ALAMEDA HEALTH SYSTEM, et al., Plaintiffs,

v.

CENTERS FOR MEDICARE AND MEDICAID SERVICES, et al., Defendants.

COUNTY OF SANTA CLARA, Plaintiff,

v.

ERIC D. HARGAN, in his official capacity as Acting Secretary, U.S. Department of Health and Human Services; et al., Defendants.

Case Nos. 16-cv-5903-PJH, 16-cv-6553-PJH

United States District Court, N.D. California.

December 18, 2017.

Alameda Health System, Plaintiff, represented by Danny Yeh Chou, Office of the County Counsel Santa Clara County.

Alameda Health System, Plaintiff, represented by Diane Ung, Foley and Lardner LLP, John Joseph Atallah, Foley and Lardner LLP & Robert Cary Leventhal, Foley and Lardner LLP.

County of Contra Costa, Plaintiff, represented by Danny Yeh Chou, Office of the County Counsel Santa Clara County, Diane Ung, Foley and Lardner LLP, John Joseph Atallah, Foley and Lardner LLP & Robert Cary Leventhal, Foley and Lardner LLP.

Regents of the University of California, Plaintiff, represented by Danny Yeh Chou, Office of the County Counsel Santa Clara County, Diane Ung, Foley and Lardner LLP, John Joseph Atallah, Foley and Lardner LLP & Robert Cary Leventhal, Foley and Lardner LLP.

County of Santa Clara, Plaintiff, represented by Danny Yeh Chou, Office of the County Counsel Santa Clara County, Ling Yang Lew, Santa Clara County Counsel's Office & Lorraine Van Kirk, Office of the County Counsel.

Centers for Medicare and Medicaid Services, Defendant, represented by Carol Federighi, USDJ-Civil Division.

Eric D. Hargan, in his official capacity as Acting Secretary, U.S. Department of Health and Human Services, Defendant, represented by Carol Federighi, USDJ-Civil Division.

ORDER RE CROSS-MOTIONS FOR SUMMARY JUDGMENT

PHYLLIS J. HAMILTON, District Judge.

The parties' cross-motions for summary judgment came on for hearing before this court on August 23, 2017. Plaintiffs Alameda Health System, County of Contra Costa, Regents of the University of California, County of San Mateo, and County of Santa Clara appeared by their counsel Robert C. Leventhal, and plaintiff County of Santa Clara appeared by its counsel Danny Y. Chou. Defendants Centers for Medicare and Medicaid Services ("CMS"), Eric D. Hargan in his official capacity as Acting Secretary of the United States Department of Health and Human Services ("HHS"),[1] and Seema Verna in her official capacity as Administrator of CMS, appeared by their counsel Carole Federighi. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS plaintiffs' motion and DENIES defendants' motion as follows.

BACKGROUND

These two related cases arise under the Medicaid Act, Title XIX of the Social Security Act, 42 U.S.C § 1396, et seq. The plaintiffs — five California public health care districts — bring a challenge under the Administrative Procedures Act, 5 U.S.C. § 701, et seq. ("APA"), to the federal government's interpretation of statutes and regulations governing compensation for outpatient hospital services under the Medicaid program.

A. Medicaid Act

Medicaid is a cooperative federal-state program under which the United States provides funds to participating states to administer "medical assistance" to individuals whose income and resources are insufficient to meet the costs of necessary medical services. Wilder v. Va. Hosp. Ass'n, 496 U.S. 498, 503 (1990), superseded on other grounds by statute; see also Cal. Assoc. of Rural Health Clinics v. Douglas, 738 F.3d 1007, 1010 (9th Cir. 2013). The federal government pays a percentage of the costs a state incurs for patient care, and, in return, the state complies with certain federal requirements. See 42 U.S.C. § 1396a.

Administration of the program is entrusted to the Secretary of HHS, who also has the authority to promulgate rules and regulations regarding Medicaid that are "not inconsistent" with the statute and are "necessary to the efficient administration of the functions" with which the Secretary is charged under the statute. See 42 U.S.C. § 1302.

State participation in the Medicaid program is voluntary, but participating states must comply with federal requirements, including Title XIX requirements, in order to receive funds. Wilder, 496 U.S. at 502. In accordance with federal law, "each State decides eligible beneficiary groups, types and ranges of services, payment levels for services, and administrative and operative procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services." 42 C.F.R. § 430.0.

The scope of a state's Medicaid program is set forth in a Medicaid "State Plan" promulgated by that state and approved by CMS. See 42 U.S.C. §§ 1316(a)(1), 1396a(b). The State Plan describes how that state administers its Medicaid program, including groups of individuals to be covered, services to be provided, methodologies for providers to be reimbursed, and the administrative requirements that states must meet to participate. 42 U.S.C. §§ 1396a(a), 1396d(a).

If CMS approves a State Plan, the federal government provides reimbursement to the state for a portion of the cost of its Medicaid benefits and plan administration, and the state pays the remainder of its Medicaid expenses. 42 U.S.C. § 1396b. The federal government calculates the federal medical assistance percentage, which determines the federal share of the cost of Medicaid services in each state, based on a formula tied to the per capita income in each state. 42 U.S.C. § 1396d(b).

In California, the Medicaid program, which is known as the California Medical Assistance Program or "Medi-Cal," covers a broad array of hospital services. Cal. Welf. & Inst. Code § 14000 et seq.; 22 Cal. Code Regs. § 50000 et seq. California has designated its Department of Health Care Services ("CDHCS") as the agency responsible for the administration of the Medi-Cal program. See Cal. Welf. & Inst. Code §§ 10720, 14000. Medi-Cal is operated under a State Plan promulgated by CDHCS and approved by CMS. See http://www.dhcs.ca.gov/formsandpubs/laws/Pages/SPdocs.aspx. ("Cal. State Medicaid Plan").

B. Disproportionate Share Hospital Payments

In 1981, Congress amended the Medicaid Act to provide additional funding to hospitals that "serve a disproportionate number of low-income patients with special needs" through "Disproportionate Share Hospital" (or "DSH") payments. See Omnibus Budget Reconciliation Act ("OBRA") of 1981, Pub. L. No. 97-35, Title XXI § 2173(B)(ii), 95 Stat. 357 (1981), codified at 42 U.S.C. § 1396a(a)(13)(A)(iv) ("DSH Statute"); see also N.H. Hosp. Ass'n v. Burwell, 2017 WL 822094, at *2 (D.N.H. Mar. 2, 2017); Virginia Dep't of Med. Assistance Servs. v. Johnson, 609 F. Supp. 2d 1, 3 (D.D.C. 2009) ("VDMAS").

The 1981 DSH Statute created a "payment adjustment" for hospitals that treat a disproportionate share of Medicaid patients. See 42 U.S.C. § 1396r-4(c), (d). Generally, states have discretion in deciding which hospitals receive DSH payments and the level of funds those hospitals will receive, see 42 U.S.C. § 1396r-4, subject to certain limits. Only costs that are not otherwise paid for by the patient, by insurance, by another third party, by Medicaid, or by any other program are eligible for DHS reimbursement. See VDMAS, 609 F.Supp. 2d at 3. In California, DSH payments are available to cover the otherwise uncompensated costs of care hospitals give to Medi-Cal patients and to the uninsured. See http://www.dhcs.ca.gov/provgovpart/Pages/DisproportionateShareHospital.aspx (last visited Dec. 18, 2017).

In 1991, Congress directed the Secretary to determine state-specific limits on federal funding for DSH payments for each fiscal year, using a statutory formula. See 42 U.S.C. § 1396r-4(f). Subject to an overall federal DSH allotment, the aggregate

amount of federal funding for DSH payments that a particular state can claim is limited by the difference between the costs that all eligible hospitals incur in providing services to Medicaid beneficiaries and to individuals with no third-party coverage for the services they receive, and the compensation (Medicaid and uninsured patient payments) received for the services. See id. This aggregate cap is referred to as the "DSH Limit" or the "State-Specific Limit." See La. Dept. of Health & Hosps. v. Ctr. for Medicare and Medicaid Servs., 346 F.3d 571, 573-74 (5th Cir. 2003). The DSH Limit is calculated based on data contained in cost reports filed by eligible hospitals. See 42 U.S.C. § 1396r-4(f).

In 1993, through the Omnibus Budget Reconciliation Act of 1993 ("OBRA 1993"), Congress amended the program to limit Medicaid DSH payments to qualifying hospitals to the amount of eligible uncompensated costs incurred. Pub. L. No. 103-66, § 13621, 107 Stat. 312, 629-33 (1993). This amendment was motivated by concerns that some hospitals were receiving DSH payments in excess of "the net costs, and in some instances, the total costs, of operating the facilities." H.R. Rep. No. 103-111, at 211-212 (1993), reprinted in 1993 U.S.C.C.A.N. 278, 538.

Thus, the hospital-specific limit ("HSL") requires that DSH payments not exceed

> the costs incurred during the year of furnishing hospital services (as determined by the Secretary and net of payments under this subchapter, other than under this section, and by uninsured patients) by the hospital to individuals who either are eligible for medical assistance under the State plan or have no health insurance (or other source of third party coverage) for services provided during the year.

42 U.S.C. § 1396r-4(g)(1)(A). While the amount of DSH payments that a specific hospital may receive is determined by the state-controlled allocation process described in the State Plan, the amount may not exceed that hospital's "uncompensated costs" of serving Medicaid and uninsured patients. For purposes of this calculation, a hospital's "uncompensated costs" are the hospital's "uncompensated care costs of providing inpatient hospital and outpatient hospital services" to Medicaid and uninsured patients. See 42 U.S.C. § 1396r-4(j)(2)(C).

Following enactment of OBRA 1993, the Health Care Financing Administration ("HCFC"), predecessor to CMS, issued a letter dated August 17, 1994, to State Medicaid Directors ("1994 CMS Letter"), to provide guidance on the meaning and effect of the new enactment. See Administrative Record ("AR") XXXXXX-XX.[2] With regard to determining the cost of services under the DSH Limit, the 1994 CMS Letter stated that "the legislative history of this provision makes it clear that States may include both inpatient and outpatient costs in the calculation of the limit," and that in defining "costs of services" under this provision, States would be permitted to use the definition of allowable costs in the State Plan, "or any other definition," so long as the costs determined under such a definition do not exceed the amounts that would be allowable" under Medicare principles of cost reimbursement (which also provide the general upper payment limit under the Medicaid program). AR 001611.

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, which amended the Medicaid Act to require that each state provide an annual report and audit of its DSH program, to enable the Secretary "to ensure the appropriateness of" the DSH payment adjustments. See 42 U.S.C. § 1396r-4(j)(1)(B). The audit must confirm, among other things, that "[o]nly the uncompensated care costs of providing inpatient and outpatient hospital services to individuals described in [§ 1396r-4(g)(1)(A)] are included in the calculation of the hospital-specific limits." 42 U.S.C. § 1396r-4(j)(2)(C). The state must recoup within one year any overpayments revealed by the audit, or the federal government may reduce its future contributions. 42 U.S.C. § 1396b(d)(2)(C), (D).

C. Federally Qualified Health Centers

Another requirement of the Medicaid Act is that states must provide as "medical assistance" payment for Medicaid-covered services provided by "Federally Qualified Health Centers" ("FQHCs") — health centers that provide medical care to an under-served population. 42 U.S.C. §§ 1396d(a)(2)(B)-(C), 1396a(bb)(1); see generally Cal. Ass'n of Rural Health Clinics v. Douglas, 738 F.3d 1007, 1014-17 (9th Cir. 2014). FQHC services are defined as physician services, services from certain other professionals, services and supplies incident to such services, and "any other ambulatory services that are otherwise included in the State Plan" that are offered by a participating FQHC. See 42 U.S.C. § 1396d(a)(2)(C). California's State Plan covers FQHC services and other ambulatory ("outpatient") services that are covered under the Plan and furnished by an FQHC. See Cal. State Medicaid Plan, Att. 3.1-A.

In addition to receiving Medicaid funding from the state, FQHCs are also eligible to receive federal grants under § 330 of the Public Health Services Act. See 42 U.S.C. § 254b; 42 C.F.R. pt. 51c; see also 42 U.S.C. § 1396d(a)(2)(C). The dual sources of FQHC funding — direct federal grants and indirect federal Medicaid dollars filtered through the states — permit an FQHC to allocate most of its direct grant dollars towards treating those who lack Medicare or Medicaid coverage. Cmty. Health Ctr. v. Wilson-Coker, 311 F.3d 132, 134 n.2 (2d Cir. 2002). To ensure that § 330 grants are not used to cover the cost of treating Medicaid patients, the Medicaid Act requires that states reimburse FQHCs for services provided to Medicaid beneficiaries. 42 U.S.C. § 254b(k)(3)(F).

The Medicaid Act also governs how a state must reimburse FQHCs for Medicaid services. States are required to pay rates based on the FQHCs' average per-visit reasonable costs of providing services to Medicaid patients, with certain adjustments. 42 U.S.C. § 1396a(bb). Such minimum payments apply to any ambulatory (i.e., "outpatient") services offered by the FQHC and which are otherwise included in the State Plan. See 42 U.S.C. § 1396d(a)(2).

Generally, an FQHC's reimbursement from the state is calculated by multiplying the number of Medicaid patient encounters by the average reasonable costs of serving Medicaid patients in 1999 and 2000, adjusted annually for inflation. See 42 U.S.C. § 1396a(bb)(1)-(3); see generally N.J. Primary Care Ass'n Inc. v. N.J. Dep't of Human Servs., 722 F.3d 527, 529 (3d Cir.2013). The amount owed by the state to reimburse an FQHC for a Medicaid patient encounter is referred to as the "Prospective Payment System," or "PPS" rate. States may reimburse FQHCs for services provided using either a PPS rate or an "alternative payment methodology" ("APM") rate (as long as the APM rate is not less than the state's PPS rate would have been). 42 U.S.C. § 1396a(bb).

D. Regulatory Background

Between 2005 and 2014, CMS engaged in the following notice-and-comment rulemaking, which provides context for the present dispute.

1. The 2008 DSH Audit Rule

On August 26, 2005, CMS published a proposed rule implementing the 2003 amendment's requirements for reporting and auditing of DSH payments, entitled "Medicaid Program; Disproportionate Share Hospital Payments" ("2005 Proposed DSH Audit Rule"). 70 Fed. Reg. 50262, CMS-2198-P (AR 000001-07); see also 70 Fed. Reg. 55812 (AR 000008-09) (amendment to correct technical error). During the 60-day comment period, CMS received 119 public comments in response to the proposed rule. 73 Fed. Reg. 77905 (AR 000622).

On December 19, 2008, CMS published a final rule addressing the reporting and auditing of DSH payments. See Medicaid Program; Disproportionate Share Hospital Payments, 73 Fed. Reg. 77,904, CMS-2198-F ("the 2008 DSH Audit Rule") (AR XXXXXX-XX). The 2008 DSH Audit Rule requires that states annually submit information "for each DSH hospital to which the State made a DSH payment." 42 C.F.R. § 447.299(c). One such piece of information is the hospital's "total annual uncompensated care costs," defined as "the total cost of care for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for the hospital services . . . ." 42 C.F.R. § 447.299(c)(16); see also 42 C.F.R. § 447.299(c)(10), (11), (14), (15).

The preamble to the 2008 DSH Audit Rule also states that the HSL is "based on the costs incurred for furnishing `hospital services' and does not include costs incurred for services that are outside either the State or Federal definition of inpatient or outpatient hospital services[;]" and that "[a] State cannot include in calculating the hospital-specific DSH limit cost of services that are not defined under its Medicaid State plan as a Medicaid inpatient or outpatient hospital service." 73 Fed. Reg. 77,907 (AR 000624). In addition, "to the extent that the inpatient and/or outpatient hospital services received are not within the definition of inpatient and/or outpatient hospital services under the State Medicaid plan, such service costs should not be included in calculating the hospital-specific DSH limit." 73 Fed. Reg. 77,913 (AR 000630).

Although the Medicaid Act does not define "outpatient services," see 42 U.S.C. § 1396d(a)(2)(A), the preamble to the 2008 DSH Audit Rule states that the State Plan must treat outpatient hospital services consistently. See 73 Fed. Reg. at 77,907 (AR 000624) ("While States have some flexibility to define the scope of `hospital services,' States must use consistent definitions of `hospital services.'"); id. at 77,913 (AR 000630) ("The treatment of inpatient and outpatient hospital services

provided to the uninsured and underinsured also must be consistent with the definition of inpatient and/or outpatient services under the approved Medicaid State plan.").

The preamble further emphasized that

> [s]tates should use a consistent treatment of physician and provider-based clinics. All costs that are associated with services that are defined and reimbursed under the approved Medicaid State plan as inpatient hospital services and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for such services may be included in calculating the hospital-specific DSH limit.

Id. at 77,926 (AR 000643). However, the preamble also states, "States do not have the flexibility to broaden or narrow the costs included in calculating the hospital-specific DSH limit, because the universe of costs is defined in the statute." Id. at 77,920 (AR 000637).

Finally, the preamble to the 2008 DSH Audit Rule provides that based on the necessity of "a trial period . . . for auditors to refine audit methodologies," the findings from Medicaid State Plan years 2005 through 2010 would be used only for the purpose of "determining hospital-specific cost limits and the actual DSH payments associated with a particular year." 73 Fed. Reg. 77906 (AR 000623). Only beginning with Medicaid State Plan year 2011 would CMS regard any audit findings that showed DSH payments exceeding HSL as representing discovery of overpayments to providers, which would trigger the return of the Federal share to the Federal government (unless the DSH payments were redistributed by the State to other qualifying hospitals). Id.; see 42 C.F.R. § 433.312(a). California's State Plan also includes a redistribution provision. See Cal. State Medicaid Plan, Att. 4.19-A, at G.3 p. 27a (AR 002248).

2. The 2008 Outpatient Definition Rule

On September 28, 2007, a little over a year prior to publication of the 2008 DSH Audit Rule, CMS published a proposed rule entitled "Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit" ("2007 Proposed Outpatient Rule"), which proposed to "amend the regulatory definition of outpatient hospital services for the Medicaid program." 72 Fed. Reg. 55,158 (AR 000672).

Among other things, the 2007 Proposed Outpatient Rule amended 42 C.F.R. § 440.20, which set forth definitions of "Outpatient Hospital Services" and "Rural Health Clinic Services," to "specify the scope of facility services covered under the Medicaid program[;]" to "modify the requirements for a participating facility[;]" to add "a comprehensive list of the scope of services that may be included under the Medicaid outpatient hospital services benefit[;]" and to "exclude[ ] all services, that are covered and paid under medical assistance under section 1905(a) of the Act" — for example, "services paid for under a fee schedule (for example, Federally Qualified Health Centers) or services that are typically covered under a different section of the State Plan (for example, rehabilitative services)." 72 Fed. Reg. 55,163 (AR 000677). CMS provided for a 30-day public comment period and received a total of 333 timely comments from States, local government, providers, and health care associations.

Numerous commenters expressed concerns, including that the rule would negatively impact the treatment of services provided by hospital-based RHCs and FQHCs for DSH purposes. See 72 Fed. Reg. 66,188-66,198 (AR XXXXXX-XX); see also AR 000681-001117. For example, Santa Clara Valley Medical Center (operated by the County of Santa Clara, a plaintiff herein) warned that although the proposed "rule neglects to refer specifically to its negative impact on DSH payments, . . . the uncompensated care costs associated with the disallowed services may no longer be included in our hospital's DSH cap." See AR 000921.

On November 7, 2008, CMS published a final rule to clarify the regulatory definition of "outpatient hospital services" ("2008 Outpatient Definition Rule"). See Medicaid Program; Clarification of Outpatient Hospital Facility (Including Outpatient Hospital Clinic) Services Definition, 73 Fed. Reg. 66,187, CMS-2213-F (AR XXXXXX-XX).

CMS explained that the goal of this rule was to

> align[] the Medicaid definition of outpatient hospital services more closely to the Medicare definition in order to: Improve the functionality of the applicable upper payment limits (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available hospital

> coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

72 Fed. Reg. 66,187-88 (AR XXXXXX-XX). Among other things, the 2008 Outpatient Definition Rule included a subsection expressly providing that hospital outpatient services exclude services that are "covered under the scope of another Medical Assistance service category under the State Plan." 72 Fed. Reg. 66,198 (AR 001129).

This provision was intended to prevent states from including hospital-based costs incurred by Rural Health Clinics ("RHCs") and FQHCs in the calculation of the DSH Limit. See 72 Fed. Reg. 66,187 (AR 001118). The 2008 Outpatient Definition Rule would have redefined hospital outpatient services as limited to services that "[a]re not covered under the scope of another Medical Assistance service category under the State Plan." 72 Fed. Reg. 66,194-66,198 (AR XXXXXX-XX). That is, whereas prior regulations permitted "an overlap between services that meet the definition of outpatient hospital services and also meet the definition of a service under another benefit category," there would be "no such overlap" under the final rule. 72 Fed. Reg. 66,195 (AR 001126).

After the 2008 Outpatient Definition Rule was published, Congress enacted a statute which, among other things, prohibited CMS from implementing the Rule prior to June 30, 2009. See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 5003(c) 123 Stat 115, 503. On May 6, 2009, CMS published a proposed rule to rescind the 2008 Outpatient Definition Rule. 74 Fed. Reg. 21,232, CMS-2213-P2 (AR 001130). On June 30, 2009, following submission of additional public comment, see AR 001136-001257, CMS issued a final rule rescinding the 2008 Outpatient Definition Rule. See Medicaid Program: Rescission of School-Based Administration/Transportation Final Rule, Outpatient Hospital Services Final Rule, and Partial Rescission of Case Management Interim Final Rule. 74 Fed. Reg. 31,183, CMS-2213-F2 (AR 001258).

CMS made the decision to rescind the 2008 Outpatient Definition Rule "[i]n light of concerns raised about the adverse effects that could result from [the] regulation[ ], in particular, the potential restrictions on services available to beneficiaries and the lack of clear evidence demonstrating that the approaches taken in the regulation[ ] are necessary." 74 Fed. Reg. 31,183 (AR 001258).

In particular, CMS acknowledged concerns that the rule would prohibit hospitals from including certain hospital-based clinic costs in the DSH Limit calculation. 74 Fed. Reg. 31,189 (AR XXXXXX-XX). For example, RHCs had argued that this would increase Medicaid costs because clinics would close and their patients would need to be treated in hospital emergency rooms at a higher cost (since clinics generally are more cost-effective than hospital emergency rooms). Id. CMS stated that the rescission of the Rule should alleviate these fears: "This final rule should eliminate the concerns expressed by the clinics and other providers by reinstating the regulatory definition of `outpatient hospital services' at [42 C.F.R.] § 440.20 that existed before the final rule became effective." Id.

Nevertheless, CMS also asserted that

> [t]he rescission of the Outpatient Hospital Services final rule has no impact on the provisions of the DSH Auditing and Reporting final rule. The DSH rule provides guidance to States on those outpatient hospital service costs that should be included in DSH calculations, which is independent from the outpatient hospital service clarification provided in the Outpatient Hospital Services final rule.

Id.

3. 2014 DSH Payments Uninsured Definition Rule

On January 18, 2012, CMS published a proposed rule entitled "Medicaid Program; Disproportionate Share Hospital Payments — Uninsured Definition" ("2012 DSH Proposed Rule"). 77 Fed. Reg. 2500, CMS-2315-P (AR XXXXXX-XX). CMS proposed to add new 42 C.F.R. § 447.298, which would define through regulation "individuals who have no health insurance (or other source of third party coverage) for the services furnished during the year," for purposes of calculating the hospital-specific DSH limit as described in § 1923(g) of the Medicaid Act. 77 Fed. Reg. 2503 (AR 001275).

In the preamble to the proposed rule, CMS noted that after publication of the 2008 DSH Audit Rule, numerous states, members of Congress, and related stakeholders had expressed their concern that the Rule's definition of "uninsured" deviated from prior guidance and would have a significant financial impact on states and hospitals. 77 Fed. Reg. 2501 (AR 001273). CMS stated that the 2012 Proposed Rule was "designed to mitigate some of the unintended consequences of the

uninsured definition put forth in the 2008 DSH final rule and to provide additional clarity on which costs can be considered uninsured costs for purposes of determining the hospital-specific limit." Id.

On December 3, 2014, CMS issued the final 2014 Disproportionate Share Hospital (DSH) Payments-Uninsured Definition Rule ("2014 DSH Payments Uninsured Definition Rule"). 79 Fed. Reg. 71,679, CMS-2315-F (AR 001592). In the preamble, CMS reiterated that the 2014 DSH Payments Uninsured Definition Rule was "designed to mitigate some of the unintended consequences of the uninsured definition" put forth in the 2008 DSH Audit Rule and to provide additional clarity on which costs can be considered uninsured costs for purposes of determining the hospital-specific limit." 79 Fed. Reg. 71,680 (AR 001593). The rule provided that, in auditing DSH payments, the test for "uncompensated costs of furnishing hospital services" to individuals who are Medicaid-eligible or uninsured would be applied on a "service-specific basis." Id.

CMS stated further that the Medicaid Act "describes uninsured individuals as those `who have no health insurance (or other source of third party coverage) for the services furnished during the year.'" See id. CMS claimed that while the 2014 DSH Payments Uninsured Definition Rule's definition of "uninsured" might affect "the calculation of the hospital-specific DSH limit," the final Rule "[did] not modify the DSH allotment amounts" or have any effect on "a state's ability to claim FFP for DSH payments made up to the published DSH allotment amounts." Id.

In the preamble to the final rule, CMS described the 2012 DSH Proposed Rule as proposing to describe the scope of the new regulation (42 C.F.R. § 447.298) and to define the terms "Individuals who have no health insurance (or other source of third party coverage) or the services furnished during the year;" "Health insurance coverage limit;" "No source of third party coverage for a specific inpatient hospital or outpatient service;" "Determination of an Individual's Third Party Coverage Status;" and "Service-Specific Coverage Determination." See 79 Fed. Reg. 71,682 (AR 001595).

In the section of the preamble entitled "Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments" (AR 001595-001603), CMS noted that "a few commenters" had requested that CMS "confirm that uninsured costs of hospital-based outpatient departments and clinics are to be included in the calculation of uncompensated care costs, irrespective of whether the hospital department or clinic is a federally qualified health care (FQHC) for Medicaid purposes."[3] 79 Fed. Reg. 71,684 (AR 001597). In its response, CMS stated that

> Services that could be included in more than one benefit category must be treated consistently for payment purposes, since the payment methodologies are different for each benefit category. In particular, if a hospital elects to have a department meet the conditions to participate in Medicaid as a provider of FQHC services, and claims payment for its services as an FQHC, the services of that department are not considered outpatient hospital services. Although the FQHC may be provider based, its services are not recognized or paid as outpatient hospital services, but instead are covered and paid for as an FQHC service under section 1905(a)(2)(C) of the Act. Section 1923(g) of the Act only permits costs and revenues associated with services furnished as inpatient hospital and outpatient hospital services to be included when calculating the hospital-specific DSH limit. Congress provided for a different, cost-based, payment methodology for FQHCs, under sections 1902(a)(15) and 1902(bb) of the Act and did not provide for DSH payments as part of that methodology. In sum, states cannot include costs and revenues associated with FQHC services because payment for the services is authorized under a statutory benefit separate and distinct from outpatient hospital services that entitles the provider to a cost-based payment rate.

Id.

F. The Present Dispute

The hospitals operated by the plaintiff health care districts provide significant amounts of uncompensated care to Medi-Cal and uninsured patients, and have qualified for DSH payments. See Declaration of Paul E. Lorenz, CEO of Santa Clara Valley Medical Center ("Lorenz Decl.") ¶¶ 4-8; and Declaration of David Cox, CFO of Alameda Health System ("Cox Decl."), Declaration of Patrick Godley, COO and CFO of Contra Costa Health Services ("Godley Decl."), Declaration of Gina Caroll, Director of Reimbursement at UC Irvine ("Carol Decl."), and Declaration of David McGrew, CFO of San Mateo Medical Center ("McGrew Decl.") ¶¶ 2 and 4. Each of plaintiffs' hospitals also operates at least one certified hospital-based FQHC. Lorenz Decl. ¶ 5; Cox, Godley, Caroll, and McGrew Decls. ¶ 2.

Plaintiffs have always accounted for the costs of operating their hospitals with FQHC certification as hospital "outpatient" department costs — and therefore have included the FQHCs' uncompensated care costs of providing services to both Medi-Cal and uninsured patients as DSH-eligible costs, which take into account the offsetting of the Medi-Cal PPS payments. See Lorenz Decl. at ¶ 6; Cox, Godley, Carol, and McGrew Decls. at ¶ 2.

In a letter dated July 31, 2015, CDHCS wrote CMS regarding the statement in the preamble to the final 2014 DSH Payments Uninsured Definition Rule (CMS-2315-F) that services of hospital-based FQHCs are not "recognized or paid as outpatient hospital services." AR 002124. CDHCS argued that hospital-based FQHCs in California provide outpatient hospital services that are recognized under the State Plan, and that the FQHC PPS methodology does not alter the categories of service defined under the State Plan. AR XXXXXX-XX. CDHCS added that while California supported the implementation of CMS-2315-F "as reflected in the actual regulatory language," it believed that "certain interpretations articulated by CMS in its preamble are unsupported by the text of the new regulation and the Medicaid statutes[,]" and that this "interpretive departure" was a substantive rule subject to the notice-and-comment procedures of the APA. AR 002129.

CMS responded to CDHCS letter in a letter dated January 11, 2016. AR 002130. CMS stated that the requirement to exclude FQHC service costs from the DSH limit "was in effect before the promulgation of" the 2014 DSH Payments Uninsured Definition Rule, CMS-2315-F. Id. CMS asserted that the language in the preamble to CMS-2315-F, which CDHCS challenged in the July 31, 2015, letter, was "a restatement of CMS policy articulated in prior regulatory and sub-regulatory guidance," which included the 2008 DSH Audit Rule "and associated sub-regulatory guidance." Id.

CMS asserted that because § 1923(g)(1) of the Social Security Act, 42 U.S.C. § 1396r-4(g)(1), limits costs included in calculating the hospital-specific DSH limit to "hospital services" provided to Medicaid-eligible individuals and individuals with no source of third-party coverage for the services received, and because "hospital services" is used elsewhere in the Medicaid statute to refer to inpatient and outpatient hospital services, CMS has interpreted § 1923(g)(1) to mean that costs included in the HSL must be for services that meet a definition of inpatient hospital services and outpatient hospital services under the Medicaid-approved State Plan, and that the cost of any services outside those definitions would necessarily be excluded from the calculation of the hospital-specific DSH limit. Id.

CMS claimed that it had articulated this policy in the final 2008 DSH Audit Rule, pointing to the statements in the preamble that the HSL is based on "costs incurred for furnishing `hospital services' and does not include costs incurred for services that are outside either the State or Federal definition of inpatient or outpatient hospital services[,]" and that "[a] State cannot include in calculating the hospital-specific DSH limit costs of services that are not defined under its Medicaid state plan as a Medicaid inpatient or outpatient hospital service." AR XXXXXX-XX (citing 73 Fed. Reg. 77,907).

CMS asserted that in California's Medicaid-approved State Plan, hospital-based FQHC services and outpatient hospital services are "separately reimbursed," as indicated by the fact that "[o]utpatient hospital base [sic] payments are paid on a fee schedule that does not apply to hospital-based FQHCs[;]" the fact that "FQHC/RHC reimbursement specifies reimbursement for provider-based FQHCs/RHCs[;]" the fact that [g]overnmental hospital CPE-funded outpatient hospital supplemental payments utilize a cost methodology that explicitly excludes FQHC costs from the outpatient hospital cost computation[;]" the fact that "[i]n the private hospital quality assurance fee-funded supplemental payment, outpatient hospital services explicitly exclude hospital-based FQHC services by definition[;]" and the fact that "[c]ost reimbursement for LA County hospital outpatient hospital services, hospital-based physician services, and LA county clinic services also explicitly excludes FQHC services." AR 002131.

Based on the above, CMS stated that hospital-based FQHC costs "cannot be included in the calculation of the hospital-specific DSH limit." Id. CMS added that there were only limited circumstances where a state could include the costs of certain services provided in an FQHC in the calculation of the HSL, specifically, when such services "meet the federal and state plan definition of `outpatient hospital services' and the state pays for the services under the `outpatient hospital services' state plan reimbursement methodology." Id.

In a letter dated May 19, 2016, CDHCS informed all California hospitals that operate FQHCs — including those operated by the plaintiff health care districts — that CDHCS has been forced by CMS to exclude hospital-based FQHC costs from the calculation of the DSH Limit, at a minimum beginning with the calculations for state fiscal year 2012-2013. See Lorenz Decl. at ¶ 9 and Ex. B thereto, and Cox, Godley, Carol, and McGrew Decls. at ¶ 3 and Ex. A thereto.

In a letter dated July 15, 2016, CMS informed CDHCS of the results of its content review of the DSH audit and report for the California State Plan rate year 2011. AR 002132. Among other things, CMS advised that the audit report identified costs for

hospital-based FQHCs which were improperly included in the calculations of a number of designated public hospitals' hospital-specific DSH limits, and that in accordance with § 1923(g)(1) of the Medicaid Act, such costs were disallowed because under the California State Plan, FQHC services, including hospital-based FQHC services, are not reimbursed as "hospital services." Id. Thus, CMS asserted, "all FQHC costs need to be removed from the hospital-specific DSH limit calculations." Id.

Plaintiffs contend that they rely on the DSH Program to mitigate losses due to the costs of providing hospital outpatient services through FQHCs to the uninsured because they do not receive PPS payments for patients who are not covered by Medi-Cal. They assert that their reliance on DSH payments is further compounded because in practice the Medi-Cal PPS payments do not cover the actual costs of the Medi-Cal services provided, as Medicaid no longer operates pursuant to a 100-percent-reimbursement model as it did in 1992 when the states were first required to provide Medicaid coverage for services furnished by FQHCs. Plaintiffs contend that prior to the commencement of this dispute, neither CMS nor CDHCS ever required those costs to be excluded. See Lorenz Decl. at ¶ 6; Cox, Godley, Carol, and McGrew Decls. at ¶ 2.

Plaintiffs argue that in arriving at the determination that services of hospital-based FQHCs are not "recognized or paid as outpatient hospital services," CMS implicitly acknowledged that it never promulgated any rule or regulation implementing what plaintiffs refer to as the "New Rule" and/or reviving the rescinded 2008 Outpatient Definition Rule. According to plaintiffs, CMS simply pretended that Congress' rejection of its earlier attempt never happened and that hospital-based FQHC costs had always been excluded from the calculation of the DSH Limit. Plaintiffs contend that this provision set forth in the preamble to the final 2014 Uninsured Definition Rule amounts to a reversal of CMS' prior practice or position. They claim that CMS has improperly taken this action without complying with the notice-and-comment provisions of the APA, and that the decision was arbitrary and capricious and otherwise not in accordance with the law.

In the FAC, plaintiffs assert four causes of action — (1) a claim that CMS violated 5 U.S.C. § 706(2)(D), in failing to follow notice-and-comment rulemaking procedures when it promulgated the 2014 DSH Payments Rule; (2) a claim that CMS violated 5 U.S.C. § 706(2)(A) in that its amendment of 42 C.F.R. § 440.20(a) was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (3) a claim alleging agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C); and (4) a claim for declaratory relief, seeking a judicial declaration as to whether plaintiffs can be required to exclude from their DSH Payment calculations the uncompensated costs they incur in providing outpatient hospital services at their hospital-based FQHCs, and a declaration that the implementation of the Preamble to 42 C.F.R. § 440.20 is invalid and contrary to law.

DISCUSSION

A. Legal Standard

The APA limits the scope of judicial review to the administrative record. 5 U.S.C. § 706 (directing the court to "review the whole record or those parts of it cited by a party"). The scope of review is normally limited to "the administrative record in existence at the time of the [agency] decision and [not some new] record that is made initially in the reviewing court." Lands Council v. Powell, 395 F.3d 1019, 1030 (9th Cir. 2005) (citation omitted).

A motion for summary judgment may be used to seek judicial review of agency administrative decisions within the limitations of the APA. Nw. Motorcycle Ass'n v. U.S. Dep't of Agric., 18 F.3d 1468, 1471-72 (9th Cir. 1994). Generally, the court should grant a motion for summary judgment if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Addisu v. Fred Meyer, Inc., 198 F.3d 1130, 1134 (9th Cir. 2000). The moving party bears the initial burden of informing the court of the basis for the motion and identifying the portions of the pleadings, depositions, answers to interrogatories, admissions, or affidavits that demonstrate the absence of a triable issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

However, because the role of the court under the APA is not to "find facts" but is limited to reviewing the administrative record, there can be no genuine issue of material fact. See Occidental Eng'g Co. v. INS, 753 F.2d 766, 769 (9th Cir. 1985). Thus, the usual standard for summary judgment does not apply. See San Joaquin River Group Auth. v. Nat'l Marine Fisheries Serv., 819 F.Supp.2d 1077, 1083-84 (E.D. Cal. 2011); see also Nw. Motorcycle Assoc., 18 F.3d at 1471. Nevertheless, "summary judgment is an appropriate mechanism for deciding the legal question of whether the agency could reasonably have found the facts as it did." Occidental, 753 F.2d at 770.

Under the APA, a court may set aside an agency's final action if the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This is a "highly deferential" standard under which there is a presumption that the agency's action is valid "if a reasonable basis exists for its decision." Kern Cnty. Farm Bureau v. Allen, 450 F.3d 1072, 1076 (9th Cir. 2006). A reviewing court may also "hold unlawful and set aside agency action, findings, and conclusions" that are "without observance of procedure required by law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C), (D). Unlike substantive challenges, "review of an agency's procedural compliance is exacting, yet limited." Kern Cnty. Farm Bureau, 450 F.3d at 1076. The reviewing court determines "the adequacy of the agency's notice and comment procedure, without deferring to an agency's own opinion of the . . . opportunities it provided." Id. (internal citation and quotation marks omitted).

"Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." Bannister v. U.S. Dep't of the Treasury, 2011 WL 7109220 at *2 (N.D. Cal. Mar. 10, 2011) (citing Sierra Club v. Mainella, 459 F.Supp. 2d 76, 90 (D.D.C. 2006)).

B. The Parties' Cross-Motions

Plaintiffs challenge the position taken by CMS in the preamble to the final 2014 DSH Payments Uninsured Definition Rule — that the services of hospital-based FQHCs are not "recognized or paid as outpatient hospital services." Plaintiffs assert that CMS' "New Rule" constitutes a final administrative action and is subject to review under the APA.

Plaintiffs argue that because this provision was not the product of notice-and-comment rulemaking, defendants have acted without observance of procedure required by law, in violation of 5 U.S.C. § 706(2)(D). Alternatively, they contend that in excluding hospital-based FQHC costs from the DSH limit calculation, the "New Rule" is arbitrary, capricious, and an abuse of discretion, and otherwise not in accordance with the law, in violation of 5 U.S.C. § 706(2)(A). They also argue that CMS cannot apply the "New Rule" retroactively.

Defendants assert that CMS was not required to engage in notice-and-comment rulemaking when it determined that hospital-based FQHC costs would be excluded from the DSH limit calculation. Defendants also contend that CMS' interpretation implements the plain meaning of the Medicaid statute, and that even if the court were to find the statute ambiguous, that interpretation by CMS must be upheld as reasonable and entitled to deference.

C. Analysis

Plaintiffs contend that CMS has effectively amended the calculation of the DSH Limit and the definition of "outpatient services," and that the "New Rule" should thus have been issued in accordance with the notice-and-comment provisions of the APA.

"Rulemaking" is the process of "formulating, amending, or repealing a rule." See 5 U.S.C. § 551(5). "Rule," in turn, is defined broadly to include "statement [s] of general or particular applicability and future effect" that are designed to "implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4); see Perez v. Mortg. Bankers Assoc., 135 S.Ct. 1199, 1203 (2015). The APA, requires federal agencies — when adopting, repealing, or amending rules — to issue in the Federal Register a public "Notice of Proposed Rulemaking" setting forth "either the terms or substance of the proposed rule[,] or a description of the subjects and issues involved." 5 U.S.C. §§ 553(b), 551(5).

Notice-and-comment rulemaking is intended to be a process of reasoned decision-making. Conn. Light & Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525, 528 (D.C. Cir. 1982). It is designed to give interested persons, through written submissions and oral presentations, an opportunity to participate in the rulemaking process. Id.; see also 5 U.S.C. § 553(c). An agency must consider and respond to significant comments received during the period for public comment. See Perez, 135 S.Ct. at 1203 (citing Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971)).

Rules issued through the notice-and-comment process are often referred to as "legislative rules" because they have the "force and effect of law." Perez, 135 S.Ct. at 1203 (citing Chrysler Corp. v. Brown, 441 U.S. 281, 302-03 (1979)). Nevertheless, not all "rules" must be issued through the notice-and-comment process. Id. The APA provides that unless another statute states otherwise, the notice-and-comment requirement "does not apply" to "interpretative rules, general

statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). Whether an agency rule is interpretive or legislative is a question of law. Hemp Indus. Assoc. v. Drug Enforcement Admin., 333 F.3d 1082, 1086 (9th Cir. 2003).

The term "interpretive rule" is not further defined by the APA. In general terms, however, interpretive rules merely explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule. Id. at 1087. The critical feature of interpretive rules is that they are "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." See Perez, 135 S.Ct. at 1204 (citing Shalala v. Guernsey Mem. Hosp., 514 U.S. 87, 99 (1995)); see also Gunderson v. Hood, 268 F.3d 1149, 1154 (9th Cir. 2001). The absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules. Id. The other side of that calculus, however, is that interpretive rules "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." Perez, 135 S.Ct. at 1204 (citation omitted).

Legislative rules, by contrast, "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." Hemp Indus., 333 F.3d at 1087 (citing Yesler Terrace Comm'ty Council v. Cisneros, 37 F.3d 442, 449 (9th Cir. 1994)). Unlike interpretive rules, valid legislative rules have the "force of law." Id.; see also Shalala v. Guernsey Mem. Hosp., 514 U.S. 87, 99 (1995) ("Interpretive rules . . . do not have the force and effect of law and are not accorded that weight in the adjudicatory process . . . .").

Plaintiffs contend that CMS' rule excluding FQHC costs from the DSH calculation is a legislative rule that contradicts CMS' own prior regulations. They note that, although the Medicaid Act does not define "outpatient hospital services," CMS regulations broadly define "outpatient hospital services" to include all "preventive, diagnostic, therapeutic, rehabilitative, or palliative services that . . . "[a]re furnished to outpatients[,]" "by or under the direction of a physician[,]" and "by an institution that . . . [i]s licensed or formally approved as a hospital by an officially designated authority for State standardsetting[,]" and "[m]eets the requirements for participation in Medicare as a hospital." See 42 C.F.R. § 440.20(a).

By definition, plaintiffs contend, services performed at hospital-based FQHCs clearly qualify as "outpatient hospital services" within the meaning of the definition in 42 C.F.R. § 440.20(a). They argue that CMS' "New Rule" effectively amends § 440.20(a) by excluding hospital-based FQHC costs from the definition of outpatient hospital services and reinstates the narrower definition of outpatient hospital services that CMS rescinded in 2009. "[I]f a second rule repudiates or is irreconcilable with a prior legislative rule, the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative." Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1109 (D.C. Cir. 1993) (quotation marks and brackets omitted). Plaintiffs assert that because CMS' "New Rule" is legislative, it should have been issued in accordance with the notice-and-comment provisions of the APA.

Plaintiffs also claim that CDHCS has long been aware of, and has approved of, the inclusion of hospital-based FQHCs' costs as DSH-eligible costs. They contend that defendants — which have audited California's DSH payments since January 2010, and unsuccessfully attempted to prohibit the inclusion of those costs in 2008 — were also necessarily aware of this practice.

In addition, plaintiffs point to a July 30, 1999, letter from the then-Secretary of HHS, stating that where a state has licensed RHCs (Rural Health Clinics, which are treated similarly to FQHCs under the Medicaid statute) as hospital outpatient departments, and they are certified as part of the hospital, the state would be able to include the uncompensated care costs related to RHC-provided hospital outpatient services in the calculation of a hospital's DSH payment limit. AR 001953. They also point to the statements by CMS in the June 30, 2009, rescission of the 2008 Outpatient Definition Rule, acknowledging the burden on health care districts were CMS to define "outpatient" to eliminate costs of hospital-based RHCs and FCHCs for DSH purposes. See AR 001258, et seq.

Defendants argue, however, that CMS was not required to subject the "interpretation" in the preamble to the final 2014 DSH Payments Uninsured Definition Rule to notice-and-comment rulemaking, because it was simply an "interpretive" rule of the type used by an agency to advise the public of the agency's construction of the statutes and rules it administers. Defendants claim that CMS' interpretation simply "implements" what they refer to as "the plain language of the Medicaid statute."

Defendants contend that because the Medicaid statute distinguishes between "inpatient hospital services," "outpatient hospital services," and "FQHC services," 42 U.S.C. § 1396d(a)(1), (2)(A), (C), those three categories are necessarily mutually exclusive, and that "outpatient hospital services" thus cannot also be included within the category of "FQHC services." They argue that because the DSH statute provides that "the costs incurred during the year of furnishing hospital

services" may be included in the HSL calculation, 42 U.S.C. § 1396r-4(g)(1)(A); and because the statute further requires a state to certify in the DSH audit process that the calculation of the HSL includes "[o]nly the uncompensated care costs of providing inpatient hospital and outpatient hospital services" to Medicaid-eligible individuals and uninsured individuals, 42 U.S.C. § 1396r-4(j)(2)(C); the result is that the "hospital services" included in the HSL can only be inpatient and outpatient hospital services, not FQHC services.

Defendants assert that CMS has long interpreted the DSH statute as prohibiting hospitals from including in the calculation of the HSL the uncompensated costs incurred by hospital-based FQHCs that are defined and reimbursed under the FCHC benefit category under the State Plan. They claim that CMS simply reiterated this "policy" in December 2014, in its response to a comment submitted with regard to the 2012 DSH Proposed Rule. They concede that neither the statute nor the regulation spell out the details of how the restriction to "inpatient" and "outpatient" "hospital services" is to be applied in practice to every type of service covered by Medicaid, but they argue that CMS' "interpretation" in the preamble to the final 2014 DSH Payments Uninsured Definition Rule simply explains how this statutory language applies to a particular category of services — FQHC services.

As for the State Plan, defendants note that the "FQHC" benefit is listed separately from the benefit for "[o]utpatient hospital services" and that the Plan provides that each FQHC can choose whether it wants to be reimbursed under PPS methodology or under an APM provided for in the Plan. See AR XXXXXX-XX; Cal. State Plan Att. 3.1-A. Thus, they assert, because the two benefits are listed separately, services provided by a hospital-based FQHC cannot properly be included as costs of "outpatient hospital services" in the calculation of that hospital's hospital-specific DSH limit. Similarly, defendants assert, base payments for outpatient hospital services are made according to a fee schedule that does not apply to hospital-based FQHCs, see id., Att. 4.19-B, at 1-3.2 & Supp. 17 (AR XXXXXX-XX); and that FQHCs, including specifically provider-based FQHCs, are paid under a different methodology (PPS or APM), see id. at 6-6V (AR XXXXXX-XX). Finally defendants contend that other parts of the State Plan distinguish between FQHC services and outpatient hospital services, including provisions relating to "Supplemental Reimbursement for Public Outpatient Hospital Services," id., Att. 4.19-B, at 47 & Supp. 22 (AR 002297, 002323); and certain cost-based reimbursement rules applicable to Los Angeles County, see id., Att. 4.19-B, Supp. 5 (AR 002305).

In sum, defendants argue, the Medicaid statute provides that only the costs incurred in providing inpatient or outpatient hospital services may be included in the HSL calculation, and defines FQHC services as a separate medical assistance category from inpatient or outpatient hospital services (citing 42 U.S.C. §§ 1396d(a)(2); 1396r-4(g)(1)(A), (j)(2)(C)). Further, they contend, the California State Medicaid plan clearly defines and reimburses FQHC services separately from inpatient or outpatient hospital services. Therefore, they argue, CMS has properly determined that such costs may not be included in the HSL, and the interpretation at issue here was not required to be subject to notice-and-comment rulemaking.

Whether an agency rule is interpretive or legislative is a question of law. Chief Probation Officers of Cal. v. Shalala, 118 F.3d 1327 (9th Cir. 997). An agency can issue a legislative rule only by using the notice-and-comment procedure described in the APA, unless it publishes a specific finding of good cause documenting why such procedures "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b), (b)(B). In contrast, an agency need not follow the notice-and-comment procedure to issue an interpretive rule. § 553(b)(A). In this case, the distinction between the two is significant, because if the challenged "New Rule" is an interpretive rule, it is valid despite the absence of notice-and-comment procedures, whereas if it is a legislative rule, it is invalid because of CMS' failure to comply with the rule-making procedures. See Hemp Indus., 333 F.3d at 1087.

Here, plaintiffs claim it is a legislative rule, and defendants take the position that it is an interpretive rule. The court finds that CMS' "New Rule" is legislative, and that it should therefore have been issued in accordance with the notice-and-comment provisions of the APA. See N.H. Hosp. Ass'n v. Burwell, 2016 WL 1048023, at *16 (March 11, 2016); Tex. Children's Hosp. v. Burwell, 76 F. Supp. 3d 224, 241 (D.D.C. 2014).

Valid legislative rules — unlike interpretive rules — have the "force of law." See Hemp Indus., 333 F.3d at 1087; see also Guernsey Mem. Hosp., 514 U.S. at 99. A rule has the "force of law" (1) when, in the absence of the rule, there would not be an adequate legislative basis for enforcement action; (2) when the agency has explicitly invoked its general legislative authority; or (3) when the rule effectively amends a prior legislative rule. Hemp Indus., 333 F.3d at 1087; see also Erringer v. Thompson, 371 F.3d 625, 630 (9th Cir. 2004).

In this case, the court finds that there would be no legislative basis for enforcement actions absent the "New Rule." That is, defendants have pointed to nothing in the Medicaid statute and nothing in the implementing regulations that makes it unlawful for hospitals to include uncompensated FQHC costs in DSH Payment calculations.

CMS has consistently defined "outpatient hospital services" to include services provided by hospital-based FQHCs. For decades, CMS has implemented a single definition of "outpatient hospital services" — currently codified at 42 C.F.R. § 440.20(a) — that, by its terms, encompasses outpatient hospital services provided by hospital-based FQHCs. Section 440.20(a) provides, in its entirety, as follows:

> (a) Outpatient hospital services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that —
>
> (1) Are furnished to outpatients;
>
> (2) Are furnished by or under the direction of a physician or dentist; and
>
> (3) Are furnished by an institution that
>
> (i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and
>
> (ii) Meets the requirements for participation in Medicare as a hospital; and
>
> (4) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of "outpatient hospital services" those types of items and services that are not generally furnished by most hospitals in the State.

42 C.F.R. § 440.20(a).

Nevertheless, notwithstanding this long-standing and consistent definition, in January 2016, CMS advised plaintiffs that hospital-based FQHCs' costs must be excluded from the DSH Limit calculation. See AR XXXXXX-XX. In doing so, CMS did not cite to a single regulation or statute implementing this new DSH Limit. The "New Rule" is inconsistent with § 440.20(a), as the services provided by the hospital-based FQHCs at issue here meet the definition of "outpatient hospital services" set forth in the regulation. Defendants do not dispute that, as required by CMS' definition, the services provided by plaintiffs' FQHCs are provided to outpatients; by or under the direction of a physician or dentist; and by a licensed or formally approved hospital that meets the requirements for participation in Medicare as a hospital. Nor do defendants dispute that these services constitute "preventive, diagnostic, therapeutic, rehabilitative, or palliative services" under § 440.20(a). Moreover, the New Rule does not appear to even address the same subject matter as the regulation it purports to "interpret."

The court disagrees with defendants' contention that because the "New Rule" advises the public of the agency's construction of its statutes and rules it administers, it is merely an "interpretation" of the DSH Statute and its own regulations, and is therefore exempt from the notice-and-comment provisions of the APA. There is no statutory or regulatory language that can be interpreted to mean that a hospital forfeits DSH payments for outpatient hospital services by obtaining FQHC certification for the hospital outpatient department that provides those services. Thus, the "New Rule" does not "clarify" the meaning of any statute or regulation, but is instead purely legislative.

Defendants contend that because FQHC services and outpatient hospital services are listed separately in the Medicaid Act, the two service categories are mutually exclusive — which it claims is shown by the fact that outpatient hospital services and services offered by FQHCs are listed as distinct service categories under its regulations and the State Plan. However, CMS is simply assuming as true the very premise that it is attempting to prove — that being listed as distinct service categories means that outpatient hospital services and services of FQHCs are mutually exclusive. However, defendants point to no language in the Medicaid Act or its regulations that supports this underlying premise.

Nor does California's State Plan exclude outpatient hospital services provided by hospital-based FQHCs from the definition of outpatient hospital services found in 42 C.F.R. § 440.20(a). As with the Medicaid Act and CMS' regulations, California's State Plan merely lists FQHC services and outpatient hospital services separately, and describes their payment methodologies. It is true that defendants have cited examples where California's State Plan expressly excludes FQHC

services from being counted as outpatient hospital services in specific instances, but these examples do not support defendants' argument. Indeed, there would be no need for the State Plan to identify specific instances where services provided by FQHCs are not counted as outpatient hospital services if such services were categorically excluded from the definition of outpatient services.

Defendants' claim that the "New Rule" is interpretive is also belied by the fact that CMS previously attempted to exclude services provided by hospital-based FQHCs from the definition of outpatient hospital services via the formal notice-and-comment process, when it adopted the 2008 Outpatient Hospital Services Rule. However, in rescinding the Rule, CMS withdrew the requirement that hospital outpatient services be services that were not also included in other service categories. CMS properly initiated notice-and-comment rulemaking in 2008, but having put the proposed rule through the public comment process, and having rescinded it, CMS cannot now argue that its "New Rule" somehow remained in force after its rescission as part of some informal interpretive rule-making.

Nor do the portions of the preamble to the final 2008 DSH Audit Rule that CMS now contends support its "New Rule" set forth the restrictions that CMS ascribes to them. CMS focuses on two statements in the preamble, which are underlined below:

> [T]he hospital-specific limit is based on the costs incurred for furnishing "hospital services" and does not include costs incurred for services that are outside either the State or Federal definition of inpatient or outpatient hospital services. While States have some flexibility to define the scope of "hospital services," States must use consistent definitions of "hospital services." Hospitals may engage in any number of activities, or may furnish practitioner or other services to patients, that are not within the scope of "hospital services." A State cannot include in calculating the hospital-specific DSH limit cost of services that are not defined under its Medicaid State plan as a Medicaid inpatient or outpatient hospital service . . . .
>
> States should use a consistent treatment of physician and other provider-based clinics. All costs that are associated with services that are defined and reimbursed under the approved Medicaid State plan as inpatient hospital services and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for such services may be included in calculating the hospital-specific DSH limit.

73 Fed. Reg. 77,907, 77,926 (AR 000624, 000643) (emphasis added).

Neither of these statements provides support for CMS' "New Rule." Requiring that states "use consistent definitions of `hospital services'" or "consistent treatment of physician and other provider-based clinics" does not preclude states from consistently defining outpatient hospital services to encompass services that are reimbursed under different payment schemes like the hospital-based FQHC payment scheme, as California has done. See AR 000624. Nor does any other portion of the preamble to the December 19, 2008 DSH final rule or the FAQs support the "New Rule."

Moreover, the two statements cited by CMS are not "representative" of the preamble to the final 2008 DSH Audit Rule, see Tex. Children's Hosp., 76 F.Supp. 3d at 236, which, by its own terms, "only relate[s] to reporting and auditing," AR 000622; and "does not alter any of the substantive standards regarding the calculation of hospital costs," AR 000623; see also AR 000624 ("the [2008 DSH final] rule does not substantively change the standards for DSH payments, or for the review of hospital-specific limits on such payments."); AR000638 ("does not change the underlying statutory requirements for DSH payments"); AR 000623 ("does not alter any of the substantive standards regarding the calculation of hospital costs").

Further, even if the cited portions of the preamble to the final 2008 Audit Rule did support CMS' "New Rule," they still would not justify that "New Rule" because a preamble cannot amend an existing regulation. See Tex. Children's Hosp. 76 F. Supp. 3d at 237. When CMS issued the final 2008 Audit Rule, its regulation narrowing the definition of outpatient hospital services (the 2008 Outpatient Definition Rule) had just been published. However, that narrowed definition was rescinded before it was implemented, and any limitations articulated in the preamble to the final 2008 Audit Rule — which could only be based on the rescinded definition — would not survive CMS' own repeal of that definition. Accordingly, CMS' "New Rule" cannot be based on the final 2008 Audit Rule or the preamble to that rule.

Finally, to the extent that defendants intend to suggest that CMS properly engaged in notice-and-comment rulemaking with regard to the "New Rule," by issuing the 2012 DSH Proposed Rule, and in issuing the 2014 DSH Payments Uninsured Definition Rule, the court finds that CMS' notice-and-comment procedure was inadequate for the further reason that it did

not afford interested parties the opportunity to comment on whether the proposed exclusion of FQHC "outpatient" costs from the DHS calculation conformed to the requirements of the Medicaid Act and to the provisions of the CMS-approved California State Plan.

Where notice-and-comment rulemaking is required, the dispositive question in assessing the adequacy of notice is whether an agency's final rule is a "logical outgrowth" of the rule proposed (i.e., the request for comment). Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158, 174 (2007). In general, a final rule is a "logical outgrowth" of a proposed rule "only if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." Veterans Justice Grp., LLC v. Sec'y of Veterans Affairs, 818 F.3d 1336, 1344 (Fed. Cir. 2016). In determining whether interested parties could reasonably have anticipated the final rule from the draft, "one of the salient questions is `whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule.'" Nat. Res. Def. Council v. U.S. EPA, 279 F.3d 1180, 1186 (9th Cir. 2002).

The publication of the challenged provision in the preamble of the final 2014 DSH Payments Uninsured Definition Rule did not comply with the requirements of notice-and-comment rulemaking. The 2012 DSH Proposed Rule was directed at defining through regulation "individuals who have no health insurance (or other source of third-party coverage) for the services furnished during the year." 77 Fed. Reg. 2500 (AR 001272). The preamble to the Proposed Rule indicated that it was "designed to mitigate some of the unintended consequences of the uninsured definition put forth in the [final 2008 DSH Audit Rule] and to provide additional clarity on which costs can be considered uninsured costs for purposes of determining the hospital-specific limit." 77 Fed. Reg. 2501 (AR 001273).

Nowhere in the Proposed Rule did CMS indicate any intention to exclude FQHC and RHC "outpatient" costs from the DHS calculation. It was only in the final 2014 DSH Payments Uninsured Definition Rule — which described the focus of the Proposed Rule as defining certain terms related to "uninsured" individuals — and then only in one brief section of the preamble, that CMS stated that "if a hospital elects to have a department meet the conditions to participate in Medicaid as a provider of FQHC services, and claims payment for its services as an FQHC, the services of that department are not considered outpatient hospital services." 79 Fed. Reg. 71,684 (AR 001597).

CMS described this statement as a response to "[a] few commenters" who had requested that CMS "confirm that uninsured costs of hospital-based outpatient departments and clinics are to be included in the calculation of uncompensated care costs, irrespective of whether the hospital department or clinic is a [FQHC] for Medicaid payment purposes." However, the fact that one or more commenters may have made such a request is not sufficient to show that the "New Rule" is a logical outgrowth of the 2012 DSH Proposed Rule, where it is not mentioned at all.

CMS had previously, in June 2009, rescinded a final Rule that purported to define "outpatient hospital services" to, among other things, exclude services provided by FQHCs. However, rather than again engaging in notice-and-comment rulemaking, CMS simply inserted this new provision excluding FQHC costs from the DHS calculation into the preamble of the final 2014 DSH Payments Uninsured Definition Rule. CMS' assertion that this provision was consistent with prior "regulatory and sub-regulatory guidance," which included the 2008 DSH Audit Rule, is unpersuasive, as the 2008 DSH Audit Rule did not include a provision excluding outpatient services by FQHCs from the category of "outpatient hospital services" for purposes of the DHS calculation.

The point of notice-and-comment rulemaking is that public comment will be considered by an agency and the agency may alter its action in light of those comments. See Hall v. U.S. EPA, 273 F.3d 1146, 1163 (9th Cir. 2001). There is no requirement that the notice of proposed rulemaking announce the final rule that ultimately is adopted, and the final rule permissibly may differ from versions that were presented to the public in the notice of proposed rulemaking. See id. (citation omitted). However, where the final rule makes no mention of an important component of the final rule that is promulgated, the final rule is not a "logical outgrowth" of the proposal on which the public had the opportunity to comment. See Citizens for Better Forestry v. U.S. Dept. of Agriculture, 481 F.Supp. 2d 1059, 1072-73 (N.D. Cal. 2007). In such a case, the public's right to comment is not protected, see Hall, 273 F.3d at 1163, and the agency has failed to comply with the requirements of notice-and-comment rulemaking.

CONCLUSION

In accordance with the foregoing, the court GRANTS plaintiffs' motion and DENIES defendants' motion. Because CMS' "New Rule," which excludes services provided by a hospital-based FQHC from the definition of "outpatient hospital services" for purposes of the DHS calculation, is a legislative rule which was not promulgated in accordance with the requirements of notice-and-comment rulemaking, defendants violated § 706(2)(D). See Tex. Children's Hosp., 76 F. Supp. 3d at 241; N.H. Hosp. Ass'n, 2016 WL 1048023, at *16.

"Ordinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid." Idaho Farm Bureau Fed'n v. Babbitt, 58 F.3d 1392, 1405 (9th Cir. 1995). Accordingly, because CMS failed to engage in notice-and-comment rulemaking, the challenged provision must be set aside. Where a court vacates an agency action under § 706(2)(D), the court need not determine whether that same agency action would have been arbitrary and capricious, or would otherwise have exceeded the agency's authority, had it been taken under the appropriate procedures. See, e.g., Iowa League of Cities v. EPA, 711 F.3d 844, 877 (8th Cir. 2013). In this case, the court declines to speculate whether a rule that was promulgated in the absence of proper notice and comment would or would not, if (hypothetically) properly promulgated, violate some other section of § 706(2), or whether it could or should be applied retroactively.

The court retains jurisdiction to enforce the terms of this order, and to make such further orders as may be necessary and appropriate. The parties shall meet and confer, and, no later than December 22, 2017, shall submit a proposed judgment.

IT IS SO ORDERED.

[1] At the time the complaints in the above-entitled actions were filed, the Secretary of HHS was Sylvia Mathews Burwell. She resigned effective January 20, 2017. As of the date of this order, the Acting Secretary is Eric D. Hargan. Pursuant to Federal Rule of Civil Procedure 25(d), Acting Secretary Hargan is substituted as a defendant.

[2] The parties have divided the record into the Rulemaking Record (Bates XXXXXX-XXXXXX) and the Administrative Record (Bates 001953-002326). For convenience, the court cites to the record generally as "AR ___."

[3] The only such public comment the court was able to locate in the record filed by the parties was submitted by the California Association of Public Hospitals and Health Systems. See AR 001379.