COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT CIVIL ACTION No. 2084CV01604

RONALD GOLDMAN & 27 OTHER TAXPAYERS

vs.

SECRETARY OF THE EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION TO DISMISS AND PLAINTIFFS' CROSS-MOTION FOR PRELIMINARY INJUNCTION¹

Ronald Goldman and twenty-seven other Massachusetts taxpayers (the "Plaintiffs") bring this action under G.L. c. 29, § 63, challenging the legality of the expenditure of state funds by the Commonwealth's Medicaid program, MassHealth, to reimburse medical providers of neonatal male circumcisions performed in the absence of a diagnosed medical condition requiring the procedure. The MassHealth program is administered by the Defendant, Secretary of the Executive Office of Health and Human Services ("MassHealth" or the "Defendant"), which now moves to dismiss the Plaintiffs' Verified Complaint ("Complaint") pursuant to Mass. R. Civ. P. 12(b)(6). For the reasons which follow, the Defendant's motion shall be <u>ALLOWED IN PART</u> and <u>DENIED IN PART</u>.

¹ The Court acknowledges the amicus briefs submitted by Morten Frisch, M.D., Ph.D., D.Sc. and Doctors Opposing Circumcision.

² No action shall be taken on the Plaintiffs' Cross-Motion for Preliminary Injunction, it appearing to the Court, and having the assent of the parties, that the record for such matter is not yet sufficiently developed.

BACKGROUND

I. The Federal Medicaid Program

The Medicaid program was established in 1965 in Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Act"). Medicaid was designed to provide federal financial assistance to states that choose "to furnish medical assistance to certain categories of needy persons." Moe v. Secretary of Admin. & Finance, 382 Mass. 629, 633 (1981); see also 42 U.S.C. § 1396-1. At the federal level, the Medicaid program is administered by the Centers for Medicare & Medicaid Services ("CMS"), a division of the United States Department of Health and Human Services ("HHS"). Douglas v. Independent Living Ctr. of. S. California, Inc., 565 U.S. 606, 610 (2012). States choosing to participate in the program must submit a plan of administration to CMS that complies with the Act and with regulations promulgated by HHS. See 42 U.S.C. § 1396a; Guilfoil v. Secretary of Exec. Office of Health & Human Servs., 486 Mass. 788, 789 (2021).

"Participating States are required to cover the costs of care for the 'categorically needy,' which the [A]ct defines as those individuals who are unable to cover the costs of their basic needs and who already receive or are eligible for certain forms of public assistance." <u>Daley v. Secretary of Exec. Office of Health & Human Servs.</u>, 477 Mass. 188, 190 (2017). States may additionally elect to provide benefits to "medically needy" individuals, defined to include "people who have income and resources to cover the costs of their basic needs but not their necessary medical care." <u>Id.</u> (citation omitted); <u>see also 42 U.S.C. § 1396a(a)(10)(C)</u>.

³Although it is often thought that Medicaid involves the dollar-for-dollar reimbursement of medical care for the indigent by the federal Government, the program is actually "a cooperative one" that requires participating states to pay between 17% and 50% of the annual costs that their programs incur for patient care. <u>Arkansas Dept. of Health & Human Servs.</u> v. <u>Ahlborn</u>, 547 U.S. 268, 275 (2006). The amount of federal assistance states receive is determined by a formula tied to each state's per capita income. <u>See</u> 42 U.S.C. § 1396d(b); <u>Ahlborn</u>, 547 U.S. at 275 & n.4.

Participating states are also required to cover certain types of medical assistance, including, *interalia*, "physicians' services," which are defined as "professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls" 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(5); 1395x(q); see also 42 C.F.R. § 440.50 (defining "physicians' services" as services "furnished by a physician — (1) Within the scope of practice of medicine or osteopathy as defined by State law; and (2) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy").

Beyond these federal requirements, "states have wide latitude to determine the scope of coverage and to institute wide-ranging and comprehensive medical programs under their medical assistance plans." Roe v. Norton, 522 F.2d 928, 933 (2d Cir. 1975). To that end, the Act identifies various optional categories of medical assistance that states may choose to provide. Some of these categories are highly specific, such as eyeglasses and prosthetic devices, and others more broadly framed, such as "medical care, or any other type of remedial care recognized under State law" 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a); 42 C.F.R. § 440.225. Accordingly, Medicaid coverage evidences "a high degree of diversity from state to state, reflecting each state's own determination of its medical and social priorities." Roe, 522 F.2d at 933.

Each state's Medicaid plan must also include "reasonable standards" for determining both eligibility for coverage and the extent of medical assistance to be provided, which standards must be "consistent with the objectives" of the Act and "provide such safeguards as may be necessary to assure . . . that care and services will be provided in a manner consistent with simplicity of administration and the best interests of the recipients." 42 U.S.C. §§ 1396a(a)(17), (19). Further, all state plans must:

"provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area[.]"

42 U.S.C. § 1396a(30)(A) ("Section 30(A)").

Once a state plan is approved by CMS, the federal Government subsidizes a formulaic portion of the state's expenses in administering its Medicaid program. 42 U.S.C. §§ 1396a(b), 1396b. If the United States Secretary of Health and Human Services (the "Federal Secretary") later determines that a state has failed "to comply substantially" with the requirements set forth in 42 U.S.C. § 1396a or with any aspects of the state's own plan, he may withhold the state's federal reimbursement payments until he "is satisfied that there will no longer be any such failure to comply." 42 U.S.C. § 1396c.

II. <u>Massachusetts' Medicaid Program</u>

A. MassHealth Overview

The Commonwealth's Medicaid program, more commonly known as MassHealth, is administered by the Defendant in accordance with the terms of G.L. c. 118E. Chapter 118E, section 15 requires MassHealth to "provide Medicaid benefits" for all medical care and services required under the federal Act, and accords the Defendant discretion regarding whether and to what extent to provide Medicaid benefits "for such additional medical care or services" as federal law permits. G.L. c. 118E, § 15. In this connection, MassHealth is required to "formulate such methods, policies, procedures, standards and criteria, except medical standards and criteria, as may be necessary for the proper and efficient operation of [MassHealth] in a manner consistent with simplicity of administration and the best interests of recipients." G.L. c. 118E, §

12. The agency thus "may adopt, promulgate, amend and rescind rules and regulations suitable or necessary to carry out" its statutory obligations, <u>id.</u>, and determine the "amount, duration and scope" of covered care. See G.L. c. 118E, § 15; see also G.L. c. 118E, § 7 (granting MassHealth the power "to make, amend, and repeal rules and regulations for the management of its affairs"). "Such rules and regulations may include appropriate limitations on care and services based on such criteria as medical necessity or utilization control procedures." G.L. c. 118E, § 15.

Pursuant to its statutory authority, the Defendant enacted 130 Code Mass. Regs. § 450.204 ("Section 450.204"), which regulation states that MassHealth "does not pay. . . provider[s] for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service . . . where such service . . . is not medically necessary." See also 130 Code Mass. Regs. § 433.451(B)(1) (MassHealth does not pay for surgery services that are "experimental, unproven, cosmetic, or otherwise medically unnecessary"). Section 450.204 further provides that:

"(A) A service is medically necessary if

- (1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and
- (2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency."

Section 450.204 additionally requires medically necessary services to "be substantiated by records including evidence of such medical necessity and quality," and dictates that providers make such records available to MassHealth upon request. Moreover, all inpatient services

⁴ "Rules and regulations which restrict eligibility or covered services require a public hearing under section 2 of chapter 30A." G.L. c. 118E, § 12.

provided to MassHealth members are subject to a process known as "utilization review," whereby the Defendant "will review inpatient services provided to members to determine the medical necessity . . . of such services." 130 Code Mass. Regs. § 415.414(B). "If, as the result of any review, the [Defendant] determines that any hospital inpatient admission, stay, or service provided to a member was not covered under the member's coverage type . . . the [Defendant] will not pay for that inpatient admission, stay, or service." Id. § 415.414(D).

B. MassHealth's Coverage of Neonatal Male Circumcision

"[P]hysicans are required to bill MassHealth for their services using numeric codes . . . listed in the current procedural terminology manual published by the American Medical Association" Jacobs v. Massachusetts Div. of Med. Assistance, 97 Mass. App. Ct. 306, 309 (2020). Each of these codes, known as "CPT codes," is assigned a rate of reimbursement. Id. The CPT codes for neonatal male circumcision (54150 and 54160) are classified as surgery CPT codes. See 101 Code Mass. Regs. § 316.05(2). The scope of MassHealth's coverage for services billed under a surgery CPT code is set forth in its regulations governing physicians' services. See 130 Code Mass. Regs. § 433.000 et seq.

Pursuant to these particular regulations, MassHealth "pays for all medicine and surgery CPT codes in effect at the time of service, except for those codes listed in Section 602 of Subchapter 6 of the Physician Manual." Id. § 433.452; see also id. § 433.408(A) (codes listed in Section 602 of Subchapter 6 of the Physician Manual require prior authorization to determine medical necessity as a pre-condition for reimbursement). The regulations thus imply, and the Plaintiffs expressly allege, that no prior authorization is required for care and services

⁵ This regulation states that all surgery CPT code descriptions are listed on spreadsheets on the Defendant's website at www.mass.gov/regulations/101-CMR-31600-surgery-and-anesthesia-services. The Court has confirmed that the CPT codes for neonatal male circumcision are thus listed on the relevant spreadsheet.

encompassed by the former group of codes, which includes the CPT codes for neonatal male circumcision. Reimbursement for care and services falling under these codes is nonetheless subject to the medical necessity requirements of 130 Code Mass. Regs. § 450.204. See id. § 433.452 (reimbursement for all medicine and surgery CPT codes in effect at the time of service is "subject to all conditions and limitations described in MassHealth regulations at 130 CMR 433.000 and 450.000: Administrative and Billing Regulations."); see also id. § 433.451(B)(6) (MassHealth does not pay for "services billed with otherwise covered service codes when such codes are used to bill for nonpayable circumstances as described in 130 CMR 433.404") and id. § 433.404(B) (identifying the provision of a "medically unnecessary procedure or treatment" as a nonpayable circumstance).

III. The Plaintiffs' Petition

Plaintiff Ronald Goldman ("Goldman") is the founder and executive director of the Circumcision Resource Center, a non-profit organization dedicated to informing the public about the practice of neonatal infant circumcision. On April 21, 2017, Goldman sent the Defendant a letter asking him to identify his position on "stopping MassHealth payments for elective neonatal male circumcisions which are done for cosmetic and other non-medical motives[.]" Goldman's letter stated, in pertinent part, that:

"No national medical organization in the world claims that neonatal male circumcisions are necessary, and a dozen national and international organizations oppose circumcision. The Centers for Medicare and Medicaid Services code for elective circumcision is defined as 'circumcision in the *absence* of medical indication.' It is 'elective surgery for purposes other than remedying health states.' The foreskin is a natural, healthy, functioning body part. <u>Therefore, using Medicaid funding for elective neonatal male circumcision is unlawful under both federal and state law."</u>

(Emphasis in original).

On May 12, 2017, Goldman received a response from the Defendant. That response stated, in relevant part, as follows:

"MassHealth coverage of clinical services is based on recommendations of professional medical societies and expert panels, a review of existing peer-reviewed literature, and the most recent data as detailed below.

The American Academy of Pediatrics (AAP) updated its Circumcision Policy Statement in 2012. In it the AAP Task Force on Circumcision reviewed over 1,000 studies in the English-language medical literature from 1995 to 2010 and concluded that 'preventative health benefits of elective circumcision of male newborns outweighs the risks of the procedure.' The AAP task force recommended 'it is important for that [sic] clinicians routinely inform parents of the health benefits and risks of male newborn circumcision in an unbiased an [sic] accurate manner' and 'parents should ultimately decide whether circumcision is in the best interests of their male child.' This policy statement is also supported by the American Congress of Obstetricians and Gynecologist[s] (ACOG).

The American Urological Association's board of directors re-affirmed its circumcision policy statement in 2012 that states 'that neonatal circumcision has potential medical benefits and advantages as well as disadvantages and risks' and recommended that 'when circumcision is being discussed with parents and informed consent obtained, medical benefits and risks, and ethnic, cultural, religious and individual preferences should be considered.'

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. . . . MassHealth is dedicated to providing comprehensive, evidence-based coverage that best serves the healthcare needs of its members. For this reason neonatal circumcision remains a covered service."

Goldman and twenty-seven other Massachusetts taxpayers subsequently filed the instant action. In their Verified Complaint, the Plaintiffs allege that MassHealth is aware that most neonatal circumcisions are performed at the election of parents, for cultural and religious reasons unrelated to medicine, and are not "medically necessary" under MassHealth's own definition of the term. The Plaintiffs further allege that, notwithstanding this awareness, MassHealth has a policy and practice of providing Medicaid coverage for neonatal male circumcisions without subjecting claims seeking reimbursement for the procedure to utilization review or otherwise

inquiring into whether the procedure was in fact medically necessary. The Plaintiffs argue that MassHealth's circumcision policy thus violates state and federal law, and seek to enjoin MassHealth from reimbursing physicians and hospitals for performed circumcisions unless a physician provides a valid diagnosis of a medical condition requiring the procedure and a certification that it was in fact medically necessary. The Plaintiffs also seek an order requiring MassHealth to establish an institutional review board to ensure compliance, and further requiring MassHealth to report to the Board of Registration in Medicine any physicians who unlawfully seek reimbursement for circumcisions that are not medically necessary.

DISCUSSION

I. Motion to Dismiss Standard

The Defendant has moved to dismiss the Plaintiffs' claims pursuant to Mass. R. Civ. P. 12(b)(6). To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "factual 'allegations plausibly suggesting (not merely consistent with)' an entitlement to relief"

Iannacchino v. Ford Motor Co., 451 Mass. 623, 636 (2008) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007)). "The allegations must be more than 'mere labels and conclusions,' and must 'raise a right to relief above the speculative level." Buffalo-Water 1, LLC v. Fidelity

Real Estate Co., LLC, 481 Mass. 13, 17 (2018) (quoting Galiastro v. Mortgage Elec. Registration Sys., Inc., 467 Mass. 160, 165 (2014)). The Court's review is limited to the factual allegations of the complaint and to facts contained within any annexed exhibits, see Eigerman v. Putnam Invs., Inc., 450 Mass. 281, 285 n.6 (2007), as well as any matters of public record and documents relied upon in the complaint. See Marram v. Kobrick Offshore Fund, Ltd., 442 Mass. 43, 45 n.4

⁶ It is worth noting that, although the Plaintiffs contend that neonatal male circumcision is *never* medically necessary, they have not asked the Court to declare this as a matter of law. The Verified Complaint's prayers for relief instead seek only equitable remedies that would require *MassHealth* to assess the medical necessity of the procedure in cases where Medicaid reimbursement is sought.

(2004); Schaer v. Brandeis Univ., 432 Mass. 474, 477 (2000). The Court must "accept as true the factual allegations in the complaint and the attached exhibits, [and] draw all reasonable inferences in the plaintiff's favor. . . ." Buffalo-Water 1, LLC, 481 Mass. at 17.

II. Analysis

The Plaintiffs bring this action under G.L. c. 29, § 63, which gives Massachusetts taxpayers the right to challenge the Commonwealth's expenditure of funds "for any purpose or object or in any manner other than that for and in which. . . [it] has the legal and constitutional right and power to expend money or incur obligations[.]" The Plaintiffs argue that 42 U.S.C. § 1396a(30)(A) and 130 Code Mass. Regs. § 450.204, independently and in combination, prohibit MassHealth from covering neonatal male circumcisions under Medicaid without conducting any inquiry as to whether the procedure was medically necessary in each case for which reimbursement is sought. Therefore, according to the Plaintiffs, MassHealth's putative policy of covering neonatal circumcisions without verifying medical necessity produces an illegal expenditure of state funds that may be enjoined pursuant to G.L. c. 29, § 63.

In his Motion to Dismiss, the Defendant argues that violations of 42 U.S.C. § 1396a(30)(A) and 130 Code Mass. Regs. § 450.204 are not subject to private enforcement or to taxpayer challenges brought pursuant to G.L. c. 29, § 63. Accordingly, the lone question presented for decision is whether G.L. c. 29, § 63 gives the Plaintiffs standing to challenge MassHealth's claimed policy of reimbursing medical providers for unnecessary neonatal male circumcisions as an illegal expenditure under 42 U.S.C. § 1396a(30)(A) and/or 130 Code Mass. Regs. § 450.204.⁷ The Court will address the viability of Plaintiffs' G.L. c. 29, § 63 taxpayer petition to enforce these federal and state law provisions, in turn.

⁷ For purposes of Rule 12, the Court must assume that MassHealth is, in fact, providing reimbursement for circumcision procedures that are not medically necessary. However, it is worth emphasizing that, beyond the

A. 42 U.S.C. § 1396a(30)(A)

Section 30(A) of the federal Medicaid Act requires state Medicaid programs to "safeguard against unnecessary utilization" of care and services. The Plaintiffs argue that MassHealth's neonatal male circumcision policy contravenes Section 30(A), by expressly allowing for the utilization of an unnecessary surgical service rather than safeguarding against it. The Defendant counters that the Act precludes private enforcement of Section 30(A) and, relying upon Armstrong v. Exceptional Child Ctr., Inc., 575 U.S. 320 (2015), argues that the Plaintiffs' attempt to enforce the requirement of medical necessity under Section 30(A) must be rejected. The Defendant is correct.

In <u>Armstrong</u>, medical service providers in Idaho sued the state agency responsible for administering the state's Medicaid program, claiming that its reimbursement rates were lower than Section 30(A) permitted. The Supreme Court observed that federal statutory authority to withhold Medicaid funding was the "sole remedy" that Congress had provided for a State's failure to comply with federal requirements, and concluded that "even if the existence of" a sole remedy "might not, by itself, preclude the availability of equitable relief, it did so when combined with the judicially unadministrable nature of the statutory text." <u>Armstrong</u>, 575 U.S. at 328. The Court thus opined that:

"It is difficult to imagine a requirement broader and less specific than §30(A)'s mandate that state plans provide for payments that are 'consistent with efficiency, economy, and quality of care,' all the while 'safeguard[ing] against unnecessary utilization of . . . care and services.' Explicitly conferring enforcement of this judgment-laden standard upon the Secretary alone establishes, we think, that Congress 'wanted to make the agency remedy that it provided exclusive,' thereby achieving 'the expertise, uniformity, widespread consultation, and resulting administrative guidance that can accompany agency decisionmaking,'

jurisdictional question joined by the Defendant's motion, the issue of medical necessity itself, and whether and/or under what circumstances MassHealth can reimburse medical providers for neonatal male circumcision in accordance with this standard, is not presently before the Court.

and avoiding 'the comparative risk of inconsistent interpretations and misincentives that can arise out of an occasional inappropriate application of the statute in a private action.' . . . The sheer complexity associated with enforcing §30(A), coupled with the express provision of an administrative remedy, §1396c, shows that the Medicaid Act precludes private enforcement of §30(A) in the courts."

Id. at 328-29 (quoting Gonzaga Univ. v. Doe, 536 U.S. 273, 292 (2002)). Armstrong's unqualified holding that the Act precludes private enforcement of Section 30(A) forecloses the Plaintiffs' effort to challenge MassHealth's coverage of neonatal male circumcision as a violation of this federal law.

The Plaintiffs nonetheless argue that their action is distinguishable from the claim addressed in <u>Armstrong</u>, because it is based on a violation of Section 30(A)'s language requiring states to "safeguard against unnecessary utilization" of covered care and services rather than its language concerning reimbursement payment requirements. The Court does not agree.

As set forth *ante*, <u>Armstrong</u>'s holding that "the Medicaid Act precludes private enforcement of Section 30(A) in the courts" was clear and unqualified. 575 U.S. at 329. Moreover, to reach this conclusion, the Court observed that private enforcement of Section 30(A) was "judicially unadministrable" due to the breadth of its payment directives *and* the safeguarding requirements at issue in the case then at bar. <u>Id.</u> at 328 ("It is difficult to imagine a requirement broader and less specific than § 30(A)'s mandate that state plans provide for payments that are 'consistent with efficiency, economy, and quality of care,' all the while 'safeguard[ing] against unnecessary utilization of . . . care and services.'"). Indeed, the federal Act does not even define what constitutes "unnecessary care;" and, in the absence of clear

⁸ The Plaintiffs contend that "unnecessary care" is all care that is not "medically necessary." It does not appear, however, that any court has addressed whether the federal Act requires all covered procedures to be medically necessary since the 1970s; and, since that decade, the Act and its governing regulations have been revised and amended innumerable times. Several of the reported decisions from that era found that the Act's references to "necessary medical services" were not a limitation on the *services* eligible for Medicaid reimbursement, but rather

statutory guidance as to what it meant by that term, judicial efforts to determine what care and services are "unnecessary" under Section 30(A) would almost certainly result in the "inconsistent interpretations" and "inappropriate applications" of the statute that Congress sought to avoid. <u>Id.</u> at 328-29. <u>Cf. Blessing v. Freestone</u>, 520 U.S. 329, 343-44 (1997) (quoting <u>Livadas v. Bradshaw</u>, 512 U.S. 107, 132 (1994)) (enforcing requirement that state organizations employ "sufficient staff," in the absence of statutory guidance as to the meaning of that term, "would certainly 'strain judicial competence'").

Further to the foregoing, the Court observes that <u>Armstrong</u> found that the entirety of Section 30(A) is "a directive to the federal agency charged with approving state plans . . ." <u>Id.</u> at 321. Together with the other state plan requirements enumerated in 42 U.S.C. § 1396a, Section 30(A) "merely describes what states must do to ensure continued funding," and thereby defines those circumstances in which the federal Government can withhold or limit a state's Medicaid

[&]quot;a limitation on persons eligible for Medicaid payments." See Roe v. Norton, 380 F. Supp. 726, 728 (D. Conn. 1974) (rev'd on other grounds, 522 F.2d 928 (2d Cir. 1975)); Coe v. Hooker, 406 F. Supp. 1072, 1081 (D. N.H. 1976) (the federal Medicaid Act uses the term "necessary medical services"... to modify eligible individuals"). Consistent with this observation, and during the same time period, the U.S. Supreme Court noted in dicta that the state of Connecticut was "free — through normal democratic processes" — to decide that nontherapeutic abortion should be funded through its Medicaid program. Maher v. Roe, 432 U.S. 464, 480 (1977).

Today, there are still many aspects of the Act and its governing regulations that suggest federal law does not strictly require covered services to be medically necessary. For example, federal regulations provide that medical necessity requirements are merely an optional component of each state's service plan, see 42 C.F.R. § 440.230(d) (state agencies "may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures") (emphasis added), and expressly allow for coverage of non-medical holistic care. See 42 C.F.R. § 440.230. It also remains true that, throughout the Act, "the assistance to be made available to those who are eligible is described simply as 'medical assistance' without the qualifying adjective 'necessary,'" and that "the detailed statutory definition of 'medical assistance,' 42 U.S.C. § 1396d, contains no reference to medical necessity, and does broadly include 'medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law." Roe, 380 F. Supp. at 728 (citing 42 U.S.C. § 1396d(a)(6)). However, there is at least one provision of the Act that suggests medical necessity is required for reimbursement. Specifically, 42 U.S.C. § 1320c-5 requires medical providers seeking Medicaid reimbursement to "assure, to the extent of [their] authority that services or items ordered or provided. under [the] Act ... will be provided economically and only when, and to the extent, medically necessary[.]" In view of the very limited nature of the parties' briefing on whether the federal Act in fact requires all covered services to be medically necessary, the Court declines to decide the issue at this time. Assuming, arguendo, that the federal Act does require medical necessity, the parties' briefing is also insufficient to determine whether state Medicaid programs like MassHealth are nevertheless free to cover services that are not medically necessary at the offering state's sole expense (that is, without any federal reimbursement).

funding. See M.A.C. v. Betit, 284 F. Supp. 2d 1298, 1306 (D. Utah 2003). To that end, the Act only authorizes the Federal Secretary to withhold Medicaid payments from a state if he determines that "in the administration of the plan there is a failure to comply substantially" with the requirements set forth in 42 U.S.C. § 1396a or any aspects of the state's plan. See 42 U.S.C. § 1396c (emphasis added). The Supreme Court has recognized that substantial compliance statutory schemes have an "aggregate" focus that requires the Federal Secretary to determine compliance holistically. See, e.g., Gonzaga Univ. v. Doe, 536 U.S. 273, 288-89 (2002) (Section 1983 claim under 20 U.S.C. § 1232g precluded, in part, due to substantial compliance scheme); Blessing, 520 U.S. at 343-44 (Section 1983 claim under Title IV-D of Social Security Act not viable, in part, because statutory scheme only required "substantial compliance" with federal regulations). Therefore, assuming arguendo that MassHealth's coverage of neonatal male circumcision does violate Section 30(A), the Act's substantial compliance scheme would not necessarily require the Federal Secretary to find that MassHealth has violated the Act and, on that basis, withhold Medicaid funds. Allowing a private action to enforce Section 30(A) alone would thus contravene the text and structure of the Act for the very reasons the Supreme Court identified in Armstrong. See Long Term Care Pharm. Alliance v. Ferguson, 362 F.3d 50, 57 (1st Cir. 2004) (Section 30(A) "has no rights creating language and identifies no discrete class of beneficiaries"); Equal Access for El Paso, Inc. v. Hawkins, 509 F.3d 697, 703-04 (5th Cir. 2007) (holding Section 30(A) does not confer private right of action because it "speaks only in terms of institutional policy and practice, has an 'aggregate' rather than an individualized focus, and is not concerned with whether the needs of any particular person or class of individuals has been satisfied."). Accordingly, the Court concludes that the Plaintiffs' focus on Section 30(A)'s

"safeguarding" requirements does not render the holding of <u>Armstrong</u> (and its preclusion of private enforcement of the regulation) inapplicable.

The Plaintiffs alternately argue that, unlike the medical provider plaintiffs in <u>Armstrong</u>, who argued for an implied right of action under federal law, they have a *direct* right of statutory enforcement under G.L. c. 29, § 63. This argument, equally in circumvention of <u>Armstrong</u>, fails to persuade.

In Tulare Local Health Care Dist. v. California Dep't of Health, 328 F. Supp. 3d 988 (N.D. Cal. 2018), the United States District Court of the Northern District of California rejected an effort to enforce Section 30(A) under state law, holding that "the Armstrong decision does not leave room for this court to find that, although Congress precluded all means of enforcing §30(A) other than the withholding of federal funds, private parties may also enforce § 30(A) through any enforcement mechanisms the several states might enact." Id. at 998. The Court finds Tulare persuasive, and joins in its conclusion that the broad holding of Armstrong precludes the Plaintiffs from invoking state law to enforce Section 30(A). Accord Santa Rosa Memorial Hosp., Inc. v. Kent, 25 Cal. App. 5th 811, 821 (Cal. Ct. App. 2018) (holding that "the reasoning in Armstrong applies equally to proceedings" seeking to enforce provisions of the federal Act "in state as well as federal courts").

B. <u>130 Code Mass. Regs.</u> § 450.204

Although the Plaintiffs cannot rely on state law to evade the Supreme Court's express preclusion of private enforcement of the federal Medicaid requirements reflected in Section 30(A), <u>Armstrong</u> does not perforce bar them from utilizing G.L. c. 29, § 63 as a vehicle to enforce Medicaid mandates promulgated under state law. <u>See Armstrong</u>, 575 U.S. at 329 (specifically foreclosing the private enforcement of Section 30(A), as opposed to all laws

governing Medicaid programs). See also Planned Parenthood Gulf Coast, Inc. v. Kliebert, 141 F. Supp. 3d 604, 640-42 (M.D. La. 2015) (refusing to apply Armstrong "beyond the confines" of Section 30(A) by extending its holding to prohibit actions to enforce other Medicaid provisions). Cf. O.B. v. Norwood, 838 F.3d 837, 843 (7th Cir. 2016) (affirming injunction against state brought by Medicaid beneficiaries seeking to enforce portions of the federal Act requiring state Medicaid agencies to provide certain diagnostic services). The Plaintiffs' lawsuit—premised on the contention that MassHealth's circumcision policy independently violates 130 Code Mass. Regs. § 450.204—seeks to do just that.

Section 450.204 states that MassHealth "does not pay. . . provider[s] for services that are not medically necessary," and sets forth a two-part definition of what constitutes a "medically necessary" service. The Plaintiffs argue that MassHealth's policy and practice of covering neonatal male circumcisions without verifying in each case whether the procedure did, in fact, meet Section 450.204's definition of a medically necessary service constitutes an expenditure that MassHealth does not have the legal right to make. 9/10 This claim is neither barred by Armstrong's explicit holding that private enforcement of Section 30(A) is prohibited, nor precluded in principle by the reasoning Armstrong relies upon in support of that holding. Unlike the "judgment-laden standard" of Section 30(A), a determination of whether MassHealth has a

⁹ The Plaintiffs also argue that MassHealth's circumcision policy violates 130 Code Mass. Regs. § 415.401, which states that MassHealth "pays for inpatient hospital services that are medically necessary and appropriately provided as defined by [Section 450.204]." However, unlike Section 450.204, this regulation does not state that MassHealth "only" pays for medically necessary services; nor does it, in terms, bar MassHealth from paying for services that are *not* medically necessary. For this reason, the Court's analysis will center only on the Plaintiffs' arguments with respect to Section 450.204.

¹⁰ Although the Plaintiffs principally rely on Section 450.204 as the state law predicate for their Section 63 claim, it appears that 130 Code Mass. Regs. § 433.451(B)(1), which states that MassHealth does not pay for surgery services that are "experimental, unproven, cosmetic, or otherwise medically unnecessary," provides a secondary basis for their argument that MassHealth's circumcision policy permits expenditures that the agency does not have the legal right to make.

policy and practice of covering neonatal male circumcisions without confirming the procedure to have been medically necessary is not subjective or amorphous, does not call for the exercise of any particular expertise or policy balancing, and is no different from the sorts of determinations "that courts routinely make in various contexts." <u>Planned Parenthood Arizona. Inc.</u> v. <u>Betlach</u>, 727 F.3d 960, 968 (9th Cir. 2013).

The Court next considers whether the expenditure of state funds in violation of an agency regulation represents a proper basis for a taxpayer petition under G.L. c. 29, § 63. ¹¹ Section 63 broadly allows taxpayers to challenge any imminent expenditures that the Commonwealth does not have the "legal and constitutional right and power to expend[.]" G.L. c. 29, § 63. Like statutes and constitutional provisions, administrative regulations can define or limit an agency's legal rights and powers and thereby bind the agency with the force of law. See Da Lomba's Case, 352 Mass. 598, 603 (1967); see also Northbridge v. Natick, 394 Mass. 70, 76 (1985) ("An agency must follow its own regulations even in the face of inconsistent internal guidelines."). It follows, then, that Section 450.204 defines the circumstances in which MassHealth has and lacks the legal right to expend funds to cover physicians' services under the Medicaid program.

MassHealth's alleged expenditure of state funds in violation of Section 450.204 is, therefore, a proper basis for suit under G.L. c. 29, § 63. ¹²

¹¹ The parties have not cited, and the Court has been unable to locate, any G.L. c. 29, § 63 cases specifically predicated on an agency's failure to comply with its own regulations.

¹²The Defendant argues that Section 450.204 is irrelevant, in view of state and federal Medicaid statutes investing MassHealth with discretion to cover procedures that are not medically necessary. As set forth *ante*, however, regardless of the discretion that MassHealth may possess, the agency must exercise such discretion in accordance with administrative regulations that have the force of law. It is the view of the undersigned that MassHealth ceded any discretion it had to pay for neonatal circumcisions that are not medically necessary when it promulgated Section 450.204. See Restaurant Consultants, Inc. v. Alcoholic Beverages Control Comm'n, 401 Mass. 167, 170 & n.8 (1987) ("By its regulation . . . the [defendant] has ceded whatever discretion it may have had under the statute."); Royce v. Commissioner of Corr., 390 Mass. 425, 427 (1983) ("Once an agency has seen fit to promulgate regulations, it must comply with those regulations.").

The Court now turns to the question of whether the Plaintiffs have put forward sufficient allegations to establish that MassHealth has a policy and practice of expending Medicaid funds in violation of Section 450.204. As the Defendant acknowledges in his Memorandum, Section 450.204's medical necessity requirement "is inherently fact-intensive, requiring a provider to apply the factors set forth in the regulation to the individual's [sic] members needs and the proposed procedure." (Defendant's Memorandum, at p. 6). Assuming, as the Court must in the precincts of Rule 12, that the Plaintiffs' allegations in their Complaint are true, MassHealth is aware that most circumcisions are not medically necessary (as defined in Section 450.204), and are in most cases performed at the election of parents for cultural and religious reasons having nothing to do with the health of the infant. The Plaintiffs contend that MassHealth nonetheless maintains a practice of covering neonatal male circumcisions without subjecting claims seeking reimbursement for such procedures to the utilization review process prescribed by 130 Code Mass. Regs. § 415.414(B), or otherwise conducting any inquiry as to whether the given procedure was medically necessary. The Plaintiffs have thus established, at least in a manner sufficient to clear the bar of Rule 12, that MassHealth is spending money for a purpose "other than that [for] which" it has the "legal . . . right and power to expend money," and thereby stated a plausible claim for relief under G.L. c. 29, § 63.

The Defendant argues that the Plaintiffs' effort to enforce Section 450.204 via taxpayer challenge is foreclosed by the holding of <u>Boston Med. Ctr. Corp.</u> v. <u>Secretary of Exec. Office of Health & Human Servs.</u>, 463 Mass. 447 (2012), in which four hospitals asserted that MassHealth had imposed unreasonably low payment rates in violation of its obligations under G.L. c. 118G, § 11. <u>See</u> 463 Mass. at 453-54. To determine whether the Legislature had created a private right of action to enforce this duty, and thereby waived the Commonwealth's sovereign immunity, the

SJC considered "whether it would be reasonable as a matter of public policy for the Legislature" to create a duty under G.L. c. 118G, § 11 that lacked a judicial remedy. <u>Id.</u> at 456. The Court found that judicial review of the rates MassHealth set under Section 11 "would be complex and difficult[,]" requiring, among other things, an assessment of whether a hospital's actual costs are reasonable. <u>Id.</u> at 456-57. In light of this observation, the SJC affirmed the lower court's finding that setting payment rates "necessarily calls for the application of technical expertise that the Court lacks, and the exercise of judgment and discretion that the [L]egislature has not entrusted to the Court." <u>Id.</u> at 458. The SJC thus held that the plaintiff hospitals did not have a right to sue under G.L. c. 118G, § 11, determining that it "would be reasonable for the Legislature to conclude that the fair and cost-effective provision of hospital services to MassHealth patients would not be furthered by judicial review." Id.

The Defendant urges the Court to apply <u>Boston Med. Ctr.</u> broadly, and extend its reasoning to bar private actions (such as the Plaintiffs') to enforce *any* laws governing MassHealth operations. The Court declines to do so. Unlike the hospitals in <u>Boston Med. Ctr.</u>, the Plaintiffs in the instant case are not calling upon the Court to assess whether MassHealth has properly exercised its discretion in fulfilling a statutory duty. Instead, the Court in this case is asked to determine whether or not MassHealth is exercising its discretion at all, where the agency's own regulation unambiguously requires it to do so. This determination is *not* driven by application of the factors embodied in the underlying regulation itself, and does *not* require the Court to supplant MassHealth's discretion as to how the regulation should be applied. The Court need only resolve whether MassHealth is taking steps to ensure that the neonatal male circumcisions for which it provides Medicaid reimbursement coverage are medically necessary as that term is defined in Section 450.204. In clear contrast to the payment requirements at issue

in <u>Boston Med. Ctr.</u>, this determination does *not* require "the application of technical expertise that the Court lacks" or "the exercise of judgment and discretion" concerning an issue that the Legislature entrusted MassHealth to resolve. <u>Boston Med. Ctr.</u>, 463 Mass. at 458.

The Defendant relatedly argues that <u>Brennan</u> v. <u>Governor</u>, 405 Mass. 390 (1989), precludes taxpayer suits based on laws that do not themselves confer a private right of action. The Court does not agree. In <u>Brennan</u>, a group of taxpayers argued that the deputy commissioner of the Commonwealth's Division of Capital Planning and Operations had unlawfully expended state funds to acquire property, because he did not first comply with what the taxpayers believed to be statutory pre-requisites. <u>Brennan</u>, 405 Mass. at 394-95. The taxpayers additionally argued that the deputy commissioner's request for proposals had been drafted too narrowly, and that his feasibility report did not satisfy statutory requirements. <u>Id.</u> at 396-98. Holding that the taxpayers could not maintain their G.L. c. 29, § 63 action because they had failed to establish the Commonwealth had acquired the property in violation of any laws, the SJC found that the alleged statutory "pre-requisites" were not pre-requisites at all, that state officials "had a rational basis for writing the request for proposals as they did," and that the challenged feasibility study had, in fact, satisfied all statutory requirements. <u>Id.</u> at 396, 400.

The term "private right of action" does not appear anywhere in <u>Brennan</u>, and in fact has nothing to do with the case's holding. Rather, the taxpayer claims in <u>Brennan</u> failed because the plaintiffs did not establish that the defendant had expended funds in violation of any legal obligation. Here, by contrast, the Plaintiffs have clearly set forth allegations that *do* establish that MassHealth is expending taxpayer funds to cover a particular physician service without determining whether it was medically necessary in the manner required by its regulation.

Brennan thus lends no support to the Defendant's argument that the Plaintiffs cannot bring a taxpayer action to enforce a MassHealth violation of Section 450.204.

Finally, the Defendant argues that allowing the Plaintiffs to maintain a judicial action to enforce Section 450.204 will open the floodgates to untold numbers of taxpayer challenges to Medicaid coverage for other arguably unnecessary or controversial services. Perhaps so. But if MassHealth wishes to discourage taxpayer challenges to the Medicaid coverage it provides for circumcision or other physician procedures, it has all the authority it needs to either relax or broaden its definition of "medical necessity," and/or ensure that it sufficiently inquires into the medical need of any services for which reimbursement is sought. See G.L. c. 118E, §§ 7, 12, 15. It is MassHealth, therefore, that has opened the floodgates here; and it must be the agency, not the Court, that closes them.¹³

Accordingly, the Court concludes that the Plaintiffs have stated a viable claim for relief under G.L. c. 29, § 63, to the extent they allege that MassHealth is illegally expending funds for neonatal male circumcisions without determining whether such procedures are medically necessary as required by 130 Code Mass. Regs. § 450.204.

CONCLUSION AND ORDER

For all the foregoing reasons, the Defendant's Motion to Dismiss the Complaint is

ALLOWED insofar as the Plaintiffs' G.L. c. 29, § 63 petition is based on 42 U.S.C. §

1396a(30)(A). The Motion to Dismiss, however, is **DENIED** to the extent the Plaintiffs' petition is based on 130 Code Mass. Regs. § 450.204. No action is taken on Plaintiffs' Cross-Motion for

¹³ The Defendant points out that the Medicaid plans that exist in most states cover neonatal male circumcision. As set forth <u>supra</u> at note 8, however, the Court expresses no opinion as to whether the federal Medicaid Act requires covered services to be medically necessary or whether states can offer optional services not covered by the Act at their own expense. Without answers to these questions, and more information regarding the particular Medicaid programs in place in other states, the undersigned is not prepared to draw any conclusions from the experience of these other states that bear on the legal issue presented in the case at bar.

Preliminary Injunction, the Court inviting the resubmission of this motion following an appropriate period of discovery or a stipulation to agreed facts.

SO ORDERED.

Robert B. Gordon

Justice of the Superior Court

Dated: March 10, 2021