FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

CALIFORNIA PHARMACISTS Association; California Medical Association; California Dental Association; California Hospital Association; California Association for Adult Day SERVICES; MARIN APOTHECARY, INC., DBA Ross Valley Pharmacy; SOUTH SACRAMENTO PHARMACY: FARMACIA REMEDIOS, INC.; ACACIA Adult Day Services; Sharp MEMORIAL HOSPITAL; GROSSMONT HOSPITAL CORPORATION; SHARP CHULA VISTA MEDICAL CENTER; SHARP CORONADO HOSPITAL AND HEALTHCARE CENTER; FEY GARCIA; CHARLES GALLAGHER, Plaintiffs-Appellees,

No. 09-55532 D.C. No. 2:09-cv-00722-CAS-MAN **OPINION**

DAVID MAXWELL-JOLLY, Director of The California Department of Health Care Services, Defendant-Appellant.

v.

Appeal from the United States District Court for the Central District of California Christina A. Snyder, District Judge, Presiding

Argued and Submitted January 19, 2010-Pasadena, California

Filed March 3, 2010

Before: Stephen Reinhardt, William A. Fletcher and Milan D. Smith, Jr., Circuit Judges.

Opinion by Judge Milan D. Smith, Jr.

COUNSEL

Edmund G. Brown Jr., Attorney General of California, Jennifer M. Kim, Shannon M. Chambers and Randall R. Murphy, Supervising Deputy Attorneys General, and Gregory M. Cribbs, Deputy Attorney General, Los Angeles, California, for defendant-appellant David Maxwell-Jolly.

Lloyd A. Bookman, Byron J. Gross, and Jordan B. Keville, Hooper, Lundy & Bookman, Inc., Los Angeles, California, for plaintiffs-appellees California Pharmacists Association, et al.

OPINION

MILAN D. SMITH, JR., Circuit Judge:

We are once again asked to consider whether the California Department of Health Care Services (Department) Director, David Maxwell-Jolly (Director), should be enjoined from implementing state legislation reducing payments to certain medical service providers. In this latest set of appeals, Plaintiffs-Appellees (California Pharmacists), a group of adult day health care centers (ADHCs), hospitals, pharmacies, and beneficiaries of the State's Medicaid program, Medi-Cal, challenge a five percent reduction in those payments.¹ We affirm, and hold that the district court did not abuse its discretion in granting California Pharmacists's motion for a preliminary injunction because the State failed to "stud[y] the impact of the [five] percent rate reduction on the statutory factors of efficiency, economy, quality, and access to care" prior to implementing the rate reductions. *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644, 652 (9th Cir. 2009) (*Independent Living II*).

FACTUAL AND PROCEDURAL BACKGROUND

I. Medicaid and Medi-Cal

Under Title XIX of the Social Security Act (the Medicaid Act), 42 U.S.C. § 1396 et seq., the federal government provides funds to participating states to "enabl[e] each State, as far as practicable . . . to furnish . . . medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. "Medicaid is a cooperative federal-state program that directs federal funding to states to assist them in providing medical assistance to low-income individuals." Katie A. ex rel. Ludin v. Los Angeles County, 481 F.3d 1150, 1153-54 (9th Cir. 2007). As we have stated many times, it is the states that choose whether to participate in Medicaid. Should a state choose to participate in the Medicaid program, it must comply with federal Medicaid law. Id. California has chosen to participate in the program.

¹Here we deal only with providers and beneficiaries of ADHCs. Mirroring the analysis of today's holdings, we address the challenges to AB 1183 with respect to pharmacy and hospital providers, as well as their beneficiaries, in two separate, concurrently filed memorandum dispositions.

To receive federal funds, states must administer their programs in compliance with individual "State plans for medical assistance," which require approval by the federal Secretary of Health and Human Services. 42 U.S.C. § 1396-1. The State plan must "[s]pecify a single State agency established or designated to administer or supervise the administration of the plan." 42 C.F.R. § 431.10. The Defendant-Appellee's agency, the Department, "is the state agency responsible for the administration of California's version of Medicaid, the Medi-Cal program." *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1493 (9th Cir. 1997) (*Orthopaedic II*).

The Medicaid Act provides detailed requirements for state plans. *See* 42 U.S.C. § 1396a(a)(1)-(73). One of those provisions is § 1396a(a)(30)(A) (hereafter § 30(A)), the provision at issue in this appeal. Under § 30(A), a state plan must:

provide such methods and procedures relating to ... the payment for ... care and services ... as may be necessary ... 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.

Id. § 1396a(a)(30)(A). Thus, a state plan must establish health care provider reimbursement rates that are, among other things: (1) "consistent with high-quality medical care" (quality of care); and (2) "sufficient to enlist enough providers to ensure that medical services are generally available to Medicaid recipients" (access to care). *Indep. Living Ctr. of S. Cal., Inc. v. Shewry*, 543 F.3d 1050, 1053 (9th Cir. 2008) (*Independent Living I*).

II. Assembly Bill 5

On February 16, 2008, the California legislature enacted Assembly Bill X3 5 (AB 5) in special session. *See* 2008 Cal.

Legis. Serv. 3rd Ex. Sess. Ch. 3. AB 5 reduced by ten percent payments under the Medi-Cal fee-for-service program for physicians, dentists, pharmacies, ADHCs, clinics, health systems, and other providers for services provided on or after July 1, 2008. Cal. Welf. & Inst. Code § 14105.19(b)(1). Section 14105.19 of the California Welfare & Institutions Code also reduced payments to managed health care plans by the actuarial equivalent of the ten percent payment reduction. *Id.* § 14105.19(b)(3). Finally, AB 5 reduced payments to acute care hospitals not under contract with the Department for inpatient services. *Id.* § 14166.245(c). Under AB 5, these cuts were scheduled to take effect on July 1, 2008.

In Independent Living II, a group of pharmacies, health care providers, senior citizens' groups, and Medi-Cal beneficiaries brought an action under the Supremacy Clause, alleging that AB 5 conflicted with the requirements of § 30(A). We agreed, and held that under Orthopaedic II § 30(A) requires the Director to set provider reimbursement rates that " 'bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs.' " Indep. Living II, 572 F.3d at 651 (quoting Orthopaedic II, 103 F.3d at 1496). We explained that Orthopaedic II interpreted § 30(A) to require the Director to " 'rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting." Id. at 652 (quoting Orthopaedic II, 103 F.3d at 1496). However, prior to enacting AB 5,

[t]he Director failed to provide any evidence that the Department or the legislature studied the impact of the ten percent rate reduction on the statutory factors of efficiency, economy, quality, and access to care . . . , nor did [the Director] demonstrate that the Department considered reliable cost studies when adjusting its reimbursement rates.

Id.

III. Assembly Bill 1183

On September 16, 2008, the California legislature passed Assembly Bill 1183 (AB 1183), which became effective on September 30, 2008. *See* Cal. Legis. Serv. Ch. 758. AB 1183 amended § 14105.19(b)(1) to provide that the ten percent rate reductions previously called for in AB 5 would end on February 28, 2009. *Id.* AB 1183 also added § 14105.191 and amended § 14166.245 of the California Welfare & Institutions Code, for either one percent, five percent, or ten percent rate reductions, depending on provider type. *See* Cal. Welf. & Inst. Code §§ 14105.191, 14166.245.

On January 29, 2009, California Pharmacists challenged the AB 1183 Medi-Cal reimbursement rate reductions. California Pharmacists sought to enjoin the Director from implementing AB 1183's five percent reduction in payments to ADHCs. ADHCs provide an alternative to institutional care, responding to the State's need "to establish and to continue a community-based system of quality adult day health care which will enable elderly persons or adults with disabilities to maintain maximum independence." Cal. Health & Safety Code § 1570.2. Though recognizing the need for custodial care, the California legislature has concluded that "overreliance on [custodial] care has proven to be a costly panacea in both financial and human terms, often traumatic, and destructive of continuing family relationships and the capacity for independent living." *Id.*

The district court granted the preliminary injunction. It held that California Pharmacists had demonstrated a likelihood of success on the merits for three reasons. First, the legislative history showed no indication that the legislature considered § 30(A) prior to passage of AB 1183. Second, since the Department was given no discretion to alter the rate reductions imposed by the legislature, any analysis that the Department completed in February 2009, and thus after the reductions were enacted, did not satisfy the requirements of *Orthopaedic II*. And third, any analysis conducted by the Department was inadequate because the Department relied on costs incurred at intermediate care facilities (NF-As), which the district court considered to be an inadequate proxy for ADHC costs. The district court also held that California Pharmacists had demonstrated a risk of irreparable harm and that the balance of equities and public interest weighed in favor of injunctive relief. The Director timely appealed.

The Director raises three issues on appeal. First, the Director argues that the district court erred in holding that the legislature itself was required to conduct cost studies or analyses prior to enactment of AB 1183 to determine whether the proposed rate reductions complied with the efficiency, economy, and quality of care provisions of § 30(A). Second, the Director contends that even if the legislature was required to conduct the relevant analysis, the district court committed clear error in concluding that the legislature did not adequately consider the § 30(A) factors prior to enacting AB 1183. Third, the Director argues that the district court erred in concluding that California Pharmacists had met their burden of demonstrating irreparable harm with respect to reduced reimbursement rates under AB 1183.

JURISDICTION AND STANDARD OF REVIEW

We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1292(a)(1). A district court's decision to grant or deny a preliminary injunction is reviewed for abuse of discretion. *Indep. Living II*, 572 F.3d at 651. We recently restated our two-part test used to determine whether a district court has abused its discretion. First, we "determine de novo whether the trial court identified the correct legal rule to apply to the relief requested." *United States v. Hinkson*, 585 F.3d 1247, 1262 (9th Cir. 2009) (en banc). If the trial court did not identify the correct legal rule, it abused its discretion. *Id.* at 1262.

Second, we must determine if the district court's "application of the correct legal standard was (1) 'illogical,' (2) 'implausible,' or (3) without 'support in inferences that may be drawn from the facts in the record.' "*Id.* (quoting *Anderson v. City of Bessemer City*, 470 U.S. 564, 577 (1985)).

In granting a request for a preliminary injunction, a district court abuses its discretion if it "base[s] its decision on an erroneous legal standard or clearly erroneous findings of fact." *Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1156 (9th Cir. 2006), *abrogated on other grounds by Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365 (2008). We review conclusions of law de novo and findings of fact for clear error. *Id.* Under this standard, "[a]s long as the district court got the law right, it will not be reversed simply because the appellate court would have arrived at a different result if it had applied the law to the facts of the case." *Id.* (internal quotation marks omitted).

DISCUSSION

[1] In seeking a preliminary injunction in a case in which the public interest is involved, a plaintiff must overcome four hurdles. Thus, California Pharmacists must show that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest. *Cal. Pharms. Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 849 (9th Cir. 2009) (citing *Winter*, 129 S. Ct. at 376); *see also Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir. 2009).

I. Likelihood of Success on the Merits

[2] In Orthopaedic II, we held that § 30(A) requires

the Director [to] set hospital outpatient reimbursement rates that bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs. To do this, the Department must rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting.

103 F.3d at 1496.

We address the Director's arguments in turn.

A. The Body Responsible for Complying with § 30(A)

First, the Director argues that *Orthopaedic II* did not hold that rate setting must be based upon pre-enactment legislative studies undertaken and completed by the legislature itself prior to legislative action authorizing a state department to implement rate reductions. According to the Director, at issue in *Orthopaedic II* were statutorily mandated rate changes not unlike those set pursuant to AB 1183. However, despite those enactments, we focused solely on the Department's actions, rather than on the legislature's, and thus only the Department is required to consider the § 30(A) factors. We disagree.

In Orthopaedic II, none of the disputed rate-settings was actually set by the legislature. See Orthopaedic Hosp. v. Kizer, No. 90-4209, 1992 WL 345652 (C.D. Cal. Oct. 5, 1992) (Orthopaedic I). To the contrary, the legislative enactments granted the Director broad discretion to set the applicable rates in the face of general governing criteria. See, e.g., Orthopaedic I, 1992 WL 345652, at *7 (describing that reimbursement rates for rural hospitals were to "be set at a level which will provide incentives for rural hospitals to focus on the provision of outpatient services and . . . reduce the financial losses incurred by the facilities"); *id.* at *8 (describing that for delivery services rates the Department "shall eliminate the Medi-Cal reimbursement for Caesarean and

non-Cesarean section deliveries); id. at *9 (statute required the Department to amend the method for reimbursing disproportionate share hospitals for outpatient services, to which the "Department responded by developing a new payment methodology"). Since the Director set the challenged rates, Orthopaedic II addressed whether the Medicaid Act "requires the Department to consider the costs hospitals incur in delivering services when setting specific payment rates under [§ 30(A)]." 103 F.3d at 1496 (emphases added). Looking to the clear language in the statute, we noted that § 30(A) "provides that payments for services must be consistent with efficiency, economy, and quality of care, and that those payments must be sufficient to enlist enough providers to provide access to Medicaid recipients." Id. We reasoned that costs were an integral factor to be considered in the payment calculus, since "[t]he Department cannot know *that it is setting rates* that are consistent with [§ 30(A)'s relevant factors] without considering the costs of providing such services." Id. (emphasis added). Thus, we held that "payments for hospital outpatient services must bear a reasonable relationship to the costs of providing quality of care incurred by efficiently and economically operated hospitals." Id.

[3] Unlike the statutes at issue in *Orthopaedic II*, the State has taken a different approach to setting rates under AB 1183. Under AB 1183, the legislature mandated that the Director reduce provider payments by a fixed percentage. See, e.g., Cal. Welf. & Inst. Code § 14105.191(b)(2) ("[P]ayments to the following classes of providers shall be reduced by 5 percent for Medi-Cal fee-for-service benefits[.]"). Thus, the Director is misguided in arguing that our focus on the Department in Orthopaedic II absolves the legislature of the same requirements when it sets rates. In other words, in Orthopaedic II, there was no question that the Department set reimbursement rates. Those rates provided payments for the medical service at issue under the State's plan-there, hospital outpatient services. We had no reason to focus on what the State legislature considered before rates were set since the legislature was one step removed from the regulations promulgated by the Department. As noted, the legislature merely outlined broad goals for the Department, a process separate and distinct from determining the *effect* of a specific rate reduction on the statutory factors of efficiency, economy, quality, and access to care. Yet if the legislature elects to bypass the Department, and set rates itself, it must engage in the same principled analysis we required of the Director in *Orthopaedic II*.

Moreover, in *Orthopaedic I*, the Director made the inverse of the argument he asserts here. There, he argued that in enacting the governing statutes, the legislature considered the relevant § 30(A) factors, thus excusing the Department's need to do the same when it set rates based on the legislature's commands. See Orthopaedic I, 1992 WL 345652, at *7-11. The district court rejected this argument, holding first that the statutes did not "purport to establish any specific payment rates," id. at 7, and second that even if the legislature had considered the relevant factors, that did not "relieve the Department of the obligation to further consider [the relevant factors] in exercising what discretion it had in implementing the legislature's general mandate," id. at 9. In addition, the court noted, "nor is there adequate evidence in the record demonstrating that the state legislature at any time considered [the relevant factors] in connection with the equalization of rates." Id. The district court explained:

In sum, *if* there was evidence *both* that (1) in setting the challenging rates, the Department had merely in rote fashion been implementing a precisely-crafted statutory enactment that did not permit the Department to exercise any significant discretion whatsoever, and further, that (2) the legislature in enacting the statute had expressly considered "efficiency, economy, and quality of care," the Court might agree that the Department need not have considered "efficiency, economy, and quality of care," at all. But there is convincing evidence of neither.

Id. Thus, we are not telling the State something new.

Indeed, we find no distinction between the method by which rates were set under either AB 1183 or AB 5. Under AB 5, the California legislature enacted a statutorily mandated across-the-board rate reduction. In holding that the Director violated § 30(A) when he implemented AB 5's rate reductions, we held "[t]he Director failed to provide any evidence that the Department or the legislature studied the impact of the ten percent rate reduction on the statutory factors . . . prior to enacting AB 5." Indep. Living II, 572 F.3d at 652 (emphases added). We noted several times our concern with the context in which the *legislation* was passed, and focused on what State officials failed to consider prior to enactment. See id. at 655-56 (holding that the State's decision to pass legislation reducing Medi-Cal reimbursement rates for purely budgetary concerns violated federal law); id. at 656 (concluding that the State's Legislative Analyst was the only "State official" to have "considered-let alone studied" the impact of the rate reduction on services provided to Medi-Cal beneficiaries); id. at n.12 ("Nothing in the record connects the decision to cut Medi-Cal reimbursement rates by ten percent across-the-board to a factfinding process initiated by state officials."). Such an approach is consistent with that of our sister circuits, where in the context of legislative, as opposed to agency, rate-setting, they too have focused on ensuring that the legislative body had information before it so that it could properly consider efficiency, economy, quality of care, and access to services before enacting rates. See Minn. Homecare Ass'n, Inc. v. Gomez, 108 F.3d 917, 918 (8th Cir. 1997) (holding that although the agency did not provide any formal § 30(A) analysis to the legislature, lobbyists "actively participated in the . . . legislative session" such that the legislature adequately considered § 30(A) when it raised reimbursement rates); cf. Ark. Med. Soc'y, Inc. v. Reynolds, 6 F.3d 519, 530 (8th Cir. 1993) (refusing to consider evidence offered during agency hearings regarding the effect of rate cuts on accessibility because it "could only be confirmed by historical data accumulated after the cuts were made").²

[4] In sum, we find nothing remarkable in holding that the final body responsible for setting Medicaid reimbursement rates must study the impact of the contemplated rate reduction on the statutory factors of efficiency, economy, quality of care, and access to care prior to setting or adjusting payment rates. We emphasize that the State need not follow "any prescribed method of analyzing and considering [the § 30(A)] factors." Minn. Homecare Ass'n, 108 F.3d at 918; Orthopaedic II, 103 F.3d at 1498 (refusing to impose a "rigid formula" for the Department to follow). But as we stated in Orthopaedic II, "Congress intended payments to be flexible within a range; payments should be no higher than what is required to provide efficient and economical care, but still high enough to provide for quality care and to ensure access to services." 103 F.3d at 1497. The only way to ensure that Congress's intent is realized is for the State to study the impact of the contemplated rate change on the statutory factors prior to setting rates. Thus, in no way do we mean to suggest that the State is proscribed from setting or adjusting reimbursement rates. We simply reaffirm that if it does so, it must comply with federal law.

²The Director's reliance on *Folden v. Wash. State Dep't of Soc. & Health Servs.*, 981 F.2d 1054 (9th Cir. 1992), is also misplaced. In *Folden*, the owners of fourteen nursing home care facilities challenged Washington state Medicaid payments under a now repealed section of the Medicaid Act known as the Boren Amendment. 981 F.2d at 1056. We have numerous times rejected the Director's attempt to "graft past judicial interpretation of the Boren Amendment onto this court's interpretation of § 30(A)." *Indep. Living II*, 572 F.3d at 654-56 & nn.11-12; *Alaska Dep't of Health and Soc. Servs. v. Ctrs. for Medicare and Medicaid Servs.*, 424 F.3d 931, 940-41 (9th Cir. 2005).

B. Legislative Consideration Prior to Setting Rates

Having determined that the State legislature was required to study the impact of the five percent rate reduction on the statutory factors of efficiency, economy, quality, and access to care prior to enacting AB 1183, we next consider whether it did so. The Director argues that even though the legislature was not required to do so, the district court committed clear error in concluding that the legislature did not adequately consider the § 30(A) factors prior to implementing AB 1183.

In support of his argument, the Director submits the declaration of the Department's Deputy Director for Legislative and Governmental Affairs. The Deputy Director states that in May 2008, the Senate and Assembly proposals were released in public hearings held by the Senate and Assembly Budget Committees. According to the Deputy Director, Department employees "provid[ed] information, technical assistance, and responses to numerous inquiries to legislative staff members concerning the various 5% and 1% rate reductions that were included in AB 1183." The Director also references the May 30, 2008, agenda released by the Assembly Budget Subcommitee No. 1 on Health and Human Services. That agenda lists certain "items to be heard" including proposed actions to "Maintain Essential Health Care Services and Eligibility," such as "Restore 10% provider rate cut for physicians and other healthcare providers" and "Partially restore long-term care rate reductions enacted in AB 5 X 3 (reduce cut from 10% to 5%)." The only proposed action that includes a discussion relevant to ADHCs explains that individuals with developmental disabilities living in Intermediate Care Facilities are eligible for ADHC services, and that such clarification in a trailer bill is necessary so that the State's Department of Developmental Services will no longer have to "fund these ADHC services at 100 percent General Fund cost."

Next, the Director points to the California Senate Committee on Budget and Fiscal Review for May 30, 2008, which includes recommendations for modification of several rate reductions or elimination of services. With respect to ADHC services, one entry contains the same description of the proposed trailer bill needed to clarify that individuals with developmental disabilities in Intermediate Care Facilities are eligible for participation in the ADHC Program. The other entry relevant to ADHCs is a brief explanation of the Department's request for an increase in funds for ADHC services due to an increase in enrollees.

The Director also points to the June 11, 2008, Subcommittee 3 Health, Human Services, Labor, and Veterans Affairs Major Action Report. That Report notes certain of the Department's "Highlights for the Medi-Cal Program." The Deputy Director calls particular attention to the entry that indicates that the 2008-09 budget bill "Provided a partial restoration to the rates reimbursed under Medi-Cal by providing a 5 percent across-the-board restoration to the 10 percent reduction as proposed by the Governor and taken in Special Session through [AB 5]. In the Medi-Cal Program, this resulted in an increase of about \$597 million (\$302 million General Fund)." The Report also noted adoption of the ADHC proposals set forth above.

The Director further points to the Budget Conference Committee 2008 Action List dated July 9, 2008, which shows seven items that the Assembly and Senate voted on, ultimately contained in AB 1183, such as "Partial Restoration of Medi-Cal Fee-For-Service Provider Payments" and "Partial Restoration of Medi-Cal Pharmacy Rate." The Director argues that this Action List illustrates "that the Assembly and Senate voted on the very Medi-Cal rate reduction language that was ultimately contained in AB 1183." The July 2008 Summary Overview Budget Conference Committee Report summarizes many of the rate reductions enacted as part of AB 1183. Finally, the Director refers to the State's Legislative Analyst Office's analysis of the 2008-09 Budget, which includes recommendations from the State's Legislative Analyst concerning the Governor's proposed reductions to provider reimbursement.

[5] The district court explicitly mentioned the legislative history described above (with the exception of the Legislative Analyst Office's analysis), and determined that it does not show that there was consideration of the § 30(A) factors. We agree, since the legislative history nowhere mentions any of the § 30(A) factors, see Orthopaedic I, 1992 WL 345652, at *8 ("Tellingly—although not dispositively the terms 'efficiency,' 'economy,' and 'equality [sic] of care' appear nowhere in these documents."), and is concerned solely with budgetary matters, see Indep. Living II, 572 F.3d at 659 ("State budgetary concerns cannot . . . be the conclusive factor in decisions regarding Medicaid." (internal quotation marks omitted)). Indeed, the legislative history contains no indication that, in adjusting rates under AB 1183, the State " 'rel[ied] on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting.'" Id. at 652 (quoting Orthopaedic II, 103 F.3d at 1496). The Legislative Analyst Office's analysis of the 2008-09 Budget appears to be the very same report we referenced in *Independent Living II*. See id. at 656. It discusses the Governor's proposal of a ten percent provider rate reduction, which the State's own Legislative Analyst recommended rejecting for all providers except hospitals because those rate reductions had "the potential to negatively impact the operation of the Medi-Cal Program and the services provided to beneficiaries by limiting access to providers and services." It is hardly clear error for the district court to have failed to mention a report conducted without regard to the specific rate reductions before it. Accordingly, we will not disrupt the district court's factual findings, as they are not clearly erroneous.

C. The Department's Analysis

The Director also argues that the district court erred in failing to consider the analysis conducted by the Department, completed after the law's enactment. In rejecting the Department's analysis, the district court held that AB 1183 did not provide the Department with any discretion, citing Cal. Welf. Code § 14105.191(a), which provides & Inst. that "[n]otwithstanding any other provision of law, in order to implement changes in the level of funding for health care services, the director shall reduce provider payments." (emphasis added). The district court reasoned that since the Department was not given any authority to alter the rate reduction imposed by the legislature, the Department's post hoc analysis does not satisfy the requirements of Orthopaedic II. The district court went on to hold that even if a post hoc analysis was sufficient, the Department relied on an inadequate proxy for ADHC costs when it considered data for NF-As.

[6] To satisfy § 30(A), any analysis of reimbursement rates on the statutory factors of efficiency, economy, quality, and access to care, must have the potential to influence the ratesetting process. See Indep. Living II, 572 F.3d at 652 n.9 (holding that the district court did not abuse its discretion in concluding that *post hoc* rationalizations of the disputed reimbursement rates do not satisfy the procedural requirements of Orthopaedic II); see also Orthopaedic II, 103 F.3d at 1499 ("[T]he Department must consider hospitals' costs based on reliable information when setting reimbursement rates" (emphases added)); Ark. Med. Soc'y, 6 F.3d at 530. Yet the Department's analysis of AB 1183 with respect to ADHCs was issued on February 24, 2009, more than five months after the legislature enacted AB 1183, but prior to the cuts' implementation. Therefore, for the Department's analysis to have the requisite potential effect, the Director would have to have discretion regarding implementation of the rates.

In his reply brief, and for the first time in this litigation, the Director argues that the Department's post-enactment study is sufficient because the Department retained discretion under AB 1183 not to *implement* the reductions before March 1, 2009. Thus, the Director argues, the Department's February

24, 2009, analysis would still be meaningful because the Director had authority to affect rates by deciding not to implement them.³ Although the Director has clearly waived this argument by failing to raise it in his opening brief, *see Indep. Towers of Wash. v. Washington*, 350 F.3d 925, 929 (9th Cir. 2003), we nevertheless consider and reject the Director's argument on the merits.

The Director argues that if the Department determined that the reduced payments for any services would not comply with the relevant 30(A) factors, the Department retained the discre-

³The Director's argument that he has discretion regarding the rates is drawn from a footnote in the district court's analysis in Orthopaedic I. There, the Director argued that legislative consideration of the § 30(A) factors excused the Department from again having to consider § 30(A). In rejecting that argument, the district court noted that the relevant statutory enactments "gave the Department fairly wide discretion in implementing the basic changes outlined in the statute." Orthopaedic I, 1992 WL 345652, at *9. To buttress that conclusion, the district court pointed out that under the Medicaid Act, the "ultimate responsibility" for administration of a state's Medicaid program is entrusted to a "single state agency." Id. at n.14 (quoting 42 C.F.R. § 431.10). As a result, the district court concluded that under federal law, the state agency has the "final say in what payment rates to set, notwithstanding a legislature's efforts to provide broad guidelines for the agency." Id. (emphasis added). The court found it particularly relevant that the California legislature directed the Department to "seek federal approval for this section, if necessary." Id. (citing California Senate Bill 2563) (internal quotation marks omitted). The court also noted that subsection (a) under the Medi-Cal enabling statute grants the Department "extremely broad authority" to "comply with legislative budgetary enactments" only to the extent that those enactments comply with federal law. Id.

As we have described, there are a number of notable differences between the legislative enactments at issue in *Orthopaedic I* and AB 1183, thus raising the question of whether, under AB 1183, the Director had the "final say in what payment rates to set." *Id.* However, because we reject the Director's argument for the reasons set forth below, we do not decide whether differences between AB 1183 and the legislative enactments at issue in *Orthopaedic I* are dispositive of the Director's discretion in this case.

tion⁴ not to implement those reductions. As a result, the legislature made implementation of the rate reductions dependent on whether the Department determined that they complied with federal law.⁵

The Director relies on § 14105.191(i), which states:

The department shall promptly seek any necessary federal approvals for the implementation of this section. To the extent that federal financial participation is not available with respect to any payment that is reduced or limited pursuant to this section, the director may elect not to implement that reduction or limitation.

Cal. Welf. & Inst. Code § 14105.191(i). The Director also points to the Medi-Cal enabling statute, Cal. Welf. & Inst. Code § 14105(a):

The director shall prescribe the policies to be followed in the administration of this chapter, may limit the rates of payment for health care services, and

⁵We need not decide whether a study completed after rates have been set complies with § 30(A) where the Department has discretion not to implement the rates. For purposes of our analysis only, we assume such a study would suffice, but do not so hold because we find that the Director did not retain any discretion in this case.

⁴At oral argument the Director conceded that he did not have authority to change the rates set by the legislature, but, he argued, he could exercise a veto power based on a determination that the rates did not comply with the statutory factors in § 30(A). We need not decide whether the type of discretion contemplated by § 14105(a) of the California Welfare & Institutions Code is different from that under § 14105.191(i). That is, that the Director may "limit the rates," or "adopt regulations setting rates" under § 14105(a) would seem to provide for a different type of discretion than deciding simply not to implement the rates as set. However, because we hold that the Director did not retain any discretion to act once rates had been set, we do not discuss the distinction, if any, between the discretion contemplated by § 14105(a) as opposed to § 14105.191(i).

shall adopt any rules and regulations as are necessary for carrying out, but are not inconsistent with, the provisions thereof.

Subsection (a) goes on to provide:

In order to implement expeditiously the budgeting decisions of the Legislature, the director shall, to the extent permitted by federal law, adopt regulations setting rates that reflect these budgeting decisions within one month after the enactment of the Budget Act and of any other appropriation that changes the level of funding for Medi-Cal services.

Cal. Welf. & Inst. Code § 14105(a).

[7] The Director's is not the most natural reading of the statute. Section 14105.191(i) does not clearly invest the Director with the discretion not to implement the legislature's rate reductions. Rather, it first directs the Department to "seek any necessary federal approvals" to implement the rate reductions. Cal. Welf. & Inst. Code § 14105.191(i). Only then does it permit the Director not to implement any reduction "[t]o the extent that federal financial participation is not available." Id. (emphasis added). Thus, the most natural reading would seem to be one of budgetary concern; if federal money is not available for any particular payment reduction, the Director may choose to save the State money by not implementing the reduction. Such a reading comports with the budgetary nature of AB 1183's legislative history. See Ariz. State Bd. For Charter Sch. v. U.S. Dep't of Educ., 464 F.3d 1003, 1008 (9th Cir. 2006) ("When a natural reading of the statute[] leads to a rational, common-sense result, an alteration of meaning is not only unnecessary, but also extrajudicial.").

[8] The Director asks that we read into the statutory text a process by which the Department could first analyze the impact of the five percent payment reduction on the 30(A)

factors and then elect to implement the reduction based on that analysis. However, regardless of whether any such process was contemplated in the statute, the record clearly demonstrates that no process of the kind the Director envisions took place. First, on September 30, 2008, the Department submitted its State Plan Amendment, incorporating AB 1183's rate reductions. In its State Plan Amendment, the Department stated that it had "determined that payments will continue to comply with any upper spending limits contained in Part 447 that were adopted to implement the 'efficiency, economy, and quality of care' provision of [§ 30(A)]. Beneficiaries will continue to have access to covered services as required by Part 447." Yet the Department did not issue a § 30(A) analysis until February 24, 2009 and produced nothing that would indicate that it studied the impact of AB 1183 on efficiency, economy, quality, and access to care prior to September 30, 2008. The State Plan Amendment also does not mention the Department's discretion not to implement the rate reductions based on federal participation.

In addition, on February 13, 2009, the State published notice in the California Regulatory Notice Register that "Section 14105.191 of the [Welfare and Institutions] Code is reducing the payments that would otherwise be paid for [adult day health care services] under the current rate methodology from 10 percent to 5 percent for dates of service on or after March 1, 2009. The State's Notice further provided that the Department

is mandated by state law to implement the above change in reimbursement. [The Department] has considered the impact of this reimbursement on providers and Medi-Cal beneficiaries. [The Department's] assessment is that reimbursement will continue to compensate a high percentage of costs incurred for these facility services and that Medi-Cal beneficiaries will continue to have access to these services consistent with [§ 30(A)]. As with the State Plan Amendment, the Notice pre-dates any analysis issued by the Department, yet definitively announces payment reductions from ten to five percent. Moreover, the Notice states that the Department "is mandated" to implement the rates, further undermining the Director's reading of § 14105.191(i).

[9] In sum, the Director's argument that he retained discretion not to implement AB 1183's rate reductions is not supported by the record. The Department's February 24 analysis issued well after decisions had been made to reduce payments by five percent, and nothing in the record indicates that the Department retained the discretion not to implement the rate reductions based on a § 30(A) analysis. To comply with § 30(A), the State must study the impact of the contemplated rate reduction on the statutory factors of efficiency, economy, quality, and access to care prior to legislative enactment or in a manner that allows meaningful consideration of such input prior to implementation. Here, the State did neither.

[10] In addition, regardless of whether the Director retained the discretion to act in the manner he posits, we agree with the district court that the Department's analysis was insufficient. Reviewing for clear error, we hold that the district court did not abuse its discretion in finding that the Department's reliance on NF-A rather than ADHC data was inadequate. The Department looked to the average costs of only six NF-A facilities, with widely varied costs, as a proxy for the 313 ADHCs in the Medi-Cal program. In its ADHC analysis, completed in February 2009, the Department explained that it had "just begun the process of auditing the costs of ADHCs for purposes of establishing rates under the new costs based methodology that is scheduled to go into effect on August 1, 2010[,]" and therefore, "in order to assess how ADHC reimbursement compares to the costs that may be incurred by an ADHC in providing ADHC services to Medi-Cal recipients," it used as a proxy how Medi-Cal reimbursement compares to NF-A costs. The Director concedes that a prospective cost reimbursement methodology for ADHCs is "still more than one year away." In the meantime, nothing in the record indicates that the district court clearly erred in concluding that the Department's use of NF-A costs was an inadequate proxy for ADHC costs. *Cf. Orthopaedic II*, 103 F.3d at 1500 (holding that the Department violated § 30(A) when readopting reimbursement rates for *hospitals*' costs by not considering *hospitals*' costs when reevaluating its rates). Accordingly, it was not an abuse of discretion for the district court to have rejected the Department's analysis.

II. Irreparable Harm

The Director also argues that the district court erred in holding that California Pharmacists demonstrated a likelihood of irreparable harm. After reviewing the evidence, the district court held that "the evidence submitted by plaintiffs indicate[s] that Medi-Cal beneficiaries are at risk of losing access to ADHC services due to the AB 1183 rate reduction." The Director argues that in determining whether California Pharmacists have shown a likelihood of irreparable harm, the district court was required to compare Medi-Cal beneficiaries' access to ADHC services to that of the general population's.

Once again, under \S 30(A), each state's Medicaid plan must be

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). This is referred to as the "equal access to care provision," *Orthopaedic II*, 103 F.3d at 1498, and requires that a state plan establish reimbursement rates sufficient to enlist enough providers to ensure that medical services are generally available to Medicaid recipients, *id.* at 1497. The Director argues that the district court erred in fail-

ing to apply the equal access to care provision in the context of plaintiffs' claims of irreparable injury. In other words, the Director argues that there can be no finding of irreparable harm where "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." § 30(A). According to the Director, applying this standard here, the evidence before the district court established that ADHC services are not generally available to the general population and thus California Pharmacists made no showing of irreparable injury.

In Independent Living II, we discussed the distinction between § 30(A)'s procedural and substantive requirements. We considered the "potential difficulties inherent in assessing substantive compliance with the factors laid out in § 30(A),' which made more attractive, by comparison, the "processoriented view of the statute espoused in Orthopaedic [II]." Indep. Living II, 572 F.3d at 657. While explaining that there is a difference between substantive and procedural compliance with § 30(A), id. at 656, we also explained their interdependence, since "it is fair to assume that a rate that is set arbitrarily, without reference to the Section 30(A) requirements, is unlikely to meet the equal access and quality requirements," id. at 657 (internal quotation marks omitted). We reaffirmed Orthopaedic II's requirement that states comply with the procedural components of § 30(A) by setting provider reimbursement rates only after consideration of the relevant statutory factors of efficiency, economy, quality, and access to care. Id.

[11] The Director's approach to the irreparable harm analysis conflates § 30(A)'s procedural and substantive requirements. We do not require plaintiffs to show the State has committed a substantive violation of § 30(A)'s access provision when they can show that the State did not comply with § 30(A)'s procedural components. In other words, showing a procedural violation of the statute—that is, the State's failure to consider the impact of the contemplated rate on the statutory factors set forth in § 30(A)-may demonstrate a likelihood of success on the merits that the setting of provider reimbursement rates conflicts with § 30(A). Determining whether plaintiffs have made a sufficient showing of irreparable harm is a separate inquiry, which does not turn on the State's substantive compliance with § 30(A). Rather, to show a risk of irreparable harm, plaintiffs may show either, as Medicaid beneficiaries, "that enforcement of a proposed rule 'may deny them needed medical care[,]" Indep. Living II, 572 F.3d at 658 (quoting Beltran v. Myers, 677 F.2d 1317, 1322 (9th Cir. 1982)), or, as Medicaid providers, that they will lose considerable revenue through the reduction in payments that they will be unable to recover due to the State's Eleventh Amendment sovereign immunity, Cal. Pharms. Ass'n, 563 F.3d at 850-52.

[12] Requiring a substantive violation of the equal access to care provision in order to meet the irreparable injury prong would also run afoul of our Supremacy Clause jurisprudence. In California Pharmacists, we held that in an action brought under the Supremacy Clause, a finding of irreparable harm does not turn on "whether the plaintiffs asserting the economic injury were in any sense intended beneficiaries of the federal statute on which the Supremacy Clause cause of action was premised." Id. at 851. Because "[a] cause of action based on the Supremacy Clause obviates the need for reliance on third-party rights," private parties bringing a Supremacy Clause cause of action can "enforce the structural relationship between the federal and state governments so long as they ha[ve] Article III standing as, essentially, private enforcers of the Supremacy Clause." Id. Thus, as stated above, plaintiffs need only show harm to Medi-Cal service providers or their members in order to obtain injunctive relief. Id. at 850. The Director's more narrow approach would allow injunctive relief only where plaintiffs are able to show that Medi-Cal beneficiaries have worse access to care and services than that available to the general population.

[13] Finally, we have stated that even if § 30(A) imposes a substantive requirement, a rate reduction might still conflict with the statute if *at least some* providers stop treating Medi-Cal beneficiaries. *Indep. Living II*, 572 F.3d at 656-57. The Director concedes that here, the evidence indicates that at least some ADHC Medi-Cal providers would stop treating beneficiaries due to AB 1183. Thus, even if we were to require a substantive violation of the statute to support a finding of irreparable harm, we would find that violation here.

[14] Therefore, we reject the Director's argument that there can be no finding of irreparable harm unless the plaintiffs show a substantive violation of § 30(A)'s access to care provision. The Director makes no serious attempt to dispute the district court's factual finding that, in light of the evidence, "Medi-Cal beneficiaries are at risk of losing access to ADHC services due to the AB 1183 rate reduction." Upon our review of the evidence, we do not find the district court's conclusion to be clearly erroneous. Accordingly, the district court did not abuse its discretion in finding that California Pharmacists established sufficient irreparable harm to warrant a pre-liminary injunction.

III. Balance of Equities and the Public Interest

Finally, the Director argues that because of the State's deepening fiscal crisis, a preliminary injunction should not issue. The Director insists that the legislature be allowed to exercise "its considered judgment" in a manner that serves the best interests of both Medi-Cal recipients and the State as a whole, and that injunctions against payment reductions have forced the State to eliminate many optional Medi-Cal services. The district court recognized the State's interest in meeting its financial obligations but held that the State's financial were outweighed by the public's interest in access to health care, particularly because "nothing . . . prevents [the State] from imposing a rate reduction after . . .

appropriately consider[ing] and appl[ying] the relevant factors."

[15] "The public interest analysis for the issuance of a preliminary injunction requires us to consider 'whether there exists some critical public interest that would be injured by the grant of preliminary relief.' " Indep. Living II, 572 F.3d at 659 (quoting Hybritech Inc. v. Abbott Labs., 849 F.2d 1446, 1458 (Fed. Cir. 1988)). We have held that "there is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as 'the most needy in the country." Id. (quoting Schweiker v. Hogan, 457 U.S. 569, 590 (1982)). We continue to recognize this important public interest in the context of social welfare cases. As the district court stated, the State is free to exercise its "considered judgment" and reduce Medi-Cal reimbursement rates. Yet it may not do so for purely budgetary reasons, Ark. Med. Soc'y, 6 F.3d at 531, nor may it do so in a manner that violates federal law, Indep. Living II, 572 F.3d at 659. Accordingly, we hold that the district court did not abuse its discretion in concluding that the balance of hardships and the public interest weighed in favor of enjoining implementation of the five percent rate reduction required by AB 1183.

CONCLUSION

We have now handed down multiple decisions instructing the State on § 30(A)'s procedural requirements. We trust that the State now understands that in order for it to comply with § 30(A)'s "requirement that payments for services must be consistent with efficiency, economy, and quality of care, and sufficient to ensure access," *Orthopaedic II*, 103 F.3d at 1500, it must: (1) "rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting," *id.* at 1496; *and* (2) study the impact of the contemplated rate change(s) on the statutory factors *prior to* setting rates, or in a manner that allows those studies to have a meaningful impact on rates before they are finalized. Because the State did neither with respect to AB 1183, we affirm the district court's order granting California Pharmacists's motion for a preliminary injunction.

AFFIRMED.