3-23-1999

Rite Aid Of PA Inc v. Houstoun

Filed March 22, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 98-1823, 98-1879, 98-1880

RITE AID OF PENNSYLVANIA, INC., et al

v.

FEATHER O. HOUSTOUN,

PENNSYLVANIA PHARMACISTS ASSOCIATION
(Intervenor in D.C.)

Feather O. Houstoun, as
Secretary of the Department
of Public Welfare for the
Commonwealth of Pennsylvania

Appellant in No. 98-1823

RITE AID OF PENNSYLVANIA, INC.,

Appellant in No. 98-1879

v.

FEATHER O. HOUSTOUN

PENNSYLVANIA PHARMACISTS ASSOCIATION
(Intervenor in D.C.)

RITE AID OF PENNSYLVANIA, INC.

v.

FEATHER O. HOUSTOUN

PENNSYLVANIA PHARMACISTS ASSOCIATION
(Intervenor in D.C.)

Pennsylvania Pharmacists
Association,

Appellant in No. 98-1880

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 97-2120)
District Judge: Honorable Harvey Bartle, III

Argued February 18, 1999

BEFORE: GREENBERG, LEWIS, and BRIGHT,*
Circuit Judges

(Opinion Filed: March 22, 1999)

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*Honorable Myron H. Bright, Senior Judge of the United States Court of Appeals for the Eighth Circuit, sitting by designation.

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OPINION OF THE COURT

GREENBERG, Circuit Judge.

I. INTRODUCTION

This appeal concerns a procedural challenge to the Pennsylvania Department of Public Welfare's ("Department") promulgation of revised regulations governing payment rates for prescription drugs and related services provided to Medicaid recipients pursuant to Title XIX of the Social Security Act, 42 U.S.C. SS 1396-1396v ("Medicaid Act").1 The Department appeals from an order and judgment of the United States District Court for the Eastern District of Pennsylvania, entered August 31, 1998, enjoining it from applying revised formulas to pay pharmacies for prescription drugs and related services under the Medicaid program which were to become effective October 1, 1995. Rite Aid of Pennsylvania and the Pennsylvania Pharmacists Association ("PPA") cross-appeal from the district court's order to the extent that it upheld procedures the

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1. In order to assist the readers of this opinion, we set forth the letter abbreviations that the parties have used which we also use: Average Wholesale Price (AWP); Estimated Acquisition Cost (EAC); Federal Upper Limit (FUL); Health Care Financing Administration (HCFA); Department of Health and Human Services (HHS); Independent Regulatory Review Commission (IRRC); Medical Care Advisory Committee (MAAC); Maximum Allowable Costs (MAC); Omnibus Budget Reconciliation Act (OBRA); Pennsylvania Pharmacists Association (PPA); and State Plan Amendment (SPA).

Department followed in promulgating the regulations. See Rite Aid of Pennsylvania, Inc. v. Houstoun, 1998 WL 631966 (E.D. Pa. Aug. 31, 1998). The district court exercised jurisdiction under 28 U.S.C. SS 1331, 1343 and we exercise jurisdiction under 28 U.S.C. S 1291. For the reasons that follow, we will reverse the order and judgment and dismiss the cross-appeals.

II. FACTUAL AND PROCEDURAL HISTORY

A. Statutory and Regulatory Background.

Medicaid is a cooperative state-federal program through which the federal government provides funds to the states to assist the poor, elderly, and disabled to receive medical care. 42 U.S.C. S 1396. See Cleary v. Waldman, 1999 WL 53046, at *3 (3d Cir. Feb. 8, 1999). The Medicaid Act requires states to pay for certain services and allows them to provide additional services. 42 U.S.C. S 1396a(a)(10); 42 C.F.R. SS 440.210-440.225. The states, in accordance with federal law, establish eligible beneficiary groups, types and ranges of service, payment levels for services, and administrative and operating procedures and make payment for services directly to the individuals or entities furnishing the services. 42 C.F.R. S 430.0. The Department is the state agency responsible for the administration of Pennsylvania's version of Medicaid.

States that choose to participate in Medicaid must submit a State Plan to the United States Department of Health and Human Services ("HHS") for approval. The State Plan describes the policy and methods used to set payment rates for each type of service included in the program. See, e.g., Wilder v. Virginia Hosp. Ass'n, 496 U.S. 498, 502, 110 S.Ct. 2510, 2511 (1990). The state also must submit any subsequent proposed amendment (State Plan Amendment, or "SPA") to the HHS for approval. The amendment, of course, must meet federal requirements. 42 U.S.C. SS 1396a(b); 42 C.F.R. SS 430.10, 430.12. Pennsylvania law requires that the Pennsylvania Independent Regulatory Review Commission ("IRRC") review and approve the Department's proposed amendments before the Department seeks HHS approval. Pa. Stat. Ann. tit. 71, #8E8E # 745.1 to 745.15 (West 1990).

Pennsylvania has opted to cover prescription drugs and related services in its State Plan. 42 U.S.C. S 1396d(a)(12); 42 C.F.R. S 440.120(a). Federal legislation controls program costs for Medicaid prescription drug benefits by establishing upper limits, or Maximum Allowable Costs ("MACs"), for certain drugs. Certain generic drugs are reimbursed at the Federal Upper Limit ("FUL") as mandated by the Health Care Financing Administration ("HCFA") of the HHS.2 For brand name drugs, states reimburse for the lower of the pharmacy's "usual and customary charges" or the Estimated Acquisition Cost ("EAC"), which is the state's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer. See 42 C.F.R. S 447.301. Prior to the adoption of the revisions at issue here, the Department defined the EAC as the full Average Wholesale Price ("AWP") for the drug as found in the Department's pricing services.

Rite Aid and members of the PPA voluntarily participate as enrolled providers in the Pennsylvania Medical Assistance Program pursuant to provider agreements executed with the Department. See 55 Pa. Code. S 1121. The agreements provide for the Department to reimburse Rite Aid and other pharmacies for prescription drugs and related services in accordance with applicable federal and state laws and regulations. We detail here only those laws and regulations material to this appeal.

Among such federal laws is 42 U.S.C. S 1396a(a)30(A) ("section 30(A)"), which instructs that State Plans must

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least

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2. By federal regulation, reimbursement for those generic drugs specified by HCFA may not exceed the FUL. 42 C.F.R. S 447.332.

> to the extent that such care and services are available to the general population in the geographic area . ..

If a state chooses to amend its State Plan, federal regulations require it to consult with a "medical care advisory committee" ("MAAC"), which will advise the state agency director. See 42 C.F.R. S 431.12(b). The committee must "have an opportunity for participation in policy development and program administration, including furthering participation of recipient members in agency programs." Id. S 431.12(e). As set forth above, the state also must submit an SPA for approval by the HHS through the HCFA. See 42 C.F.R. S 430.12(c)(ii). The HCFA must act on the SPA within 90 days of submission or it is approved automatically. See 42 U.S.C. S 1396n(f)(2); 42 C.F.R. S 430.16. Federal statutes and regulations establish the criteria for the HCFA to make its decision. See 42 C.F.R. S 430.15(a).

Among other regulations affecting state payment rates under section 30(A) is a requirement for public notice for changes in "methods and standards for setting payment rates for services" before the effective date of the change. 42 C.F.R. S 447.205. The regulation requires notice of both the "proposed change" and of the final change within 60 days of its becoming effective, providing a period for public comment and criticism. Id. Pennsylvania regulations require a 60-day public comment period in accordance with 42 C.F.R. S 447.205. See 55 Pa. CodeS 1101.70.3

B. Pennsylvania Pharmacy Reimbursement Regulations.

The Department must create formulae and rates to govern two components of prescription drug and services reimbursement. First, it determines what the pharmacies will receive for the ingredient cost of the drugs; second, it determines a "dispensing fee": a per-prescription payment

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3. The state regulation provides:

> Federal regulations at 42 C.F.R. 447.205 require the Department . . . to give a 60 day public notice of proposed Statewide changes in any method or level of MA [Medical Assistance] reimbursement that would affect program expenditures by 1% or more during the 12 months following the effective date of the change.

which compensates pharmacies for the costs associated with dispensing a prescription to a Medicaid recipient.

Prior to the October 1, 1995 rate revisions, the Department reimbursed pharmacies for the ingredient cost for brand name drugs at the AWP. For generic drugs, the formula follows the state MAC guidelines. (The pre-1995 state MAC guidelines were set at the 70th percentile price of those drugs found in the United States Department of Health Generic Drug Formulary, an instrument which no longer exists.) The dispensing fee was $3.50 per-prescription.

Pennsylvania had good reason to revise these rates. For several years prior to 1994, the HCFA had been advising the Department that its reimbursement rates were high, given, among other reasons, changes in the drug marketplace. See, e.g., letter from HCFA to Secretary of Public Welfare, John F. White, Jr., (Nov. 27, 1990). App. at 1881. The HCFA informed the Department that it would not accept AWP levels for "EAC without a significant discount being applied," unless the Department provided documentation that the actual acquisition cost equaled the full AWP. Id.4 Furthermore, at the end of 1994, a three-year moratorium imposed by federal law which prevented the Department from amending its pharmacy reimbursement formulae was due to expire. See 42 U.S.C.S 1396r-8(e)(1).

Thus, in September 1994, the Department proposed to modify pharmacy reimbursements by requiring pharmacies to charge the Department the lowest rate they charged any other third-party payor, including private insurers. The proposal was forwarded to the pharmacy subcommittee of the MAAC, and sent to the Governor's Budget Office as a plan to save the State approximately $21.4 million for the fiscal year 1995-96 (July 1-June 30). The Governor included the projected savings in the State's budget, although the Department had not yet secured approval for the change from the State or federal bodies responsible for such review.

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4. The HCFA noted that the full AWP overstated the drug prices by as much as 10%-20% in some states, although it did not single out or discuss Pennsylvania in particular. Id.

Not surprisingly, pharmacies were concerned about the impact of the proposed cuts, and voiced many criticisms and suggestions. The MAAC and the pharmacy community stated that it was unreasonable for the Department to compare Medicaid to private, third-party payor plans, because, among other reasons, pharmacies face special costs in participating in the Medicaid program and serving Medicaid recipients. Among other alternatives, the pharmacies asked the Department to study "what it costs to fill a Medicaid prescription in Pennsylvania and allow a reasonable profit." Letter from the PPA to Secretary Feather O. Houstoun (May 12, 1995). App. at 1081.

While considering the proposals discussion participants offered, the Department conducted its own review and evaluation, although it did not study what Medicaid provision of pharmaceutical services cost in Pennsylvania. The Department, however, delayed the anticipated implementation date of January 1, 1995, as it reviewed its alternatives.

After postponing the revision's proposed effective date, the Department chose a new reimbursement structure: the EAC for brand name drugs would be cut to AWP-10%. For generic drugs with an FUL, the maximum acquisition cost was the FUL. For generic drugs for which the HHS has not determined an FUL, the Department adopted limits set by a private pricing service, "BaseLine Prices," to be revised every six months. The dispensing fee was raised from $3.50 per-prescription to $4.00 per-prescription. The Department revised the definition of "usual and customary" to require pharmacies to reduce their usual and customary charge for a given prescription to include any discounts the pharmacy would have given the Medicaid recipient if the recipient had not been covered by Medicaid, i.e., as if they had paid cash or been covered by a third-party payor.

The Department considered such information as state pharmacy licensing laws and OBRA counseling requirements,5 and input from the MAAC and its pharmacy

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5. Specifically, Pa. Stat. Ann. tit. 63, SS 390-1 to 390-9, and 49 Pa. Code
S 27.19 (requiring pharmacists to offer to conduct a "Prospective Drug

subcommittee. It also sought other data, such as the geographical distribution of independent and chain drugstores throughout the state and participation rates of other third-party plans.

The Department primarily relied upon the following data: (1) reimbursement rates provided by 13 third-party payors for brand name drugs in Pennsylvania for approximately 200 private plans operating in the state; (2) reimbursement rates for brand name drugs paid by neighboring states, HCFA Region III states and other states with high Medicaid expenditures;6 and (3) purchase prices of 15 highly-used, randomly selected drugs, reviewed by Joseph Concino ("Concino"), the Department's Medical Assistance Policy Specialist on Pharmacy. Concino showed that the pharmacies could purchase almost every one of the selected drugs at or below the FUL rate. He found that the state's pre-1995 rates were higher than any of the third-party payors' rates, and that the proposed change -- from AWP to AWP-10%, and from a dispensing fee of $3.50 to $4.00-- also would provide higher rates than those of third-party payors.

Among other findings, the Department learned in its review that Pennsylvania was fifth in the nation for Medicaid program expenditures, and that it was the only state surveyed that did not use FULs as the cost limit for generic drugs. It was one of just four states using the full AWP for brand name drugs, had the highest rate of Medicaid payments for Region III states, and the highest Medicaid expenditures of the top ten drug expenditure states.

Review" to ensure that drug will not have adverse result for patient). Further, under federal law, Medicaid State Plans must include a Prospective Drug Review requirement, 42 U.S.C. S 1396r-8(g)(2). OBRA is the Omnibus Budget Reconciliation Act, 42 U.S.C.S 1396r-8(g)(2) (regulating pharmacies).

6. HCFA Region III states include Delaware, the District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. The Department also surveyed California, Florida, Illinois. Louisiana, Michigan, New Jersey, New York, Ohio, and Texas.

On August 8, 1995, the Department submitted the amended regulations to the IRRC, which received comments during its review, and presented the Department with a series of questions, to which the Department replied in writing. The Department published a notice on August 26, 1995, in the Pennsylvania Bulletin, 25 Pa. Bull. 3540 (Aug. 26, 1995) stating that the Department "will amend" the reimbursement rates and provided a synopsis of the changes, and that copies of the notice (that is, the very same notice available at 25 Pa. Bull. 3540) would be available at local agencies throughout the Commonwealth. After an IRRC public meeting with representatives of the Department, the public, and pharmacies present, the regulations were deemed approved by the IRRC on September 8, 1995, to take effect on October 1, 1995. On September 23, 1995, the text of the Department order adopting the regulations was published in the Pennsylvania Bulletin. See 25 Pa. Bull. 3978 (Sept. 23, 1995). In the order the Department stated that:

> The MA (Medical Assistance) program cannot ignore the trends occurring -- in other state Medicaid programs, private third-party plans and reimbursement rates accepted by Pennsylvania pharmacies. As a prudent buyer of medical care for its clients, the Department must obtain similar rates extended to those of other third-party payors and other Medicaid agencies. Therefore, to make the pharmacy payment policies for the MA program comparable with other private and public payment policies, the Department is adopting the following revisions: . . .

On December 29, 1995, the Department sent the SPA to the HCFA for approval. The HCFA approved the revised SPA on May 7, 1995, with changes effective retroactively to October 1, 1995.

C. Procedural History.

Rite Aid filed an action against the Secretary of the Department of Public Welfare on March 27, 1997, approximately 17 months after the revised regulation took effect. Rite Aid alleged that in adopting the revisions the Department had violated various provisions of Title XIX of

the Social Security Act and related regulations and state statutes, as well as the due process clause of the Fourteenth Amendment. The parties filed cross-motions for judgment on the pleadings, and on November 3, 1997, the district court granted judgment in favor of the Department on Rite Aid's claim that the Department violated 42 C.F.R. S 447.205 by not publishing notice of the proposed change and by not providing a public comment period. 42 C.F.R. S 447.205(a) and (d)(1). In addition, the court granted the Department judgment on Rite Aid's due process claim.

The court, however, ruled in favor of Rite Aid on its claim that section 30(A) contains a discrete "procedural" component and thus it denied the Department's motion for a judgment on the pleadings on that issue. It also upheld Rite Aid's claim that the Department violated 42 C.F.R. S 447.205(c)(4) by failing to identify a local agency where the proposed reimbursement changes were available for public review. Thus, it granted Rite Aid a judgment on the pleadings on that issue. Rite Aid of Pennsylvania, Inc. v. Houstoun, 998 F. Supp. 522 (E.D. Pa. 1997).

On January 12, 1998, the PPA moved to intervene as a plaintiff; and the district court granted the motion on February 20, 1998. On May 8, 1998, the court, on Rite Aid's and the PPA's motion to define the scope of review and limit discovery, issued an opinion and order limiting its review of the Department's compliance with section 30(A) to the administrative record. Rite Aid of Pennsylvania v. Houstoun, 1998 WL 254082 (E.D. Pa. May 8, 1998).

On August 31, 1998, the court granted Rite Aid's and the PPA's motion for summary judgment and denied the Department's motion for summary judgment. It found that the Department had violated section 30(A) because it acted arbitrarily and capriciously procedurally in adopting the revisions. Accordingly, it enjoined the Department from reimbursing pharmacies for drugs supplied to Medicaid recipients on or after October 1, 1998, in accordance with the rates in dispute. See Rite Aid of Pennsylvania, Inc. v. Houstoun, 1998 WL 631966 (E.D. Pa. Aug. 31, 1998). Moreover, it found that the Department did not comply with its obligations under 42 C.F.R. S 431.12 to meet with the MAAC to discuss the regulations. The court, however, did

not void the regulations on that ground. At the same time, the court rejected Rite Aid's and the PPA's claim that section 30(A) required the Department to conduct a study of actual pharmacy costs before revising the payment schedule.

The Department filed a notice of appeal on September 8, 1998, amended on September 28, 1998; Rite Aid and the PPA filed cross-appeals on September 29, 1998, challenging the district court's holding that section 30(A) did not require the Department to conduct a study of actual pharmacy costs, as well as its holding that the Department had not violated 42 C.F.R. S 447.205(a) by not publishing prior notice of the proposed changes. The district court and this court denied the Department's motions to stay the injunction by orders entered September 18, 1998, and October 26, 1998, respectively. Thus, the revisions have not been in effect and the Department has been using the prior rates.

III. DISCUSSION

We emphasize that Rite Aid and the PPA on this appeal have not challenged the substantive impact or results of the revised rates as failing to comply with section 30(A). See Minnesota Homecare Ass'n Inc. v. Gomez, 108 F.3d 917, 918 (8th Cir. 1997) (concurring opinion). Rather, they challenge the way in which the Department set and promulgated the new rates. In particular, they argue that the Department (1) failed to comply with section 30(A) because section 30(A) mandates that a certain kind of process be followed in revising the pharmacy reimbursement rates, and (2) acted arbitrarily and capriciously in so doing. The district court accepted these contentions and thus in this opinion we largely focus on these points.7 The parties agree that we exercise plenary

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7. The Department argues at least in part that Rite Aid and the PPA may not sue to enforce the Medicaid regulations as section 30(A) "does not support a private cause of action." Brief at 27. The district court rejected
this argument and we agree with this result. Rite Aid, 998 F. Supp. at 525-26. In the district court Rite Aid argued that "substantively" the SPA

review over the district court's decision. See Olson v. General Elec. Astrospace, 101 F.3d 947, 951 (3d Cir. 1996). In this regard, we point out that the district court predicated its result, including issuing the injunction, on its construction of section 30(A) and its relatedfinding that the Department acted arbitrarily and capriciously in adopting the revisions, rather than on other equitable considerations. See AMP Inc. v. AlliedSignal Corp., 1999 WL 86843 at *3 (3d Cir. Feb. 18, 1999). Thus, this appeal does not require us to review an exercise of discretion.

A. The District Court Properly Confined its Review to the Administrative Record.

Initially, we agree with the district court's determination in its May 8, 1998 order to base its decision on the existing administrative record. While we are not aware of any court that has held specifically that in reviewing section 30(A) issues a court must confine itself to the agency's administrative record, in general judicial review should be on "the administrative record already in existence, not some new record made initially in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142, 93 S.Ct. 1241, 1244 (1973); C.K. v. New Jersey Dep't of Health and Human Servs., 92 F.3d 171, 182 (3d Cir. 1996).8 Thus, the district court properly ruled that it would not create a new record nor base its review on any "post-hoc rationalizations" made by the Department after it had taken the disputed action. Rite Aid, 1998 WL 254082 at *1 (citing Citizens to Preserve Overton

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was invalid because "the revised reimbursement rates are too low to satisfy the statutory requirements." Id. At 528. The court, however, declined to rule on this contention because it held that a determination of "[w]hether the rates are consistent with efficiency, economy, and quality of care requires further development of the record." Id. In the circumstances, our opinion does not preclude Rite Aid and the PPA from making a "substantive" challenge to the revisions.

8. Because the Department participated in an IRRC hearing on September 7, 1995, and because regulations were notfinal until they were deemed approved on September 8, 1995, the court considered the administrative record to include documents before the Secretary through that date, a decision not challenged on appeal.

Park, Inc. v. Volpe, 401 U.S. 402, 419, 91 S.Ct. 814, 825 (1971)).

B. The District Court Erred in Holding that 30 (A) Imposes a "Procedural" Requirement.

The district court held that section 30(A) imposes a "procedural" requirement on state agencies. We disagree with the district court on this point, as we conclude that section 30(A) mandates only substantive compliance with its specified factors of efficiency, economy, quality of care, and access.

To date, three courts of appeals have addressed the question of whether section 30(A) has a procedural requirement. The Courts of Appeals for the Eighth and Ninth Circuits have ruled that section 30(A) requires that the state agency make some investigation or conduct a study. See Arkansas Med. Soc'y, Inc. v. Reynolds, 6 F.3d 519, 530 (8th Cir. 1993) (Agency "must consider the relevant factors of equal access, efficiency, economy, and quality of care as designated in [section 30(A)] when setting reimbursement rates."); Minnesota HomeCare Ass'n, Inc., 108 F.3d at 918; Orthopaedic Hosp. v. Belshe, 103 F.3d 1491 (9th Cir. 1997), cert. denied, 118 S.Ct. 684 (1998). The Court of Appeals for the Seventh Circuit has held, however, that there is no such requirement, but rather that section 30(A) requires simply that whatever change is adopted produce the substantive results demanded by the statute. See Methodist Hosps, Inc. v. Sullivan, 91 F.3d 1026, 1030 (7th Cir. 1996).

We agree with the Court of Appeals for the Seventh Circuit that section 30(A) requires the state to achieve a certain result but does not impose any particular method or process for getting to that result. Id. Thus, section 30(A) does not require any "particular methodology" for satisfying its substantive requirements as to modifications of state plans.9 However, we will not go as far as did that court as

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9. The district court believed that its holding was not contrary to that of the Court of Appeals for the Seventh Circuit's result in Methodist Hosp., but its logic seems strained. Rite Aid, 998 F. Supp. at 527. On the one hand, the district court observed that the court of appeals held that

to say that the Department literally may act like any other buyer of health care by offering a certain price, and seeing what response or result that price brings forth; that is, that the "states may behave like other buyers of goods and services in the market: they may say what they are willing to pay and see whether this brings forth an adequate supply." Id. We decline to adopt that approach because ordinarily, at least, a state may not act arbitrarily and capriciously, although other actors in the market may do so if they so choose. While section 30(A) does not govern the process by which it sets its prices, as we explain below other doctrines do control that process and protect the public from the possible ill effects of an agency testing out new formulae or prices at random, then correcting the results once a violation has occurred.

The courts of appeals' split thus arises from the question whether section 30(A) demands a process which will ensure future results, or merely the result itself. In reaching our result we will not read procedural criteria into section 30(A). That section requires that the state "assure" certain outcomes, including efficiency, economy, etc., but it does not call explicitly for any particular findings. Thus, it is up to a state to determine how it will "assure" the outcomes. We reiterate that section 30(A) does not specify a particular process for a state agency to follow in establishing rates.10

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section 30(A) does not require "comprehensive studies" such "that would put an environmental impact study to shame." Id. (citing Methodist Hosp., 91 F.3d at 1029). But the district court asserted that "by this language, Methodist does not conclude that 30(A) eliminates any mandate for evaluation of the statutory factors before revising the rates."
Id. (citing Methodist Hosp., 91 F.3d at 1030). In fact, Methodist Hosp. does eliminate any such mandate: that is why its holding differs from those of the Courts of Appeals for the Eighth and Ninth Circuits on this point.

10. "Assure" is defined by Black's Law Dictionary as "[t]o make certain and put beyond doubt. To . . . ensure positively." Black's Law Dictionary 123 (6th ed. 1990). Webster's Third New International Dictionary defines "assure" similarly as "to make certain the coming or attainment of: ensure," in its sixth definition for the term. Webster's Third New International Dictionary 133 (1986).

What the section does require is that the agency achieve proper results in revising its State Plan.

The district court analogized section 30(A) to the Boren Amendment, which dealt with reimbursement rates for institutional providers under Medicaid, but now has been repealed. See 42 U.S.C. S 1396a(a)(13)(A); Rite Aid, 1998 WL 631996, at *4. The Boren Amendment instructed state agencies to make findings and assurances that their Medicaid reimbursement rates promote economy, efficiency, quality of care, and equal access, 42 U.S.C. S 1396a(a)(13)(A),11 and thus, to that extent, it was undeniably similar to section 30(A). See Arkansas Med. Soc'y, 6 F.3d 519, 524 (noting similarity of function and language). But in contrast to section 30(A), the Boren Amendment directed the states as to the procedure they must follow in formulating a reimbursement rate, specifically requiring that states take into account certain findings. New Jersey Hosp. Ass'n v. Waldman, 73 F.3d 509, 513 (3d Cir. 1995). Federal regulations implementing the Boren Amendment outline the specific "findings" a state agency must make whenever it made "a change in its methods and standards." 42 C.F.R. S 447.253(b).12 The

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11. The Boren Amendment required the Department to set inpatient reimbursement rates that "the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services . .. and to assure that individuals eligible for medical assistance have reasonable access . . . to inpatient hospital services of adequate quality; and such State makes further assurances, satisfactory to the Secretary, for the filing of uniform cost reports by each hospital . . . and periodic audits by the State of such reports." 42 U.S.C. S 1396a(a)(13)(A).

12. The implementing regulations specify that the following findings be made:

(b) Findings. Whenever the Medicaid agency makes a change in its methods and standards, but not less often then annually, the agency must make the following findings:

(1) Payment rates. (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by

district court noted that section 30(A), unlike the Boren Amendment, "does not require the State to utilize any prescribed method of analyzing and considering said factors [of economy, efficiency, quality of care and access]," and that section 30(A) does not require the agency to study any "specific" item "such as actual pharmacy costs." Rite Aid, 1998 WL 631966, at *4 (internal quotation marks omitted). We will not read back from section 30(A) to say that the section implicitly requires that a state follow a specific procedure or demonstrate that it has reviewed each factor. Thus, the situation under the Boren Amendment is distinguishable from that here.

Rite Aid and the PPA contend in their cross-appeals that without knowing pharmacies' costs, the Department could not know what price would lead to adequate, quality service. See Orthopaedic Hosp., 103 F.3d at 1500 (agency must study actual provider costs in revising Medicaid payments). Preliminarily, on this issue we point out that Rite Aid and PPA are not by their cross-appeals seeking additional relief. See United States v. Tabor Court Realty Corp., 943 F.2d 335, 342-45 (3d Cir. 1991). Rather, they advance the issue as an alternative ground to affirm the summary judgment and injunction. University of Md. v. Peat Marwick Main & Co., 923 F.2d 265, 275 (3d Cir. 1991). Thus, we will dismiss the cross-appeals.

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efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services--

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs;[and]

. . . .

(C) The payment rates are adequate to assure that recipients have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

42 C.F.R. S 447.253(b).

Addressing the point raised in the cross-appeals on the merits, we think it consistent with our reading of section 30(A) that a finding of the pharmacies' costs is not mandated: within the agency's discretion, pharmacies' costs may be considered or not, so long as its process of decision-making is reasonable and sound. Moreover, there was evidence that the Department is familiar with providers' costs through setting the EAC and the dispensing fee, although it did not conduct a special study in this case. Thus, we approve the district court's holding that the Department was not required to conduct a study of actual pharmacy costs before revising the payment schedule. Rite Aid, 998 F. Supp. at 527.

C. The District Court Erred in Holding that th e Department was Arbitrary and Capricious.

As we have indicated, the district court, in addition to concluding that section 30(A) has a procedural component, found that the Department's action in adopting the revisions was procedurally arbitrary and capricious. Thus, we must make our own determination whether the action was arbitrary, capricious, or an abuse of discretion, or otherwise was not in accordance with law, or if the action failed to meet statutory, procedural or constitutional requirements. See, e.g., Davis Enterprises v. United States Envtl. Protection Agency, 877 F.2d 1181, 1184 (3d Cir. 1989). We may find that an action is arbitrary and capricious if the agency relied on factors other than those intended by Congress, did not consider "an important aspect" of the issue confronting the agency, provided an explanation for its decision which "runs counter to the evidence before the agency," or is entirely implausible. See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 103 S.Ct. 2856, 2867 (1983). Our standard of review is narrow. Id. at 43-44, 103 S.Ct. at 2867. We must "uphold [an agency's] decision of less than ideal clarity if the agency's path may reasonably be discerned." Id. at 43, 103 S.Ct. at 2867 (internal citations omitted). Of course, if a reasonable person could rely on the agency's studies to reach its conclusions, the conclusions are not arbitrary.

The district court found the review arbitrary and capricious at least in part because it already had decided, incorrectly in our view, that section 30(A) imposed duties on the Department to consider how its rates affected the section 30(A) factors. Thus, the Department, for example, could not rely on some independent guarantee of compliance. Rite Aid, 1998 WL 631966, at *5. The district court held that while the Department had discretion in how to conduct its review, it was obligated to consider all of the section 30(A) factors. Id. at *4.

We are aware that Motor Vehicle Mfrs. requires us to examine whether the agency has "entirely failed to consider an important aspect of the problem," and that each of the section 30(A) factors may be considered to be relevant issues. Motor Vehicle Mfrs., 463 U.S. at 43, 103 S.Ct. at 2867. Moreover, we believe that the Department might have done a better job in its review by considering systematically and thoroughly all the implications of its rate revisions, and, as we discuss below, in communicating its thought processes and decision to the public and to participants in the review.

The Department gave some of the section 30(A) factors more attention than others. In particular, it paid greater consideration to economy and efficiency than to provision of quality of care and access to care providers comparable to that enjoyed by the general population. Cuts in Medicaid funding have enormous implications for the well being of some of Pennsylvania's most vulnerable people, and the pharmacy community is correct in pointing out that profit margins are already small for many of its members. Nevertheless, given our deferential and narrow standard of review, we find that the Department did not arbitrarily and capriciously decide to use AWP-10%, FULs and BaseLine Prices for ingredient costs and to raise the dispensing fee by $0.50.

The district court relied upon three aspects of the Department's review of data in holding that the Department's review was arbitrary and capricious with respect to the section 30(A) factors of efficiency, economy, and quality of care. Rite Aid, 1998 WL 631966, at *4-*8. Concluding that it was arbitrary and capricious with regard

to those factors, it did not reach the comparable access factor, id. at *10, although the parties have briefed it extensively.13 First, the court noted a statement made in January 1995 by then-Secretary of Public Welfare, Karen Snider, who wrote to a state senator and referred to discounted AWP rates used by other third-party payors as "prearranged and arbitrary." Id. at *5. Because the Department used such "prearranged and arbitrary" rates as a basis for deciding to lower its rates to Medicaid providers, the district court concluded that its decision was arbitrary, reasoning that the fact that pharmacies had accepted those rates did not mean that the Department could conclude that the rates satisfied the section 30(A) factors of efficiency and economy. Id. The Department points out, however, that the Secretary's reference was to industry-wide practices, and occurred in the context of noting that Medicaid payments exceeded those of other prescription plans. Brief at 35-36.

Second, the district court asserted that the Department's comparisons with other states' reimbursement rates was unacceptable because, as the HCFA itself had cautioned in a statement to the Department, what is reasonable in one state may not be reasonable for Pennsylvania's needs. Rite Aid, 1998 WL 631966, at *5. The Department relied on the HCFA's approval of rates paid in other states as evidence that those rates conformed with the section 30(A) requirements. The district court recognized that Pennsylvania could review other states' payments as a basis for determining its own payments, yet held that it could not conclude that its payments for brand name drugs would be "economical and efficient because of data from other states." Rite Aid, 1998 WL 631966, at *5.

Last, the court singled out Concino's cost studies on select generic and brand name drugs. Under the revised regulations, reimbursement for generic drugs is predicated

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13. The district court did not reach the access issue, concluding that such review was unnecessary, but it appears that the Department viewed access largely in terms of whether there would be an adequate number of pharmacies serving Medicaid clients, not whether Medicaid clients had the same or better access than the general population.

either on the FUL or on the private services's guidelines. Id. at * 6. The district court stated that adoption of the FULs for generic drugs in itself does not ensure efficiency and economy, and that the Department would "have to evaluate the rates for the remaining generic drugs [not covered by a FUL] as well as all of the brand name drugs." Id. The district court referred to several criticisms of Concino's price surveys, and Rite Aid and the PPA expand on them in their briefs. Among other issues, Rite Aid and the PPA complain that the drug sample of eight brand name and 15 generic drugs was too small, these neither were selected randomly nor representative, the pricing data did not come from the pharmacies, and Medicaid payment involves variables not at issue with reimbursement by private plans. See Brief at 27-29.

While Rite Aid and the PPA contend that a better survey and analysis of the drug market and the State's place in it could have been done, those deficiencies do not make the overall process arbitrary and capricious. See Methodist Hosp., 91 F.3d at 1029-30. (difficulties of gathering data for and creating comprehensive study of major segment of market). The district court's criticism of the price survey led to its conclusion that the Department behaved arbitrarily and capriciously in part because the court already had concluded that "the Department may not rely on its third-party payor survey or its evaluation of other states' rates." Rite Aid, 1998 WL 631966, at *7. We find, however, that the Department's study, which included data about other states and payors, supported its revision. While we doubt that a rational person would rely on the Concino study alone to reach the Department's decision, the Department has shown that by considering the study and other sources of information, it made a reasonable effort to anticipate the effects of its action.

The district court held that it was unreasonable for the Department to rely upon laws or regulations which independently ensure quality care, finding that the Department under section 30(A) had an obligation to consider the impact of rate changes on quality of care. Rite Aid, 1998 WL 631966, at * 8. But we find that it was reasonable for the Department to consider the statutory

guarantees of quality of care and the necessity for the IRRC to approve the changes as being in the public interest, as valid evidence suggesting that pharmacies operating under the rate revisions would have to provide quality care. Cf. Orthopaedic Hosp. v. Belshe, 103 F.3d at 1497 (requiring agency to satisfy for itself maintenance of quality of care).

The Department's finding that at least 40 states discounted AWP by, on average, 10%, and that the eight large, non-government plans studied discounted AWP by at least 10% and, in some cases, discounted AWP by even a higher percentage, supported its determination that AWP-10% would allow pharmacies to maintain provision of care and earn a profit. Furthermore, the plans paid lower dispensing fees than the $3.50 previously offered by the Department. Thus, the Department was aware that with the revised rates, Pennsylvania's program would pay more than most states and more than those of other major Pennsylvania payors.

Regarding the dispensing fee, the question is whether the Department was irrational in raising its fee by less than what the pharmacies sought, or whether it should have researched this change more thoroughly before the revision's promulgation. We find that the Department took into account and considered various suggestions as to what the fee ought be, and that it selected the increase considering that it would keep Pennsylvania's payments higher than those of other third-party payors. Although budgetary considerations may not be the sole basis for a rate revision, they may be considered given that section 30(A) mandates an economical result. See, e.g., Arkansas Med. Soc'y, 6 F.3d at 530.

D. The District Court Did Not Err in Holding that the Department Failed to Consult with the MAAC.

The Department had a duty under 42 C.F.R. S 431.12 to consult with the Pennsylvania MAAC during its review process. 42 C.F.R. S 431.12(e) (State MAAC "must have opportunity for participation in policy development and program administration."). The district court concluded that the Department did not fulfill that duty, but did not determine whether that failure alone would support the

issuance of an injunction, as it determined to enjoin the application of the revision because it perceived that the Department failed to comply with section 30(A) and acted arbitrarily and capriciously. Rite Aid, 1998 WL 631966, at *10. We agree that the Department did not comply with its duty to consult adequately with the MAAC, but find that the violation cannot support the injunction.14

The Department met with the MAAC on October 25, 1994, but the revisions subsequently adopted in 1995 differed from those presented at that meeting. The MAAC did not meet again until September 28, 1995, after the revisions' promulgation, and the MAAC pharmacy subcommittee did not meet again until December 1995. The Department's discussions with individual members of the subcommittee during that time did not satisfy its duty to consult with the MAAC during the review. Indeed, Richard Lee, Acting Deputy of the Department, conceded in July 1995, just before the Secretary sent the revised rates to the IRRC for review, that "the process [of consultation with the MAAC] got out of channel during the discussion, and the regulations were not discussed directly with the Pharmacy Subcommittee." Minutes of the MAAC Meeting, July 27, 1995. We recognize that 42 C.F.R. S 431.12(e) requires "participation" and not "approval," but the October 1994 consultation involved the earlier version of rates, which had been modified significantly by September 1995.

The Court of Appeals for the First Circuit has noted that case law under 42 C.F.R. S 431.12(e) "suggests that States should undertake their MAAC consultations as early in the Plan amendment process as practicable, preferably before any final decision on proposed changes to their reimbursement methodologies," though "the HCFA regulations prescribe no time bar for the recommended MAAC consultation," and that it is reasonable to think that "MAAC consultation is sufficient as along as it occurs

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14. Rite Aid and the PPA raise this issue on their cross-appeals. As we have explained, they should have advanced the issue as an alternative basis to affirm. The Department contends that 42 C.F.R. S 431.12 is not privately enforceable but we agree with the district court that it is. Rite
Aid, 998 F. Supp. at 525-26.

before final HCFA approval of the Plan amendment." Visiting Nurse Ass'n of North Shore, Inc. v. Bullen, 93 F.3d 997, 1010 n.14 (1st Cir. 1996). Here, while there was early consultation, there was no further consultation prior to final approval. Furthermore, the Department itself recognized that the review process had bypassed consultation with the MAAC.

However, this violation cannot supply a basis to sustain the injunction. In Burgess v. Affleck, 683 F.2d 596, 599-600 (1st Cir. 1982), the Court of Appeals for the First Circuit found a case of "borderline" compliance with the MAAC regulation, but held that as the MAAC's involvement was advisory and it had no veto power, an injunction was not an appropriate remedy. Therefore, it reversed the district court's grant of an injunction entered on that basis, finding that relief at best would involve requiring consultation with the MAAC before implementation of revisions. Here, too, we think the violation is"not egregious," id., and that it would not be appropriate to sustain the district court's injunction on the basis of the 42 C.F.R. S 431.12 violation.

E. The District Court Erred in Holding that the Department Violated 42 C.F.R. S 447.205 (c).

The district court held that the Department violated 42 C.F.R. S 447.205(c) by failing to "[i]dentify a local agency in each county . . . where copies of the proposed changes are available for public review." Rite Aid, 998 F. Supp. at 530. The first question on this point is whether the Department's August 25, 1995 notice constitutes published notice of a "proposed" change. See 25 Pa. Bull. 3540 (Aug. 26, 1995). The August 25, 1995 notice stated that the Department "will amend" the reimbursement rates, and gave a synopsis of the changes. Id. In order to determine whether the Department thus had announced a proposed change, the court framed the question as whether on that date the rates were final or not, as the Department's own public comment period had ended by August 25, 1995. Moreover, the rates already had been submitted to the IRRC for approval, though they were not yet approved. The court properly concluded that, as the IRRC had its own public comment period, and the rate change was subject to ultimate

approval by the IRRC, the notice was not final, although the agency had determined what it wished the rates to be. Rite Aid, 998 F. Supp. at 528-29. Because the notice preceded the effective date, we agree that the changes were "proposed" and public comment would not have been futile.

The second question is whether the content of the August 25, 1995 notice of proposed changes was sufficient. The district court simply concluded that "[n]otifying readers about another location where they can read the same notice is not sufficient." Id. at 530. Wefind that the availability of the same notice itself in local agencies satisfied the regulation, as it contained sufficient information and detail for public consideration. Burgess, 683 F.2d at 602. Clearly, though, the Department did the bare minimum to meet its duty in this regard.

Finally, Rite Aid and the PPA argue that the Department failed to provide 60 days of public comment on the "proposed" rates before changing the rates, as required by 55 Pa. Code S 1101.70. Federal law no longer requires a 60-day period between proposal notice and the effective date of the rate change. See 46 Fed. Reg. 58677 (Dec. 3, 1981). The district court properly rejected the contention that it should incorporate Pennsylvania's law into the federal public notice requirement, because the state agency had not expressed its clear intent to do so. Rite Aid, 998 F. Supp. at 529-30. See Mississippi Band of Choctaw Indians v. Holyfield, 490 U.S. 30, 43, 109 S.Ct. 1597, 1605 (1989).

IV. CONCLUSION

Because we hold that section 30(A) does not include procedural requirements, and because the Department's 11-month period of data gathering, consultation, and review before promulgating the changes was not so deficient as to be arbitrary and capricious, we will reverse the district court's grant of partial summary judgment to Rite Aid, and vacate the injunction. The deficiencies we have identified in the Department's procedures do not justify a different result. We will dismiss Rite Aid's and the PPA's cross-appeals because they are unwarranted procedurally and in any event are without merit. We will

remand the case to the district court for further proceedings consistent with this opinion.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit