UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MISSOURI DEPARTMENT OF SOCIAL SERVICES, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 20-3611 (ABJ)

MEMORANDUM OPINION

This case involves a dispute between the Missouri Department of Social Services ("Missouri") and defendants the U.S. Department of Health and Human Services ("HHS") and the Secretary of the HHS, concerning the reimbursement defendants provide to states under the Medicaid program for state expenditures on "family planning services and supplies." The Medicaid statute requires HHS to reimburse states 90 percent of their expenditures for these services and supplies, a higher level than for many other expenditures under the program. Following an audit by HHS's Office of the Inspector General of Missouri's claims for prescription contraceptive drugs, the agency disallowed reimbursement to the state at the 90 percent level for some of the claims because the state failed to show that the contraceptives involved in those claims had been "prescribed for a family planning purpose." Missouri filed an administrative appeal, asserting that the statute does not permit defendants to require states to make an individualized showing of the reason why an oral contraceptive was prescribed to any particular patient; since all

oral contraceptives fall within the therapeutic class of drugs that prevent pregnancy, they should all be reimbursed at the 90 percent rate. Defendants' Departmental Appeals Board denied the appeal, and this lawsuit seeks judicial review of defendants' interpretation of the statute and the Board's decision based on it.

For the following reasons, the parties' motions for summary judgment will each be granted in part and denied in part. The Court finds that the agency has adopted a permissible interpretation of the statute, and it will enter judgment in favor of defendants on Count I. But the Court will grant plaintiff's motion as to Count II and order that HHS Departmental Appeals Board Decision No. 3019 and the CMS disallowance that was upheld by that decision be vacated because this is a change in agency practice that has not been announced or explained.

BACKGROUND

I. Legal Framework

A. The Medicaid Program and Statute

The Medicaid program, jointly funded by federal and state governments, provides medical care to eligible low-income individuals. *Grossmont Hosp. Corp. v. Burwell*, 797 F.3d 1079, 1081 (D.C. Cir. 2015). Congress established the program, set forth in Title XIX of the Social Security Act, to provide federal payments to states for "medical assistance" that states provide to qualifying individuals under their state Medicaid plans. *See* 42 U.S.C. § 1396b(a). The Center for Medicare and Medicaid Services ("CMS"), which is a component of defendant HHS, is responsible for implementing the federal side of the program under the statute. *Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 954 (D.C. Cir. 2019), citing 42 U.S.C. § 1396 *et seq*.

The federal payments to states are governed by statute, *see* 42 U.S.C. § 1396b(a), and are referred to as "federal financial participation" ("FFP"). 42 C.F.R. § 400.203; 45 C.F.R. § 95.4.

Generally speaking, federal financial participation is a percentage of the actual costs that states incur in providing medical assistance to qualified individuals, known as the "federal medical assistance percentage" or FMAP. *See* 42 C.F.R. § 400.203. The FMAP varies by state based on each state's per capita income and ranges from a statutory minimum of 50 percent to a maximum of 83 percent. *See* 42 U.S.C. §§ 1396b(a)(1), 1396d(b); 1905(b); 42 C.F.R.§ 433.10(a)–(b).

But sometimes the statute calls for payments to states at a higher percentage than the typical federal medical assistance percentage. One such occasion is when states provide "family planning services and supplies," and that provision is at issue here.

Section 1396b(a)(5) requires the federal government to pay:

> an amount equal to 90 per centum of the sums . . . which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies.

42 U.S.C. § 1396b(a)(5); *see also* 42 C.F.R. § 433.10(c)(1) ("Under section 1903(a)(5) of the Act, the Federal share of State expenditures for family planning services is 90 percent.").[1] Neither the statute nor HHS regulations define "family planning services and supplies." *See* 42 C.F.R. § 440.40(c) (reserving definition).

1 While states have flexibility in establishing their Medicaid plans, the statute sets certain requirements for state plans, including that they must provide "family planning services and supplies . . . to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies." 42 U.S.C. § 1396d(a)(4)(C); *see Harris v. McRae*, 448 U.S. 297, 308 (1980) ("[I]f a State agrees to establish a Medicaid plan that satisfies the requirements of Title XIX, which include several mandatory categories of health services, the Federal Government agrees to pay a specified percentage of 'the total amount expended . . . as medical assistance under the State plan.'"), quoting 42 U.S.C. § 1396b(a)(1).

B. Agency Publications

Although there is no definition for "family planning services and supplies," the State Medicaid Manual (the "Manual") provides guidance to states on the Medicaid program.[2] The CMS publication "provides instructions, regulatory citations, and information for implementing provisions of Title XIX of the Social Security Act (the Act)." Manual, Forward. According to the Manual, its instructions "are official interpretations of the law and regulations, and, as such, are binding on Medicaid State agencies." Manual, Forward; *see also Penn., Dep't of Pub. Welfare v. Dep't of Health & Hum. Servs.*, 647 F.3d 506, 509 (3d Cir. 2011) (stating that the Manual "serves as the official HHS interpretation of the law and regulations").

CMS has also published a Financial Management Review Guide ("Review Guide") that explains how defendants review and audit claims that states submit for Medicaid payments. Two versions of the Review Guide are relevant to this case: the 2002 Review Guide and the 2010 Review Guide. *See* Administrative Record [Dkt. # 24] ("A.R.") 149–68; A.R. 103–37.[3]

II. Factual and Procedural Background

HHS's Office of the Inspector General ("OIG") has an Office of Audit Services, which conducts audits "to help reduce fraud, waste, abuse, and mismanagement." Office of Audit Services – Mission, 83 Fed. Reg. 55,553, 55,555 (Nov. 6, 2018). OIG audits are conducted "in accordance with Government Auditing Standards and follow[] applicable legal, regulatory, and

2 *The State Medicaid Manual*, CMS.gov, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927 (last visited Mar. 30, 2022).

3 Page citations to the Administrative Record refer to the Bates numbers at the bottom right of each page.

administrative requirements." *Id.* This case arises out of an OIG audit of Missouri's claims for contraceptives.

Beginning in the 2000s, OIG conducted audits of the family planning claims submitted by the following states:

- New Jersey, *see* HHS OIG, Review of Pharmacy Claims Billed as Family Planning Under New Jersey's Medicaid Program, A-02-05-01019 (Jul. 26, 2007), A.R. 192–214 ("N.J. Audit");
- New York, *see* HHS OIG, Review of Pharmacy Claims Billed as Family Planning Under the New York State Medicaid Program, A-02-05-01018 (Jul. 25, 2007), A.R. 216–41 ("N.Y. Audit");
- Kansas, *see* HHS OIG, Review of Family Planning Pharmacy Claims Submitted by Selected Providers Under the State of Kansas Medicaid Program, A-07-10-04157 (Jun. 2010) A.R. 271–92 ("Kan. Audit");
- Colorado, *see* HHS OIG, Review of Prescribed Drug Costs in the Colorado Medicaid Family Planning Program, A-07-11-01095 (Oct. 17, 2011), A.R. 294–316 ("Colo. Audit");
- North Carolina, *see* HHS OIG, North Carolina Incorrectly Claimed Enhanced Federal Reimbursement for Some Medicaid Services that were Not Family Planning, A-04-10-01089 (Jun. 13, 2012), A.R. 243–69 ("N.C. Audit"); and
- Missouri, *see* HHS OIG, Missouri Did Not Always Correctly Claim Costs for Medicaid Family Planning Drugs for Calendar Years 2009 and 2010, A-07-12-01118 (Jan. 2014), A.R. 318–37 ("Missouri Audit").

OIG conducted an audit of Missouri's family planning drug claims from October 2012 through August 2013. Missouri Audit, A.R. 331. It reviewed claims made in 2009 and 2010, during which plaintiff submitted 358,779 Medicaid claims for contraceptives.[4] A.R. 331. Of those claims, OIG selected a random sample of 107 contraceptive claims and contacted the prescribing

4 OIG did not review an additional 46,328 claims that either adjusted claims in quarters outside of the audit period or were determined to be immaterial. A.R. 331.

provider for each to determine "whether the drug on the sampled claim was prescribed for a family planning purpose." A.R. 332. For eight of the 107 sampled claims, OIG "did not receive sufficient information from the providers regarding the purposes of the prescriptions," and it asked the state agency to provide documentation showing the purpose of each prescription. *Id.* OIG also gave the underlying medical records for one claim to OIG's Chief Medical Officer "to determine whether the medical record affirmatively documented a family planning purpose." *Id*.

Missouri received a draft of OIG's findings, and it responded by letter dated December 26, 2013. Missouri Audit, A.R. 336–37. It objected to the draft's recommendations that it (a) refund the federal government $487,351, (b) refund any additional amounts related to family planning drugs improperly claimed after the audit period, and (c) strengthen its internal controls to ensure that drug costs submitted for federal reimbursement appropriately identify the claims that are eligible for reimbursement at the 90 percent rate. A.R. 336–37. Missouri stated that it that relies on "contraceptive therapeutic class codes to determine if a drug claim is for family planning purposes" for Medicaid reimbursement. A.R. 336. It explained that the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requires pharmacies to use a single standard based on National Drug Codes[5] to identify a drug being submitted for payment; the standard does not allow for diagnosis codes to be supplied; and pharmacies cannot transmit diagnosis information with their drug claims. A.R. 336. Missouri took the position that therefore,

5 The National Drug Code refers to a unique, three-segment number that "serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily." *Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150, 162 n.12 (D.D.C. 2020), quoting Nat'l Drug Code Directory, U.S. Food & Drug Admin., https://www.fda. gov/drugs/drug-approvals-and-databases/national-drug-code-directory (last visited Mar. 31, 2022).

"all pharmaceuticals in the contraceptive therapeutic class should be eligible for the enhanced federal financial participation." *Id.* ("[W]hile a participant may request contraception for another reason, it still could prevent a pregnancy despite the medical records not supporting the reasons for taking a contraceptive drug.").

OIG issued the final report of its Missouri audit on January 28, 2014, *see* Missouri Audit, A.R. 318–37, reporting issues with twenty-two of the 107 sampled claims.[6] A.R. 326. It extrapolated those findings to estimate that plaintiff had received unallowable reimbursement in 2009 and 2010 totaling $487,351. A.R. 326. And it found that "the State agency's internal controls automatically classified contraceptive drugs as family planning services even in cases when the medication in question may have been prescribed for another (non-family planning) purpose." A.R. 326.

OIG did not change its findings based on Missouri's comments, and on March 2, 2018, CMS advised plaintiff by letter that based on the Missouri Audit, it had disallowed $487,351 of the state's claims for contraceptives. CMS Disallowance Letter (Mar. 2, 2018), A.R. 28–31 ("Disallowance Letter").

On April 16, 2018, plaintiff appealed the disallowance to HHS's Departmental Appeals Board pursuant to Section 1116(e)(2) of the Social Security Act. Notice of Appeal of Disallowance

6 "Of the 22 claims, 21 were eligible for reimbursement only at the regular FMAP because the drugs were not prescribed for a family planning purpose (13 claims) or because the State agency could not support that the drugs were prescribed for a family planning purpose (8 claims). The other claim of the 22 was ineligible for reimbursement because the State agency lacked supporting documentation." A.R. 326.

Number MO/2018/001/MAP, A.R. 25–26; Br. of Appellant Mo. Dep't of Soc. Servs., A.R. 45–68 ("Missouri Appeal Br.").

On October 13, 2020, the Board denied plaintiff's appeal. *See* Decision, HHS Departmental Appeals Board, Decision No. 3019, A.R. 1–24 ("Board Decision"). Noting that plaintiff did not challenge certain aspects of the audit, A.R. 7–8, and that the Board will generally defer to an agency's interpretation of a statute that the agency is responsible for implementing "if that interpretation is 'reasonable' and the non-federal party had adequate and timely notice of the interpretation," the Board upheld CMS's interpretation of the statute that "prescription contraceptive drugs are ineligible for 90 percent FFP unless the drugs were prescribed for a family planning purpose." A.R. 8, 10. The Board also upheld the disallowance because plaintiff failed to provide evidence confirming the sample claims "were for contraceptive drugs that had been sought or prescribed for a family planning purpose." A.R. 11.

On December 11, 2020, plaintiff filed this lawsuit, challenging defendants' interpretation of the statute and the Board's decision based on that interpretation. Compl. [Dkt. # 1] ¶¶ 37–40. On June 4, 2021, plaintiff filed a motion for summary judgment. Pl.'s Mot. for Summ. J. [Dkt. # 14]; Pl.'s Mem. in Supp. of Summ. J. [Dkt. # 14-1] ("Pl.'s Mem."). On October 4, 2021, defendant filed a combined opposition and cross-motion for summary judgment. Defs.' Cross-Mot./Opp. [Dkt. ## 20, 21] ("Defs.' Mot./Opp."). On November 17, 2021, plaintiff filed its combined opposition to defendants' motion and its reply brief. Pl.'s Reply in Supp. of Mot. for Summ. J. & Resp. in Opp. to Defs.' Mot. [Dkt. ## 22, 23] ("Pl.'s Opp./Reply"). Defendant did not file a reply brief.

On November 17, 2021, the administrative record was filed. *See* A.R.

STANDARD OF REVIEW

Summary judgment is appropriate when the pleadings and evidence show that "there is no genuine dispute as to any material fact and [that] the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). However, in cases involving review of agency action under the Administrative Procedure Act ("APA"), Rule 56 does not apply due to the limited role of a court in reviewing the administrative record. *Select Specialty Hosp.-Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 21 (D.D.C. 2011). Under the APA, the agency's role is to resolve factual issues and arrive at a decision that is supported by the administrative record, and the court's role is to "determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769–70 (9th Cir. 1985), citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971); *see also Richards v. I.N.S.*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

Under the APA, a court must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), in excess of statutory authority, *id.* § 706(2)(C), or "without observance of procedure required by law," *id.* § 706(2)(D). However, the scope of review is narrow. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The agency's decision is presumed to be valid, *see Citizens to Preserve Overton Park*, 401 U.S. at 415, and the court must not "substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43. A court must be satisfied, though, that the agency has examined the relevant data and articulated a satisfactory explanation for its action, "including a

rational connection between the facts found and the choice made." *Alpharma, Inc. v. Leavitt*, 460 F.3d 1, 6 (D.C. Cir. 2006) (citations omitted) (internal quotation marks omitted).

In reviewing an agency's interpretation of a statute, courts use the two-step analysis outlined in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984). Step one involves determining whether Congress has spoken directly to the precise question at issue. If it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress," and that is the end of the matter. *Id.*; *Nat'l Treasury Emps. Union v. Fed. Labor Relations Auth.*, 392 F.3d 498, 500 (D.C. Cir. 2004). If the statute is silent or ambiguous on the question, *Chevron* instructs the court to go on to a second step and determine "whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. An agency's interpretation will warrant deference if it is reasonable. *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991).

ANALYSIS

Plaintiff has sued defendants under the Administrative Procedure Act. It alleges in Count I that "[t]he Defendants' decision that 'a prescription contraceptive drug is reimbursable at the 90 percent rate only if it was provided for a family planning purpose' is arbitrary and capricious, an abuse of discretion, and contrary to law." Compl. ¶ 38. Count II alleges that the Board's decision upholding the disallowance of Missouri's 2009 and 2010 claims based on that decision was unlawful and arbitrary and capricious as well. Compl. ¶ 40.

I. Count I: The agency's interpretation does not violate the Social Security Act.

A. *Chevron* Step One: The agency's interpretation is not precluded by the statute.

At the first step of the *Chevron* analysis, courts must determine whether Congress has spoken directly to the question at issue. 467 U.S. at 842. The burden is on a plaintiff challenging

an agency interpretation of a statute to "do more than offer a reasonable or, even the best, interpretation" of the statute; plaintiff must instead show "that the statute *unambiguously* forecloses the [agency's] interpretation." *Vill. of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 661 (D.C. Cir. 2011). In other words, if a court determines "that statutory ambiguity has left the agency with a range of possibilities and that the agency's interpretation falls *within* that range, then the agency will have survived *Chevron* step one." *Id.* at 660 (emphasis in original).

Courts use the traditional tools of statutory construction – examination of the statute's text, legislative history, structure, and purpose – to determine whether Congress has spoken to the precise question at issue. *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012), quoting *Bell Atl. Tel. Cos. v. F.C.C.*, 131 F.3d 1044, 1047 (D.C. Cir. 1997).

Section 1396b(a)(5) requires defendants to pay states

> an amount equal to 90 per centum of the sums . . . which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies.

42 U.S.C. § 1396b(a)(5); *see also* 42 C.F.R. § 433.10(c)(1). Congress did not define the term "family planning services and supplies" in the statute, and CMS has not defined it through regulation either. *See* Pl.'s Mem. at 3, citing 42 C.F.R. § 440.40(c) (reserving definition); Defs.' Mot./Opp. at 2 (same).

Defendants argue that the lack of a statutory definition is enough to render the term ambiguous, requiring the Court to proceed to step two of the *Chevron* analysis. *See* Defs.' Mot./Opp. at 9. Plaintiff submits that even in the absence of a definition, the provision as a whole is clear. Pl.'s Opp./Reply at 5, citing *Petit*, 675 F.3d at 781.

Section 1396b governs "Payments to States," and it requires "the Secretary (except as otherwise provided in this section)" to pay states an amount equal to the federal medical assistance

percentage "of the total amount expended during such quarter as *medical assistance* under the State plan; plus" the six items enumerated at subsections (2)–(7). 42 U.S.C. § 1396b(a)(1) (emphasis added). The enumerated subsections include the requirement that the Secretary pay 90 percent of "sums expended . . . which are attributable to" a state's furnishing of "family planning services and supplies." 42 U.S.C. § 1396b(a)(5).

Section 1396d, the statute's "Definitions" section, defines "medical assistance" to mean "payment of part or all of the cost" of a list of types of "care and services." 42 U.S.C. § 1396d(a). The definition includes a list of who may receive "medical assistance," *id.* § 1396d(a)(i)–(xvii), and a list of the specific services that fall under the term. *Id.* § 1396d(a)(1)–(31).[7] That list includes:

> family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies.

Id. § 1396d(a)(4)(C). In other words, the "Definitions" section establishes what is paid for and for whom, and the "Payments to States" section sets forth how much is paid. But neither spells out what falls within the category of "family planning services and supplies."

Pointing to this structure, plaintiff argues that the two provisions read together mean that as long as a state furnishes "family planning services and supplies" within the meaning of "medical assistance" – to Medicaid recipients who wish to receive them and are of child-bearing age, including minors considered to be sexually active – CMS must pay the heightened reimbursement

7 The definition covers a broad range of care and services, from inpatient and outpatient hospital services to dental service to respiratory care services to hospice care. *See* 42 U.S.C. § 1396d(a)(1)–(2), (10), (18)–(19).

for the services and supplies, as set forth in section 1396b(a)(5). *See* Pl.'s Opp./Reply at 4–5. "[I]f x, then y – if a State provides family planning services and supplies, then it is entitled to 90 percent FFP." Pl.'s Opp./Reply at 4. According to plaintiff, defendants improperly narrowed the scope of the provision by adding a purpose requirement not found in the text, and the agency exceeded its authority when it required states to prove that a contraceptive drug was prescribed to a Medicaid recipient for a family planning purpose. Pl.'s Opp./Reply at 4–5.

But "family planning supplies" means "family planning supplies" is a circular argument, and it does not answer the first *Chevron* question: is the agency's reading *foreclosed* by the statute? *Vill. of Barrington,* 636 F.3d at 661. While Missouri's reading of the provision may be reasonable, for *Chevron* step one, it does not matter if the plaintiff offered a reasonable, or even a better interpretation of the statute; it must show that the statute unambiguously rules out the defendants' interpretation. *See Chevron,* 467 U.S. at 843 n.11. Here, nothing in either the ordinary meaning of the words in the text or the structure of the statute mandates plaintiff's interpretation. *See Petit*, 675 F.3d at 781–82; *Vill. of Barrington*, 636 F.3d at 661.

Congress did not elaborate on the meaning of the term "family planning services and supplies;" it simply included these items within the care and services covered as "medical assistance." 42 U.S.C. § 1396d(a)(4)(C). And Congress was silent on how defendants would determine the sums expended by states "*attributable* to the[ir] . . . furnishing . . . of family planning services and supplies," providing only that those sums would be reimbursed at 90 percent. 42 U.S.C. § 1396b(5) (emphasis added). Thus, Congress left CMS "with a range of possibilities" as to how to determine if a particular item or procedure is a family planning supply eligible for the 90 percent rate. *Vill. of Barrington*, 636 F.3d at 660.

Furthermore, the Court cannot find that defendants' interpretation "has clearly exceeded" the statute's terms. *Id.* at 659. Plaintiff's focus on the "effect" of a drug – relying on its National Drug Code to confirm whether it falls within the category of therapeutic contraceptive drugs, Pl.'s Mem. at 11 – is certainly one way to determine if a state's expenditure on a contraceptive drug is "attributable" to its provision of family planning services and supplies. 42 U.S.C. § 1396b(a)(5). Defendants' focus on the "purpose" of the drug – requiring a showing of why the contraceptive was in fact prescribed – is another. Defs.' Mot./Opp. at 10. Both interpretations are possible based on the text of the statute, and that ends the Court's involvement at this step of the analysis.

A review of the statute's legislative history and purpose does not alter this conclusion. There is no dispute that Congress added sections 1903(a)(5) and 1905(a)(4)(C) to the Social Security Act in 1972 to make family planning a benefit to Medicaid patients and to provide enhanced federal reimbursement for it. Pl.'s Mem. at 13; Defs.' Mot./Opp. at 11. As both parties point out, the Senate Report said:

> In addition to the provision of counseling, services and supplies *designed to* aid those who voluntarily choose *not to risk an initial pregnancy*, emphasis would be placed upon assisting those families with children who desire to *control family size* in order to enhance their capacity and ability to seek employment and better meet family needs.

S. Rep. No. 92-1230, at 297 (1972) (emphasis added). While Missouri submits that this supports its position, *see* Pl.'s Mem. at 13–14 (emphasizing that Congress sought to provide for family planning "services and supplies 'designed to' avoid pregnancy" and that contraceptives are designed to avoid pregnancy), the Court agrees with the defendants that to the extent the legislative history sheds light on Congressional intent at all, it is consistent with the notion that Congress had a family planning purpose in mind. *See* Defs.' Mot./Opp. at 11–12 (emphasizing that Congress sought to provide them to individuals who desire "not to risk an initial pregnancy" and to help

parents with children "control family size," not to subsidize contraceptives prescribed for other medical reasons).

In sum, while Congress plainly intended to make family planning a benefit to Medicaid recipients and provide enhanced reimbursement for "family planning services and supplies," the statute does not unambiguously foreclose defendants' reading of the term. Therefore, the Court must proceed to the second step of the *Chevron* analysis.

B. *Chevron* Step Two: The agency has adopted a permissible construction of the statute.

The second step of the *Chevron* analysis requires the Court to determine whether an agency's interpretation is "based on a permissible construction of the statute." *Chevron,* 467 U.S. at 843. In conducting this analysis, courts "defer to the agency's permissible interpretation, but only if the agency has offered a reasoned explanation for why it chose that interpretation." *Vill. of Barrington*, 636 F.3d at 660. At *Chevron* step two, a court "may not disturb an agency rule unless it is 'arbitrary or capricious in substance, or manifestly contrary to the statute.'" *Mayo Found. for Med. Educ. & Rsch. v. United States*, 562 U.S. 44, 53 (2011) (citation omitted).

Since CMS did not define "family planning services and supplies" by regulation, defendants cite to the State Medicaid Manual as "the primary source for CMS's interpretation" of the statute. Defs.' Mot./Opp. at 2, 13. An agency's interpretations of a statute "contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron*-style deference." *Christensen v. Harris County,* 529 U.S. 576, 587 (2000). They are "'entitled to respect' under *Skidmore v. Swift & Co.*, but only to the extent that those interpretations have the 'power to persuade.'" *Id.*, quoting *Skidmore v. Swift & Co.,* 323 U.S. 134, 140 (1944) (internal citations omitted).

As a threshold matter, the Court must decide whether there is a persuasive statement before it to "respect" at all. The parties agree that the State Medicaid Manual has remained unchanged since 1988, but they differ as to whether it in fact calls for the interpretation of the statute that the agency utilized in this case. Defs.' Mot./Opp. at 2–3; Pl.'s Mem. at 3–4. CMS expressly relied on the State Medicaid Manual in disallowing Missouri's claims, *see* Disallowance Letter, A.R. 29, and the Board deferred to CMS's interpretation of the statute in upholding the disallowance. Board Decision, A.R. 6, 8–10.[8] Yet plaintiff insists that the Manual does not require that a contraceptive drug be prescribed for a family planning purpose to be eligible for higher reimbursement. Pl.'s Mem. at 14–16. While the Manual is not a model of clarity, here too, the language favors the defendants. The Manual does not address contraceptives specifically, but it does hearken back to the legislative history and state that the 90 percent reimbursement rate only covers supplies and services prescribed for a family planning purpose.

Section 4270.B of the State Medicaid Manual, and its two subordinate paragraphs, address family planning services and supplies:

> B. Scope of Services.--The term "family planning services" is not defined in the law or in regulations. However, the Senate Report accompanying the law stresses Congress' intent of placing emphasis on the provision of services to "aid those who voluntarily choose not to risk an initial pregnancy," as well as those families with children who desire to control family size. In keeping with Congressional intent, you may choose to include in your definition of Medicaid family planning services only those

8 Plaintiff asserts that that the Board has no authority to interpret the statute and its application of the Manual is not accorded any deference because it is an adjudicatory body. *See* Pl.'s Opp./Reply at 17, citing 42 C.F.R. §§ 93.207(a), 430.42(g)(2); *S.G. Loewendick & Sons, Inc. v. Reich*, 70 F.3d 1291, 1294 (D.C. Cir. 1995); *Kiewit Power Constructors Co. v. Sec'y of Lab.*, 959 F.3d 381, 394 (D.C. Cir. 2020). But the Board made clear that it was not interpreting the statute, and it deferred to CMS's interpretation in any event. Board Decision, A.R. 6, 8–11.

> services which either prevent or delay pregnancy, or you may more broadly define the term to also include services for the treatment of infertility. . . .

State Medicaid Manual § 4270.B, A.R. 136–37. This general introductory paragraph supports an interpretation that contraceptives prescribed for medical purposes other than family planning would not fall within the scope of the permissible definition.

Two additional paragraphs fall under section 4270.B.

> 1. Services Available For FFP 90 Percent Rate.--In general, FFP at the 90 percent matching rate is available for the costs of counseling services and patient education, examination and treatment by medical professionals in accordance with applicable State requirements, laboratory examinations and tests, medically approved methods, procedures, *pharmaceutical supplies and devices to prevent conception,* and infertility services, including sterilization reversals. . . .

Id. § 4270.B.1, A.R. 137 (underlines in original, italics added). Subparagraph 1 includes contraceptives among the family planning services described in section 4270.B for which the 90 percent rate is available "[i]n general," and it does not explicitly exclude contraceptives prescribed for other purposes.[9] *Id.* But the Manual goes on:

> 2. Services Not Available For FFP 90 Percent Rate.--FFP at the 90 percent rate is not available for the cost of a hysterectomy (see §4435) nor for costs related to other procedures performed for medical reasons, such as removal of an intrauterine device due to infection. *Only items and procedures clearly provided or performed for family planning purposes may be matched at the 90 percent rate*. . . .

Id. § 4270.B.2, A.R. 137 (underlines in original, italics added). Subparagraph 2 sets clear limits on the "family planning services" eligible for reimbursement at the highest rate: "only items . . . clearly provided . . . for family planning purposes." *Id.*

---

9 One could argue that the use of the language "supplies and devices *to* prevent pregnancy," as opposed to "supplies and devices *that* prevent pregnancy," incorporated a purpose test in subparagraph B.1, but since the government has not advanced such a nuanced interpretation, and the text is, at best, ambiguous on that point, that will not be a basis for the Court's ruling.

CMS's disallowance letter recited that section 4270.B.1 of the Manual "indicates that the 90% FFP rate is available for the costs of pharmaceutical supplies and devices to prevent conception," and that section 4270.B.2 "indicates that only items and procedures clearly provided or performed for family planning purposes" may receive the 90 percent rate. Disallowance Letter, A.R. 29. For that reason, since OIG found that twenty-one Missouri claims for contraceptives were either not prescribed for a family planning purpose, or Missouri could not document that they were, the state's claims for reimbursement of those claims at the 90 percent level were disallowed. *See* A.R. 29.

Missouri contends that since section 4270.B.1 authorizes reimbursement at the higher level for "contraceptives," that is the end of the matter. *See* Pl.'s Mem. at 15. It argues that defendants are improperly conflating the two subsections of the State Medicaid Manual, importing the "family planning purposes" language in subsection 2, which concerns costs incurred for "medical reasons" that are ineligible for the 90 percent rate, to subsection 1, which concerns costs for services "to prevent pregnancy" that are eligible for the 90 percent reimbursement. *See* Pl.'s Mem. at 15.

But both paragraphs are subsections of the same paragraph – 4270.B – which sets out the agency's view of the principles intended to inform the definition of "family planning services." A.R. 136–37. And plaintiff's reading of subsection 1 completely ignores the presence of the qualifying term "[i]n general." *See* § 4270.B.1, A.R. 137 ("*In general*, FFP at the 90 percent matching rate is available for . . . pharmaceutical supplies and devices to prevent conception . . . .") (emphasis added).

Moreover, while the first sentence of subsection 2 does concern costs for "procedures performed for medical reasons," which are *not* available for the higher rate, the second sentence is much broader; it states a general rule describing the "*[o]nly* items and procedures" that *are*

available. § 4270.B.2, A.R. 137 (emphasis added). These circumstances support the agency's contention that the general statement in B.1 and the clear prohibition in B.2 can and should be read together, and that the Manual is consistent with the agency's current position that contraceptives, like any other "items," must meet the family planning purpose test.

While the Manual may not unequivocally foreclose plaintiff's interpretation, it is certainly consistent with the agency's reading. So to the extent the Manual is a longstanding statement of policy entitled to respect, it supports a finding that the interpretation advanced in the Disallowance Letter is a reasonable and permissible interpretation of the statute in light of its legislative history and purpose.

The parties also point to other agency letters and decisions, which were cited by the Board, to support their arguments. *See* Pl.'s Mem. at 16–20; Defs.' Mot./Opp. at 16–18; Board Decision, A.R. 5–9. First, the Board pointed to a State Health Official ("SHO") letter issued on June 14, 2016. *See* Board Decision, A.R. 8–9, citing SHO Letter #16-008.[10] The letter's stated purpose was to "clarify previous guidance on the delivery of family planning services and supplies to all Medicaid beneficiaries . . . effective immediately," including "the purpose of the family planning visit." A.R. 349. It addressed dual purpose visits and explained, "when family planning services and supplies are delivered during a medical visit in which family planning and non-family planning services are furnished," the family planning costs are eligible for the higher reimbursement if "[t]he family planning purpose" is to "prevent[] or delay[] pregnancy." A.R. 350–51. Although this letter is another expression of the need to show a family planning purpose to obtain reimbursement at the 90 percent level for a covered medical expense in general, plaintiff correctly points out that

10 SHO Letter #16-008 appears in the administrative record at A.R. 349–55.

it does not specifically announce a need to show such a purpose for contraceptives in particular. Pl.'s Opp./Reply at 14.

Two 1990 CMS letters cited by the Board in support of its decision do not directly address the contraceptives issue either. *See* Board Decision, A.R. 9. A February 22, 1990 CMS letter commented on the issue of whether pregnancy testing – which "*is normally not performed primarily for family planning purposes*" – may be eligible for higher reimbursement: it may be "when provided as part of an initial or annual family planning examination by a family planning clinic . . . performed primarily for family planning purposes." A.R. 138 (emphasis added). A February 1, 1990 letter declined a state's request "to include colposcopy, biopsy, and cryotherapy" services as family planning services because they are not performed primarily for family planning purposes but for medical reasons "regardless of whether or not the woman w[as] seeking to limit or expand the size of her family." A.R. 139. These letters similarly reflect the agency's general understanding that the 90 percent rate is limited, but both concern services clearly provided for the "medical reasons" governed by section 4270.B.2 of the Manual, and do not go so far as to address

contraceptives, which always have the effect of limiting pregnancy even if not prescribed for that goal.[11]

The plaintiff directs the Court to the CMS Financial Management Review Guide, which it contends is "the only authority that explicitly answers the key question" here. Pl.'s Mem. at 20. The Review Guide is a CMS publication that provides instructions for agency staff performing financial management reviews of claims for family planning services. *See* 2010 Review Guide, A.R. 103–137, at A.R. 105; 2002 Review Guide, A.R. 149–168, at A.R. 151. But the Review Guide itself advises the reader that it is not intended to be definitive. *See* 2010 Review Guide, A.R. 105 (stating the guide "reflects current law and policy decisions" but that there may be circumstances requiring "additional methods and review procedures not specified here"); *see also State of Illinois Dep't of Healthcare & Fam. Servs. v. U.S. Dep't of Health & Hum. Servs.*, No. 06 C 6402, 2008 WL 877976, at *4 (N.D. Ill. Mar. 28, 2008) (describing the Title XIX Financial Management Review Guide at issue in that case as "provid[ing] interpretative guidelines"). And a close reading reveals that, as with other resources cited, the Review Guide does not answer the

11 The Board also cited a 1992 decision, *New York Department of Social Services*, DAB No. 1364 (1992), which concerned a variety of medical services claimed by the state for the higher family planning rate, including for an eight-year-old with an ear infection, for an infant with a skin disorder, for a vaginal delivery, and for a patient with asthma. *New York State Dep't of Soc. Servs.*, DAB No. 1364, 1992 WL 685430, at *5 (1992); *see* Board Decision, A.R. 17–18. The Board held in that case that checking the "family planning indicator" on a Medicaid form was not sufficiently reliable on its own to support the higher reimbursement, and that the state was required to substantiate the services' relation to family planning. Board Decision, A.R. 18; *New York State Dep't of Soc. Servs.*, 1992 WL 685430, at 5. As was the case with the letters cited above, the decision made reference to section 4270.B.2 of the Manual, *see* Board Decision, A.R. 17 (this "holding was supported by the statement in section 4720.B.2"), but it does not bear directly on the more narrow issue before the Court of whether the prohibition in subsection B.2 serves to narrow the scope of what is covered under B.1.

question with such clarity as to render the agency's interpretation of the statute impermissible for *Chevron* purposes; indeed, it is internally inconsistent.

The Review Guide includes appendices that divide procedure and drug codes into categories that reflect how likely it is that the 90 percent rate would be allowed: "I. Never or Almost Never a Family Planning Service;" "II. Possibly a Family Planning Service;" and "III. Almost Always a Family Planning Service, A. Sterilization Procedure, B. Infertility Procedure, C. Other Family Planning Procedure." A.R. 165–68.

The very existence of these imprecise categories – "almost never," "possibly," and "almost always" reimbursable at 90 percent – seems to confirm defendants' contention here that the drug code alone is not meant to be dispositive. Like the Manual, the Review Guide indicates that certain services and procedures are generally eligible for the higher family planning reimbursement level while others are not. It does this by categorizing procedure and drug codes, but it does not *require* that all contraceptives, no matter why they are prescribed, are reimbursable at 90 percent. Yet within Section III, which is entitled "*Almost* Always a Contraception/Sterilization Family Planning service," A.R. 127 (emphasis added), the Guide includes a list of "CPT/HCPCS Codes Which Are *Always* Considered a Contraception/Sterilization Family Planning Service Reimbursable at the 90% Federal Match Rate," A.R. 129 (emphasis added). And that list includes the code for oral contraceptives: S4993. A.R. 129, 371.

So the Review Guide also contains support for plaintiff's position. But given the fact that it is not intended to be a policy statement that controls reimbursement decisions, but rather a general guide for claim review by the agency, and the fact that at best, it leaves one scratching one's head, the Court cannot find it to be the sort of persuasive policy statement that would warrant *Skidmore* respect, and require the Court to reject the agency's interpretation of the statute.

Christensen, 529 U.S. at 587, citing *Skidmore*, 323 U.S. at 140. For all of these reasons, then, the agency's interpretation survives step two of the *Chevron* analysis as well, and summary judgment will be granted in favor of the defendant on this issue.

The Review Guide does raise a serious question, though, which is: how can the agency publish instructions for reviewing family planning claims that designate oral contraceptives as "always" subject to the 90 percent matching rate, and yet claim at the same time that its consistent position has always been that oral contraceptives that serve other purposes are *not* eligible? This leads directly to the issue be addressed in the second section of this opinion.

II. The Board's Decision is Arbitrary and Capricious because it Deferred to a Change in the Interpretation of the Statute Implemented Without Explanation.

An agency action may be deemed arbitrary and capricious if it departs from a prior policy *sub silentio. FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009); *see Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644–45 (D.C. Cir. 2020) ("Reasoned decision-making requires that when departing from precedents or practices, an agency must offer a reason to distinguish them or explain its apparent rejection of their approach.") (internal quotation marks omitted). Missouri appealed the disallowance to the Board, and the Board upheld it. While the Court has found that the agency's interpretation of the statute is a permissible one, it also concludes that defendants have not done enough to put states on notice that they must differentiate claims for contraceptives prescribed for purely medical purposes from the vast majority that are prescribed to prevent pregnancy, and that therefore, it was unreasonable for the Board to uphold the CMS disallowance on appeal.

The APA requires that agencies explain the bases for their decisions. *Wheeler*, 956 F.3d at 644–45. This "foundational precept of administrative law is especially important where . . . an

agency changes course." *Id.* at 644. When taking an action that revises a prior agency action, the agency must "display awareness that it *is* changing position" and provide a reasoned explanation for why it is changing prior policy where it is based on new factual findings or "its prior policy has engendered serious reliance interests that must be taken into account." *Fox Television*, 556 U.S. at 515 (emphasis in original).

> Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change. When an agency changes its existing position, it need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate. But the agency must at least display awareness that it is changing position and show that there are good reasons for the new policy. In explaining its changed position, an agency must also be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account. In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.

Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 221–22 (2016) (internal citations, quotation marks, and edits omitted). Although defendants maintain that they have not changed course, the administrative record of this case indicates otherwise.

The Board acknowledged that its role in the administrative appeal was to decide "whether the disallowance is consistent with applicable statutes and regulations." Board Decision, A.R. 6. It explained that generally, it "will defer to, and apply, a federal agency's interpretation of a statute that the agency is responsible for implementing if that interpretation is 'reasonable' and the non-federal party had adequate and timely notice of the interpretation." Board Decision, A.R. 10. The parties differ as to whether the second condition was satisfied.

Noting the absence of any statutory definition for "family planning services and supplies," the Board relied on "section 4270 of the State Medicaid Manual, and subsequent CMS policy

statements that apply the manual's guidance" in reaching its decision. Board Decision, A.R. 8. Like CMS, the Board recited the language of the subsections and read them together to mean that "90 percent FFP is unavailable for a service or supply that may result in, or have the effect of, delaying or preventing pregnancy but which is provided to serve a non-family planning purpose." Board Decision, A.R. 8–10; *see also* Board Decision, A.R. 13, 13 n.15 ("The mere fact that a drug in the contraceptive therapeutic class has been prescribed to a woman of child-bearing age is insufficient evidence of the drug's eligibility for the enhanced rate" since contraceptive drugs are commonly prescribed for medical reasons, such as to treat acne or endometriosis). Deferring to CMS's interpretation of the statute and the Manual, the Board concluded:

> CMS could lawfully disallow 90 percent FFP claimed by the State for prescription contraceptive drugs absent some showing that the drugs had been prescribed for a family planning purpose (i.e., for the purpose of delaying or preventing pregnancy).

Board Decision, A.R. 11.

Plaintiff submits that the Board erred in holding that the State Medicaid Manual gave states "adequate and timely notice of" defendants' interpretation of the statute. Pl.'s Mem. at 14–16; *see* Pl.'s Opp./Reply at 8–11 (arguing that CMS has never issued a regulation or informal interpretation reflecting the interpretation defendants advance here).[12] As the discussion of the Manual in section I above demonstrates, the Manual can be more easily squared with the agency's current position than plaintiff's. But in the Court's view, it is not sufficiently unambiguous to

12 The Board found that plaintiff did not "allege that it lacked adequate notice of that longstanding interpretation when it made and claimed FFP for the contraceptive drug expenditures implicated by the disallowance," Board Decision, A.R. 11, but Missouri did argue in its appeal brief that states were not given adequate notice. *See* Missouri Appeal Br., A.R. 66–68.

support defendants' contention that the states have been well aware of the agency's reading all along.

Defendants repeatedly insist that their interpretation of the statute is long-standing. *See* Defs.' Mot./Opp. at 1, 3, 12, 15, 21. They rest this argument on their statutory arguments, the Manual, agency guidance, and the Board's Decision. Defs.' Mot./Opp. at 8–21. But the Board was clear that it was not undertaking to interpret the statute. Board Decision, A.R. 6–7. Since the other documents are consistent with the agency's current interpretation, but they do not compel the application of that reading, one needs to look further. And it is notable that the Board reached its decision without addressing the line of OIG audits in its own administrative record.[13]

The administrative record shows that in 2007, before the 2014 Missouri audit report at issue here, OIG issued audit reports with respect to family planning claims submitted by New Jersey and New York. *See* N.J. Audit; N.Y. Audit. In these audits, OIG worked with pharmacists in each state, state officials, and a CMS physician to identify whether a drug had been claimed at the 90 percent rate even though its National Drug Code indicated that it was not a drug "related to family planning." *See* N.J. Audit, A.R. 205; N.Y. Audit, A.R. 229. If a code did not appear to be related to family planning, OIG requested the underlying medical records to " further validate" its conclusion that the drug was not eligible for the 90 percent rate. N.J. Audit, A.R. 205; N.Y. Audit, A.R. 229; *see also* N.J. Audit, A.R. 207, 210–12 (investigating claims for non-contraceptives, such as hormone replacement therapy); N.Y. Audit, A.R. 229, 231, 235–37 (same). OIG recommended

13 The Board did note that Missouri's appeal brief cited the North Carolina, Kansas, and Colorado audits in the context of raising policy and other administrative concerns, but the Board did not address the audits. *See* Board Decision, A.R. 23–24 n.27, citing Missouri Appeal Br., A.R. 64–65.

that both states review the National Drug Codes in their Medicaid Management Information Systems ("MMIS") to verify that the codes relate to family planning. N.J. Audit, A.R. 208; N.Y. Audit, A.R. 232. Neither New Jersey nor New York challenged this recommendation or the conclusion that they had improperly claimed the higher rate for some drugs. *See* N.J. Audit, A.R. 213–14; N.Y. Audit, A.R. 240.

It is important to note, though, that in these two audits, OIG only reviewed medical records for prescriptions of drugs with codes that on their face did not appear to relate to family planning, and it only recommended that the states confirm that the National Drug Codes appearing in their state Medicaid systems in fact related to family planning. So those audits indicate that as of 2007, defendants did not question claims for prescription drugs that, based on their National Drug Codes, appeared to relate to family planning. Indeed, subsequent audits in the administrative record show that many states submitted family planning pharmacy claims based on these drug codes alone.

The administrative record shows that beginning in 2010, OIG took a different approach. In 2010, OIG issued a report on an audit of Kansas's family planning claims. OIG selected a sample of 100 prescription drug claims, reviewed the medical records for all of them, and found that some were "unrelated to family planning," but were prescribed instead "for hormone or bleeding control and for therapeutic reasons." Kan. Audit, A.R. 281, 283. OIG found that the state's MMIS identified "prescription drug claims . . . on a list of National Drug Codes," which "typically relate to an allowable Family Planning diagnosis," but also included "prescription drug claims that related to both family planning and non-family planning diagnoses." Kan. Audit, A.R. 283. It recommended that Kansas "strengthen" its internal controls to ensure that edits in its MMIS "appropriately identify claims that are ineligible" for the higher rate. Kan. Audit, A.R. 284. Kansas told OIG that this recommendation would require "providers to create a unique and

unprecedent process for marking each prescription of contraceptives with the diagnosis code," *id.*, to which OIG responded only that "it is the State agency's responsibility" to administer its program in accordance with federal requirements. Kan. Audit, A.R. 285.

Subsequent audits followed the same methodology and made the same recommendations. *See* Colo. Audit, A.R. 299–309 (reviewing medical records for all sampled claims and finding errors because "the State agency's internal controls automatically classified contraceptive drugs as family planning services even if the medication may have been prescribed for another (non-family planning) purpose"); N.C. Audit, A.R. 250–60 (reviewing medical records for all sampled claims); Missouri Audit, A.R. 326, 332, 336–37 (reviewing medical records for all sampled contraceptive claims and recommending that the state strengthen its internal controls, which "classified contraceptive drugs as family planning services even in cases when the medication in question may have been prescribed for another (non-family planning) purpose").

Unlike New Jersey and New York in 2007, North Carolina, Kansas, Colorado, and Missouri all objected to OIG's recommendations. North Carolina explained that its MMIS edits for identifying family planning services eligible for the 90 percent based on therapeutic classification codes has been "in place for over a decade," and that requiring all claims to be prescribed for a family planning purpose would require pharmacies to include a diagnosis code on a claim, which is inconsistent with medical practice and would burden providers and pharmacies. N.C. Audit, A.R. 266–67 (North Carolina response letter); *see also* Colo. Audit, A.R. 315 (Colorado response letter).

The states also complained that OIG's audits were inconsistent with prior audits. N.C. Audit, A.R. 267 (noting that many other states use the same methodology, and in the majority of OIG audits, "OIG found no issue with states claiming enhanced FFP on all claims for prescriptions with drugs that had been appropriately assigned to the contraceptive therapeutic classification code"); Colo. Audit, A.R. 315–316 (Colorado response letter, highlighting an OIG audit released five months earlier that did not review claims that "contained the appropriate . . . therapeutic classification codes," and objecting to the requirement to include diagnosis codes on family planning pharmaceutical claims) (emphasis omitted); Kan. Audit, A.R. 291 (Kansas response letter noting that its "queries to other states found none that require a diagnosis as part of a pharmaceutical claim").

In response to Colorado's complaint that its audits were inconsistent, OIG stated:

> In other audits, the OIG designed its tests to determine whether the other State agencies had systems in place to correctly identify contraceptive therapeutic classification codes. For this audit, not only did we verify that the claims contained these required codes, but we also performed an additional step in that we asked the prescribing physicians whether the prescriptions were actually intended for family planning purposes. This additional audit step was not performed in other OIG audits.

Colo. Audit, A.R. 309. In response to North Carolina, OIG stated only that its audits "vary in objective, scope, and methodology." N.C. Audit, A.R. 260.

Plaintiff argues that "CMS has never issued a regulation, interpretive rule, or other guidance interpreting the [statute] to impose a 'family planning purpose' requirement on supplies that are expressly designed to prevent conception, such as oral contraceptives." Pl.'s Opp./Reply at 2; *see id.* at 1 (arguing that the Board Decision and defendants' briefs to this Court are the first time CMS "has publicly announced" this interpretation). The audit reports in the administrative record and described above, along with OIG's own statement, show that OIG changed tack in how

it was applying the statute in its audits. *See* Colo. Audit, A.R. 309 ("we also performed an additional step . . . not performed in other OIG audits"). The administrative record also shows that defendants' "long-standing" interpretation of the statute was news to North Carolina, Kansas, Colorado, and Missouri, and contrary to how they programmed their state claiming systems. OIG advised individual states in their audit reports that any differences in its audits of family planning claims reflect merely a change in audit methodology. But the record indicates that states programmed their systems for pharmacy claims based on that prior methodology, some relying on prior OIG practice for more than a decade. *See, e.g.*, N.C. Audit, A.R. 267. For these reasons, the Court finds that OIG's prior audit practices "engendered serious reliance interests" by the states, which required defendants to provide a reasoned explanation of the change. *Fox Television*, 556 U.S. at 515; *see also* Review Guide, A.R. 129 ("The following CPT and HCPCS codes are always considered family planning (contraception or sterilization) services. . . . S4993").

Notwithstanding this apparent change, the Court has found no indication that defendants ever explained the change, as is required by the APA. *See Fox Television*, 556 U.S. at 515; *see also Wheeler*, 956 F.3d at 644–45. They defend this omission by repeating their contention that nothing has changed. Defs.' Mot./Opp. at 1, 3, 12, 15, 21. But to the extent the defendants rely on the set of agency letters and decisions in the record as evidence that states were already aware of how the agency would apply the statute and the Manual, those letters and decisions cannot be deemed to be the source of the necessary notice.

First, SHO Letter #16-008 was issued in 2016, *after* all of the OIG audits in the administrative record had been conducted. *See* Board Decision, A.R. 8–9; A.R. 349–55. Moreover, the plain language of the letter announces a change: it was described as a clarification, "effective immediately," to "*previous* guidance on the delivery of family planning services and supplies." A.R. 349 (emphasis added). So to the extent defendants rely on the letter to show that states were generally aware of the agency's reading of the statute, the letter shows that it still needed clarifying in 2016 and whatever clarification was provided was not available to Missouri when it submitted its claims and underwent the audit. Furthermore, as explained in section I.B above, neither of the 1990 CMS letters nor *New York Department of Social Services*, DAB No. 1364 (1992), addresses the issue.

Indeed, defendants' briefs and the Board Decision contain no glimmer of awareness that the agency has changed its position at all. Given the administrative record, the Court finds that defendants' failure to announce and explain the change in audit practices was arbitrary and capricious, even if the new approach did not violate the statute.

It is incumbent upon the agency to issue clear guidance as to how it intends to treat contraceptives in the future, to ensure that its Manual, Review Guide, and other publications are all consistent with that guidance, and to explain why it has adopted the new approach notwithstanding the concerns raised by the states about the significant burdens that will be imposed on pharmacies and physicians. Since the parties have not briefed the merits of the policy or

whether the agency's decision to proceed in that fashion is reasonable,[14] this opinion expresses no view on that matter.

CONCLUSION

For the reasons set forth above, the parties' cross-motions for summary judgment [Dkt. ## 14, 20] will each be **GRANTED** in part and **DENIED** in part; the Court will enter judgment in favor of defendants on Count I, but it will grant plaintiff's motion as to Count II and order that HHS Departmental Appeals Board Decision No. 3019 and the underlying disallowance upheld by that decision be vacated.

A separate order will issue.

AMY BERMAN JACKSON
United States District Judge

DATE: March 31, 2022

---

14 Under *State Farm*, 463 U.S. 29, a court reviewing agency action under the APA "must 'consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.'" *Id.* at 43, quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974).

> Normally, an agency [action] would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider any 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.

463 U.S. at 43. "Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." *Bowman Transp.*, 419 U.S. at 285, quoting *Citizens to Pres. Overton Park*, 401 U.S. 402, 416 (1971) (internal quotation marks omitted). A court must be satisfied, though, that the agency has examined the relevant data and articulated a satisfactory explanation for its action, "including a rational connection between the facts found and the choice made." *Leavitt*, 460 F.3d at 6 (citations and internal quotation marks omitted).