare provides indirect medical education ("IME") adjustments for teaching hospitals. 42 U.S.C. § 1395ww(d)(5)(B). Congress has consistently refused to reduce IME payments to a cost-based level, acknowledging how critical these payments are to these providers. *See* Ex. 19, MedPAC, Rep. to the Congress on Medicare Payment Policy, at 49 (Mar. 2007) ("[T]he IME adjustment has always been set higher than the estimated effect of teaching on hospitals' costs per case."). Medicare also provides additional disproportionate share hospital ("DSH") payments to support hospitals that serve large volumes of low income patients to ensure that these hospitals remain viable and available to serve the Medicare population. *See* 42 U.S.C. § 1395ww(d)(5)(F); Ex. 19,

aggregate UPL based on Medicare payment principles and with explicit federal approval, States often establish enhanced payment rates for governmental hospitals to support their unique roles serving Medicaid beneficiaries. For example:

- California Medicaid provides safety net care payments to Alameda to help stabilize the hospital as a critical Medicaid provider and support the provision of care to low income patients, including the operation of outpatient clinics and provision of preventative services such HIV, health education, and dental services. Ex. 29, Lassiter Decl. ¶ 21.
- Florida Medicaid provides enhanced payments to Lee Memorial to support its trauma department as well as services to Medicaid and low income populations, including the only perinatal intensive care program in the region and obstetrical outreach services. Ex. 31, Nathan Decl. ¶ 19.
- Oregon Medicaid provided payments to OHSU since 2001, in recognition of OHSU's role as a public academic teaching hospital and the sole provider in the State of certain under-compensated, critical specialty services. Ex. 32, Rapp Decl. ¶ 10.

The ability of State Medicaid programs to make targeted above-cost Medicaid payments is absolutely essential for the maintenance of safety net hospitals, including Alameda and many members of the Associations. Such payments help maintain the stability and viability of these providers, and allow them to address local Medicaid needs by expanding services and access. These hospitals, which are disproportionately affected by the Rule, provide a significant amount of care to Medicaid beneficiaries and the uninsured.[12] Approximately 53 percent of Plaintiff Alameda's patients are enrolled in Medicaid, and nearly 28 percent are uninsured. Ex. 29, Lassiter Decl. ¶ 10. Given that such a significant portion of safety net hospital services is provided free or through Medicaid, the enhanced Medicaid payments are even more critical to the viability of the enterprise.[13] Without the supplemental Medicaid payments supported through

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MedPAC, Rep. to the Congress, at 70, 77 . As with IME payments, Congress has maintained the DSH adjustment at existing levels, despite being advised that the adjustment has "a weak relationship to the cost of treating low-income patients." *Id.* at 68. Medicare also explicitly reimburses "critical access hospitals" at above-cost rates to ensure access to services for Medicare patients in rural areas. 42 U.S.C. § 1395f(l).

[12] *See* Ex. 25, Burch Decl. ¶ 7; Ex. 27, Baer Decl. ¶ 7, Ex. 28, McAndrews Decl. ¶ 8.

[13] *See, e.g.*, Ex. 29, Lassiter Decl. ¶¶ 10-11; Ex. 31, Nathan Decl. ¶¶ 8-10, 19; Ex. 34, Schroffel Decl. ¶¶ 9, 15.

FFP, the average NAPH member's expenditures would exceed its revenues by 7.8 percent—a condition under which no entity could maintain operations. Ex. 25, Burch Decl. ¶ 11.

Funding the Non-Federal Share of Medicaid Expenditures

Although State governments directly fund the majority of the non-federal share of Medicaid expenditures through general revenue funds, since its enactment in 1965 the Medicaid Statute has permitted States to draw on other "local sources" to fund up to 60 percent of the non-federal share. 42 U.S.C. § 1396a(a)(2). These local funds are then matched with federal funds at the applicable FMAP rate. The challenged Rule significantly restricts which entities can contribute to the non-federal share of Medicaid expenditures.

Longstanding CMS regulations allow as the non-federal share State or local "[p]ublic funds" that "are appropriated directly to the State or local Medicaid agency, or transferred from other public agencies ... to the State or local agency and under its administrative control"—known as intergovernmental transfers ("IGTs"), "or certified by the contributing public agency as representing expenditures eligible for FFP"—known as certified public expenditures ("CPEs"). 42 C.F.R. § 433.51(b) (2006). The federal government has traditionally deferred to States in determining which state or local entities are public for this purpose.

Congress has acted to prevent agency attempts to restrict States' use of local governmental funding sources. In 1991, in the course of enacting limits on two types of local sources—provider donations and provider taxes—Congress explicitly limited CMS' ability to restrict other sources of funding, specifically IGTs and CPEs.[14] Solely for purposes of these new restrictions, the statute provides a broad, inclusive definition of "unit of government."[15]

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[14] Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, Pub. L. 102-234, 105 Stat. 1793 (codified at 42 U.S.C. § 1396b(w) (1991) ("Provider Tax Amendments"); *see* 42 U.S.C. § 1396b(w)(6)(A).
[15] 42 U.S.C. § 1396b(w)(7)(G).

Around the country, governmental hospitals, including members of the Plaintiff Associations, contribute to the non-federal share pursuant to this longstanding statutory and regulatory authority, and as part of a long tradition of local government funding of health care for the poor. *See, e.g.*, Ex. 29, Lassiter Decl. ¶¶ 5, 21; Ex. 34, Schroffel Decl. ¶ 14; Ex. 30, Wardell Decl. ¶¶ 9, 15.[16] Without the use these local funding sources, many States would be unable to fund these enhanced payments, which often are the difference between viability and closure for safety net providers. *See, e.g.*, Ex. 25, Burch Decl. ¶¶ 11, 26; Ex. 34, Schroffel Decl. ¶ 24; Ex. 35, Entwistle Decl. ¶ 15.

Although IGTs and CPEs have been a permissible and integral component of Medicaid funding for local safety net systems, it is true that some States abused them in elaborate financing schemes to improperly draw down federal matching funds.[17] CMS has expressed concern that some State Medicaid programs required providers to "recycle" Medicaid payments back to the State for other uses. "Recycling" occurs when a State does not permit a provider to retain the full amount of Medicaid payments received but instead requires it to return some or all of the payments through IGTs.[18] Determined to end the practice, CMS, beginning in the summer of 2003, embarked upon a nationwide effort to uncover and terminate such abuses. Through its authority to review and approve State Plan Amendments and demonstration programs, and through its regular program review and audit procedures, CMS closely scrutinized IGTs on a State-by-State basis, and either blessed their use or insisted upon changes. This initiative was so

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[16] For example, Plaintiff Alameda, whose mission for over 140 years has been to maintain and improve the health of all county residents regardless of ability to pay, has participated in financing the non-federal share of California's Medicaid expenditures for over a decade. Ex. 29, Lassiter Decl. ¶¶ 5, 21. Declarant UCH, which since 1921 has served as a primary teaching hospital for the University of Colorado, has participated in financing the non-federal share of supplemental payments for DSH and other safety net payments since 1999. Ex. 34, Schroffel Decl. ¶ 14.

[17] *See* Government Accountability Office ("GAO") GAO-04-574, Medicaid: Intergovernmental Transfers Have Facilitated State Financing Schemes (Mar. 18, 2004).

[18] 72 Fed. Reg. 2236, 2244 (Jan. 18, 2007).

successful that, by November 2006, CMS' own data indicated that it had virtually eliminated the problem (albeit IGT programs in three States were still under review at that time).[19]

Despite this success, CMS requested that Congress enact proposals limiting Medicaid payments for governmental providers to cost and restricting the use of IGTs.[20] Congress declined to do so. *See* Ex. 25-G, Letter from Sens. John Rockefeller, Gordon Smith, *et al.*, to Sec. Michael Leavitt (Mar. 16, 2007); Ex. 25-H, Letter from Rep. Henry Waxman, *et al.*, to Sec. Michael O. Leavitt (Mar. 19, 2007). CMS then proposed to impose the changes unilaterally, despite the fact that Congress refused to grant the agency the requested legislative authority. *See* Ex. 14, Budget of the United States Government, Fiscal Year 2007, at 125.

The Rule

After CMS was unsuccessful in convincing Congress to pass legislation, CMS unilaterally issued a proposed rule on January 18, 2007 ("Proposed Rule"). 72 Fed. Reg. 2236. CMS proposed to:

- limit Medicaid payments to governmental providers to their provider-specific costs of delivering Medicaid services, while retaining the existing UPL for private providers;
- greatly restrict the permissible sources of the non-federal share of Medicaid expenditures by limiting the use of IGTs and CPEs to federally-defined "units of government"; and
- require providers to receive and retain the full amount of their Medicaid payments.

Id. at 2246-48. CMS received over 400 comment letters from providers and national associations, not a single one of which supported the Proposed Rule. Ex. 25, Burch Decl. ¶ 14.

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[19] Ex. 35-A, Letter from the University of Utah to Leslie Norwalk (Mar. 16, 2007). In particular, CMS specifically confirmed that IGT programs in 40 States are properly structured or have been revised so that they are not abusive. *See also* GAO-07-214, Medicaid Financing: Federal Oversight Initiative Is Consistent with Medicaid Payment Principles but Needs Greater Transparency (Mar. 30, 2007).

[20] CMS included legislative proposals in both its Fiscal Year ("FY") 2005 and 2006 budget proposals. Ex. 12, Budget of the United States Government, Fiscal Year 2005, at 149-50; Ex. 13, Budget of the United States Government, Fiscal Year 2006, at 143. In August 2005, the agency submitted detailed legislative language substantially similar to the provisions of the Rule to Congress requesting that Congress give the language prompt and favorable consideration. Ex. 21, Letter from Sec. Michael O. Leavitt, Secretary of CMS, to the Honorable J. Dennis Hastert, Speaker of the House of Representatives (Aug. 5, 2005).

Among other things, the commenters challenged the legal basis for the Proposed Rule and pointed out that the Rule was not directly related to CMS' purported objective of enhancing fiscal integrity. CMS also received comments from Members of Congress criticizing the Rule, questioning HHS' and CMS' statutory authority, and urging withdrawal of the Rule.[21]

On May 24, 2007, Congress passed a one-year moratorium to prevent HHS from taking further action on the Proposed Rule. U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Pub. L. No. 110-28, § 7002(a), 121 Stat. 112 (2007) ("Moratorium"). On May 25, 2007, the President signed the bill into law, which took effect immediately.[22] The Moratorium provides in pertinent part:

> Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not, prior to the date that is 1 year after the date of enactment of this Act, *take any action (through promulgation of regulation, issuance of regulatory guidance, or other administrative action)* to –
> (A) *finalize or otherwise implement provisions contained in the proposed rule published on January 18, 2007*, on pages 2236 through 2248 of volume 72, Federal Register (relating to parts 433, 447, and 457 of title 42, Code of Federal Regulations);
> (B) *promulgate or implement any rule or provisions similar to the provisions described in subparagraph (A)* pertaining to the Medicaid program established under title XIX of the Social Security Act of the State Children's Health Insurance Program established under title XXI of such Act; or
> (C) promulgate or implement any rule or provisions restricting payments for graduate medical education under the Medicaid program.

Id. (emphasis added). The Moratorium will remain in place through May 24, 2008.

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[21] *See* Ex. 25-C, Letter from Reps. Anne Eshoo and Peter King, *et. al.*, to Energy & Commerce and Ways & Means Committees (Feb. 26, 2007); Ex. 25-E, Letter from Rep. Gene Green, *et. al.*, to Sec. Michael Leavitt (Mar. 8, 2007); Ex. 25-H, Letter from Rep. Henry Waxman, *et al.*, to Sec. Michael Leavitt (Mar. 19, 2007); Ex. 25-G, Letter from Sens. John Rockefeller, Gordon Smith, *et al.*, to Sec. Michael Leavitt (Mar. 16, 2007); Ex. 25-F, Letter from Chairman John Dingell, *et al.*, to Sec. Michael Leavitt (Mar. 12, 2007). In all, 263 Members of the House and 69 Senators are on record in opposition to the Rule as of March 2008, based on these letters and an additional letter of opposition from Senators to Congressional leadership in December 2007. Ex. 25-A, Letter from Sens. Jeff Bingaman and Elizabeth Dole, *et. al.*, to Senate Finance, Energy & Commerce and Ways & Means Committees. (Dec. 12, 2007).

[22] Congress originally approved a one-year moratorium in March 2007 as part of an emergency supplemental appropriations bill, which the President vetoed. Ex. 8, H.R. 1591, 110th Cong. § 6002 (2007).

CMS was well aware of the pending Congressional moratorium and Congress' strong opposition to the Proposed Rule.[23] Nonetheless, CMS rushed the rule into final form (with numerous obvious typographical, grammatical and other errors that are typically edited out in a final proofreading)[24] and put it on display at the Federal Register office on May 25, 2007, the day the Moratorium took effect. CMS published the Rule on May 29, 2007, to be effective July 30, 2007. 72 Fed. Reg. 29748 ("Rule").[25] Attached as Exhibit 1 is a timeline of the Rule's development, along with the numerous Congressional acts and communications expressing Congress' opposition.

The Rule purports to finalize the sweeping restrictions on Medicaid payments to governmental providers and on the permissible sources of non-federal Medicaid funding. According to CMS estimates, the Rule will cut $5 billion in federal Medicaid participation between 2008 and 2013. *See* Ex. 15, Budget of the United States Government, Fiscal Year 2008, at 63. For governmental providers only, the Rule replaces the longstanding aggregate UPL based on Medicare payment principles, with a limit to the "individual provider's cost of providing Medicaid services." 72 Fed. Reg. at 29833. This cost limit will eliminate federal participation in any payments in excess of the Rule's definition of costs. It also would significantly increase administrative burdens by requiring: (1) providers to submit cost reports in a form approved by CMS, forcing some providers to switch from existing State Medicaid forms and other providers that have never before submitted Medicaid cost reports to begin doing so; and (2) providers and

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[23] In addition to public statements about the moratorium by Senate leadership, and the earlier moratorium in the vetoed Iraq funding bill, *supra* notes 21-22, the Acting Administer of CMS wrote a letter to Finance Committee leadership on March 27, 2007 expressing the agency's opposition to the moratorium. Ex. 23, Letter from Leslie Norwalk to Sens. Max Baucus and Charles Grassley (Mar. 27, 2007).

[24] *See* Ex. 24, Letter from Carol A. Herrmann-Steckel, Commission Alabama Medicaid Agency to Leslie V. Norwalk (Jul. 10, 2007).

[25] To the best of Plaintiffs' knowledge, CMS has not formally acknowledged that the Rule's purported effective date of July 30, 2007 is effectively superseded by the Moratorium and could not have effect prior to May 25, 2008, even if the Rule had been validly finalized.

States to undertake a lengthy reconciliation of interim payments based on audited cost reports finalized years later, a process which is not required under current law. *See id.*

The Rule limits for the first time the definition of a unit of government (eligible to participate in the non-federal share of Medicaid program expenditures) to entities that have taxing authority, have direct access to tax revenues of an entity with taxing authority,[26] or receive direct appropriations from the State as a State university teaching hospital. *Id.* at 29832. This definition excludes traditionally governmental providers significantly integrated within their State or local governments but lacking the direct access to tax revenues that CMS has decided is the hallmark of a governmental entity. *See* Ex. 29, Lassiter Decl. ¶¶ 5, 12-15, 21-23; Ex. 34, Schroffel Decl. ¶¶ 5, 11-13, 16-18; Ex. 31, Nathan Decl. ¶¶ 5, 6, 11-14, 20-21. States will be required to determine the governmental status of their providers pursuant to a lengthy list of newly introduced criteria requiring substantial legal analysis to evaluate.[27]

Harm to Association Plaintiffs' Members and to Plaintiff Alameda

If the Rule is not enjoined, Alameda and the other members of the Plaintiff Associations will incur substantial, imminent, and irreparable injury. Those hospitals that are governmental providers will lose millions of dollars in Medicaid payments. Those hospitals that will no be longer considered units of government eligible to contribute to the non-federal share will lose millions of dollars in Medicaid payments that those contributions have financed, and will in some cases no longer be eligible under their State Medicaid programs to receive enhanced

[26] The provider must be a sufficiently integral part of an entity with taxing authority, meaning that the unit of government must be legally obligated to fund the health care provider's expenses, liabilities, and deficits. 72 Fed. Reg. at 29832.

[27] The Rule also requires States to permit providers to retain the full amount of Medicaid payments, expands federal authority to examine associated transactions related to a provider's Medicaid payments, and imposes new requirements on documentation of CPEs. *Id.* at 29833-34. The Rule applies to State demonstrations. *Id.* at 29813 ("All Medicaid payments made under Medicaid waiver and demonstration authorities are subject to all provisions of this regulation.").

payments. These providers will be unable to recover the federal Medicaid funding lost due to the Rule, as the federal government enjoys sovereign immunity.

As examples, the Declarations demonstrate the losses faced by safety net hospital systems under the Rule: Alameda will lose $85 million; Hurley, $6-$12.8 million; Lee Memorial, $23.2 million; Thomason, $22 million; OHSU, $2.8 million; UCH, $30-35 million; and UUHC $25 million. These hospitals do not have other sources of revenue to help absorb Medicaid revenue losses of this magnitude, and have no reasonable expectation that the lost federal funds will be made up by their States. *See infra* n.55.

These losses threaten the viability of these providers. They will be required to make significant cuts in essential services on which their underserved patient populations rely and that are not otherwise available in the community, and make cuts to staff and capital programs that impact the quality of care. Some of the outcomes of the Rule include:

- Longer waits for inpatient and outpatient services, delayed surgeries
- Closing of outpatient clinics and inpatient units
- Elimination of preventive services, e.g., HIV services, health education and outreach, dental services
- Staff lay-offs
- Reductions in physician training programs
- Elimination of under-reimbursed services, often only offered by safety net providers
- Reduction or elimination of significant capital improvement projects, such as necessary department expansions
- A reduced participation in essential and beneficial community programs such as indigent care programs and disaster preparedness.[28]

[28] *See e.g.*, Ex. 29, Lassiter Decl. ¶ 21; Ex. 34, Schroffel Decl. ¶¶ 7-8, 22-23; Ex. 31, Nathan Decl. ¶¶ 24-25; Ex. 33, Valenti Decl. ¶¶ 15-17; Ex. 30, Wardell Decl. ¶¶ 20-21; Ex. 32, Rapp Decl. ¶ 14; Ex. 35, Entwistle Decl. ¶¶ 13-15.

LEGAL STANDARD FOR ISSUANCE OF INJUNCTIVE RELIEF

In evaluating a motion for preliminary injunction, a court reviews four factors: "whether (1) there is a substantial likelihood plaintiff will succeed on the merits; (2) plaintiff will be irreparably injured if an injunction is not granted; (3) an injunction will substantially injure the other party; and (4) the public interest will be furthered by the injunction." *Ellipso, Inc. v. Mann*, 480 F.3d 1153, 1157 (D.C. Cir. 2007) (citing *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)). The court should weigh each factor, and "[t]hese factors interrelate on a sliding scale and must be balanced against each other." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998). A "particularly strong" showing in one area can justify an injunction "even if the arguments in other areas are rather weak." *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995). Here, each factor favors an injunction.

ARGUMENT

I. Plaintiffs Are Likely To Succeed On The Merits Of Their Claims

A. Congress Has Directly Spoken in Opposition to a Cost Limit on Medicaid Payments to Governmental Providers

Section 1902(a) of the Social Security Act establishes the standard for States' payment methodologies for Medicaid providers. These standards have evolved since the 1970s, with Congress granting States increasingly broad authority over provider payments. Congress has repeatedly repealed prescriptive, provider-specific payment limits—including a reasonable cost limit and a reasonable charge limit—so that States could adopt flexible payment systems that reward efficiency, create incentives, and minimize administrative burdens on the State, providers, and the federal government. In imposing a cost limit now, CMS is returning to an approach Congress unmistakably rejected. Although CMS may have discretion reasonably to fill

in the details of the Medicaid Statute, it is not free to impose a fundamental revision to the statute, much less a methodology that Congress has consciously disavowed.

The Administrative Procedure Act ("APA") 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). Plaintiffs' substantive challenges to the Rule are subject to review under the two-part test outlined in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

467 U.S. 837, 842-43 (1984).

In determining whether Congress has "directly spoken" to the issues at hand, this Court should consider the text and structure of the relevant statute and the over-arching statutory scheme. As the Supreme Court has explained:

> It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." . . . A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," . . . , and "fit, if possible, all parts into an harmonious whole." . . . Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132-33 (2000) (citations omitted) (holding that review of tobacco-related legislation supported conclusion that the FDA did not have authority to regulate tobacco); *see also Kmart Corp. v. Cartier Inc.*, 486 U.S. 281, 291 (1988) (invalidating portion of regulation as an unreasonable construction of the statute and

reaffirming *Chevron*'s direction that the court "must look to the particular statutory language at issue, as well as the language and design of the statute as a whole"); *Shays v. FEC*, 414 F.3d 76, 105 (D.C. Cir. 2005) (under *Chevron* step one, a court should use the traditional tools of statutory interpretation, including "'examination of the statute's text, legislative history, and structure, as well as its purpose'") (quoting *Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997)); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069-70 (D.C. Cir. 1998) (holding FDA's regulation was inconsistent with the text and structure of the Food, Drug, and Cosmetic Act); *Ohio v. DOI,* 880 F.2d 432, 441 (D.C. Cir. 1989) ("If the court having studied the statutory text, structure and history, is left with the unmistakable conclusion that Congress had an intention on the precise question at issue 'that intention is the law and must be given effect.'").

1. Congress Has Clearly Addressed, and Rejected, a Cost Limit on Payments to Medicaid Providers

The history of Section 1902(a) of the Medicaid Statute makes it abundantly clear that Congress has rejected provider-specific cost limits of the sort adopted by CMS in its Rule. Congress experimented with cost-based payments in the 1960s and 1970s, and imposed a hospital-specific cost limit based on Medicare cost methodologies akin to the limit imposed in the Rule. It further adopted provider-specific limits based on charges applicable to all provider types. Based on concerns about (1) the inherently inflationary nature of cost reimbursement; (2) the inability under a provider-specific limit to provide payment incentives to improve care; and (3) the administrative burden of applying provider-specific limits, Congress unequivocally rejected this approach on a wholesale basis in the early 1980s. At the same time, Congress made clear that the general payment standards remaining in the Medicaid Statute were to be based on Medicare payment principles applied on an average or aggregate, rather than provider-specific, basis.

Two provisions of Section 1902(a) of the Social Security Act govern States' adoption of payment methodologies for providers. Section 1902(a)(30)(A) establishes a substantive standard applicable to payments to all providers. 42 U.S.C. § 1396a(a)(30)(A). This is the provision upon which CMS relies as its authority for imposing a cost limit on governmental providers. 72 Fed. Reg. at 2241. Section 1902(a)(13) currently establishes procedural requirements by which States must adopt methodologies for payments to *institutional* providers (such as hospitals and nursing facilities). 42 U.S.C. § 1396a(a)(13). In earlier versions of the statute, however, Section 1902(a)(13) also contained substantive standards governing institutional provider payments. Taken together, the history of these two provisions definitively establishes that Congress has addressed and rejected provider-specific cost limits.

As originally enacted in 1968, Section 1902(a)(30)(A) required States to:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments ... *are not in excess of reasonable charges consistent with efficiency, economy, and quality of care.*

Pub. L. No. 90-248, § 237(b) (emphasis added). Thus, the original provision imposed an absolute limit prohibiting payments in excess of a provider's charges.[29] Congress removed this provider-specific reasonable charge limit in the Omnibus Reconciliation Act of 1981 to give States more flexibility in establishing payment methodologies. Pub. L. No. 97-35, § 2174. In particular, Congress sought to "remove the administrative burdens this requirement of current

[29] This limitation is separate from another charges limitation contained in Section 1903(i)(3). 42 U.S.C. § 1396b(i)(3).

law imposes on the States and to provide States with the flexibility to create incentives to improve the availability and utilization of physician services under Medicaid."[30]

> In its current form, Section 1902(a)(30)(A) requires that a State Medicaid plan must:
>
> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan ... as may be necessary *to safeguard against unnecessary utilization* of such care and services and to assure that payments are consistent with *efficiency, economy, and quality of care and are sufficient to enlist enough providers* so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

42 U.S.C. § 1396a(a)(30)(A) (emphases added). This provision does not limit States to a cost-based methodology. In fact, as we show in this section, Congress adopted this standard to allow other approaches, such as prospective payment systems, which may be consistent with "efficiency" and "economy," and may better safeguard against "unnecessary utilization" of services while ensuring access to quality care.

Section 1902(a)(13) evolved along a similar path. As originally enacted, this provision required States to pay for inpatient hospital services at "reasonable cost (as determined in accordance with standards approved by the Secretary and included in the plan)." Pub. L. No. 89-97, § 121(a) (1965).[31] In 1972, Congress imposed a Medicare-related cost limit under which States' calculation of hospitals' "reasonable cost" "shall not exceed the amount which would be determined" under the Medicare statute. Pub. L. No. 92-603, § 232. This cost limit is strikingly

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[30] Ex. 4, H.R. Rep. No. 97-158, at 312, Vol. II (1981). The provision governs physician payments, hospital payments, and other providers. Congress thus granted States additional discretion "to be more creative and offer incentives for improved delivery of care" and to "structure their physician payment levels to build in incentives or bonuses for physicians who provide care in more cost effective arrangements." *Id.* at 313.

[31] The Secretary later issued detailed implementing regulations for long-term care payments, including cost-finding and cost reporting requirements, desk analysis of cost reports and periodic audits. 41 Fed. Reg. 27300 (July 1, 1976). These requirements are similar to the detailed requirements imposed on States in the Rule, that providers must submit cost reports, States must review and reconcile payments made with the cost reports, and the cost limits must be subjected to periodic audits. 72 Fed. Reg. at 29828.

similar to the one imposed by CMS in the Rule, which also requires States to calculate the cost limit using Medicare reasonable cost principles. 72 Fed. Reg. at 29749.

Just as Congress rejected subsection (a)(30)(A)'s charge limit, Congress became disillusioned with the reasonable cost framework of Section 1902(a)(13). In 1980, Congress adopted the Boren Amendment, which eliminated cost-based payments for long term care services under Medicaid that had first been adopted in 1972. Pub. L. No. 96-499, § 962(a).[32] Congress then applied this change to hospital services in 1981. Pub. L. No. 97-35, § 2173.[33]

Through the Boren Amendment, Congress explicitly rejected cost-based reimbursement to permit States to use prospective payment systems that provided greater incentives to providers to control costs, *i.e.*, to adopt standards consistent with efficiency and economy. The Senate Report described cost-based reimbursement as "inherently inflationary" and lacking "incentives for efficient performance." Ex. 2, Sen. Rep. No. 96-471, at 28 (1979). The House Report echoed this sentiment:

> The Committee recognizes the inflationary nature of the current cost reimbursement system and intends to give States greater latitude in developing and implementing alternative reimbursement methodologies that promote the efficient and economical delivery of such services. The Committee is especially interested in the development of prospective rate methodologies as a replacement for the current reasonable cost reimbursement system under Medicaid.

Ex. 4, H.R. Rep. No. 97-158, at 293.[34]

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[32] The Boren Amendment required States to pay rates "which the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards." Pub. L. No. 96-499, § 962(a) (1980). Medicare, at that time, was also in the process of rejecting reasonable cost reimbursement for similar reasons, and migrating to prospective payment systems. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983).

[33] In 1997, Congress repealed the Boren Amendment to give States even greater rate-setting flexibility. *See* Ex. 5, H.R. Rep. No. 105-149, at 590-91 (1997). Section 1902(a)(13)(A) now grants States broad authority to set payment rates for hospital services, subject to providing "a public process for determination of rates of payment." 42 U.S.C. § 1396a(a)(13)(A). The current provision thus places no cost limit or other substantive payment standard on States.

[34] This report listed the Boren Amendment among a number of provisions "which provide States with flexibility to institute a number of measures in their programs to reduce cost and make them more efficient." Ex. 4, H.R. Rep. No. 97-158, at 279. Courts have also acknowledged that the Boren Amendment granted States flexibility in setting

Congress also expected CMS (then HCFA) to apply limits on Medicaid payments on an average or aggregate, rather than provider-specific, basis. The Senate Report indicated that the regulatory limits based on Medicare payment principles would continue but that "the Secretary would only be expected to compare the *average* rates paid to SNFs [skilled nursing facilities] participating in Medicare with the *average* rates paid to SNFs participating in Medicaid in applying the limitation." Ex. 2, Sen. Rep. No. 96-471, at 29 (emphasis added). The report accompanying the 1981 Boren Amendment legislation contains a similar expectation that "the Secretary would only be expected to compare the aggregate amounts paid to hospitals by Medicaid in applying [a Medicare-related] limit." Ex. 3, Sen. Rep. No. 97-139, at 478 (1981).

Given this history of Congressional repeals, CMS does not have the authority to impose provider-specific cost limits on government providers. *See Muscogee (Creek) Nation v. Hodel*, 851 F.2d 1439, 1444 (D.C. Cir. 1988) (rejecting Department of Interior's statutory interpretation because, "It is contrary to common sense as well as sound statutory construction to read the later, more general language to incorporate the precise limitations of the earlier statute. Where the words of a later statute differ from those of a previous one on the same or related subject, the Congress must have intended them to have a different meaning."). Congress rejected a cost-limit as lacking incentives for efficiency; a return to a provider-specific cost limit is antithetical to the statutory requirement that States set rates consistent with economy and efficiency.

In *National Ass'n of Broadcasters v. Librarian of Congress*, the D.C. Circuit expressly relied on Congress' repeal of a statutory provision to understand Congressional intent. 146 F.3d 907, 919 (D.C. Cir. 1998). The court reasoned that the rescission of language by Congress in a

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payment rates, to control Medicaid costs while maintaining quality care and access to providers. *See, e.g., Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 506 (1990) ("Congress blamed mounting Medicaid costs on the complexity and rigidity of the Secretary's reimbursement regulations. . . . Thus, while Congress affirmed its desire that state reimbursement rates be 'reasonable,' it afforded States greater flexibility in calculating those 'reasonable rates.'").

subsequent legislative act was "plain evidence of the Congress's intent" to apply a different standard and the court must defer to "Congress's intent [which] is sufficiently clear." *Id.* at 919. By repealing the payment limit based on reasonable costs in Section 1902(a)(13)(A) and the payment limit of reasonable charges in Section 1902(a)(30)(A), Congress did not merely leave the issue of payment standards to agency discretion; it explicitly authorized States to adopt prospective payment methodologies not limited by each provider's individual costs. In the face of this statutory evolution, CMS is not free to re-impose a provider-specific, cost-based payment limit on governmental providers.

Judge Kessler's recent opinion in *Anna Jacques Hospital v. Leavitt*, No. 05-625, 2008 WL 510337 (D.D.C. Feb. 26, 2008) lends further support to Plaintiffs. Tracing the evolution of the Medicare statutory scheme, this Court found that prior to 1987, Congress had not directed how the wage index should be computed; but "[i]n 1987 Congress ended its silence and sharply limited the Secretary's discretion by amending the statute" to provide specific direction as to the Medicare area wage index calculation. *Id.* at *7. Applying *Chevron* step one, the Court held that the Secretary had "violated Congress' clear command" by exceeding his statutory authority. *Id.*[35] Here, Congress' "clear command" is its explicit repeal of a cost limit in favor of the looser standards embodied in the current Statute. *See also MCI Telecomm. Corp. v. AT& T Co.*, 512 U.S. 218, 231-32 (1994) (characterizing Federal Communications Commission's elimination of certain tariffs under the guise of its statutory authority to "modify" statutory requirements as, "What we have here, in reality, is a fundamental revision of the statute .... That may be a good idea, but it was not the idea Congress enacted into law . . . .").

[35] The court also found the Secretary's action to be arbitrary and capricious. 2008 WL 510337, at *8.

2. *CMS' Reimposition of a Cost Limit on Payments to Governmental Providers is Not a Reasonable Construction of the Medicaid Statute and is Arbitrary and Capricious*

Although further analysis is unnecessary given that Congress has plainly expressed its opposition to a cost limit, CMS' interpretation of Section 1902(a) must also be overturned under the second step of *Chevron* as an unreasonable construction of the statute, as well as because it is arbitrary and capricious. *Chevron*, 467 U.S. at 843. Under step two, an agency's interpretation must be "reasonable 'in light of the language, legislative history, and policies of the statute.'" *Republican Nat'l Comm. v. FEC*, 76 F.3d 400, 406 (D.C. Cir. 1996) (quoting *Natural Resources Defense Council v. EPA*, 822 F.2d 104, 111 (D.C. Cir. 1987)).[36]

Although agencies are granted deference in interpreting statutes they are charged with implementing, this deference is not without limits. In particular, an agency is entitled to less deference where it has changed its interpretation of a statute without a reasoned explanation. *See Watt v. Alaska*, 451 U.S. 259, 273 (1981) ("The Department's current interpretation, being in conflict with its initial position, is entitled to considerably less deference."). When an agency changes its position, "[w]hatever the ground for the departure from prior norms. ... it must be clearly set forth so that the reviewing court may understand the basis of the agency's action and

[36] The APA provides for a court to set aside agency action found to be arbitrary or capricious. 5 U.S.C. § 706(2). That the Rule is arbitrary and capricious renders it unreasonable under step two of *Chevron* and is also a separate basis for invalidating the Rule under the APA. "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 Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citations omitted); *see also Ashley County Med. Ctr. v. Thompson*, 205 F. Supp. 2d 1026, 1048 (E.D. Ark. 2002) ("[B]efore an agency finalizes a rule it '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.'") (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)); *Bowen v. American Hospital Ass'n*, 476 U.S. 610, 626-27 (1986) (In striking down a HCFA regulation for not containing the reasoning and evidence necessary to sustain the agency's intervention into a historically state-administered decisional process, explaining, "that there is some rational basis within the knowledge and experience of the regulators, under which they might have concluded that the regulation was necessary to discharge their statutorily authorized mission, will not suffice to validate agency decisionmaking.") (citations omitted).

so may judge the consistency of that action with the agency's mandate." *Atchison, Topeka & Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973);[37] *see also Motor Vehicles Mfrs. Ass'n,* 463 U.S. at 42 ("an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change.") CMS' new cost limit policy would contravene years of statutory and regulatory developments. The agency has failed to provide a sufficient rationale for this drastic change.

Since Congress repealed the restrictive cost and reasonable charge limits, CMS has made several conforming revisions to its provider payment rules, all of which contradict this new cost limit policy. In the aftermath of Congress' repeal of these limits, HCFA specifically adopted aggregate, rather than provider-specific, Medicare-based UPLs. 46 Fed. Reg. 47964, 47968 (Sep. 30, 1981).[38] The Medicare-based UPL adopted by HCFA prohibited payment in excess of "the amount that the agency reasonably estimates would be paid for the services under the Medicare principles of reimbursement." *Id.* at 56046 (adopting 42 C.F.R. § 447.253(b)(1)(ii)(C)(2)). HCFA based this standard on "the legislative intent" of Section 1902(a)(13) and the efficiency, economy, and quality of care standard of Section 1902(a)(30)(A).

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[37] This principle has been applied by the D.C. Circuit numerous times. *See, e.g., Alabama Education Ass'n vs. Chao*, 455 F.3d 386, 389 (D.C. Cir. 2006) (in challenge to change to long-standing agency policy, the court remanded the case to the agency because "'the Department did not provide a reasoned explanation for its new policy'") (quoting *AFL-CIO v. Brock*, 835 F.2d 912, 913 (D.C. Cir. 1987)); *Goldstein v. SEC,* 451 F.3d 873, 883 (D.C. Cir. 2006) (holding that the SEC's Hedge Fund Rule was inconsistent with prior SEC determinations and stating the SEC "has failed adequately to justify departing from its own prior interpretation"); *Bush-Quayle '92 Primary Comm., Inc. v. FEC*, 104 F.3d 448 (D.C. Cir. 1997) (vacating determination by the FEC because the FEC's determination was inconsistent with a similar ruling made during prior presidential primary campaign); *AFL-CIO*, 835 F.2d 912 (remanding case to the Department of Labor for a reasoned explanation of why it reversed a two decade old policy); *National Black Media Coalition v. FCC*, 775 F.2d 342, 356 n.17 (D.C. Cir. 1985) ("[A]n agency may not repudiate precedent simply to conform with a shifting political mood. Rather, the agency must demonstrate that its new policy is consistent with the mandate with which Congress has charged it.").

[38] HCFA admitted that the elimination of cost-based payment limits signaled that "each State should be free to decide, in setting its payment rate, whether to allow facilities an opportunity for profit." 46 Fed. Reg. at 47968. HCFA also stated that permitting "a State to use an aggregate versus facility-specific application of the limit . . . was in keeping with the congressional intent that the calculation of the limit not be administrative burden on States." 48 Fed. Reg. at 56053.

Id. at 56054. HCFA acknowledged in the preamble to this rule that Congress intended for an aggregate UPL based on Medicare payments. *Id.*

Several additional refinements of the UPL followed in subsequent years. Throughout this process, CMS (and HCFA) consistently rejected proposals to abandon the aggregate, rather than individualized, nature of the UPL, and the use of estimated Medicare payments, rather than actual and reconciled, costs.[39]

The Rule's unexplained return to a cost limit that Congress disavowed undermines the very Congressional objectives in Section 1902(a)(30)(A) that CMS previously acknowledged. A cost limit is inherently inflationary because governmental providers will have an incentive to increase, rather than reduce, costs and provide unnecessary services (to maximize payment). It deprives States of the flexibility to adopt incentives to improve care through "pay for performance" and other types of bonus payments for meeting quality standards. Finally, the Rule re-imposes the kind of administrative burden that Congress sought to eliminate, by requiring States to develop, implement, review, and audit annual cost reports and perform reconciliations that are completely unnecessary for prospective payment systems.

Aside from derogating clear Congressional intent and a quarter century of consistent agency interpretation, the Rule's cost limit on governmental providers is not rationally related to any legitimate purpose, will not accomplish the agency's objectives, and in important respects is redundant and unnecessary. CMS contends that the Rule is needed "to ensure the integrity of federal-state financial partnership" and to "strengthen[] accountability to ensure that statutory requirements within the Medicaid program are met." 72 Fed. Reg. at 2236-37. A cost limit will not advance these objectives.

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[39] *See supra* note 5.

To begin, the Rule's imposition of a strict cost limit only on governmental providers—and not other providers—defies logic, lacks any support in the scant record offered by CMS, and is arbitrary and capricious. The D.C. Circuit has warned that, "[t]o survive review under the arbitrary and capricious standard, an 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." *Tripoli Rocketry Ass'n v. BATFE*, 437 F.3d 75, 81 (D.C. Cir. 2006); *see also Bowen*, 476 U.S. at 643 ("Even according the greatest respect to the Secretary's action ... deference cannot fill the lack of an evidentiary foundation on which the Final Rules must rest."); *Swedish Hosp. corp. v. Shalala*, 1 F.3d 1261, 1263 (D.C. Cir. 1993) (construing *Burlington Mem. Hosp. v. Bowen*, 644 F. Supp. 1020 (W.D. Wis. 1986) (concluding that CMS rule was arbitrary and capricious where agency's justification "was without any reasonable basis in the rulemaking record"). CMS has fallen far short of justifying the reversal of decades of Medicaid (and Medicare) payment policy development. *See supra* at 17-21.

For CMS to have authority to implement a cost limit on governmental providers pursuant to Section 1902(a)(30)(A), the agency must determine that costs are the ultimate ceiling on "efficient and economic" payments for these providers. *See* 72 Fed. Reg. at 29823 (citing 42 U.S.C. § 1396a(a)(30)(A). Ergo, by imposing this limit on governmental providers only, CMS has inexplicably concluded that payments higher than cost may only be consistent with efficiency and economy by dint of a provider's non-governmental status.

Agencies must treat similarly situated parties similarly, absent a legitimate rationale for a distinction; yet CMS offers no explanation for this blatantly disparate treatment. *See, e.g.*, *Goldstein*, 451 F.3d at 884 (vacating as arbitrary a SEC rule that created different requirements for different-sized investment companies); *Burlington N. & Santa Fe Railway Co. v. Surface*

Transp. Bd., 403 F.3d 771, 777 (D.C. Cir. 2005) ("Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld."). Remarkably, CMS makes this distinction between efficient and economic payment levels for non-governmental providers and governmental providers for offering the *same services*. If high quality Medicaid services will be available to all Medicaid enrollees at cost-based payment levels, it stands to reason that above-cost payments would be per se unreasonable for *any* provider.[40]

CMS offers up two justifications for returning to a cost limit for governmental providers, neither of which withstands scrutiny. CMS asserts that (1) governmental providers are more likely to "use the excess of Medicaid revenue over cost to subsidize health care operations that are unrelated to Medicaid," and (2) "they may return a portion of the supplemental payments to the State as a source of revenue." 72 Fed. Reg. at 2241.

As to the first concern, CMS has either overlooked or ignored the fact that private providers are just as capable of shifting their Medicaid revenues to non-Medicaid operations as governmental providers. Moreover, CMS has offered no explanation as to why "integrity" demands that only governmental providers cease such practices. 72 Fed. Reg. at 2241. As to CMS' concern that governmental providers may return a portion of Medicaid payments to their State Medicaid agencies, the cost limit is both inadequate to prevent this result and overbroad to the extent it applies to governmental providers not engaged in such "recycling." A cost limit on

[40] In reality, governmental providers often require higher payment rates than other providers, as they frequently serve as the provider of last resort and cannot turn away Medicaid beneficiaries and the uninsured as many private providers can. Governmental providers contribute a disproportionate share of care to low income patients and offer critical yet under-reimbursed community-wide services (such as trauma care, burn care, neonatal intensive care, first response services, standby readiness capabilities, etc.). Ex. 18, Congressional Budget Office, Nonprofit Hospitals and the Provision of Community Benefits (Dec. 2006); *see also* Ex. 25, Burch Decl. ¶¶ 6-11.

payments offers no assurance that States will not require governmental providers to return a portion of their payments to the State; indeed, none of the "recycling" arrangements CMS has criticized in recent years has been premised upon a return of only above-cost revenues. In other words, payment *levels* have no bearing on whether providers are made to return funds.[41] In any event, there is a separate provision in the Rule that requires providers to retain the full amount of Medicaid payments received. 72 Fed. Reg. at 29834 (adding 42 C.F.R. § 447.207). This provision alone is sufficient to accomplish CMS' stated purpose of preventing "recycling." Moreover, as CMS itself has acknowledged, it has been able to eliminate nearly all instances of recycling through IGTs,[42] meaning that the cost limit will primarily impact governmental providers that are *not* engaged in recycling.

B. The Rule Violates the Statutory Requirement that CMS Establish Aggregate Upper Payment Limits

The cost limit provision also violates BIPA. *See supra* at 4. On October 5, 2000, CMS proposed to revise the aforementioned aggregate UPLs by requiring States to calculate separate, aggregate UPLs for State government owned or operated providers, non-State government owned or operated public providers, and private providers. 65 Fed. Reg. 60151 (Oct. 10, 2000). These UPLs were based on Medicare payment principles. 42 C.F.R. § 447.272. Shortly after CMS issued this proposed rule, Congress passed BIPA. BIPA required that CMS:

> Issue ... a final regulation *based on the proposed rule announced on October 5*, 2000 that ... modifies the upper payment limit test ... by applying *an aggregate* upper payment limit to payments made *to governmental facilities that are not State-owned or operated facilities*.

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[41] For instance, Medicaid disproportionate share hospital ("DSH") payments have been subject to a cost limit imposed by Congress since 1993. 42 U.S.C. § 1396r-4(g). Nevertheless, CMS and the Office of Inspector General ("OIG") have found instances in which providers were returning DSH payments to their States. *See, e.g.*, Ex. 22, Letter from Daniel R. Levinson, Inspector General to Mark B. McClellan, CMS Administrator (Mar. 16, 2006).

[42] *See supra* at 8-9.

H.R. 5661, 106th Cong. (emphasis added). Congress thereby directed CMS to adopt UPL regulations (1) with aggregate, rather than provider-specific, payment limits, and (2) with one of the aggregate groups being "governmental facilities that are not State-owned or operated." Moreover, the requirement that the final rule be "based on the proposed rule announced October 5, 2000" mandates that the limits must be based on Medicare payment principles as had been proposed (and not costs). BIPA therefore established UPL standards with which CMS must comply. Because Congress has clearly spoken to the issue through explicit statutory language mandating aggregate upper limits on Medicaid payments to non-state government (*i.e.*, governmental) providers, CMS is not free to adopt a provider-specific, cost-based limit on governmental providers. *See, e.g.*, *Chevron*, 467 U.S. at 846 ("[T]he agency must give effect to the unambiguously expressed intent of Congress.").

In response to commenters who pointed out the BIPA violation inherent in adoption of a cost limit, CMS suggested that it had fulfilled its BIPA obligation when it finalized the October 5, 2000 rule in January of 2001. 72 Fed. Reg. at 29775 (citing 66 Fed. Reg. 3147 (Jan. 12, 2001)). But this self-serving interpretation saps all meaning from the Congressional directive. Congress specifically singled out certain provisions of the proposed rule for implementation—including the aggregate payment limit and the existence of the category of non-State governmental providers. It is unavoidable that Congress defined for CMS the proper contours of the upper payment limits, and those contours clearly permit governmental providers to be paid in excess of costs. In requiring CMS to adopt specific aggregate upper payment limits, Congress could not have intended for CMS subsequently to undo those limits after they were finalized. Such an understanding of the BIPA mandate is irrational and unsustainable. Thus, the cost limit violates Section 705(a) of BIPA (and is also an unreasonable construction of that statute).

C. The New Definition of "Unit of Government" is Impermissibly Restrictive

In the Rule, CMS adopts a definition of "unit of government" that requires an entity to have "generally applicable taxing authority" or "direct access to generally applicable tax revenues," by being an integral part of a unit of government with taxing authority and that is legally obligated to fund the provider's expenses and liabilities. 72 Fed. Reg. at 29832.[43] These conditions contradict the definition of unit of local government and the standards for permissible local sources found in the Medicaid Statute. 42 U.S.C. § 1396a(a)(2) & 1396b(w)(7)(G). This definition directly contradicts Section 1903(w)(7)(G), which does impose such caveats on its broad definition of a unit of government. Despite the seemingly technical nature of a definitional change, its effect would be a severe constriction in the scope of State and local entities that can share in the costs of supporting the Medicaid program, based on an arbitrary distinction between governmental entities that have direct access to tax revenues and the many types of legitimate governmental entities that do not.[44] In turn, this curtailing of legitimate public sources will significantly scale back federal financial support for the Medicaid program—due to the loss of federal matching funds for the contributions of heretofore legitimate sources of the non-federal share. Congress plainly did not empower CMS to make such a fundamental change to the Medicaid program, and this new definition is patently unreasonable. *See, e.g.*, *MCI*, 512 U.S. at 231-32 (rejecting FCC's attempt to make fundamental revision to Federal Communications Act).

1. The Act Does Not Condition Eligibility to Participate in Funding the Non-Federal Share on Direct Access to Tax Revenues

In establishing joint federal-state financing for the Medicaid program, Congress spoke clearly to the broad scope of permissible sources for funding the non-federal share, and granted

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[43] Amending 42 C.F.R. § 433.50(a)(1)(i). Also meeting the new definition are entities receiving appropriated State funds as a State university teaching hospital and Indian Tribes or Tribal Organizations meeting specified criteria.
[44] Ex. 29, Lassiter Decl. ¶¶ 22-24; Ex. 31, Nathan Decl. ¶¶ 20-22, 24; Ex. 34, Schroffel Decl. ¶¶ 16-20.

States discretion to use local as well as State funds for up to 60 percent of their share.[45] 42 U.S.C. § 1396a(a)(2). Congress has required States to report quarterly to CMS "the amount appropriated or made available by the State *and its political subdivisions*" for Medicaid expenditures. 42 U.S.C. § 1396b(d)(1) (emphasis added). In keeping with our federalist system, Congress has deliberately not dictated to States which of its political subdivisions are sufficiently governmental to participate in Medicaid funding and it certainly has not conditioned local contributions on a source's access to tax revenues.

CMS has long acknowledged the broad scope of permissible contributions from "local sources" pursuant to Section 1902(a)(2) of the Act. Longstanding regulations allow States to use "[p]ublic funds" as the non-federal share if they "are appropriated directly to the State or local Medicaid agency, or transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section." 42 C.F.R. § 433.51(b). This is the interpretation that CMS is now discarding.

In so doing, CMS does not seek support in the founding provisions of the Medicaid Statute. Rather, CMS bases its dramatic restrictions of non-federal sources on a new interpretation of the 1991 Provider Tax Amendments. Pub. L. No. 102-234. This legislation imposed limitations only on non-federal share funding derived from provider taxes and donations. It did not purport to impose restrictions on other sources permitted under Section

[45] This broad financing base is reflected in the terminology Congress chose to use throughout Title XIX. The statute does not establish a "State share" of Medicaid program expenditures but rather consistently refers to the "non-federal share" to denote the portion of program expenditures not paid for by the federal government. *See, e.g.*, 42 U.S.C. §§ 1396a(a)(2); 1396b(w)(5); 1396b(w)(6). Indeed, the only statutory mandate with respect to "State" funding of the program is contained in Section 1902(a)(2) of the Act, requiring the State to provide at least 40 percent of the non-federal share of the funding.

1902(a)(2), and patently did not restrict the use of IGTs or CPEs. *See* 42 U.S.C. § 1396b(w)(1)(A).

For purposes of these restrictions, Congress set out in the 1991 legislation a definition of units of local government, which it described as a "city, county, special purpose district, or other governmental unit in the State." *Id.* § 1396b(w)(7)(G). CMS contends that, under the 1991 Amendments, *only* funds from "units of government" are permissible non-federal sources. 72 Fed. Reg. at 29752 & 29832. And yet, the Rule is unfaithful to this statutory definition. The Rule defines "unit of local government" as, "a State, a city, a county, a special purpose district, or other governmental unit in the State that *has taxing authority, has direct access to tax revenues*," or meets other narrow criteria. *Id.* at 29832 (emphasis added). If Congress had intended to narrow the definition by applying these extra conditions, it plainly could have done so. *See Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there."). In any event, this statutory definition applies only "[f]or purposes of this subsection [1903(w)]," which only addresses provider taxes and donations. 42 U.S.C. § 1396b(w)(7). In and of itself, it provides no independent basis for generally limiting local sources to those with access to tax revenues.

CMS seeks further refuge in Section 1903(w)(6)(A). CMS contends that this provision reflects Congress' "clearly expressed" intent that an entity "must be able to use funds derived from State or local taxes (or funds appropriated to State university teaching hospitals)." 72 Fed. Reg. at 29753. In keeping with Congress' discrete purpose to restrict only certain donations and taxes, however, Section 1903(w)(6)(A) actually *limits* CMS from restricting other forms of contributions by providers, including the IGTs and CPEs restricted in the Rule:

> The Secretary *may not restrict* States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this subchapter, regardless of whether the unit of government is also a health care provider, except as provided in section 1396a(a)(2) of this title [Section 1902(a)(2)], unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

42 U.S.C. § 1396b(w)(6)(A) (emphasis added). What Congress did *not* address in subsection (w)(6)(A) are contributions from local governmental sources that are neither (1) prohibited donations or taxes under Section 1903(w) (*i.e.*, "that would not otherwise be recognized as the non-Federal share"), nor (2) "derived from State or local taxes." These sources not mentioned therefore continue to be permissible pursuant to Section 1902(a)(2), which contains no tax-based limitations. 42 U.S.C. § 1396a(a)(2).

CMS instead reads the provision to delineate which funds from local governments are considered to be provider taxes or donations—which are subject to the strict requirements of the Provider Tax Amendments—*and* which funds are considered to be permissible IGTs and CPEs—notwithstanding the standard in Section 1902(a)(2). According to CMS' revised interpretation, "Section 1903(w)(6)(A) of the Act carved out an exception to the financing restrictions that Congress itself enacted in section 1903(w)." 72 Fed. Reg. at 29754. In other words, according to CMS, Section 1903(w)(6)(A) describes the *only* transfers and contributions that continue to be permissible in the wake of the 1991 law. This is flatly incorrect. By selectively restricting provider donations and taxes—but not other contributions—Congress clearly spoke to the continuing validity of other such sources authorized in Section 1902(a)(2).

CMS has not suggested that its new unit of government definition is a matter of agency discretion. Rather, CMS views the 1991 Provider Tax Amendments as Congress' "*clearly expressed* . . . intent." 72 Fed. Reg. at 29753 (emphasis added). If this 1991 legislation "clearly"

required such a restriction, however, one wonders why CMS waited until 2007 to implement this dramatic change, particularly given that the Provider Tax Amendments *required* the agency to issue conforming regulations.[46] If, as CMS now believes, Congress passed Section 1903(w) in 1991 to require the disqualification of governmental funds not derived from taxes, then the legislation specifically mandated the agency's immediate issuance of implementing regulations. The intervening 15 years of inaction belie this interpretation. At a minimum, Defendants' position in this regard is an unreasonable construction of the Statute.

2. *The Rule's Focus on Tax Revenues is Not a Reasonable Construction of the Statute, Arbitrary and Capricious, and Inconsistent with Federalism*

The new requirement that entities have direct access to tax revenues in order to contribute to the non-federal share of Medicaid expenditures, and the resulting reduction in federal financial participation, is an unreasonable construction of the Statute, arbitrary and capricious, and lacks any rational basis. CMS would require States and providers long-recognized as governmental under State law to undertake burdensome reviews to assess compliance with a vague, arbitrarily determined federal definition, where the basis for this new policy is non-existent. CMS points to nothing in the legal canon that equates access to tax revenues with governmental status.[47] Many a provider established as governmental under State law and charged with a uniquely governmental mission will suddenly be disqualified from contributing to its State's share of Medicaid funding—merely because the provider does not have direct access to tax revenues.[48] *Id.* Yet, these providers' expenses related to providing Medicaid services will be no less real than before the Rule, and States' financial burdens will only be

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[46] Under Section 5(a), "the Secretary . . . *shall issue* such regulations (on an interim or final basis) as may be necessary to implement this Act and the amendments made by this Act." Pub. L. No. 102-234, § 5(a) (emphasis added).

[47] *See, e.g.*, JOHN MARTINEZ ET AL., LOCAL GOVERNMENT LAW § 23:2 (2006) ("Local government units do not have inherent power to tax because, in contrast to the state which creates them, they are viewed as subordinate units exercising only delegated competence.")

[48] *See, e.g.*, *supra* n.44.

exacerbated. Although promoting fiscal integrity is a worthy goal, the precise evil that CMS purports to address with this initiative remains unexplained.

The arbitrary nature of CMS' delineation of appropriate units of State and local government underscores why this area has historically been left to States. In the preamble to the Rule, CMS suggests that *taxing authority* is not necessarily required, but that access to *tax revenues*, via "standard appropriations processes and without the need for a contractual arrangement . . . is a characteristic that reflects a health care provider's governmental status." 72 Fed. Reg. at 29752. CMS' suggestion merely begs the question. Although private entities may be eligible to receive appropriations of State or local tax revenues from legislatures just as governmental providers can, the Rule would exclude historically public institutions that have long contributed to their State's Medicaid programs, merely because they sustain themselves without resort to tax revenues. Ex. 29, Lassiter Decl. ¶ 22-23; Ex. 34, Schroffel Decl. ¶ 17-19; Ex. 31, Nathan Decl. ¶ 20-21.

Over the past few years, CMS has consistently raised concerns about certain financing arrangements, including many that are legally permissible under existing federal law. *See supra* at 8, 26-27. Plaintiffs are not insensitive to the agency's efforts to curtail certain abusive practices, but this new unit of government definition does not address these concerns. It will prevent legally authorized contributions from heretofore governmental providers that are not abusive at all, while continuing to allow practices that may be abusive. The consequences of this arbitrary new definition will be a reduction in the legitimate sources of non-federal revenues to support health care for the Medicaid population. The agency has offered no factual support for imposing these crippling new restrictions on State Medicaid programs and providers.

More fundamentally, CMS' imposition of a restrictive nationwide definition of units of government contravenes a core aspect of State sovereignty and principles of federalism embodied in applicable Executive Orders and the United States Constitution. The Supreme Court has held that determinations of political subdivisions and their functions "rests in the absolute discretion of the State." *Reynolds v. Sims*, 377 U.S. 533, 575 (1964) (quotations omitted); *see also City of Newark v. New Jersey*, 262 U.S. 192, 196 (1923) (holding that "[t]he regulation of municipalities is a matter peculiarly within the domain of the State"). Providers that have legitimately been deemed governmental under State law and held to be "political subdivisions" and "public agencies" by the courts will not qualify as units of government under the Rule. Ex. 31, Nathan Decl. ¶¶ 6, 12-14; Ex. 29, Lassiter Decl. ¶ 14-15; Ex. 34, Schroffel Decl. ¶ 11-12.

CMS has abandoned any notion of State discretion in this Rule.[49] CMS should not so cavalierly upset the balance established by Congress in the Medicaid Statute, which from its inception recognized the role of States as partners in the Medicaid program.

D. Issuance of the Rule Violates the Statutory Moratorium Against Taking Any Action in Furtherance of the Rule

Preliminary injunctive relief is warranted based on the Rule's substantive violations of the Social Security Act and BIPA, described above, and Plaintiffs urge the Court to rule on those bases. In addition, an injunction also should issue based on CMS' manifest violation of the Moratorium. *Chevron* does not apply to CMS' issuance of the Rule under the Moratorium. Defendants are granted no deference on this issue, which is "a pure question of statutory

[49] The agency also failed to "minimize those burdens that uniquely or significantly affect such governmental entities" or "seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions." 58 Fed. Reg. 51735, 51736 (Oct. 4, 1993) (Executive Order 12866). President Bush recently amended Order 12866, but did not change these principles. 72 Fed. Reg. 2763 (Jan. 23, 2007) (Executive Order 13422).

interpretation" and does not involve a statute Defendants are entrusted to administer. *Scheduled Airlines Traffic Offices, Inc. v. DOD*, 87 F.3d 1356, 1361 (D.C. Cir. 1996); *see also Professional Reactor Operator Soc. v. NRC*, 939 F.2d 1047, 1051 (D.C. Cir. 1991) (no *Chevron* deference owed to agency interpretation of statutes "outside the agency's particular expertise and special charge to administer"); *accord Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990).

CMS issued the Rule in direct violation of the Congressional Moratorium prohibiting the agency from doing exactly that. Perhaps more troubling, CMS issued the Rule with knowing disregard for Congressional intent. On this basis, the purportedly final Rule should be enjoined and declared invalid. The Moratorium expressly provides that CMS, for the year-long moratorium period, shall not: "take any action (through promulgation of regulation, issuance of regulatory guidance, or other administrative action) to—(A) finalize or otherwise implement provisions contained in the proposed rule published on January 18, 2007 ... [or] (B) promulgate or implement any rule or provisions similar to the provisions described in subparagraph (A)." Pub. L. No. 110-28, § 7002(a).[50] The prohibition on CMS action took effect on May 25, 2007, when the Moratorium was signed by the President. Nevertheless, CMS published the purportedly final Rule in the Federal Register on May 29, 2007 in direct and knowing violation of the Congressional Moratorium. 72 Fed. Reg. 29748.[51] This publication of the Rule in the Federal Register is an action attributable to CMS as part and parcel of the substantive rulemaking process required by the APA. 5 U.S.C. § 552(a)(1)(D).[52] CMS cannot avoid its responsibility

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[50] *See supra* at 10.

[51] *See also* 72 Fed Reg 55160 (Sept 28, 2007) (CMS acknowledging that, "on May 29, 2007 (72 FR 29748), CMS published a final rule (CMS–2258–FC) ...").

[52] The "action" finalizing the Rule is its publication, in accordance with the APA. The Federal Register Act recognizes that an agency issuance or notice can be "valid as against a person" when displayed in the Office of the Federal Register. 44 U.S.C. § 1507. By its terms, however, the Rule was not to be immediately effective. *See* 72 Fed. Reg. at 29748 (providing a July 30, 2007 effective date).

for this "action" by hiding behind the ministerial role of the Office of Federal Register in effecting the publication.

CMS may contend that it should be credited only with filing the Rule with the Office of the Federal Register on May 25th, and purportedly doing so earlier in the day than the President signed the legislation. *See* 72 Fed. Reg. at 29836 (recording date and time of submission). Leaving aside the agency's knowing disregard for Congressional intent reflected in legislation awaiting only a Presidential signature,[53] this is irrelevant, given that the action finalizing the Rule occurred four days later. 5 U.S.C. § 552(a)(1)(D). Moreover, unless otherwise specified, statutes have effect the first moment of the day they are signed into law. *See, e.g., Bd. of Comm'rs of Kearny County Kan. v. Vandriss*, 115 F. 866, 871 (8th Cir.), *cert. denied* 187 U.S. 642 (1902) ("[A] legislative act, when nothing is said to the contrary, takes effect on the day of its passage or approval and is to be regarded as in effect during the whole of that day."); *United States v. Will*, 449 U.S. 200, 225 (1980) ("[T]he law generally rejects all fractions of a day, in order to avoid disputes."); *see also Gozlon-Peretz v. United States*, 498 U.S. 395, 404 (1991) ("It is well established that, absent a clear direction ... to the contrary, a law takes effect on the date of its enactment."); *Gardner v. Collector*, 73 U.S. (6 Wall.) 499, 504 (1867) (holding that congressional acts become effective on the date they are signed by the President). As a result, the Moratorium took legal effect and was binding on CMS at 12:01 a.m. on May 25, 2007—regardless of the actual time of day the President signed the Moratorium into law.[54]

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[53] The Moratorium evinces a specific Congressional mandate that CMS not "finalize or otherwise implement" the Rule for one year—not merely to delay the Rule from taking effect. *Holloway v. United States*, 526 U.S. 1, 6 (1999) ("[T]he language of the statutes that Congress enacts provides the most reliable evidence of its intent.").

[54] At least one commentator highlighted the extensive errors throughout the Rule to illustrate the haste with which CMS purported to finalize the Rule. *See* Ex. 24, Letter from Carol A. Herrmann-Steckel, Commissioner, Alabama Medicaid Agency to Leslie V. Norwalk (Jul. 10, 2007).

In rare instances in which "substantial justice" so requires, courts will consider the precise moment a bill is actually signed into law—for instance, when a statute is criminal or penal in nature. *See, e.g.*, *Burgess v. Salmon*, 97 U.S. 381, 384 (1878) (holding that federal legislation making it an offense to distribute tobacco without a proper tax stamp could not be applied to the defendant who had sold tobacco in the morning, where the law was not signed until later that afternoon); *Taylor v. Brown*, 147 U.S. 640, 645-46 (1893) ("[A]s to the general doctrine that the law does not allow of fractions of a day, it is settled that when substantial justice requires it courts may ascertain the precise time when a statute is approved or an act done."). "Substantial justice" is not in the agency's favor here. CMS was well aware that Congress intended to prevent CMS from implementing the proposed version of the Rule. *See supra* at 11-12 & Appendix A. Rather, CMS blatantly rushed the Rule in an attempt to evade Congressional intent. Thus, substantial justice calls for strict enforcement of the Moratorium.

In fact, CMS has continued to disregard the Moratorium. After CMS' invalid issuance of the Rule, the only course of action in keeping with the clear will of Congress would have been formally to withdraw it. The Moratorium prohibits the Secretary from taking "any action," including "other administrative action," to implement the Proposed Rule. Under the APA, "agency action" includes an agency's "failure to act." 5 U.S.C. § 551(13). As a result, CMS' failure to act to withdraw the Rule amounts to a continuing violation of the Moratorium.

II. Plaintiffs Will Suffer Irreparable Harm If The Injunction Is Not Issued

Unless this Court enters an injunction preventing implementation of the Rule, Plaintiff Alameda and members of the Association Plaintiffs—as well as the low-income Medicaid and uninsured patients these hospitals serve—will suffer permanent, irreparable harm.

The Rule will result in substantial losses, and potentially even closure, for these providers.[55] Loss of these federal funds will be devastating, as the following examples of harm demonstrate:

- Alameda will lose 19 percent of its $460 million operating budget, increasing the annual deficit by $85 million and threatening the hospital's ongoing viability. Ex. 29, Lassiter Decl. ¶ 28. If Alameda remains viable, it estimates this loss will result in: longer waits in the emergency room for inpatient beds, aggravating an already significant problem; rationing of care and longer wait times in the clinics for specialists and primary care; delayed surgeries; complete closing of some outpatient primary and specialty clinics; closure of some inpatient units; a forced shift in focus to acute services rather than preventative services, resulting in sicker patients entering our facilities in the acute care setting; reduction in HIV services, physician training programs, health education and outreach programs, and dental services; and reduction in work force. *Id.* ¶ 21.
- UCH will lose $34 million, or 6 percent of its operating revenues, in Medicaid payments on which it relies to provide care to Medicaid patients as one of the two largest safety net providers in the state. As a result, UCH will have to reexamine its future participation in the Colorado Indigent Care Program, threatening access to its comprehensive specialty care for Medicaid and other low-income patients. Ex. 34, Schroffel Decl. ¶ 7-8, 22-23.
- Lee Memorial will lose $23.2 million in safety net payments it currently receives under the Medicaid demonstration waiver, or 52 percent of its $44 million budgeted margin from operations. As a result, even though Lee Memorial is the only trauma center in the region, it will be forced to consider whether the safety net services it provides can continue. In addition, Lee Memorial will be forced to delay or cease significant patient-care related capital expenditures. Ex. 31, Nathan Decl. ¶ 24-25.
- Thomason will lose $22 million annually in federal Medicaid funding, constituting nearly 7 percent of its operating budget. In order to continue operating, Thomason will be forced to develop an immediate action plan which would have to include curtailing or eliminating services to a community that is already underserved, limiting further expansion of some services despite growing community need, and cutting particularly costly services. Ex. 33, Valenti Decl. ¶ 15-17.
- Hurley will lose $6 million in annual funding, representing approximately 2 percent of the Medical Center's operating budget, if it is determined it does not fit the definition of unit of government. If Hurley continues to qualify as a unit of government, Hurley will lose approximately $12.8 million, constituting

[55] There is no indication that States will make up for the significant losses in federal funding with additional State revenues. *See* Ex. 34, Schroffel Decl. ¶¶ 24-25; Ex. 30, Wardell Decl. ¶¶ 23-24; Ex. 31, Nathan Decl. ¶26; Ex. 32, Lassiter Decl. ¶¶ 29-30; Ex. 33, Valenti Decl. ¶ 18; Ex. 35, Entwistle Decl. ¶ 15; Ex. 25, Burch Decl. ¶ 24. Even if States provided additional funds, it would not remove the harm suffered simply as a result of the loss of federal funds for which these providers rightly qualify.

approximately 4 percent of the hospital's operating budget. The impact of this loss of funds on hospital services would result in possible reductions in staffing and curtailment of plans for future capital projects that are greatly needed by the hospital and the community, such as a much needed expansion of Hurley's existing Emergency Department—the tri-county region's center for disaster preparedness. The impact on access and services for Medicaid beneficiaries would be detrimental to the Genesee County community and the more than 22 additional counties it serves. Ex. 30, Wardell Decl. ¶ 20-21.

- OHSU will lose $2.8 million annually in federal Medicaid funding, which will severely damage its ability to continue to provide health care services and fulfill its one of the core aspects of its mission, teaching. OHSU may be forced to consider cuts to its programs, including under-reimbursed specialty services, and Medicaid and charity care. Ex. 32, Rapp Decl. ¶ 12-14.

- UUHC will lose at least $25 million annually in federal Medicaid funding, which constitutes more than 3.5 percent of its operating budget. UUHC will be forced to make cuts or reductions among services such as inpatient psychiatric services, pain clinic services, community clinics, inpatient beds, and medical school support. The cuts will forestall needed improvements to our facilities and equipment and will require UUHC to limit needed expansion of some services despite growing community need. For example, its planned expansion of psychiatric services will need to be delayed pending funding resources. Ex. 35, Entwistle Decl. ¶ 13-15.

- Many safety net hospitals will be unable to meet current demand for services and will be incapable of keeping pace with the fast-paced changes in technology, research and best practice s that result in the highest quality of care, if they are able to remain viable at all. Members of NAPH have reported that they will have to: dismantle significant components of their ambulatory care system and scale down emergency departments; cut services and increase the time that patients wait to get treatment; reduce primary and preventative services; close nursing units or eliminate inpatient beds, which would have a direct impact on services to the residents; and close down teaching programs, jeopardizing the training of physicians who serve their communities. Ex. 25, Burch Decl., ¶ 19, 21-22.

- Many AHA members will be forced to endure deep cuts in services, and will be unable to deliver quality health care to those in their communities with nowhere else to turn. These cuts will further undermine the ability of hospitals to continue their substantial investments in health care initiatives, including adoption of electronic health records, reducing disparities in care provided to minority populations, and enhancing access to primary and preventative care. Ex. 26, Hatton Decl., ¶ 15-16.

- Many AAMC academic medical center members will be forced to cut essential services to Medicaid and other low-income patients. The Rule will upset the delicate balance of resources upon which teaching hospitals rely to fulfill their patient care, education, and other missions. Ex. 27, Baer Decl. ¶ 15, 19.

- N.A.C.H.'s children's hospital members will face decreases in reimbursement from reductions in benefits or coverage for their Medicaid patients and cuts to payments to

providers, decreases that will have a profound impact on their ability to provide critical medical services to all children. N.A.C.H.'s members will face decisions about service cutbacks that impact access to services for all children, include the 29 million children currently covered by Medicaid. Ex. 28, McAndrews Decl. ¶ 14-18.

The irreparable harm described here is by no means exhaustive. On March 3, 2008, the House Committee on Oversight and Government Reform published a report based on survey responses of Medicaid directors from 43 States and the District of Columbia. Ex. 20, Cmte. on Oversight and Government Reform, *The Administration's Medicaid Regulations: State-by-State Impacts* (Mar. 2008). The report concluded that the expected loss of federal funding from the responding States was over $21 billion over five years—over four times the amount estimated by CMS. Several States reported that they expected severe consequences for the health care systems in their states. Such a massive loss would cripple the fragile safety net system.

Given the precarious financial footing of the safety net providers impacted by the Rule, these losses will have significant adverse consequences on an already overburdened health care system, at a time when rising uninsurance and an economic downturn make Medicaid providers more critical than ever. No enterprise can be expected to stay in business while operating at a loss. Courts have found irreparable harm when the viability of such an enterprise is at risk. *See, e.g.*, *World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61, 67 (D.D.C. 2000) ("[E]conomic loss may constitute irreparable harm where the loss threatens the very existence of the movant's business.").

The injuries suffered by providers and patients will be irreparable because they cannot be repaired by this Court. The negative impact on many Medicaid beneficiaries and low-income communities will be long-term. Beneficiaries 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. The harm from this Rule will be immediate and for many

individuals and communities, permanent—even if the Rule is reversed in the future. Furthermore, if the Rule is not enjoined, but later found to be unlawful, Plaintiffs' will not be able to recover foregone Medicaid payments because the federal government enjoys sovereign immunity. These losses are irreparable.

The Court has recognized that "admittedly economic" injury to a plaintiff amounts to irreparable harm if "no adequate compensatory or other corrective relief" could be provided at a later date. *See Bracco Diagnostics v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (issuing injunction against Secretary of HHS); *see also Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1251 (10th Cir. 2001) (because "monetary relief might not be available to [plaintiff] because of the state's sovereign immunity," harm to plaintiff was irreparable); *Nat'l Medical Care, Inc. v. Shalala*, 1995 WL 465650 (D.D.C. June 6, 1995) (because plaintiff would be unable to recover against the government even if it subsequently prevailed on the merits, a preliminary injunction was proper).

Additionally, 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 would suffer irreparable harm if HHS was not enjoined from suspending Medicare reimbursement, as "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 Found. v. Bank of Tokyo-Mitsubishi Ltd.*, 15 F. Supp. 2d 1, 5 (D.D.C. 1997) (hospital's claim that it would have to stop taking patients constituted irreparable injury, although denying the hospital's request for injunctive relief based on the balance of harms). This Court should also find that Plaintiffs face irreparable harm from the Rule.

III. The Balance Of Harms Strongly Favors Plaintiffs

The balance of harms in this case also strongly favors Plaintiffs. Alameda, all of the providers represented by Association Plaintiffs in this case, and the Medicaid beneficiaries they serve will suffer immediate, irreparable harm should the Court permit the Rule to be implemented. By contrast, there is no harm that will inure to Defendants if the Rule is enjoined. Congress already took action to prevent the Rule from being implemented for one year. If CMS had adhered to the Moratorium, the Rule could not have been promulgated until May 25, 2008 at the earliest, and could not have become effective until at least 60 days later. *See* 5 U.S.C. § 801(a)(3). The Medicaid program operates under Congress' spending power, so it is within Congress' purview to determine what policies are helpful or harmful to the program.

In any event, a temporary delay to give the Court sufficient time to review the merits of this case does not constitute harm to Defendants. Case law supports issuing an injunction where the only injury to the defendant agency is delay. *See Inst'l Long Term Care v. Shalala*, 947 F. Supp. 15 (D.D.C. 1996) (delay in administrative process was inadequate basis for denying preliminary injunction to stop HHS from terminating a nursing home's participation in the Medicare program); *DSE, Inc. v. United States*, 3 F. Supp. 2d 1464, 1472 (D.D.C. 1998) (issuing injunction despite resulting delay in performing a government contract); *Nat'l Treasury Employees Union v. U.S. Dep't of Treasury*, 838 F. Supp. 631, 640 (D.D.C. 1993).

IV. Issuance of An Injunction Is Plainly In the Public Interest

A preliminary injunction is plainly in the public interest. Protection of the health and well-being of Medicaid beneficiaries, and preserving the fiscal viability of State Medicaid programs and the hospitals that provide Medicaid services defines the public interest in this case. *See Beverly Enterprises*, 432 F. Supp. at 1079 (pointing to the Medicare statutory and regulatory

scheme and stating that, "both Congress and the Secretary have recognized ... the compelling public interest in providing timely and uninterrupted health care funding").

Ultimately, it is not in the public interest to allow Defendants to contravene the plain language and legislative intent of the statutes governing the Medicaid program, to issue arbitrary and capricious new policies not rationally connected to any legitimate objectives, or knowingly to violate Congress' Moratorium against implementation of the Rule. There exists "a strong public interest in requiring an agency to act lawfully, consistent with its obligations under the APA." *Bracco Diagnostics*, 963 F. Supp. at 30; *see also Clarke v. Office of Fed. Hous. Enter. Oversight*, 355 F. Supp. 2d 56, 66 (D.D.C. 2004) (noting a "substantial public interest" in ensuring that a federal agency "acts within the limits of its authority"); *Mova Pharm. Corp.*, 140 F.3d at 1066 (affirming preliminary injunction based in part on the public interest in the faithful execution of laws). Consequently, it is in the public interest that Defendants be enjoined from acting unlawfully.

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., Temple University v. White,* 941 F.2d 201, 220 (3d Cir. 1991) (upholding waiver of Rule 65 bond where hospital challenged State's Medicaid payment methods; litigation seeking to preserve hospital's "role as a community hospital serving a disproportionate share of low income patients" was "clearly in the public interest."); *Bass v. Richardson,* 338 F. Supp. 478, 491 (S.D.N.Y. 1971) (waiving the bond requirement in case where the plaintiffs sued to correct abuses in a national health program that Congress intended to be vigorously and properly administered).

VI. Timing of Requested Relief

The Congressional Moratorium on the Rule expires on May 25, 2008. Accordingly, Plaintiffs respectfully request that the Court enter an Order on the Motion for Preliminary Injunction prior to that date.

CONCLUSION

For the foregoing reasons, Plaintiffs urge the Court to issue, prior to May 25, 2008, a preliminary injunction in the form submitted herewith requiring Defendants to withdraw the Rule and enjoining Defendants from enforcing the Rule.

Respectfully submitted,

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APPENDIX

Exhibits

18. Congressional Budget Office, *Nonprofit Hospitals and the Provision of Community Benefits*, Dec. 2006.

19. MedPAC, Rep. to the Congress on Medicare Payment Policy. (Mar. 2007).

20. Committee on Oversight and Government Reform, *The Administration's Medicaid Regulations: State-by-State Impacts*, March 2008.

21. Letter from Sec. Michael O. Leavitt, Secretary of CMS, to the Honorable J. Dennis Hastert, Speaker of the House of Representatives (Aug. 5, 2005).

22. Letter from Daniel R. Levinson, Inspector General to Mark B. McClellan, CMS Administrator (Mar. 16, 2006).

23. Letter from Leslie Norwalk to Sens. Max Baucus and Charles Grassley (Mar. 27, 2007).

24. Comment Letter from Carol A. Herrmann-Steckel, Commission Alabama Medicaid Agency to Leslie V. Norwalk (Jul. 10, 2007).

25. Declaration of Christine Capito Burch, Executive Director of National Association of Public Hospitals and Health Systems ("NAPH").

    A. Letter from Sens. Jeff Bingaman, Elizabeth Dole, *et al.*, to Senate Finance, Energy & Commerce and Ways & Means Committees (December 12, 2007).

    B. Letter from Sens. Richard Durbin, Elizabeth Dole, *et al.*, to Senate Finance Committee (Feb. 15, 2007).

    C. Letter from Representatives Ann Eshoo, Peter King, *et al.*, to Energy & Commerce and Ways & Means Committees (February 26, 2007).

    D. Comment Letter to Proposed Rule from NAPH to Acting Administrator Leslie Norwalk (Mar. 8, 2007).

    E. Letter from Representatives Gene Green, Michael Burgess, *et al.*, to Sec. Michael Leavitt (Mar. 8, 2007).

    F. Letter from Chairman John Dingell, *et al.*, to Sec. Michael Leavitt (Mar. 12, 2007).

    G. Letter from Sens. John Rockefeller, Gordon Smith, *et al.*, to Sec. Michael Leavitt (Mar. 16, 2007).

    H. Letter from Rep. Henry Waxman, *et al.*, to Sec. Michael O. Leavitt (Mar. 19, 2007).

I. Comment Letter to Final Rule from NAPH to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

26. Declaration of Melinda Reid Hatton, Senior Vice President and General Counsel of the American Hospital Association ("AHA").

A. Comment Letter to Proposed Rule from AHA to Acting Administrator Leslie Norwalk (Mar. 15, 2007).

B. Comment Letter to Final Rule from AHA to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

27. Declaration of Ivy Baer, Regulatory Counsel of the Association of American Medical Colleges ("AAMC").

A. Comment Letter to Proposed Rule from AAMC to Acting Administrator Leslie Norwalk (Mar. 19, 2007).

B. Comment Letter to Final Rule from AAMC to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

28. Declaration of Lawrence A. McAndrews, President and Chief Executive Officer of the National Association of Children's Hospitals ("N.A.C.H.").

A. Comment Letter to Proposed Rule from N.A.C.H. to Acting Administrator Leslie Norwalk (Mar. 12, 2007).

29. Declaration of Wright Lassiter, Chief Executive Officer of Alameda County Medical Center.

A. Comment Letter to Proposed Rule from Alameda County Medical Center to Acting Administrator Leslie Norwalk (Mar. 16, 2007).

B. Comment Letter to Final Rule from Alameda County Medical Center to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

30. Declaration of Patrick R. Wardell, President and Chief Executive Officer of Hurley Medical Center.

A. Comment Letter to Final Rule from Hurley Medical Center to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

B. Letter from the IRS to Hurley Medical Center (Oct. 18, 1995).

C. Michigan Sales and Use Tax Certificate of Exemption

31. Declaration of James R. Nathan, President and Chief Executive Officer of Lee Memorial Health System.

A. Comment Letter to Final Rule from Lee Memorial Health System to Acting Administrator Leslie Norwalk (Mar. 16, 2007).

B. Comment Letter to Proposed Rule from Lee Memorial Health System to Acting Administrator Leslie Norwalk (Jul. 18, 2007).

32. Declaration of Peter Rapp, Executive Vice President of Oregon Health & Science University.

A. Comment Letter to Proposed Rule from Oregon Health & Science University to Acting Administrator Leslie Norwalk (Mar. 7, 2007).

B. Comment Letter to Final Rule from Oregon Health & Science University to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

33. Declaration of James N. Valenti, Chief Executive Officer of R.E. Thomason General Hospital.

A. Resolution of the Board of Managers of the El Paso County Hospital District Opposing Proposed Medicaid Rule (Mar. 13, 2007).

B. Comment Letter to Proposed Rule from Thomason General Hospital to Acting Administrator Leslie Norwalk (Mar. 19, 2007).

34. Declaration of Bruce Schroffel, President and Chief Executive Officer of University of Colorado Hospital Authority.

A. Comment Letter to Proposed Rule from University of Colorado Hospital to Acting Administrator Leslie Norwalk (Mar. 19, 2007).

B. Comment Letter to Final Rule from University of Colorado Hospital to Acting Administrator Leslie Norwalk (Jul. 13, 2007).

35. Declaration of David Entwistle, Chief Executive Officer of the University of Utah Hospitals and Clinics.

A. Comment Letter to the Proposed Rule from A. Lorris Betz and David Entwistle to Acting Administrator Leslie Norwalk (Mar. 16, 2007).