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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Sharon Newton-Nations, et al., Plaintiffs, vs. Anthony Rodgers, et al., Defendants.	No. CV 03-2506-PHX-EHC **ORDER**

On December 19, 2003, Plaintiffs filed a Complaint against Defendants Anthony Rodgers, Director of the Arizona Health Care Cost Containment System ("AHCCCS"), and Tommy Thompson, Secretary of the United States Department of Health and Human Services ("DHHS" or "HHS"),[1] in their official capacities, alleging that the Defendant Secretary's actions authorizing Arizona to implement increased copayments relevant to medical coverage received through AHCCCS were unlawful. Plaintiffs allege that Defendants' actions: (1) exceeded the limited authority under 42 U.S.C. §§ 1315 and 1396o; (2) failed to comport to the human protections required by 42 U.S.C. § 3515b; and (3) were done in an arbitrary and capricious manner (Dkt. 1). The Complaint further alleges that Defendant Rodgers'

[1]Tommy Thompson was the Secretary of the Department of Health and Human Services ("HHS") at the time this case was filed. In January 2005, Michael O. Leavitt was confirmed as the Secretary of HHS. In April 2009, Kathleen Sebelius became Secretary of HHS. Thomas J. Betlach succeeded Anthony Rodgers as the Director of the Arizona Health Care Cost Containment System ("AHCCCS") in November 2009 (Dkt. 182).

imposition of the increased copayments in Arizona Administrative Code (A.A.C.) Rule R9-22-711(D) and (E) is contrary to 42 U.S.C. § 1396o, and is preempted by the Supremacy Clause of the United States Constitution; is in violation of the Due Process Clause of the Fourteenth Amendment; and is contrary to 42 U.S.C. § 1396a(a)(3). Plaintiffs seek declaratory and injunctive relief.

The Defendant Secretary of HHS is responsible for administering the federal Medicaid program (Dkt. 1 - Complaint, ¶ 20). Plaintiffs' First and Second Claims for Relief seek review of the Defendant Secretary's actions under the Administrative Procedures Act (Dkt. 1 - Complaint, pp. 25-26). State Defendant Director is responsible for administering the Medicaid program in Arizona (Dkt. 1 - Complaint, ¶ 21). Plaintiffs' Third and Fourth Claims for Relief allege a constitutional violation and violation of the Social Security Act-Medicaid against the State Defendant (Dkt. 1 - Complaint, pp. 26-27).

On March 17, 2004, the Court granted Plaintiffs' Motion for Class Certification (Dkt. 42 - Order). The class members are defined as "all Arizona Health Care Cost Containment System eligible persons in Arizona who have been or will be charged copayments pursuant to Arizona Administrative Code Amended Rule R9-22-711(E)" (Dkt. 42 - Order at pp.5-6).

On April 21, 2004, the Court granted Plaintiffs' Motion for a Preliminary Injunction (Dkt. 53 - Order [Newton-Nations et al. v. Rogers, et al., 316 F. Supp. 2d 883 (D. Ariz. 2004)]). Defendant Rodgers was enjoined pending further Order of Court from (1) imposing the mandatory copayments on prescription medications, doctors' visits and the use of the emergency room as set forth in A.A.C. Amended Rule R9-22-711(E), and (2) allowing providers to deny medical services because of a participant's inability to pay the required copayments set forth in A.A.C. Amended Rule R9-22-711(E). Defendant Rodgers was ordered within a specified time period to issue a letter to all AHCCCS providers, including pharmacies, physicians and hospitals, notifying them of the preliminary injunction and its directives.

Defendant Secretary and Plaintiffs thereafter filed Cross Motions for Summary Judgment (Dkt. 60 & 86). Defendant Rodgers filed a Response in Opposition to Plaintiffs' Motion for Summary Judgment (Dkt. 96).

On March 10, 2005, the Court granted the motion filed by Defendant Secretary of HHS to stay ruling on the cross motions for summary judgment pending resolution of Spry v. Thompson, Civil Action No. 03-121-ST (D. Or.), by the Court of Appeals for the Ninth Circuit, or until further Order of the Court (Dkt. 112).

The Ninth Circuit filed its decision in Spry v. Thompson, 487 F.3d 1272 (9th Cir. 2007) on May 21, 2007. On December 18, 2007, the stay of proceedings was lifted and the parties were allowed to re-file their motions for summary judgment (Dkt. 127).

This case is now before the Court on the parties' Cross Motions for Summary Judgment (Dkt. 135, 147 & 145)[2] as re-filed after the Spry decision. Plaintiffs and Defendant Secretary of HHS have supported their motions with their previous statements of facts and declarations filed in 2004, and as supplemented (Dkt. 135 at p. 2; Dkt. 148 at p. 3, n.1).

The Administrative Record was filed on May 21, 2004 (Dkt. 63). A Supplemental Administrative Record and Documents Inadvertently Omitted from the Supplemental Administrative Record were filed on April 22, 2008 (Dkt. 150-153).

The Court heard oral argument on July 21, 2009. The Court ordered the parties to file proposed findings of fact, conclusions of law, and objections which have now been filed (Dkt. 163, 168-170, 174-176) and which have been considered as the parties' supplemental briefing.

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[2]State Defendant Rodgers also has joined in Defendant HHS Secretary's Response and Cross Motion for Summary Judgment, Memorandum and Statement of Facts (Dkt. 145; Dkt. 146, p. 4, ¶ 1).

I.

Background Facts

Arizona participates in Medicaid through the Arizona Health Care Cost Containment System ("AHCCCS"), A.R.S. §§ 36-2901-2972 (Dkt. 88 - Plaintiffs' Statement of Facts [PSOF] ¶ 1). The AHCCCS was initiated in 1982 after the DHHS granted Arizona an "experimental, pilot, or demonstration project" waiver, pursuant to 42 U.S.C. § 1315(a) (section 1115 of the Social Security Act ["SSA"]) (Dkt. 88 - PSOF ¶ 1; Dkt. 61 - Defendant Secretary's Statement of Facts [SSOF] ¶¶ 1-2).

Plaintiffs contend that all of the AHCCCS program is a demonstration waiver project under 42 U.S.C. § 1315(a) (Dkt. 88 - PSOF ¶ 2). Defendants claim that much of Arizona's Medicaid program, though not all of it, operates as a § 1315 demonstration project that has been approved by the Secretary of HHS (Dkt. 61 - SSOF ¶ 3).

Arizona's Medicaid State Plan was approved by HHS in June 1982 and remains in effect as amended (Dkt. 61 - SSOF ¶ 3; Dkt. 88 - PSOF ¶ 1; Dkt. 101- Defendant Secretary's Response to PSOF ¶ 2). Arizona has never submitted, and the HHS Secretary has never approved, coverage for a "medically needy" population (as described in 42 C.F.R. 435 Subpart D) (Dkt. 146 - Defendant Director's Statement of Facts [DSOF] p. 2, ¶ 3; see Dkt. 100 - Exhibit 1). Plaintiffs do not receive health care services pursuant to Arizona's Medicaid State Plan (Dkt. 61 - SSOF ¶¶ 5-7). According to Defendants, Plaintiffs have been and currently are part of an "expansion population" under Arizona's demonstration project (Dkt. 61 - SSOF ¶ 8).

The citizens of Arizona passed Proposition 204 in November 2000. Plaintiffs claim that AHCCCS was expanded to cover all persons who have incomes up to 100 percent of the federal poverty level. A.R.S. § 36-2901.01. (Dkt. 88 - PSOF ¶ 3).

Following the passage of Proposition 204, Arizona received permission in early 2001 from the Centers for Medicare and Medicaid ("CMS"), an agency within the DHHS, to amend its § 1315 demonstration project to include certain non-Medicaid eligible individuals with

incomes up to 100% of the federal poverty level (Dkt. 61 - SSOF ¶¶ 1, 9 [citing Dkt. 63 - Administrative Record ("AR") 0086-0103]; Dkt. 146 - DSOF p.4, ¶¶ 2, 3 [citing A.R.S. § 36-2901.01.A]). The CMS January 18, 2001 approval letter granted Arizona "expenditure authority" under 42 U.S.C. § 1315(a)(2) (Dkt. 61 - SSOF ¶ 9 [AR 0086]; Dkt. 146 - DSOF p.4, ¶ 4). The CMS also permitted Arizona to provide expanded coverage to non-Medicaid eligible persons who incur medical expenses such that their income is reduced to 40% of the federal poverty level (Dkt. 61 - SSOF ¶ 10 [AR 0086-0103]). The parties agree that these individuals are part of Arizona's Medical Expense Deduction ("MED") program. A.R.S. §§ 36-2901(6)(v) & 36-2901.04 (Dkt. 88 - PSOF ¶ 4; Dkt. 61 - SSOF ¶ 10). The CMS granted Arizona "expenditure authority" under 42 U.S.C. § 1315(a)(2) to provide this coverage (Dkt. 61 - SSOF ¶ 10 [AR 0086]).

Plaintiffs claim these individuals are sometimes referred to as "medically needy" because the expenses they have incurred for health care have left them unable to afford to pay for additional care and services (Dkt. 88 - PSOF ¶ 4). According to Plaintiffs, AHCCCS employees have conceded that some of the Plaintiff class members are "medically needy" under 42 U.S.C. § 1396a(a)(10)(C) (Dkt. 88 - PSOF ¶ 5). Defendant Director has denied that he or AHCCCS employees have admitted that these persons or members of the Plaintiff class are "medically needy" as defined by the Medicaid statutes (Dkt. 146 - DSOF p.2, ¶¶ 2-3).

The CMS included a "cumulative list of waivers and expenditure authorities for the overall AHCCCS program" in its January 18, 2001 approval letter (Dkt. 61 - SSOF ¶ 11 [AR 0087]). All other Medicaid requirements continued to apply to the Arizona program (Dkt. 61 - SSOF ¶ 11 [AR 0096]).

Plaintiffs characterize the CMS approval as granting Arizona permission to amend its demonstration waiver to include the described individuals (Dkt. 88 - PSOF ¶ 6).

In September 2001, Arizona sought to amend its existing Medicaid demonstration project by applying for approval to conduct a demonstration under the HHS Health Insurance Flexibility and Accountability ("HIFA") demonstration initiative (Dkt. 61 - SSOF ¶ 12 [AR

0064]). The goal of the HIFA demonstration initiative was "to encourage new comprehensive state approaches that will increase the number of individuals with health insurance coverage within current-level Medicaid and [State Children's Health Insurance program] resources" (Dkt. 61 - SSOF ¶ 13).

HHS approved Arizona's HIFA application on December 12, 2001 (Dkt. 61 - SSOF ¶ 14 [AR 0064]). The CMS granted Arizona "expenditure authority" under 42 U.S.C. § 1315(a)(2) in order to:

> (1) provide Medicaid coverage to individuals over age 18 with adjusted net countable family income at or below 100 percent of the [federal poverty level], who are single adults and childless couples and who are not otherwise eligible for such coverage, except through the demonstration project amendment approved January 18, 2001; and
>
> (2) provide demonstration coverage consistent with the requirements of section 2103 to individuals whose adjusted net countable family income exceeds 100 percent of the [federal poverty level], but does not exceed 200 percent of the [federal poverty level], who are parents of children enrolled in the Arizona Medicaid or title XIX programs and who are not otherwise eligible for Medicaid or Title XIX coverage.

(Dkt. 61 - SSOF ¶ 14 [AR 0065]). The Secretary of HHS granted approval for the period from November 1, 2001 through September 30, 2006 (Dkt. 61 - SSOF ¶ 14 [AR 0064]).

Through the HIFA demonstration, Arizona was permitted access to Title XXI (State Children's Health Insurance program, or "SCHIP" funds) for the provision of services to "'certain single adults and childless couples with adjusted net incomes at or below 100% of the federal poverty level'" and parents of children enrolled in the SCHIP or Medicaid programs, with adjusted net incomes between 100-200% of the federal poverty level, who were not themselves Medicaid eligible (Dkt. 61 - SSOF ¶ 15 [AR 0065]). The persons included in Arizona's HIFA expansion overlapped to a degree with persons included in the Proposition 204 expansion (Dkt. 61 - SSOF ¶ 15). The CMS approved these new HIFA "expenditure authorities" "to demonstrate whether expanding eligibility for coverage of both

parents and single adults and childless couples will improve the overall health of the community, and reduce overall rates of uninsurance" (Dkt. 61 - SSOF ¶ 16 [AR 0065]).

The CMS December 12, 2001 approval letter included a "cumulative list of waivers and expenditure authorities for the overall AHCCCS program" (Dkt. 61 - SSOF ¶ 17 [AR 0065-0066]). All other Medicaid requirements continued to apply to the Arizona program (Dkt. 61 - SSOF ¶ 17 [AR 0076]).

Prior to October 1, 2003, the AHCCCS imposed the following copayments relevant to these groups:

Doctor's office or home visit, including any x-ray/laboratory services associated with the visit	$1.00 per visit
Non-emergency surgery	$5.00 per visit
Non-emergency use of the emergency room	$5.00 per visit

(Dkt. 88 - PSOF ¶ 8). The AHCCCS prohibited health care providers from denying care or services on account of an individual's inability to pay the copayment. A.A.C. R9-22-711(B). (Dkt. 88 - PSOF ¶ 8).

In January 2002, the State of Arizona was experiencing a deficit of nearly $1,000,000,000. The Arizona Legislature considered certain cost-saving measures as to AHCCCS, including reducing eligibility levels, cutting optional Medicaid services, dropping all home and community based services, and adding new cost-sharing requirements. These options were discussed at public hearings (Dkt. 146 - DSOF p.5, ¶¶ 5-6). The Arizona Legislature directed AHCCCS to submit a Cost Sharing Report to the Joint Legislative Budget Committee by October 1, 2002 (Dkt. 146 - DSOF p.5, ¶ 7). After a public hearing in December 2002, the Arizona Legislature informally directed AHCCCS to discuss these options with the CMS (Dkt. 146 - DSOF p.5, ¶ 8).

On or about May 2, 2003, Arizona officials notified the CMS regarding changes contemplated to the "demonstration program", including imposition of increased copayments

on the AHCCCS expansion populations (including "individuals added by the January 2001 amendment") (Dkt. 61 - SSOF ¶ 18 [AR 0058-0063]; Dkt. 88 - PSOF ¶ 10).

In or about June 2003, the Arizona Legislature amended A.R.S. § 36-2903.01.D.4 to permit the AHCCCS Director to adopt rules and procedures to require the Title XIX Waiver Group "to be financially responsible for any cost sharing requirements established in a state plan or a section 1115 [42 U.S.C. § 1315] waiver and approved by the [CMS]." Cost sharing was defined to include copayments as an option (Dkt. 146 - DSOF p.5, ¶ 10; Dkt. 88 - PSOF ¶ 9).

In a June 17, 2003 letter, the CMS informed Arizona that, with respect to the State's proposal to increase cost-sharing for "groups that are not eligible for Medicaid except through Section 1115 demonstration authority," "there are no legal restrictions on cost sharing" for this population (Dkt. 61 - SSOF ¶19 [AR 0055]). The CMS explained that in the absence of "legal restrictions on cost sharing ... states may impose higher than 'nominal' levels of cost sharing", stating in part as follows:

> Many states with section 1115 demonstrations have adopted various forms of cost sharing and applied them in amounts that vary by income level and population type (e.g., parents, children, etc.). Such cost sharing does not involve waivers, since the affected groups are not eligible under the State plan. Rather, it is documented in states' operational protocols. For Arizona, information on cost sharing for demonstration eligibles could be included in a new section on cost sharing to be added to your financial operational protocol.

(Dkt. 61 - SSOF ¶ 19 [AR0055]; Dkt. 88 - PSOF ¶11).

The CMS clarified that individuals "eligible through the Medicaid State plan may be charged no more than the maximum allowable amounts for copayments, coinsurance and deductibles specified in 42 C.F.R. 447.54" (Dkt. 61 - SSOF ¶ 20). In contrast, "expansion groups that are eligible due entirely to section 1115 authority (e.g., childless adults) are not subject to the limits on cost sharing that apply to State plan eligibles" (Dkt. 61 - SSOF ¶ 20 [AR 0054-0055]).

In June 2003, AHCCCS posted its waiver request to CMS on its web site and thereafter held public meetings throughout the State (Dkt. 146 - DSOF p.6, ¶ 12).

The AHCCCS' proposed new cost sharing rules were published on September 4, 2003. A public hearing on the rules was held on September 24, 2003 (Dkt. 146 - DSOF p.6, ¶ 12). Notices of the new copayments were sent to the Title XIX Waiver Group beginning in September 2003 (Dkt. 146 - DSOF p.6, ¶ 13). According to the State, implementation of the new copayment rule resulted from a change in state law, 42 C.F.R. § 431.220(b) (Dkt. 146 - DSOF p.6, ¶ 14).

On October 1, 2003, the AHCCCS published a final amended rule that imposed copayments on the AHCCCS expansion populations/MED participants and single adults and childless couples with incomes below the federal poverty line as follows:

Generic prescriptions, or brand name prescriptions where no generic available	$ 4.00 per prescription
Brand name prescription when generic is available	$10.00 per prescription
Non-emergency use of the emergency room	$30.00 per visit
Physician office visit	$ 5.00 per visit

(Dkt. 88 - PSOF ¶ 12 [A.A.C. Amended Rule R9-22-711(E)]; Dkt. 61 - SSOF ¶ 23).

A.A.C. Amended Rule R9-22-711(E) provides that "The provider may deny a service if the member does not pay the required copayment" (Dkt. 88 - PSOF ¶ 13).

A.A.C. Amended Rule R9-22-711(E) became effective October 1, 2003 (Dkt. 146 - DSOF p.6, ¶ 15).

The CMS approved the copayment amounts on February 20, 2004, retroactive to October 1, 2003 (Dkt. 61 - SSOF ¶ 24; Dkt. 146 - DSOF p.6, ¶ 16). The new copayments "apply only to expansion populations not included in the State plan" (Dkt. 61 - SSOF ¶ 24 [AR 0001]). The CMS found that the Arizona demonstration project with the addition of the new copayments "will continue to serve the purposes of Title XIX because the demonstration

project will continue to ensure wider health benefit coverage for low-income populations" (Dkt. 61 - SSOF ¶ 24 [AR 001-002]; Dkt. 146 - DSOF p.7, ¶ 17).

Plaintiffs cite the A.A.C. Amended Rule R9-22-711(E) copayments as exceeding approved Medicaid amounts (Dkt. 88 - PSOF ¶ 14).[3]

Approximately 18.6 percent of the generic drugs covered by AHCCCS have an average cost of $3.50 (Dkt. 88 - PSOF ¶ 19).

Plaintiffs claim that in 2006, AHCCCS submitted a § 1115 demonstration waiver to the DHHS who approved the five-year waiver to begin on October 27, 2006. The DHHS again approved the A.A.C. Amended Rule R9-22-711(E) copayments. The AHCCCS was not required to implement the copayments through a state plan amendment or waiver (Dkt. 142 - Plaintiffs' Amended Supplemental Statement of Facts ¶ 51).

Defendant HHS Secretary disputes that AHCCCS submitted a waiver to the DHHS in 2006, claiming instead that the submission was approved as a demonstration project (Dkt. 149 - Defendant Secretary's Response to Plaintiffs' Supplemental Statement of Facts ¶ 51 (Supplemental Administrative Record ["SAR"] 1-3)).

Plaintiffs cite the AHCCCS Director's report, Cost Sharing Options (submitted October 1, 2002, revised March 4, 2003), as concluding that (1) increased copayments would not provide a direct fiscal benefit to the State since AHCCCS does not collect the copayments (providers do); (2) increased copayments would add new administrative costs at the health plan or provider level to pay providers to collect the copayments; (3) increased copayments would not increase revenue to the State in the short term and any long term benefit would

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[3]Plaintiffs claimed that, for other Medicaid beneficiaries, A.A.C. Rule R9-22-711(D) imposed a $5.00 copayment for the non-emergency use of the emergency room (Dkt. 88 - PSOF ¶ 15) which exceeded the $1.00 copayment amount per visit for outpatient, physician office visits (Dkt. 88 - PSOF ¶ 16). In October 2004, AHCCCS amended A.A.C. Rule R9-22-711(D) to reduce the non-emergency use of the emergency room copayment to $1.00 (Dkt. 142 - Plaintiffs' Amended Supplemental Statement of Facts ¶ 49). The parties agree that this copayment is no longer an issue in this case (Dkt. 170, p. 9 ¶¶ 40-41; Dkt. 176, p. 7 ¶¶ 40-41).

depend on whether provider collection of copayments was sufficient to allow a future offset in pay rates to providers; and (4) for the State to generate revenue that merits an increase in copayments, the CMS should allow the State to refuse a Medicaid service if the copayment is not paid (Dkt. 88 - PSOF ¶ 17 (citing Dkt. 90 - Declaration of Ellen Sue Katz [Exhibit 2])). Defendant Secretary objects that this information is not material to the Court's analysis of the case and that Plaintiffs inappropriately rely on information outside the certified Administrative Record (Dkt. 101, ¶ 17).

Plaintiffs have submitted expert studies they claim support the following views: (1) higher copayments for medical services or prescriptions cause low-income persons to use substantially fewer essential and effective medical services or medications; (2) low-income persons cannot financially bear copayments as easily as those with higher incomes; (3) persons with incomes below the poverty line already experience hardships, such as running out of food or difficulty in paying rent or utility bills, and elevated copayments force many low-income persons to choose between health care and other basic needs; (4) research on the effects of Medicaid copayments shows that copayments generally reduce the utilization of essential health care services and medications by low-income persons; and, (5) instituting or increasing copayments is not an efficient way for states to lower their Medicaid expenditures because this approach reduces federal matching funds (Dkt. 88 - PSOF ¶¶ 32-33; Dkt. 142 - Plaintiffs' Amended Supplemental Statement of Facts ¶ 53 [citing the Second Declaration of Leighton Ku, Ph.D., M.P.H., Professor of Health Policy, George Washington University School of Public Health and Health Services, Washington, D.C.]). Defendant HHS Secretary objects that this information is not relevant or material (Dkt. 101, ¶¶ 32-33; Dkt. 149, ¶ 53).

Plaintiffs have set forth alleged deficiencies in the copayment notices sent by the State to beneficiaries (Dkt. 88 - PSOF ¶¶ 37-42).

Plaintiffs have provided the factual circumstances of certain AHCCCS participants who allegedly had to make difficult choices between paying for needed medical services and other basic necessities as a result of the copayment policies (Dkt. 88 - PSOF ¶¶ 44-46).

Defendant Secretary objects that this information is not relevant or material (Dkt. 101, ¶¶ 44-46).

Plaintiffs have provided an e-mail from Defendant Rodgers to his staff dated February 21, 2007 that states that cost sharing works against the notion of managed care (Dkt. 142 - Plaintiffs' Amended Supplemental Statement of Facts ¶ 52 [Dkt. 138 - Supplemental Declaration of Ellen Sue Katz, Exhibit 23]). Defendants object that this information is not relevant or material (Dkt. 149, ¶ 52).

Plaintiffs cite information indicating that AHCCCS' consultants assumed lower utilization rates for the services to which copays applied and increased the assumed utilization of inpatient hospital and emergency room services. A Kaiser Commission study showed that when cost sharing is applied to a population like the Title XIX Waiver Group, people will tend to forego seeing their physician and having their prescriptions filled. Use of the hospital and emergency services will increase because use of preventive services has decreased (Dkt. 88 - PSOF ¶ 18 [citing Dkt. 90 - Declaration of Ellen Sue Katz, Exhibit 1 (Defendant Rodgers' Answers to Plaintiffs' Interrogatories No. 3)]; Dkt. 170, p. 15 ¶ 66). Defendants object that this information is not relevant or material (Dkt. 101, ¶ 18; Dkt. 176, p. 14 ¶¶66-67).

II.

Standard of Review

In evaluating a motion for summary judgment, the court must view the evidence in the light most favorable to the non-moving party. Summary judgment is appropriate if there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). A material fact is one "that might affect the outcome of the suit under the governing law[.]" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact may be considered disputed if the evidence is such that a jury could find that the fact either existed or did not exist. Id., at 249. The party opposing summary judgment may not rely merely on allegations or denials in the party's pleading but its response must set out

specific facts showing a genuine issue for trial. Rule 56(e). See also, Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

The Administrative Procedures Act ("APA"), 5 U.S.C. §§ 701-706, provides for judicial review of the actions of federal agencies.

The decisions of the Secretary of HHS concerning waiver under 42 U.S.C. § 1315(a) [section 1115 of the Social Security Act] are subject to review under the APA. Beno v. Shalala, 30 F.3d 1057, 1066 (9th Cir. 1994). Section 1315(a) does not give the Secretary unlimited discretion. It allows waivers only for the period and extent necessary to implement experimental projects which are "likely to assist in promoting the objectives" of the program at issue. Beno, 30 F.3d at 1067.

The Court reviews the Administrative Record in an APA action. Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743-744 (1985). The Court may reverse the Secretary's decision if it is "contrary to law" or "arbitrary and capricious" as follows:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Beno, 30 F.3d at 1073 (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Ins., 463 U.S. 29, 44 (1983)).

"The APA does not give the court power 'to substitute its judgment for that of the agency,' but only to 'consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.'" Beno, 30 F.3d at 1073 (quoting Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971)). A court's review of whether an agency's decision was arbitrary or capricious is "highly deferential" and "presum[es] the agency action to be valid." Irvine Medical Center v. Thompson, 275 F.3d 823, 830-831 (9th Cir. 2002).

III.

Discussion

Plaintiffs argue that they are entitled to summary judgment based on several grounds: (1) A.A.C. Amended Rule R9-22-711(E) violates the copayment limits of 42 U.S.C. § 1396o and 42 U.S.C. § 1396o-1; (2) the Plaintiff class includes "medically needy" individuals and families who must be afforded cost-sharing protections under 42 U.S.C. § 1396o; (3) the challenged copayments do not serve the purpose of a demonstration project under section 1115 of the Social Security Act, 42 U.S.C. § 1315(a); (4) the challenged copayments do not promote the objectives of the Medicaid Act; (5) the federal statute governing human experimentation, 42 U.S.C. § 3515b, was violated; and, (6) Defendant Rodgers, on behalf of the State of Arizona, failed to comply with due process with respect to the copayment notices.

Defendants argue in support of summary judgment that: (1) 42 U.S.C. § 1396o and 42 U.S.C. § 1396o-1 have not been violated because neither apply, citing Spry v. Thompson, 487 F.3d 1272 (9th Cir. 2007); (2) section 1396o does not apply to individuals included in the MED Program; (3) forcing Arizona to comply with inapplicable statutory provisions threatens the viability of the demonstration projects; (4) Defendant's actions in approving Arizona's demonstration project were lawful and promote the objectives of the Medicaid Act; (5) Arizona's demonstration project does not present a "danger to the physical, mental, or emotional well-being" of its participants; and, (6) the actions of State Defendant Rodgers, on behalf of the State of Arizona, did not violate due process regarding the copayment notices.

(A) The Medicaid Framework and the Arizona Program

The Medicaid program, established by Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq., is a cooperative effort by the federal government and the states to provide medical care to persons "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. Federal financial assistance is authorized to assist states in the reimbursement of certain costs of medical treatment for needy persons. To participate in the Medicaid program, a state must have a plan for medical assistance approved

by the Secretary of Health and Human Services. Pharmaceutical Research and Manufacturers of America v. Walsh, 538 U.S. 644, 650 (2003).

Only certain individuals who meet statutory requirements regarding income and resource limitations and who fall within certain statutorily defined categories are eligible for Medicaid benefits under a state plan. See 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(a)(i)-(xiii). Certain groups must be included as eligible under a state plan and others may be included at the option of the state. See 42 U.S.C. § 1396a(a)(10). A Medicaid State Plan defines the categories of persons eligible for benefits and the specific kinds of medical services that are covered. 42 U.S.C. §§ 1396a(a)(10), (17).

A State Plan must provide coverage for the "categorically needy." The "categorically needy" includes individuals eligible for cash benefits under the Aid to Families with Dependent Children (AFDC) program (now subject to the Personal Responsibility And Work Opportunity Reconciliation Act of 1996 ["Welfare Reform law"]), the aged, blind, or disabled persons who qualify for supplemental security income (SSI) benefits, and other low-income groups such as pregnant women and children entitled to poverty-related coverage. 42 U.S.C. § 1396a(a)(10)(A)(i). The State, at its option, may also cover other persons, including the "medically needy." The "medically needy" are individuals who meet the nonfinancial eligibility requirements for inclusion in one of the groups covered under Medicaid but whose income or resources exceed the financial eligibility requirements to come within the "categorically needy" group. 42 U.S.C. § 1396a(a)(10)(C). Walsh, 538 U.S. at 650-651, nn. 4 & 5.

Once the HHS Secretary approves a state plan setting out the categories of individuals and the kinds of medical services that will be covered, the State may seek federal payment for a specified percentage of the amounts "expended ... as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1).

Section 1115 of the Social Security Act, 42 U.S.C. § 1315, permits a state to develop "experimental, pilot, or demonstration" projects to provide health care to low-income citizens. 42 U.S.C. § 1315(a)(1). A state, pursuant to such an option, may:

> develop Medicaid "pilot" or "demonstration" projects that experiment with new methods of providing health care to low-income citizens. The Secretary may approve such projects if they will "assist in promoting the objective" of the Medicaid system. ... Upon granting such approval, the Secretary can waive certain federal requirements that would normally apply to traditional Medicaid programs. ... The Secretary also has authority to "regard" costs for a demonstration project as an "expenditure" pursuant to that state's Medicaid plan.

Pharmaceutical Research and Manufacturers of America v. Thompson, 313 F.3d 600, 602 (D.C. Cir. 2002), as modified, 321 F.3d 1134 (D.C. Cir. 2003).

Demonstration projects can take one of three forms: (1) waiver only under 42 U.S.C. § 1315(a)(1)(e.g., a demonstration project consisting solely of a waiver of certain Medicaid requirements for persons eligible under the State plan (Medicaid-eligible individuals)); (2) expansion [expenditure] only under 42 U.S.C. § 1315(a)(2)(A) (e.g., a demonstration project consisting solely of an expansion of health care coverage to persons not eligible under the State plan (non-Medicaid eligible individuals) or for services not otherwise covered under the State plan); or (3) combination (e.g., a demonstration project including both a waiver component under § 1315(a)(1) and an expansion [expenditure] component under § 1315(a)(2)(A)). (See Dkt. 148 - Defendant Secretary's Memorandum at pp. 6-7).

Arizona has a Medicaid State Plan approved by HHS. Members of the Plaintiff class, while of low income and in need of medical care, are not eligible for Medicaid under Arizona's State Plan, that is, they are not "categorically needy" individuals. Arizona has opted not to include coverage for the "medically needy" population in its State Plan (Dkt. 146 - DSOF pp. 2-3, ¶ 3; see Dkt. 100 - Exhibit 1).

In early 2001, the HHS Secretary approved Arizona's request to amend or expand its demonstration project to include certain non-Medicaid eligible individuals: persons with incomes up to 100% of the federal poverty level (AR 0086-0103); and persons who incur

medical expenses such that their income is reduced to 40% of the federal poverty level (AR 00086-0103) who are part of Arizona's MED program. A.R.S § 36-2901.04. The CMS invoked its "expenditure authority" under 42 U.S.C. § 1315(a)(2) in allowing Arizona to offer this expanded coverage (AR 0086). The persons included in Arizona's HIFA expansion in December 2001 overlapped to a degree with persons included in the Proposition 204 expansion and were not Medicaid eligible. The CMS cited its "expenditure authority" under 42 U.S.C. § 1315(a)(2) in approving the HIFA demonstration's expanded coverage. These groups allegedly include members of the Plaintiff class. In October 2006, CMS approved Arizona's request to extend its section 1115 demonstration project for the period from October 27, 2006 through September 30, 2011.

The challenged increased copayments implemented in A.A.C. Amended Rule R9-22-711(E) in October 2003 apply to alleged non-Medicaid eligible "expansion groups" who are not included in the State plan. The CMS also approved these copayment amounts in its October 2006 approval of Arizona's request to extend its Medicaid demonstration project.

(B) Spry v. Thompson

In Spry v. Thompson, Oregon sought through a demonstration project to expand medical coverage to needy persons who were not eligible for Medicaid. 487 F.3d at 1274. At issue in Spry were the "categorically needy" who were eligible for Medicaid, the "medically needy" for whom the State may provide at its option, and the "expansion population," persons who were not as badly off as the categorically needy and the medically needy and who may be covered under a demonstration project. The Oregon demonstration project included higher premiums and higher copayments for the expansion population than would be allowed under Medicaid. The Secretary of HHS approved Oregon's demonstration project. The Secretary took the position that no waiver was needed for the expansion population. Plaintiffs sued, seeking injunctive and declaratory relief to prevent Oregon from requiring them to pay the heightened premiums and copayments. The district court granted summary judgment in favor

of the plaintiffs on the copayments and in favor of defendants on the premiums. Both sides appealed.

On appeal, the question was whether the Secretary's approval of Oregon's demonstration project, including the mandatory copayments, exceeded his authority under Section 1115 of the Social Security Act, 42 U.S.C. § 1315(a). The Ninth Circuit held that it did not, explaining that the restrictions on the imposition of copayments under 42 U.S.C. § 1396o applied only to the "categorically needy" and the "medically needy" populations who were eligible for Medicaid coverage under a State plan, and that they do not apply to "expansion" populations. Id., at 1276.

Although 42 U.S.C. § 1396o(f) limited the waivers of the copayment provisions for demonstration projects, this limitation did not apply to expansion populations. "People in the expansion population are not made worse off by inclusion in a demonstration project less favorable to them than to the categorically and medically needy because, without the demonstration project, they would not be eligible for Medicaid at all." Id., at 1276. The Ninth Circuit recognized that, while the waiver for demonstration projects under 42 U.S.C. § 1315 can cover expansion populations as well as the categorically and medically needy, it was for a different purpose beneficial to state governments rather than to covered individuals. "The waiver in section 1315 enables state governments to count costs 'which would not otherwise be included' or 'which would not otherwise be permissible use' to be 'regarded as' state plan expenditures and permissible use of funds for purposes of federal reimbursement." Id., at 1277.

The Ninth Circuit considered plaintiffs' argument that if a state covers an expansion population, then the premium and copayment limits apply to the expansion population, noting that the core of plaintiffs' argument was that "the people in an expansion population are deemed 'eligible' for Medicaid." Id., at 1277. The Court rejected plaintiffs' argument, explaining that "section 1315 only discusses which 'expenditures,' not which individuals for whom the money is expended, are to be 'regarded as' being under the state Medicaid plan."

In contrast, section 1396 "affects limitations on Medicaid-eligible patients' premiums and co-payments." Id. "[T]he term 'eligible' in section 1396o means eligible for Medicaid, not merely eligible to receive benefits under a state plan, or 'regarded as' eligible for Medicaid federal reimbursement." Id.

(C) Analysis

(1) Whether implementation of the increased cost-sharing payments violates 42 U.S.C. §§ 1396o and 1396o-1.

Plaintiffs argue that imposition of the increased cost-sharing payments violates §§ 1396o and 1396o-1 which provide for limitations on such payments (Dkt. 135 - Plaintiffs' Memorandum at pp. 13-16). Plaintiffs argue that § 1396o-1 imposes cost-sharing rules on all groups who are receiving medical assistance under the Medicaid Act or some other way and then divides those groups into subgroups for purposes of determining flexibility regarding the imposition of cost-sharing. For persons whose incomes are below 100 percent of the federal poverty level, § 1396o-1 requires a state to abide by the nominal cost-sharing provisions under § 1396o. Plaintiffs argue that application of § 1396o-1 is not tied to participation in a state plan. (Dkt. 154 - Plaintiffs' Reply at pp. 13-15).

Defendant HHS Secretary argues that §§ 1396o and 1396o-1 apply only to a state plan and therefore are inapplicable here because the increased cost-sharing payments at issue concern Arizona's demonstration or expansion population, not persons eligible for Medicaid through a state plan. Defendant Secretary describes Plaintiffs as non-disabled, non-blind, childless adults or parents whose income exceeds the Medicaid maximum and who are not included in the Arizona Medicaid State Plan (Dkt. 148 at pp. 2, 14, 19-20).

Section 1396o refers to the "State plan". Section 1396o(a) states that, "[s]ubject to subsections [ ], the State plan shall provide that in the case of individuals described in subparagraph (A) or (E)(i) of section 1396a(a)(10) of this title who are eligible under the plan – ..." § 1396o(a). While § 1396o limits a state's ability to collect premiums and copayments for certain individuals, it applies to persons "who are eligible under the [state plan]". §

1396o(a), (b). Section 1396o(a) permits a state plan to impose nominal cost sharing on mandatory populations, that is, the categorically needy. Section 1396o(b) permits a state plan to impose nominal cost sharing on non-mandatory populations who are Medicaid eligible, that is, optional, medical needy populations. Spry, 487 F.3d at 1276. Plaintiffs are not persons eligible for Medicaid through a state plan.

Plaintiffs argue that the increased cost-sharing payments could only be accomplished "through a State plan amendment" pursuant to § 1396o-1(a), which did not occur. Plaintiffs argue that the cost-sharing payments did not occur pursuant to a demonstration project waiver. (Dkt. 135 - Plaintiffs' Memorandum at pp. 14-16).

Section 1396o-1was added in 2006 (Dkt. 154 - Plaintiffs' Reply p. 14). Section 1396o-1(a)(1) provides in part: "a State, at its option and through a State plan amendment, may impose premiums and cost sharing for any group of individuals (as specified by the State). ..." A "State plan amendment" would suggest a state plan. Plaintiffs are not eligible for Medicaid under a state plan.

Spry held that the waiver limitation under § 1396o(f) applies only to mandatory populations under § 1396o(a) ("categorically needy") or the optional populations under § 1396o(b) ("medically needy"), not to expansion populations. Spry, 487 F.3d at 1276. The amendment to § 1396o(f) did not change this conclusion. The amendment added the phrase "and section 1396o-1 of this title" to the version of § 1396o(f) that was considered in Spry.

The HHS Secretary, through the CMS, invoked "expenditure authority" under 42 U.S.C. § 1315(a)(2) in allowing Arizona to offer the expanded coverage. Plaintiffs are not eligible for Medicaid under a state plan so there was no need for a waiver.

The HHS Secretary has determined that persons not eligible for coverage under Arizona's Medicaid State Plan may be included within a demonstration project with increased copayments under the Secretary's expenditure authority. The HHS Secretary has "exceptionally broad authority" under the Medicaid statute as a result of the Secretary's expertise with respect to the Medicaid provisions. Wisconsin Dep't of Health and Family

Servs. v. Blumer, 534 U.S. 473, 497 (2002). "The Secretary's position warrants respectful consideration." Id.

Sections 1396o and 1396o-1 do not apply to Plaintiffs. Defendants did not act in violation of sections 1396o and 1396o-1.

(2) Whether § 1396o applies to individuals included in the MED Program.

Plaintiffs argue that some class members "are families or individuals who are medically needy as described in the Medicaid Act." Plaintiffs argue that these class members are "protected by the nominality and waiver requirements of 42 U.S.C. § 1396o(b)."

More specifically, Plaintiffs argue that medically needy state plan populations are included within Arizona's MED program based on statements made by an AHCCCS employee to DHHS, an alleged acknowledgment in a communication between the AHCCCS and CMS that "some individuals in the [MED] program are actually in the State plan (although the majority are 1115 expansion folks)," and reference by AHCCCS to its contractors that "MEDs may have a categorical link to a Title XIX category" (Dkt. 135 - Plaintiffs' Memorandum at pp. 26-27; see Dkt. 142 - Plaintiffs' Amended Supplemental Statement of Facts ¶ 48). Plaintiffs argue that the State cannot deny cost-sharing protections to class members within the MED population who fit the medically needy description by labeling them "expansion populations."

Plaintiffs argue that when an individual or family obtains coverage as the result of a Medicaid program expansion, that individual or family is not an "expansion population" under Spry unless they are a childless, non-disabled adult. If the characteristics of these individuals or families meet the description of a categorically needy or medically needy population group, they must be recognized as state plan populations, citing 42 U.S.C. §§ 1396a(a)(10)(A), (C), 1396o(a), o(b) (Dkt. 135 - Memorandum at pp. 25-29).

Plaintiffs argue that Defendants must adhere to 42 U.S.C. §§ 1396o(b) and o(e), by imposing only nominal copayments and prohibiting health care providers from denying care to persons who are unable to pay the copayment. Defendants can only escape these

requirements pursuant to an experimental waiver under 42 U.S.C. § 1396o(f) or through the authorized options under 42 U.S.C. § 1396o-1, neither of which Defendants selected. Plaintiffs argue that the proper analysis under Spry is whether the population group at issue is described in 42 U.S.C. § 1396a(a)(10) of the Medicaid Act and thus "coverable" under the state Medicaid plan. If so, then that population group is protected by the Medicaid Act, including the cost sharing provisions (Dkt. 154 - Plaintiffs' Reply at pp. 8-11).

Defendant HHS Secretary argues that Plaintiffs have not pointed to any evidence within the certified Administrative Record that shows there are persons within the MED population who are "medically needy." Defendant emphasizes that the Medicaid Act does not define medically needy individuals but instead permits states, at their option, to elect under the state plan to extend Medicaid eligibility to persons within certain broad categories who meet state-determined financial standards, citing 42 U.S.C. § 1396a(a)(10)(C). Defendant argues that Plaintiffs are not eligible for coverage under Arizona's Medicaid State Plan and Arizona has opted not to cover "medically needy" individuals within its Medicaid State Plan. In Arizona, there is no "medically needy" population within the Medicaid framework. Plaintiffs receive benefits under the demonstration project.

Defendant argues that the language of § 1396o(b) is not on its face limited to optional populations and refers to populations who are eligible under a state plan other than mandatory populations. Section 1396o(b) therefore does not apply to Plaintiffs. Defendant argues that Plaintiffs have alleged a hypothetical in the event Arizona chooses to include an optional medically needy population within its State Plan. (Dkt. 148 at pp. 24-27; Dkt. 156 at pp. 6-11).

As previously recognized, a state at its option may include the medically needy in its state plan. Section 1396o(b) "permits a state plan to impose income-related premiums and nominal cost sharing on non-mandatory populations who are Medicaid eligible, i.e., optional, medically needy populations." Spry, 487 F.3d at 1276. Section 1396o(b) refers to a "state plan" and the populations who are eligible under the state plan and included within the state

plan. Arizona has opted not to include a "medically needy" population in its State Plan. Plaintiffs, or persons within the MED group, therefore cannot be considered "medically needy" under a Medicaid state plan or the Medicaid laws. Section 1396o(b) does not apply to Plaintiffs.[4]

Plaintiffs argue that it was an abuse of discretion for the HHS Secretary to approve the increased copayments pursuant to a section 1115 expenditure. Plaintiffs cite A.R.S. § 36-2919 which refers to A.R.S. § 36-2903.01. A.R.S. § 36-2903.01.B.5 provides that the AHCCCS Director shall apply for and accept federal funds as authorized in support of the system and that "[s]uch funds may be used only for the support of persons defined as eligible pursuant to title XIX of the social security act or the approved section 1115 waiver." A.R.S. § 36-2903.01.D.4 provides that the Director may adopt rules or procedures to require persons to be financially responsible for any cost sharing requirements "established in a state plan or a section 1115 waiver" and approved by the CMS. Plaintiffs argue that the AHCCCS Director was authorized to proceed only through a state plan provision or a section 1115 waiver, not through a section 1115 expenditure (Dkt. 154 - Plaintiffs' Reply at pp. 6-8).

Defendant HHS Secretary argues that the Administrative Record shows that Arizona has consistently used the term "1115 waiver" broadly to cover both waiver and expenditure

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[4]Defendant HHS Secretary argues that the Court erred in its preliminary injunction ruling by finding that the parties had agreed that Plaintiffs are "medically needy" under the Medicaid framework (Dkt. 148 - Defendant's Memorandum at pp. 6, 14; see Dkt. 53 - Order at p. 9). In support of their request for a preliminary injunction, Plaintiffs had argued that a demonstration project granted under § 1315 is to be considered part of a Medicaid state plan and the populations affected by the demonstration are to be considered Medicaid recipients under the state plan (Dkt. 38). Defendants' summary judgment briefing and evidence has clarified that Arizona has opted not to include coverage for the "medically needy" population in its State Plan and therefore no Plaintiff can be considered "medically needy" within the Medicaid framework. The intervening decision in Spry appears to have rejected the argument that "the people in an expansion population are deemed 'eligible' for Medicaid." Spry, 487 F.3d at 1277.

authority (Dkt. 156 - Defendant's Reply at pp. 12-13). This does appear supported by the Administrative Record.

The record shows that the HHS Secretary approved Arizona's request pursuant to the Secretary's expenditure authority under 42 U.S.C. § 1315(a)(2). "[N]o waiver is necessary for expansion populations not eligible for Medicaid ... ." Spry, 487 F.3d at 1277. In Arizona, Plaintiffs are included within the expansion populations. Plaintiffs have not shown error in the Defendant Secretary's decision.

(3) Whether Arizona's demonstration project "demonstrates" anything.

Section 1115 [42 U.S.C. § 1315(a)] authorizes "experimental, pilot, or demonstration" projects "likely to assist in promoting the objectives" of the Medicaid program. Plaintiffs argue that Congress meant for section 1115 projects to test experimental ideas. Plaintiffs argue that Arizona's demonstration project, originally approved more than 26 years ago, allowed the State to implement AHCCCS, a novel approach to providing Medicaid through mandatory enrollment of beneficiaries into managed care organizations. Plaintiffs argue that the use of managed care is no longer novel or untested, and that by 2003, when the heightened copayments were introduced, a rigorous body of research had verified the negative health and fiscal impacts that result when heightened copayments are imposed on poverty-level populations. Plaintiffs argue that the record shows that AHCCCS implemented the higher copayments for budgetary reasons which is not permissible for a § 1115 project. Plaintiffs argue that there is nothing experimental, pilot or demonstration at issue and that it was error for Defendant HHS Secretary to grant the State's request to impose the heightened copayments (Dkt. 135 - Plaintiffs' Memorandum at pp. 17-21).

Defendant HHS Secretary argues that the project which provides Plaintiffs with health care coverage is an "experimental, demonstration or pilot project" within the meaning of 42 U.S.C. § 1315. Defendant argues that the copayments are a cost-sharing measure that, from the perspective of state financing, enables the larger demonstration project, which allows non-

Medicaid eligible plaintiffs to receive benefits as opposed to leaving Plaintiffs with no health care coverage whatsoever. Defendant argues that the Administrative Record of the Secretary's approval reflects a determination to improve the overall health of the community, and is designed with the goal of reducing the uninsured rate. Defendant Secretary contends that the relevant factors were considered, the copayments are lawful, and the Court should defer to the Secretary's determination that the demonstration project including the increased copayments furthers the purpose of the Medicaid statute (Dkt. 148 - Defendant's Memorandum at pp. 28-30).

Plaintiffs argue that even if the copayments were used as a cost-saving measure to enable a larger demonstration project, the use of copayments must test a "unique and previously untested use of copayments," citing 42 U.S.C. § 1396o(f)(1) (Dkt. 154 - Plaintiffs' Reply at p. 16). As Defendant has pointed out, however, § 1396o(f)(1) applies only to "[c]harges imposed under waiver authority of the Secretary." 42 U.S.C. § 1396o(f). The copayments at issue were approved under the HHS Secretary's expenditure authority and therefore the standards set forth in § 1396o(f)(1) do not apply (see Dkt. 156 - Defendant's Reply at p. 14).

With respect to the alleged demonstration value of the project or copayments, the parties cite the following discussion from Beno v. Shalala, 30 F.3d 1057 (9th Cir. 1994), regarding application of § 1115 (42 U.S.C. § 1315):

> The statute was not enacted to enable states to save money or to evade federal requirements but to 'test out new ideas and ways of dealing with the problems of public welfare recipients.' [citation omitted] Thus, the Secretary must make some judgment that the project has a research or a demonstration value. A simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy this requirement. Rather, the 'experimental or demonstration project' language strongly implies that the Secretary must make at least some inquiry into the merits of the experiment - - she must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration.

Beno, 30 F.3d at 1069 (see Dkt. 135- Plaintiffs' Memorandum at pp. 17-18; Dkt. 148 - Defendant Secretary's Memorandum at p. 28).

The court record and the Administrative Record show that during 2002 and 2003 cost-sharing measures were authorized with respect to certain expansion population groups in view of the State's financial deficit (Dkt. 146 - DSOF p. 5 ¶¶ 5-17; Dkt. 63 - AR 001-004, 0025-0027). In February 2004, the CMS granted approval to the State for the program with the increased copayments retroactive to October 2003 (Dkt. 63 - AR 001-002).

The Administrative Record shows that the CMS December 2001 approval letter stated, "[w]e are granting the new expenditure authorities listed above to demonstrate whether expanding eligibility for coverage of both parents and single adults and childless couples will improve the overall health of the community, and reduce overall rates of uninsurance. This result would promote the objectives of the Act" (Dkt. 63 - AR 0065). Plaintiffs point out, however, that this finding pertains to the Secretary's approval of the amendment to the demonstration project that allowed the use of Title XXI funds for certain expanded coverage, not to any purported reason for the heightened and mandatory copayments (Dkt. 175, p. 11 ¶ 1). The CMS stated in the February 2004 approval letter regarding the demonstration project with the additional higher copayments, "[w]e believe that the approved demonstration project will continue to serve the purposes of Title XIX because the demonstration project will continue to ensure wider health benefit coverage for low-income populations" (Dkt. 63 - AR 001). More specific recommendations regarding demonstration value relevant to the project with the increased copayments were not set forth in either the State's application or the HHS Secretary's approval.

Plaintiffs cite the Director's report on Cost Sharing Options as stating that increased copayments possibly would not provide a direct fiscal benefit to the State, and that the State could generate revenue only by denying health care outright to persons unable to pay the copayments (Dkt. 88 - PSOF ¶ 17; Dkt. 135 - Plaintiffs' Memorandum at pp. 11-12; Dkt. 154 - Plaintiffs' Reply at p. 17). Plaintiffs also cite Defendant Rodgers' information that in

implementing the heightened copayments AHCCCS assumed lower utilization rates for the services to which the copayments applied and increased the assumed utilization of inpatient hospital and emergency room services (Dkt. 154 - Plaintiffs' Reply at p. 17). Defendant objects that this information is irrelevant and immaterial as outside the Administrative Record (Dkt. 101, ¶ 17). However, a court may consider materials outside the administrative record that are necessary to determine whether the agency considered all relevant factors. Northwest Environmental Advocates v. National Marine Fisheries Service, 460 F.3d 1125, 1145 (9th Cir. 2006).[5]

In supplemental briefing, Defendant Secretary argues that the effect of the demonstration project at issue is to reduce the effective cost of medical care to certain low-income persons from 100% of the market rate down to the copayments listed in A.A.C. Amended Rule R9-22-711(E) (Dkt. 168 - ¶ 11). Plaintiffs object, however, that the heightened copayments increase their health care costs (Dkt. 175, p. 4 ¶ 6). Defendant Secretary argues that prior to 2001, Arizona did not provide health care benefits as through the demonstration project at issue, and that the demonstration project represents a novel approach to the provision of medical assistance to low-income populations (Dkt. 168 - ¶¶ 12, 19). Plaintiffs object that this is a new argument with no evidentiary support in the record. Plaintiffs argue that the information provided by Dr. Ku shows that other states have imposed copayments of a similar nature for the same services and that Arizona's application and the Secretary's approval did not delineate any unique or untested uses of copayments in the project (Dkt. 175, pp. 7-8 ¶ 6).

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[5]Where the HHS Secretary has not considered all relevant factors, the appropriate remedy is to remand to the Secretary for further consideration. See Florida Power & Light Co. v. Lorion, 470 U.S., at 744 (remand to the agency is the appropriate action "if the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it").

Information in the Supplemental Administrative Record appears to indicate that Arizona's program was cost-effective as of 2006 without implementation of the increased copayments (and while the copayments remained at nominal amounts) (SAR 6-82; see specifically SAR 20). During the oral argument hearing on July 21, 2009, when the Court inquired about Arizona's deficit, no specific information was provided other than an estimated "triple" what it had been in 2003 (Dkt. 165 at p. 18).[6]

As discussed in Beno, § 1115 was not enacted to enable states to save money, and implies that the Secretary must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration. Moreover, the court cannot adequately discharge its duty to engage in "substantial inquiry" if it is required to take the agency's word that it considered all relevant matters. Asarco, Inc. v. United States Environmental Protection Agency, 616 F.2d 1153, 1159-1160 (9th Cir. 1980).

The Court is mindful that agency action generally must be examined by scrutinizing the administrative record at the time the agency made its decision. Asarco, Inc., 616 F.2d at 1159. The focus of judicial review is not on the wisdom of the agency's decision. Id.

The Administrative Record shows that in 2002-2003, the State determined that imposition of increased copayments was necessary to enable the State to provide the extensive health care coverage. The HHS Secretary approved the project with the increased copayments as demonstrating whether the project will continue to ensure wider health benefit coverage for low-income populations. Whether cost-sharing is a reasonable means of providing care to certain expansion populations during a state fiscal shortage appears consistent with the meaning of § 1315. The Administrative Record shows suggested monitoring provisions as

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[6]Defendant Secretary argued in opposing entry of a preliminary injunction that enjoining Arizona from collecting the copayments from AHCCCS expansion populations would jeopardize the State's ability to continue to provide expanded health care services for AHCCCS expansion populations (Dkt. 53 - Order at p. 6). Defendant Rodgers did not argue that the State would face a financial burden if A.A.C. Amended Rule R9-22-711(E) was enjoined (Dkt. 53 - Order at p. 7 n.4).

relevant to evaluating the usefulness of the program (Dkt. 63 - AR 009-0027; SAR 81-82). "This flexibility for the state facilitates the goal of demonstration projects, developing new and better ways to provide medical assistance to the needy, including those who are not eligible for Medicaid." Spry, 487 F.3d at 1277. The Secretary's determination is not contrary to law or arbitrary and capricious.

(4) Whether the challenged copayments promote the objectives of the Medicaid Act.

The purpose of the Medicaid Act is to furnish medical assistance to certain families and individuals whose incomes and resources are insufficient to meet the costs of necessary medical care. 42 U.S.C. § 1396. Plaintiffs argue that the HHS Secretary violated the requirements of section 1115 [42 U.S.C. § 1315] that demonstration projects be consistent with the objectives of the Medicaid Act. Plaintiffs argue that the increased copayments require class members in effect to provide a subsidy for generic drugs, that Medicaid cost-sharing requires only nominal copayments, and that it was unlawful to allow Medicaid-participating providers to deny services when Plaintiff class members are unable to pay the copayment. Plaintiffs argue that Defendant HHS Secretary failed to provide public notice and a comment period before authorizing increased copayments so as to avoid preventable harm to Plaintiff class members (Dkt. 135 - Plaintiffs' Memorandum at pp. 21-23).

Defendant HHS Secretary argues that the AHCCCS demonstration project advances Medicaid objectives because it expands coverage to the uninsured who are not eligible for Medicaid. Defendant argues that Arizona's cost-sharing provisions enable the State to expand coverage and maintain a state health care system that goes beyond the approved Medicaid State Plan (Dkt. 148 - Memorandum at p. 31). The HHS Secretary initially approved the demonstration project for a period of five years, and then extended that approval for another limited five year period (Dkt. 63 - AR 0064; SAR 1-3).

The Administrative Record shows that as a result of the demonstration project, Plaintiffs and others within the expansion populations are provided an opportunity for health

care coverage, even with the higher copayments, where coverage might not otherwise be provided. Defendant HHS Secretary expressed the opinion that Arizona's demonstration project promotes "the objectives of the Act" (Dkt. 63 - AR 0065) and ensures "wider health benefit coverage for low-income populations" (Dkt. 63 - AR 001). The HHS Secretary approved the Arizona demonstration project for the "extent" and "period" appropriate to enable the State to carry out the project. 42 U.S.C. § 1315(a). Defendant is to be accorded deference with respect to this decision. Defendant HHS Secretary has not acted in an arbitrary and capricious manner or contrary to law.

(5) Whether the federal statute governing human experimentation has been violated.

The Social Security Act prohibits the HHS Secretary from using federal funds to pay for any experimental program or project that may present a human danger. Pursuant to 42 U.S.C. § 3515b, federal funds may not be used:

> to pay for any research program or project or any program, project, or course which is of an experimental nature, or any other activity involving human participants, which is determined by the Secretary or a court of competent jurisdiction to present a danger to the physical, mental, or emotional well-being of a participant or subject of such program, project, or course, without the written, informed consent of each participant or subject, ...

Plaintiffs argue that multiple studies have established that heightened copayments cause low-income persons to forego or limit essential and effective medical services and prescription drugs. Plaintiffs argue that the copayments were implemented without the written consent of each demonstration participant and there is no evidence in the Administrative Record that Defendants considered the effects the copayments would have on the participants' well-being (Dkt. 135 - Plaintiffs' Memorandum at pp. 23-25). Plaintiffs note that the heightened copayments were approved by Defendant Secretary after this litigation had been filed (Dkt. 154 - Plaintiffs' Reply at pp. 18-19).

Defendant Secretary argues that a reduction in benefit levels does not generally amount to the sort of "danger" to which § 3515b is directed and that the evidence shows that the

demonstration program serves the policies of Medicaid law. Defendant argues that the alternative to increased copayments is possibly no medical coverage or elimination of an entire class of benefits, such as prescription drugs, or cutbacks in the populations to be serviced. Defendant argues that the required determination as to "danger" is part and parcel of the broader inquiry under 42 U.S.C. § 1315, that is, whether the demonstration program will serve the policies of the Medicaid program (Dkt. 148 - Memorandum at pp. 33-34). In supplemental briefing, Defendant Secretary agrees that the potential harm of the demonstration project should be considered and that the record shows this issue was considered. Defendant cites the Secretary's findings in 2001, and in 2004 with the changes resulting in the increased copayments, that the project would promote the objectives of the Medicaid Act, continue to serve the purposes of Medicaid, and ensure wider health benefit coverage for low income populations, as showing consideration of the effect of the higher copayments (Dkt. 176 at pp. 30-31 ¶¶ 63-68).[7]

Plaintiffs' information regarding the alleged financial and health care hardships caused by the increased copayments is based on some 15 declarations dated 2004 submitted by Plaintiffs (Dkt. 170 ¶¶ 52-60 [citing Dkt. 15 & 16]) and Dr. Ku's declarations dated August 2004 and March 2008 (Dkt. 92 & 137). This information was not considered in the administrative proceedings. During the oral argument hearing, Plaintiffs' counsel provided a vague response when asked about Plaintiffs' status and circumstances (Dkt. 165 at pp. 4-5).

Regarding Defendants' argument implying that Arizona could terminate its coverage of the expansion populations, Plaintiffs object that "Proposition 204 is a voter-approved initiative that requires the expanded coverage and that cannot be overridden by the AHCCCS director or the legislature" (Dkt. 170, p. 61 ¶ 132). Defendant Secretary has responded that "[t]here is no federal law that forces Arizona to provide medical assistance to Plaintiffs. ...

[7]Defendant Secretary also appears to argue that § 3515b does not apply to Plaintiffs who are members of the expansion population (Dkt. 176, p. 17 ¶ 1).

Notwithstanding the approval of Proposition 204 by Arizona voters, the Secretary was not required to approve the demonstration project" (Dkt. 176, p. 39 ¶ 132). This issue has not been further briefed by the parties and so the Court has not considered it.

As noted in Spry, "[p]eople in the expansion population are not made worse off by inclusion in a demonstration project less favorable to them than to the categorically and medically needy because, without the demonstration project, they would not be eligible for Medicaid at all." Spry, 487 F.3d at 1276. The Court finds no violation of § 3515b based on review of the Administrative Record.

(6) Whether the State's copayment notices complied with Due Process.

Plaintiffs argue that the notices Defendant Rodgers sent to class members regarding the increased copayments did not comply with due process requirements of the United States Constitution or the Medicaid law. Plaintiffs have set forth the notice requirements under the Medicaid regulations concerning an "action affecting a claim.", 42 C.F.R. §§ 431.206, 431.210, 431.211, noting that the term "action" is defined as a "termination, suspension or reduction of Medicaid eligibility or covered services." 42 C.F.R. § 431.201.

Defendant Rodgers argues that the sole reason for the change in copayments was a change in state law and therefore no hearing was required under 42 C.F.R. § 431.220(b). Defendant Rodgers argues that the notices AHCCCS provided in 2003 were sufficient under due process standards because they were written, stated the action intended to be taken, cited the specific law and regulation that supported the action, explained the right to a hearing and continued services if a hearing was requested, and were mailed in most instances at least 10 days before implementation of the copayment changes (Dkt. 145 - Defendant Rodgers' Memorandum [citing Dkt. 90 - Declaration of Ellen Sue Katz, Exhibits 8-10]). Defendant Rodgers argues that the issue of the sufficiency of the notices has been rendered moot by the intervening injunction issued by the Court.

As Plaintiffs are not eligible for Medicaid under Arizona's State Plan, any notice requirement under the Medicaid regulations would appear not to apply. Defendant points out

that the notices provided were required by the operational protocol with the federal government (Dkt. 174, p. 4, ¶¶ 120-121 [citing Dkt. 90 - Declaration of Ellen Sue Katz - Exhibit 12, p. v-3]).

In the alternative, an adequate notice under the Constitution and the Medicaid framework must detail the reason for the proposed action and must be reasonably calculated to apprise the claimant of the action taken and afford the claimant an opportunity to present any objection. Goldberg v. Kelly, 397 U.S. 254, 267-268 (1970); Rodriguez v. Chen, 985 F. Supp. 1189, 1194 (D. Ariz. 1996).

The record shows three versions of the notices as provided between September 20 and December 6, 2003 (Dkt. 90 - Declaration of Ellen Sue Katz, Exhibits 8-10). The notices initially described the coverage and copayment changes as based on a change in state law and provided contact information in the event of questions. The subsequent notices included this information and additionally informed the claimant of the opportunity for a hearing. The Court finds that the notices overall were sufficient for purposes of due process.

Accordingly,

IT IS ORDERED that Defendants' Motions for Summary Judgment (Dkt. 147 & 145) are granted.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Summary Judgment (Dkt. 135) is denied.

IT IS FURTHER ORDERED that the Preliminary Injunction (Dkt.53) is vacated.

IT IS FURTHER ORDERED that Judgment shall be entered in favor of Defendants and against Plaintiffs.

DATED this 26th day of March, 2010.

Earl H. Carroll
United States District Judge