Cruz et al v. Zucker

2016 | Cited 0 times | S.D. New York | July 6, 2016

UNITED STATES COURT SOUTHERN OF YORK

CRUZ, AR'ES PIVA of

HOWARD ZUCKER,

State

S. U.S.D.J.

(JSR) OPINION ORDER

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2016,

See 2016, 2016 407920. DISTRICT DISTRICT NEW ---------- x ANGIE I.H., KPAKA, and themselves and all others similarly situated,

Plaintiffs, -v- as Commissioner of the Department of Health [of the of New York],

Defendant. ---------- x JED RAKOFF,

14-cv-4456

AND

Plaintiffs claim that New York wrongly denies Medicaid coverage for treatment of gender dysphoria in two material respects. First, they challenge N.Y. R. & Regs. tit. 18, § 505.2(1), which provides coverage for gender reassignment surgery and hormone therapy but excludes coverage for individuals under eighteen (the "Age Exclusion") .

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Second, plaintiffs also claim that§ 505.2(1) wrongfully imposes a blanket ban on coverage of cosmetic procedures related to gender dysphoria, including medically necessary cosmetic procedures (the Exclusion").

The details of this case are discussed in greater detail in

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§ 505.2(1) previously excluded coverage of gender reassignment surgery for individuals under twenty-one if it resulted in sterilization. However, effective April 27, § 505.2(1) was amended to establish a minimum age of 18 for gender reassignment surgery, even when the surgery would result in sterilization. Notice of Adoption dated April 12, N.Y. Reg. Plaintiffs' claims against the earlier prohibition on surgeries resulting in sterilization for individuals under 21 are therefore dismissed as moot.

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("DOH") 2015 See Update

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See Update v. 116 F. Supp. 3d 334, 337-41 (S.D.N.Y. familiarity with which is here presumed. The now has four motions before it. First, defendant asks the to reconsider its decision on his motion to dismiss. Specifically, he wants the

to revisit its conclusion that§ 505.2(1) imposes a blanket ban on cosmetic procedures. the defendant asks the to decertify the plaintiff class. Finally, both parties move for summary judgment. For the following reasons, the denies defendant's motions except for parts of his motion for summary judgment, and grants plaintiffs' motion for summary judgment in part.

First, defendant moves for reconsideration of this decision on his motion to dismiss. defendant

argues that§ 505.2(1) does allow cosmetic procedures when they are medically necessary. He bases his argument on guidance released by the New York Department of Health in June (the "June Guidance"). New York Department of Health Medicaid Program, Medicaid Vol. 31 No. 6 (June 2015). The June Guidance explicitly supersedes earlier guidance, published in March (the "March Guidance") which stated that "payment will not be made for [a list of cosmetic surgeries that can be used to treat gender dysphoria.]" New York Department of Health Medicaid Program, Medicaid Vol. 31 No. 3 (March 2015). Although the June Guidance still states that "[p]ayment

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Second "a will not be made for any procedures that are performed solely for the purpose of improving an individual's it implicitly allows coverage of some cosmetic procedures when

of medical necessity is provided and prior authorization is New York Department of Health Medicaid Medicaid Vol. 31 No. 6 at 7 (June 2015).

the June Guidance recasts the March Guidance's list of prohibited cosmetic surgeries as [that] will be presumed to be performed solely for the purpose of improving appearance and will not be covered, unless justification of medical necessity is provided and prior authorization is

Id. Defendants argue that the June Guidance should effectively end plaintiffs' facial attack on the Cosmetic Exclusion because, if the June Guidance were a proper interpretation of§ 505.2(1), it would show that§ 505.2(1) allows coverage for medically necessary cosmetic surgeries.

Defendants also argue that the June Guidance affects the Court's consideration of the ripeness of

plaintiffs' claims. claim is not ripe for adjudication if it rests upon contingent future events that may not occur as such as the denial of coverage for medically necessary cosmetic surgeries. Texas v. 523 296, (1998) (internal quotation marks omitted). However, the Circuit does not require futile gesture as a prerequisite for adjudication in

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Opinion

"[T]he federal court." Desiderio v. Nat'l Ass'n of Sec. Dealers, Inc., 191 F.3d 198, (2d Cir. 1999) (quoting Williams v. Lambert, 46 F.3d 1275, (2d Cir. 1995)). Although plaintiffs did not plead that they had requested and been denied cosmetic surgeries, the Court held that their claims were nonetheless ripe because the plain language of§ 505.2(1) bars coverage of cosmetic surgeries and so requests for such surgeries pursuant to § 505.2(1) would be futile. In reaching this conclusion the Court relied, in part, on the March Guidance. See dated July 29 at 28, ECF No. 52. But, according to the June Guidance, plaintiffs' request for cosmetic surgeries under§ 505.2(1) would not necessarily be futile, and defendants' ripeness arguments would rest on a stronger foundation.

In response to these various points, plaintiffs first argue that the Court should not take the June Guidance into account because it was released after the Court made its decision denying defendant's motion to dismiss. However, there is no rule requiring that, on a motion for reconsideration, the Court must limit itself to facts or evidence existing at the time of its initial decision. major grounds justifying reconsideration are 'an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice.'" Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd., 956 F.2d 1245, 1255 (2d Cir. 1992) (quoting 18 C.

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Cooper, Practice Procedure 790). Court

See U.S. (2002)

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Christopher SmithKline Corp., S. Ct.

Second Circuit Wright, A. Miller & E. Federal & § 4478 at The will therefore consider the June Guidance to ensure that its past decision was not clear error or manifest injustice.

The June Guidance is significant because, in many circumstances, a court is bound to give deference to an agency's interpretation of its own ambiguous regulation. Barnhart v. Walton, 535 212, 221 (upholding deference to agency interpretation of regulations even when agency recently enacted the regulations in response to litigation); Auer v. Robbins, 519

452, 461-63 (1997) (deferring to agency interpretation submitted in amicus brief). Defendant argues that the should defer to the June Guidance as the authoritative interpretation of§ 505.2(1) because both were promulgated by

However, deference to an agency's interpretation of its own regulation is not always warranted. For one thing, "Auer deference is warranted only when the language of the regulation is ambiguous." v. Harris 529 576, 588

Moreover, "[d]eference is undoubtedly inappropriate when the agency's interpretation is plainly erroneous or inconsistent with the regulation." v. Beecham 132 2156, 2166 (2012) (internal quotation marks omitted). The has explained that an

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Opinion 2015, interpretation is "'plainly erroneous' . where the plain language of the regulation itself or some other indication of the agency's intent at the time of promulgation compels a different result." Florez ex rel. Wallace v. Callahan, 156 F.3d 438, 442 (2d Cir. 1998).

Here, the Court will give no deference to the June Guidance because the plain language of§ 505.2(1) unambiguously forecloses its interpretation. The Court already held as much in its earlier decision on defendant's motion to dismiss. See dated July 29, at 28, ECF No. 28 ("Section 505.2(1), by its plain terms, excludes coverage for the procedures deemed 'cosmetic.'") However, because the Court did cite the March Guidance in its earlier analysis, it now holds that the March Guidance was not essential to its decision, for which the text of§ 505.2(1) provides a sufficient foundation.

Section 505.2(1) consists of five relevant subsections. Subsections (1), (2), and (3) provide coverage for medically necessary hormone therapy and gender reassignment surgery for Medicaid recipients over 18. 18 N.Y.C.R.R. § 505.2(1) (1)-(3) Subsection (4) specifically excludes a list of services and procedures from coverage, including "cosmetic surgery, services, and procedures" and provides a non-exhaustive list of explicitly excluded cosmetic procedures. 18 N.Y.C.R.R. § 505.2(1) (4) (v). Subsection (5) defines "cosmetic surgery, services, and

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- procedures" to mean "anything solely directed at improving an individual's appearance." 18 N.Y.C.R.R. § 505.2(1) (5). Defendant argues that (5) should be construed not as an elaboration of the items excluded by (4), but as an allowance for provision of coverage for cosmetic procedures that would otherwise be excluded outright by (4). See Memorandum of Law in Support of Defendant's Motion to Dismiss the Amended Class Action Complaint at 22-23, ECF No. However, no provision of § 505.2(1) states that coverage will be provided for cosmetic procedures of any kind. Defendant's argument would be on surer footing - and§ 505.2(1) would be at least ambiguous if§ 505.2(1) contained a catch-all provision establishing coverage for all medically necessary treatments of gender dysphoria. It does not. Instead, § 505.2(1) carefully provides for only two treatments for gender dysphoria, hormone therapy and gender reassignment surgery, and states outright that "[p]ayment will not be made for breast augmentation, . electrolysis,

[or] facial bone reconstruction, reduction, or sculpturing" procedures plaintiffs allege they need.§ 505.2(1)(4). This unambiguous language renders the June Guidance clearly erroneous and undeserving of deference.

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Because§ 505.2(1) categorically

2 Because the unambiguous language of§ 505.2(1) is a sufficient basis to deny defendant's motion for reconsideration, the Court need not reach plaintiffs' other arguments against giving deference to the June Guidance, including the inconsistency

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See Support 2016, ECF

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DOH See bars coverage for cosmetic surgeries, plaintiffs need not be required to attempt to gain approval for these surgeries under § 505.2(1). Their facial challenge to the regulation is ripe without such futile gestures.

It is of no moment that two named plaintiffs, Kpaka and

have received prior approval of Medicaid coverage for cosmetic surgeries under the June Guidance. Declaration of Ronald J. Bass in of Defendant's May 11, Letter, Exs. 1-7, No. 122. Plaintiffs' claims are directed solely at § 505.2(1), and, as defendant himself has argued, the implementation of the June Guidance is irrelevant to their suit.

Declaration of dated Aug. 17, 3, 7, No. 59 (explaining that plaintiff's pre-enforcement facial challenge has nothing to do with how§ 505.2(1) has been "operationalized" and that defendant's present motion for reconsideration turns on the purely legal question of the interpretation of§ 505.2(1)). The questions of whether plaintiffs have benefited from defendant's publication of guidance that contradicts a duly promulgated regulation and under what authority he undertook that publication are not before the

Plaintiffs do not share defendant's apparent ability to

between the March and June Guidances, material from§ SOS.2(1)'s promulgation suggesting intended a blanket ban on cosmetic procedures, and the convenience of the June Guidance as a litigating position. Plaintiffs' Memorandum of Law in Opposition to Defendant's Motion for Reconsideration at 11-13,

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Court disregard duly promulgated regulations and allege that any valid application of the plain language of§ 505.2(1) would stop them from receiving coverage for medically necessary cosmetic surgeries. Because these allegations continue to state a valid claim for relief, the denies defendant's motion for reconsideration of his motion to dismiss.3

Second, the denies defendant's motion to decertify the plaintiff class. August 22, 2014, before§ 505.2(1) was amended to provide coverage of some medically necessary treatments for gender dysphoria, the parties entered a

Stipulation and of certifying a class consisting of:

All New York State Medicaid recipients who have been diagnosed with Gender Identity Disorder or Gender Dysphoria, and whose expenses associated with medically necessary Gender Identity Disorder- or Gender Dysphoria-related treatment are not reimbursable by Medicaid pursuant to 18 § 505.2(1). No. 92. 3

Relatedly, defendant argues that plaintiffs' Exclusion claims have been mooted by issuance of a Notice of Rule Making amending§ 505.2(1) to track the language of the June Guidance. New York Department of Health Notice of Rule Making dated April 26, with New York Department of Health Medicaid Medicaid Vol. 31 No. 6 (June 2015). The does not moot plaintiffs' claims because it is not a final rule and is not binding. In addition, under N.Y. Law§ must respond to public comments on the and undertake other procedural steps before the is finalized. The cannot base its decision on a document subject to change. The also declines to stay the case until the is finalized. The present motions have been pending for months and, while the has entertained several rounds of supplemental briefing, delaying its decision any further would be unfair to the parties and the public.

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WPATH SOC 10 Stipulation and dated August 22, ECF No. 23.

now requirements of 23(a) or 23(b) (2). First, defendant argues that a single class containing members challenging solely the Cosmetic Exclusion and members challenging solely the Age Exclusion cannot satisfy the typicality requirement of Rule 23(a) (3). Typicality

satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability.u Marisol A. v. Giuliani, 126 F.3d 372, 376 (2d Cir. 1997) (internal quotation marks omitted). Defendant argues that the claims of class members challenging solely the Cosmetic Exclusion do not arise from the same course of events as those challenging the Age Exclusion because gender dysphoria works differently in children and adolescents than in adults. The World Professional Association for Transgender Health Standards of Care Standards of

state that are a number of differences in the

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The Court puts significant weight on the Standards of Care. Plaintiffs' expert Dr. Nicholas Gorton stated in his expert report that

there are many local standards of care, but the most widely recognized and utilized international standard for treating transgender people is the Standards of Care of the World Professional Association for Transgender Health which provides practical clinical guidance for heal th care providers treating transgender patients. has been internationally recognized by much of the developed

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WPATH phenomenology, developmental course, and treatment approaches for gender dysphoria in children, adolescents, and adults." Declaration of John Gasior dated Aug. 28, Ex. 14 Standards of

Care") at ECF No. 83. Defendant also points out that any class member older than eighteen will not be directly affected by any legal judgment pertaining to the Age Exclusion.

respond that defendant has overstated the typicality requirement. They also rely on Marisol A. but point out that the Second Circuit affirmed class certification in that case, even though the district court "conceptualiz[ed] the common legal and factual questions at [a] high level of abstraction." Marisol A., 126 F.3d at 377. Marisol A. involved a class of essentially all children who were in the custody of or should have been in the custody of New York City's child welfare system. Although "no single plaintiff [was] affected by each and every legal violation alleged in the complaint, and . . no single specific legal claim . affect[ed] every member of the class," the Second Circuit recognized that the plaintiffs' "injuries derive[d] from a unitary course of conduct by a single system."

western nations for decades and is more recently being adopted by insurers in the Expert Report of Nicholas Gorton, MD, DABEM, Declaration of Christopher J. McNamara dated August 28, 38, ECF No. 74. Defendant does not meaningfully attack the authority of the Standards of Care and indeed relies in part on them.

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DOH's Id. at 377. Plaintiffs contend that the reasoning of Marisol A. calls for class certification in this case.

The Court reads Marisol A. a third way. Plaintiffs are correct that a faithful application of Marisol A. allows class certification here. However, in Marisol A., the Circuit also directed the district court to create subclasses under Fed. R. Civ. 23(c) (4). The Circuit suggested that the district court "divide the . . class based on the commonality of the [plaintiffs'] particular circumstances, the type of harm the plaintiffs allegedly have suffered, and the particular systemic failures which the plaintiffs assert have occurred." Id. at 379. The Court concludes that this is also the best approach in the present case. Defendant is correct that the claims of class members solely challenging the Cosmetic Exclusion - i.e. any class member over the age of eighteen - are typical of the claims of members challenging solely the Age Exclusion only at a "high level of abstraction," with the claims of each group implicating different legal and factual questions. Marisol A., 126 F.3d at 377. For instance, publication of the June Guidance raised legal questions specific to members challenging the Cosmetic Exclusion (discussed above) but also resolved key factual questions pertinent to that group's claims (discussed below). Meanwhile, the factual questions surrounding the claims of class members challenging the Age Exclusion remain unresolved.

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Court's Second Complaint ("SAC")

S.V. See SAC ECF Order 2016, ECF These differences are not fatal to the certification of the overall class, but they do suggest a natural division into two subclasses: the first consisting of all class members aged eighteen and older (the and the second consisting of all class members younger than eighteen (the "Age

. Defendant objects that the creation of subclasses is inappropriate here because the Age would lack an adequate class representative. To be an adequate class representative, a named plaintiff must, at the very least, be a member of the class. Bailey v. Patterson, 369 31, 32-33 (1962). Three of the named plaintiffs, Angie Ar' es Kpaka, and Riya are over the age of 18. Therefore, they are not members of the Age and cannot serve as class representatives for it. However, with the permission, plaintiffs filed a Amended adding two new named plaintiffs, A.B. as parent and natural guardian of M.B. and N.V. as legal guardian of 164-87, No. 114; dated April 1, No. 113. M.B. is a fourteen- year-old, categorically needy Medicaid recipient with gender dysphoria; she allegedly applied for and was denied Medicaid coverage of pubertal suppressants,

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which two physicians

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"Pubertal suppressants" are hormones that can delay the onset of puberty until further medical decisions are made, thereby sparing adolescents with gender dysphoria the anguish of going

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Olson, recommended she begin taking. 164-76. is a thirteen-year-old, categorically needy Medicaid recipient with gender dysphoria; she allegedly applied for and was denied Medicaid coverage of pubertal suppressants, which a physician prescribed for her. 177-87. Plaintiffs submitted a Declaration from a physician treating M.B. and attesting to their medical need for pubertal suppressants and that she prescribed pubertal suppressants to each of them. Declaration of Dr. Carolyn Wolf-Gould dated April 21, ECF No. 115. A.B. as parent and natural guardian of M.B. and N.V. as legal guardian of are adequate class representatives of the Age Subclass.

Defendant makes one more argument based on the differences between the Cosmetic Subclass and the Age Subclass, under Rule 23 (b) (2). Rule 23 (b) (2) requires that party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Defendant argues that the Court could award final relief with respect to the Cosmetic Exclusion, but not the Age Exclusion, or vice versa. Defendant is correct that the differing legal and factual questions implicated by the Cosmetic and Age Exclusion make this a possibility. However, the creation of

through puberty in the wrong gender. Expert Report of Johanna

M.D., Declaration of Christopher J. McNamara Ex. 27 16, ECF No. 94.

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See, subclasses cures this defect and is a more appropriate course than decertification. Marisol A. v. Giuliani, 126 F.3d 372, 378 (2d Cir. 1997). Accordingly, the Court certifies the

and the Age Defendant raises one additional argument against both subclasses under Rule 23 (b) (2). Defendant invokes a line of

Circuit cases approving denials of class certification when defendants are public officials. Berger v. Heckler, 771 F.2d 1556, 1566-67 (2d Cir. 1985). This doctrine first took definite shape in Galvan v. Levine, F.2d 1255, 1261 (2d 1973) (Friendly, J.), where the Circuit explained that in such cases "what is important . . is that the judgment run to the benefit not only of the named plaintiffs but of all others similarly situated." However, in Galvan, "[t]he

ha[d] made clear that it [understood] the [court's] judgment to bind it with respect to all claimants; indeed even before entry of the judgment, it withdrew the challenged policy even more fully than the court ultimately directed and stated it did not intend to reinstate the policy." Id. at 1261. Defendant has not taken such steps here. Moreover, the Galvan doctrine has generally been applied to denials of class certification in the first instance. Berger v. Heckler, 771 F.2d 1556, 1566-67 (2d Cir. 1985). A doctrine that rests on a public official's acceptance of the applicability of a judgment to a

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See broad group does not apply when the public official has moved to decertify an existing class and thereby attacks the broad applicability of a judgment. Accordingly, defendant's 23(b) (2) argument fails.

Defendant also raises several arguments directed either at the Cosmetic Subclass or the Age Subclass. To begin with, defendant argues that the Cosmetic Subclass fails the commonality requirement of Rule 2 3 (a) (2) . Rule 2 3 (a) (2) , there must be "questions of law or fact common to the class." In particular, plaintiffs' "claims must depend upon a common contention of such a nature that it is capable of classwide resolution which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." Wal-Mart Stores, Inc. v. Dukes, 131 Ct. 2541, 2551 Defendant argues that the Cosmetic Subclass runs afoul of Dukes because each class member's individual medical circumstances will determine whether

specific treatments are medically necessary and available under§ 505.2(1). This argument would have more force if plaintiffs were challenging the implementation of a regulation that allowed any coverage of cosmetic procedures, in line with the June Guidance. However, plaintiffs have brought a facial challenge against a regulation that unequivocally bans all cosmetic procedures. supra. Section 505.2(1)'s ban is the "glue" holding together plaintiffs'

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See 2015 claims as required by Dukes: if the ban violates the federal law, each of the claims brought by members of the Cosmetic Subclass will be resolved "in one stroke." Dukes, 131 Ct. at 2551, 2552.

Further, defendant argues that named plaintiffs Cruz and Kpaka fail the typicality requirement of Rule 23(a) (3) because they have failed to show that the cosmetic treatments they seek are medically necessary for them. Typicality does "require[] that the claims of the class representatives be typical of those of the class." Marisol A. v. Giuliani, 126 F.3d 372, 376 (2d Cir. 1997). However, Cruz and Kpaka have adequately demonstrated medical necessity for purposes of class certification. In re

Litig., 471 F.3d 24, 41 (2d Cir. ("[T]he district judge must receive enough evidence, by affidavits, documents, or testimony, to be satisfied that each Rule 23 requirement has been met."). Cruz submitted a declaration stating that her doctor has determined that breast augmentation is medically necessary for her. Declaration of Angie Cruz dated 8, ECF No. 96. Defendants do not point to any evidence contradicting Cruz's declaration, apart from an absence of documents in Cruz's medical records that state the medical necessity of cosmetic surgeries. Declaration of John Gasior dated Aug. 28, Ex. 1, ECF No. 83. In light of Cruz's declaration, the Court cannot rely on an absence of unspecified documents in Cruz's medical

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See Program, Update 2015). records which otherwise confirm that Cruz was diagnosed with gender identity disorder to conclude that cosmetic treatments are not medically necessary for her. Cruz's claims are sufficiently typical for her to serve as class representative.

Defendant also points out that Kpaka's medical records do not contain documents specifically certifying that cosmetic procedures are necessary for her. Declaration of John Gasior dated Aug. 28, Ex. 2, ECF No. 83. However, he does not dispute that Kpaka has received prior approval for coverage of breast augmentation and facial feminizing surgeries. Reply Memorandum of Law in Further Support of Defendant's Motion for Summary Judgment at 6, ECF No. 98. the terms of the June Guidance, Kpaka could only have received prior approval if the surgeries were medically necessary. New York Department of Health Medicaid Medicaid Vol. 31 No. 6 (June

Given this uncontested evidence of medical necessity, the Court concludes that Kpaka's claim are sufficiently typical for her to serve as class representative.

It should be noted that defendant does not challenge the medical necessity of cosmetic procedures for Christie. Accordingly, even if (contrary to fact) Cruz and Kpaka had failed to demonstrate the typicality of their claims, the appropriate response would be the dismissal of Cruz and Kpaka as class

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Plaintiffs' representatives, rather than the decertification of the entire class.

Further still, defendant argues that Cruz and Kpaka fail the adequacy requirement of Rule 23 (a) (4). 23 (a) (4) requires that plaintiffs demonstrate that class counsel is qualified, experienced, and generally able to conduct the litigation.

must also demonstrate that there is no conflict of interest between the named plaintiffs and other members of the plaintiff class." Marisol A. v. Giuliani, 126 F.3d 372, 378 (2d Cir. 1997) (citation and internal quotation marks omitted). Defendant claims that his typicality arguments also apply to the adequacy requirement. See Memorandum of Law in Support of Defendant's Motion to Decertify the Class at 12-13, ECF No. But lack of medical necessity would not bear on the adequacy of plaintiffs' counsel nor on any conflict of interest between Cruz, Kpaka, and other Cosmetic Subclass members.

counsel has repeatedly demonstrated it is qualified, experienced, and able to conduct this litigation, and the Court sees no conflict of interest between Cruz, Kpaka, and other Cosmetic Subclass members. Defendant's adequacy arguments fail.

Additionally, defendant raises an argument against the Cosmetic Subclass under Rule 23 (b) (2). Defendant argues that he has not acted on grounds that apply to the entire Cosmetic Subclass and, instead, any denials of coverage to class members

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20 are the result of individual factors. Defendant's argument on this point proceeds similarly to his commonality arguments and meets the same fate: because§ 505.2(1) categorically bans coverage for cosmetic surgeries, defendant has acted on grounds that apply to the entire Injunctive relief dissolving§ 505.2(1)'s ban would resolve all claims of the members of the Accordingly, the

satisfies Rule 23 (b) (2). Finally, defendant raises an argument directed at the Age

After plaintiffs filed the the received supplemental briefing from the parties regarding the addition of the two new named plaintiffs. In his supplemental briefing, defendant objects that A.B. as parent and natural guardian of M.B. and N.V. as legal guardian of lack class standing. "[A] plaintiff has class standing if he plausibly alleges (1) that he 'personally has suffered some actual . injury as a result of the putatively illegal conduct of the defendant,' and (2) that such conduct implicates 'the same set of concerns' as the conduct alleged to have caused injury to other members of the putative class by the same defendants." Health & Welfare Fund v. Goldman & 693 F.3d 145, 162 (2d (citations omitted). Defendant does not dispute that the new named plaintiffs satisfy the first prong but argues that they fail the second prong because they have demonstrated only a medical need

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504 U.S. 560-61 for pubertal suppressants, while the claims of Age members are also based on bans on coverage for gender reassignment surgery and cross-sex hormone therapies. However, the conduct of defendant that caused the new named plaintiffs' injuries, namely the denial of Medicaid coverage for prescribed pubertal suppressants, was his enforcement of § 505.2(1) 's complete ban on any coverage of treatments for individuals under 18. This conduct does not merely implicate the same set of concerns as the conduct underlying the other Age members' claims, it is in fact the same. All members of the Age

have allegedly been injured by defendant's enforcement of§ 505.2(1)'s ban on under-18 coverage. As such, the new named plaintiffs have class standing to assert the claims of the Age

Based on the foregoing analysis, the denies defendant's motion to decertify the plaintiff class.

Third, the denies in part defendant's motion for summary judgment on standing grounds. Article III standing requires an "injury in causal connection between the injury and the conduct complained and redressability, such that "the injury will be redressed by a favorable decision." Lujan v. Defenders of Wildlife, 555, (1992) (internal quotation marks omitted). To satisfy these requirements at the summary judgment stage, a plaintiff "must 'set forth' by

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See 2015 CRUZ00002625-26, ECF Christie's

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Court affidavit or other evidence 'specific facts,' which for purposes of the summary judgment motion will be taken to be true." Id. (citation omitted).

Defendant claims that named plaintiffs Kpaka, and

lack standing. First, defendant argues that claims are either unripe or moot. Defendant's ripeness arguments are directed at claim for electrolysis procedures, for which she has demonstrated medical necessity, but which she has not applied for and been denied coverage. Declaration of John Gasior dated Aug. 28, Ex. 3 at No. 83 (documenting medical need for electrolysis and facial feminizing surgery) . The does not require "a futile gesture as a prerequisite for adjudication in federal court." Desiderio v. Nat'l Ass'n of Dealers, Inc., 191 F.3d 198, (2d 1999). Because§ 505.2(1) bans coverage of electrolysis, does not need to go through the futile process of applying for and being denied coverage.

The fact that has received approval for other procedures banned by§ 505.2(1), ostensibly pursuant to the June Guidance, has no bearing on whether her attempts to receive coverage for electrolysis would be futile. This is because the plain language of§ 505.2(1) bars coverage of these procedures and the is bound to apply the language of a duly promulgated regulation as opposed to non-binding guidance that

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508 U.S. defendant can change at his discretion. Compare New York Department of Health Medicaid Program, Medicaid Vol. 31 No. 3 (March (no coverage for electrolysis) with New York Department of Health Medicaid Program, Medicaid Vol. 31 No. 6 at 7 (June (coverage for medically necessary electrolysis). Whatever murky largesse may have motivated the June Guidance and approval of Christie's other procedures cannot be relied upon to defeat the futility of opposing the plain language of a regulation. Christie has standing to bring her claims even without denials in hand.

Defendant also argues that Christie's other claims are moot because she has received prior approval for coverage of mammoplasty and facial feminization surgeries. Declaration of Ronald J. Bass in Support of Defendant's May 11, Letter, Exs. 1-4, ECF No. 122. These approvals were ostensibly granted pursuant to the June Guidance. With respect to the procedures for which Christie has won approval, the Court applies "the 'well settled' rule that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice." Ne Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville,

656, 662 (1993) (internal quotation marks omitted). In the context of a challenged statute on appeal, the Supreme Court has explained that repeal of an unconstitutional statute does not

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Court's vacated." City Castle, U.S.

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Compare

ECF Support

ECF moot a plaintiff's claim because a repeal not preclude [the promulgating body] from reenacting precisely the same provision if the District judgment were of Mesquite v. Aladdin's Inc., 455 283, 289 (1982). In the same way, without a judgment in this case there is nothing to stop defendant from revoking the June Guidance and denying coverage of all cosmetic procedures. Indeed, because§ 505.2(1) is a duly promulgated regulation while the June Guidance is non binding guidance, the June Guidance need not even be revoked defendant could simply begin to enforce his own regulation again. Medicaid recipients should not be forced to suffer through a cloud of uncertainty when requesting medically necessary procedures and hope that defendant will continue to defy his own regulation. claim is not moot, and she has standing.

Defendant also argues that Kpaka lacks standing because she has failed to show that any cosmetic procedures are medically necessary for her. This is an odd argument for defendant to make because he simultaneously argues that Kpaka's claims are moot because she has received prior approval for mammoplasty and facial feminization surgeries. Reply Memorandum of Law in Further Support of Defendant's Motion for Summary Judgment at 4,

No. 98 with Reply Memorandum of Law in Further of Defendant's Motion for Summary Judgment at 6, No. 98. Ostensibly, Kpaka could only have received prior approval if,

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Update

Summary ECF Support

Summary ECF

Cruz

Cruz's under the terms of the June Guidance, she had provided "justification of medical necessity." New York Department of Health Medicaid Program, Medicaid Vol. 31 No. 6 (June 2015). With respect to Kpaka, then, it appears defendant has taken three contradictory positions at once: under§ 505.2(1)'s ban on coverage of cosmetic procedures, Kpaka's medical necessity is irrelevant; under defendant's standing argument, Kpaka's medical necessity has not been established; and, under defendant's mootness argument, Kpaka's medical necessity was established and addressed. The undisputed facts are consistent only with defendant's third argument, on mootness, see Memorandum of Law in Opposition to Defendant's Motion for Judgment at 8 n.4, No. 95; Reply Memorandum of Law in Further of Defendant's Motion for Judgment at 6, No. 98, but defendant's mootness argument fails for the reasons explained above: defendant cannot short-circuit a plaintiff's standing by gratuitously approving some medically necessary procedures in contravention of the plain language of his own regulation. There is no factual dispute that Kpaka has standing and, as a legal matter, her claims are not moot.

Further, defendant argues that lacks standing because she has failed to document that a mammoplasty is medically necessary for her. medical records do not contain any document stating that a mammoplasty is medically necessary, nor

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See

"has

Sept. 2015, 10,

P.

See 801, 802.

See 701. has she received prior approval for a mamrnoplasty. Declaration of John Gasior dated Aug. 28, 2015, Ex. 1, ECF No. 83. Instead, Cruz has submitted a declaration stating that her doctor determined breast augmentation to be medically necessary for [Cruz]." Declaration of Angie Cruz dated 8,

ECF No. 96. Although the Court could rely on this declaration for purposes of class certification, on a motion for summary judgment the Court cannot consider material that would not be admissible under the Federal Rules of Evidence. Fed. R. Ci v. 5 6 (c) (2) . Cruz's declaration that her doctor determined breast augmentation was medically necessary for her is inadmissible hearsay because it offers her doctor's statement for its truth. Fed. R. Evid. Cruz cannot testify directly to the medical necessity of breast augmentation surgery because she is not a medical expert. Fed. R. Evid. Accordingly, plaintiffs' have not raised a triable question of fact as to whether breast augmentation surgery is medically necessary for Cruz: apart from the diagnoses of gender identity disorder that are present in Cruz's medical records, admissible evidence of medical necessity is lacking.

Plaintiffs argue that this lack of evidence is irrelevant because they can establish standing without demonstrating medical necessity. Specifically, they argue that because they have raised a facial challenge to§ 505.2(1), named plaintiffs need not show

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Plaintiffs

See

508 U.S. Univ. U.S. 280

Plaintiffs medical necessity. claim they are situated similarly to plaintiffs challenging racial quotas in public contracting and racial-based admissions policies; the Supreme Court has held that such plaintiffs need not show that they would have been awarded contracts or gained admission in absence of the challenged policies. Ne Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville, 656, 666 (1993); Regents of

of Cali. v. Bakke, 438 265, n.14 (1978). But this overextends plaintiffs' valid defense to defendant's ripeness argument. Although Cruz does not need to go through the futile process of opposing§ 505.2(1)'s plain language in an attempt to redress her alleged injury, if she does not establish that some cosmetic surgeries are medically necessary for her, she has no definite injury in the first place. Thus, Cruz is differently situated from the plaintiffs in Northeastern Florida Chapter and Bakke, who had established they were members of a group that had suffered a denial of equal treatment.

have not alleged, nor have they produced any evidence indicating, that cosmetic surgeries are medically necessary for every person with gender dysphoria. Accordingly, not every individual with gender dysphoria is injured by§ 505.2(1). In the absence of admissible evidence of the medical necessity of mammoplasty procedures for Cruz, she has not demonstrated she is a member of the group harmed by§ 505.2(1). Accordingly, the Court dismisses Cruz's

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U.S.C. (10) "Availability

"must

U.S.C. (10)

440.210

"defined 440.10 440.50, 440.70"). 440.50(a) "physicians' "services

State

State "[e]ach claim on standing grounds, but otherwise denies defendant's motion for summary judgment on standing grounds.

Fifth, on plaintiffs' first claim, for violations of 42

§ 1396a(a) (A) (Medicaid's Provision"), the Court denies defendant's motion for summary judgment and grants plaintiffs' motion with respect to the Cosmetic Exclusion, but grants defendant's motion in part and denies plaintiffs' motion with respect to the Age Exclusion. The Availability Provision requires that a state Medicaid plan provide for making medical assistance available [to all categorically needy individuals], including at least" certain enumerated types of care and services, including inpatient hospital services and physicians' services. 42 §§ 1396a(a) (A), 1396d(a). The statute does not clearly delimit the exact extent of the services it requires, although its implementing regulations provide some more detail. See, 42 C.F.R. § (requiring provision of certain services, including those in [42] C.F.R. §§

through§ For instance, 42 C.F.R. §

defines services" as furnished by a physician . [w]ithin the scope of practice of medicine or osteopathy as defined by law; and [b]y or under the personal supervision of an individual licensed under law to practice medicine or osteopathy." More broadly, service must be sufficient in amount, duration, and scope to

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Supreme

DeSario 80,

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DeSario Second "the reasonably achieve its purpose." 42 § 440.230(b). Although

[Medicaid] agency may place appropriate limits on a service based on criteria such as medical necessity or on utilization control procedures," it not arbitrarily deny or reduce the amount, duration, or scope of a required service . solely because of the diagnosis, type of illness, or condition." 42 § 440.230(c), (d).

The Court has implied, but not held, that the Medicaid Act requires states to provide medically necessary care, see Beal v. Doe, 432 438, 444 (1977) statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage."); and several circuits have held that medical necessity is the appropriate standard to determine the scope of services required by the Medicaid Act, see, Hern v. Beye, 57 F.3d 911 (10th Cir. 1995); Dexter v. Kirschner, 984 F.2d 979, 983 (9th 1992); v. Preisser, 623 F.2d 546, 549 (8th 1980) The Circuit previously rejected this approach as and unworkable," but the Court vacated its judgment in light of guidance issued by the Health Care Financing Administration. v. Thomas, 139 F.3d 96 (2d Cir. 1998), vacated sub nom. v. Thomas, 525 (1999) Although vacated, however, is still a useful guide. The

Circuit there held that state must extend coverage

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state." Choate, U.S. 303

"agency

procedures." C.F.R. 440.230(d) Proper

See, Pharm. U.S. (2003)

"assuring care." Choate, U.S. 303

Court

See 906, (10th Cir. ("[A]

30 through reasonable standards with .

. the 'general aim of assuring that individuals will receive necessary medical care' and each category of service must be sufficient in amount, duration, and scope to adequately (although not fully) meet the needs of the Medicaid population of the Id. at 96 (quoting Alexander v. 469 287, (1985)). It seems that DeSario must be correct that coverage of every single medically necessary treatment is not automatically required by the Availability Provision. After all, a Medicaid may place appropriate limits on a service based on criteria such as medical necessity or on utilization control 42

§ (emphasis added). utilization control procedures, as distinct from medical necessity, may limit the provision of services. Research and Mfrs. of America v. Walsh, 538 644 (plurality opinion) (upholding prior authorization processes). But any limiting criteria other than medical necessity must ultimately serve the broader aim of that individuals will receive necessary medical Alexander v. 469 287, (1985).

Against the background of this somewhat fractured legal regime, plaintiffs ask the to adopt a rule that a state may not place an outright ban on medically necessary treatments for a particular diagnosis. Hern v. Beye, 57 F.3d 911

1995) state law that categorically denies coverage for

U.S.C.

Provision

DeSario 80, a specific, medically necessary procedure except in those rare instances when the

patient's life is at stake is not a 'reasonable standard [ ] consistent with the objectives of [the Act],' but instead contravenes the purposes of Title XIX." (citation omitted) (quoting 42 § 1396a(a) (17))); White v. Beal, 555 F.2d 1146, 1151 (3d Cir. 1977). Defendant does not meaningfully oppose this rule, preferring instead to argue that § 505.2(1) does not impose any outright bans and that the June Guidance's prior authorization requirements are acceptable limitations on coverage.

The Court therefore adopts this "never-say-never" rule. The Availability and its implementing regulations do allow a state to say "only sometimes" and to limit coverage of specific treatments when the state has good reasons for doing so - reasons that ultimately uphold the provision of necessary medical care to needy individuals. But a state cannot say "never" when it comes to medically necessary treatments, because there are no such reasons justifying categorical bans on medically necessary treatment. A categorical ban on medically necessary treatment for a specific diagnosis would not "adequately . . meet the needs of the Medicaid population of the state." v. Thomas, 139 F.3d 96 (2d Cir. 1998).

With respect to the Cosmetic Exclusion, there are no genuine factual disputes material to the determination that defendant has

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Plaintiffs' Pursuant

Program, Update 2015); Support

2016,

2015, CRUZ00002625-26,

Provision.

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Plaintiffs

Provision. See Support Plaintiffs'

50 enacted a categorical ban on medically necessary treatments for a specific diagnosis. Specifically, "[d]efendant does not contest that presumptively cosmetic procedures listed in§ 505.2(1) may be medically necessary for some patients diagnosed with GD." Defendants Response and Counter-Statement to Statement of Material Facts to Local Rule 56.1 138, ECF No. 87. Moreover, by publishing the June Guidance and approving cosmetic procedures for Christie and Kpaka, defendant

has demonstrated that cosmetic procedures can be medically necessary for individuals with gender dysphoria. See New York Department of Health Medicaid Medicaid Vol. 31 No. 6 (June Declaration of Ronald J. Bass in of Defendant's May 11, Letter, Exs. 1-7, ECF No. 122; Declaration of John Gasior dated Aug. 28, Ex. 3 at

ECF No. 83. As discussed above, § 505.2(1) enacts a categorical ban on coverage for cosmetic procedures. See supra. As such, plaintiffs prevail on their § 1983 claim that § 505.2(1) violates the Availability Accordingly, the Court grants plaintiffs' motion and denies defendant's motion for

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also argue that the June Guidance's restrictions on eligibility for breast augmentation surgery violate the Availability Memorandum of Law in of

Motion for Summary Judgment at 6-7, ECF No. 76. However, the June Guidance - and therefore this issue - is not presently before the Court. § 5. 2 (1) (4) (v) (b) states unequivocally that "[p]ayment will not be made for . . breast augmentation."

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See§ 505.2(1) U.S.C. "Compendia

"[a] State

See U.S.C.

("FDA")

See

"Medicaid

"(I)

United States DRUGDEX System". U.S.C. summary judgment on plaintiffs' Availability Provision claim with respect to the Cosmetic Exclusion.

With respect to the Age Exclusion, the Court denies plaintiffs' motion for summary judgment on their Availability Provision claims and grants defendant's motion in part. To begin with, part of defendant's motion must be granted as a matter of law. Plaintiffs seek treatments of two kinds: surgeries and hormone therapies, including pubertal suppressants and cross-sex hormone therapies.

There is no dispute that§ 505.2(1) categorically bans coverage for all of these treatments for individuals younger than 18. (2)-(3). However, under 42 § 1396r-8(d)(l)(B)(i) (the Requirement"), may exclude or otherwise restrict coverage of a covered outpatient drug if . the prescribed use is not for a medically accepted indication," defined as any use approved by the FDA or included in the Medicaid Compendia.

7 42 § 1396r-8(k)(6). There is no dispute that the hormone therapies sought by plaintiffs are neither approved by the Food and Drug Administration nor listed in the Medicaid Compendia for the purpose of treating gender dysphoria in minors.

Plaintiff's Opposition to Defendant's Local Rule 56.1

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The Compendia" are drug information databases, consisting of the American Hospital Formulary Service Drug Information; (II) [the] Pharmacopeia-Drug Information (and its successor publications), and (III) the

Information 42 § 1396r-8(g) (1) (B) (i)

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ECF

U.S.C. Statement of Material Facts 67, No. 93. As such, for purposes of plaintiffs' Availability Provision claims, the Compendia Requirement allows defendant to exclude coverage of them.

Plaintiffs argue that the Compendia Requirement does not apply to the hormone therapies they seek because they are not "covered outpatient drugs." In particular, plaintiffs argue that, to the extent hormone therapies are provided in the context of a physician visit, they are not covered outpatient drugs because, under 42 § 1396r-8(k) (3),

[t] he term 'covered outpatient drug' does not include any drug provided as part of, or as incident to and in the same set ting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug) : (A) Inpatient hospital services (D) physicians' services. (E) Outpatient hospital services. § 1396r-8 (k) (3) continues on to state that "[s]uch term also does not include . . a drug . used for a medical indication which is not a medically accepted indication." Thus, plaintiffs' argument regarding the context of when the hormone therapies are provided is unnecessary because the Medicaid Act explicitly excludes "off-label" hormone therapies from the definition of "covered outpatient drugs."

Although plaintiffs' argument does highlight the inartful drafting of the Medicaid Act - if the term "covered outpatient

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Compendia

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Co., Supp. 2001).

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Court drug" does not include a drug used for a non-medically accepted indication, how can the exclude or restrict coverage of a covered outpatient drug's use for a non-medically accepted indication? - nonetheless, reading the statute as a whole, the

concludes that the definition of "covered outpatient drug" reinforces the Requirement because "[r]eimbursement under Medicaid is, in most circumstances, available only for 'covered outpatient drugs.'" ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert 147 F. 2d 39, 44- 45 (D. Mass. In short, defendant may exclude coverage of the hormone therapies under either the Requirement of § 1396r-8 (d) (1) (B) (i) or the definition of covered outpatient drugs of § 1396r-8 (k) (3). As such, the grants defendant's motion for summary judgment on plaintiffs' Availability Provision claims with respect to hormone therapies and dismisses these claims.

Genuine disputes of material fact prevent the from granting either party's motion for summary judgment on plaintiffs' Availability Provision claims with respect to surgeries. In particular, the medical necessity of surgeries as treatments for gender in individuals under 18 is genuinely disputed. Before discussing this factual dispute, however, the

must resolve a preliminary matter: the parties dispute what facts are relevant to a determination of medical necessity. Plaintiffs argue that physicians "have 'primary responsibility'

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Plaintiffs' 104. 80

Plaintiffs'

Put to determine what treatment patients should receive." Reply Memorandum of Law in Further Support of Motion for Summary Judgment at 3 n.3, ECF No. Defendant claims that DeSario v. Thomas, 139 F.3d (2d Cir. 1998), "[took] issue with the view that a Medicaid beneficiary's physician 'deserves almost complete deference in determining medical necessity'" and that "prevailing medical knowledge and scientific evidence" should control. Defendant's Memorandum of Law in Opposition to

Motion for Summary Judgment at 6, 7, ECF No. 86 (quoting DeSario, 139 F.3d at 95). Defendant also frames the inquiry not as a determination of whether a treatment is medically necessary but instead as a question of whether the state's determination of medical necessity is reasonable. Id.

The differences between the parties' positions are artificial. Although the medical community is not a monolith, individual physicians, as members of a self-regulating professional community, are expected to adhere to standards of "prevailing medical knowledge and scientific evidence." another way, "prevailing medical knowledge" is largely defined by the practice of individual physicians. As such, testimony of individual physicians as well as any other evidence of prevailing medical knowledge is relevant to a court's determination of medical necessity. Moreover, because of the way New York has defined "medical necessity" and because it has enacted a

36

See Comp. Codes 500.l(b)

Constance Sept. 10, ECF DOH

C.F.R.

See, Comp. Codes categorical ban on the treatments at issue, there is no difference between determining the medical necessity of a treatment and evaluating the reasonableness of the state's determination of whether a treatment is medically necessary. N.Y. R. & Regs. tit. 18, § ("The department will limit the amount, duration and scope of medical assistance authorized to be provided . to medical care, services and supplies which are medically necessary and appropriate, consistent with quality care and generally accepted professional standards."); Declaration of Donohue dated 11, 2015, No. 88 (stating that the adopted the Age Exclusion on the basis of§ 500.l(b)). As an administrative matter, the state makes "determinations" of medical necessity, consistent with

its power under the Medicaid regulations to "place[s] appropriate limits on a service based on criteria such as medical necessity." 42 § 440.230(d). But when the state makes such determinations, it is simply synthesizing an administrative rule based on the accumulated knowledge of the medical community. The Department of Health cannot assemble evidence from the medical community but then, on its own, alter some of the substantive results. e.g., N.Y. R. & Regs. tit. 18, § 513.6(e). The grounds for finding a treatment medically necessary or for finding the state's determination of lack of necessity unreasonable will be therefore be same: the

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See

U.S. 303 testimony of physicians and evidence of prevailing medical and scientific knowledge.

DeSario is not to the contrary. DeSario did not actually "take issue" with the unremarkable notion that physicians should be the primary arbiters of medical necessity. Instead, it pointed out that, if the Medicaid Act did obligate states to cover every last medically necessary treatment, such that an individual physician could legally obligate the state to cover a treatment simply by writing a prescription, then states would be severely limited in their efforts to control costs. DeSario, 139 F.3d at 95-96 (observing that the only cost control measures available to states in such a scenario would be to cut back on any optional services). The Second Circuit's solution in DeSario was not to take determinations of medical necessity out of the hands of medical professionals, where they rightfully belong. Instead, as discussed above, the Second Circuit held that the Medicaid Act does not obligate states to cover all medically necessary treatments: proper utilization control procedures can be used to control costs, if they ultimately "assur[e] that individuals will receive necessary medical care." Alexander v. Choate, 469 287, (1985).

Plaintiffs have produced two reports from expert witnesses testifying that the same treatments that are effective for adults with gender dysphoria can be effective and medically necessary

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See Olson, Sept.

2015, ECF

Christopher 2015, ECF

DOH.

Oregon University Center Policy "OHSU for minors with gender dysphoria. Expert Report of Johanna

M.D., Declaration of Christopher J. McNamara dated Aug. 28, Ex. 27 14-22, No. 74; Expert Report of Nicholas Gorton, MD, DABEM, Declaration of J. McNamara dated Aug. 28, Ex. 38 at 15-17, No. 74. Indeed, one expert concludes that "treatment of youth is more effective in many ways than treatment of transgender adults" because gender dysphoria is exacerbated over time by repeated traumas and because puberty causes significant physical changes that can be difficult to reverse or mask later in life. Id. at 16.

Defendant claims that the medical community has not yet reached a consensus on the safety and efficacy of the treatment of gender dysphoria in minors. He primarily relies on the testimony of one expert witness, John W. Williams, M.D., and a fact witness, a representative of However, Dr. Williams did not address the safety or efficacy of treatments for gender dysphoria for minors in his expert report. Instead, Dr. Williams drew conclusions regarding the quality of two literature reviews submitted by defendant, one compiled by a private health consultancy, Hayes, Inc., (the "Hayes report") and the other compiled by the Health & Science for Evidence-based (the report"). In particular, Dr. Williams stated that "[b]ased on my experience in working with

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OHSU

MHSc, Second Zoey S. Support Summary

OHSU

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Plaintiffs' Statement Pursuant 150,

OHSU

40 and/or utilizing research reports from and Hayes I am confident that these reports represent scientifically valid work." Expert Report of John W. Williams Jr, MD, Declaration of Chenitz in Further of Defendant's Motion for Judgment Ex. A at 5, ECF No. 112.

The Hayes report and the report, as well as the studies cited therein, are inadmissible hearsay. Defendant has not offered the authors of the reports or any of the underlying studies they cite as witnesses. Defendant also has not offered any expert witnesses who reasonably relied on the reports within the meaning of Fed. R. Evid. or 803(18) (A). Dr. Williams did not rely on the contents of the reports; he evaluated their methodology. The reports are also not admissible as learned treatises under Fed. R. Evid. 803(18) (B). No expert has established the reports as reliable authority. Indeed, because Dr. Williams is not an expert on treatments of gender dysphoria, he cannot competently

testify about the authority of the reports. Defendant's Response and Counter-Statement to

of Material Facts to Local Rule 56.1 ECF No. 87. Moreover, defendant has offered no reasonable basis for the Court to take judicial notice of the reports' authority. For instance, they have not been peer-reviewed by the wider medical community. Accordingly, the Court excludes the Hayes and

reports as inadmissible hearsay and concludes that Dr.

DOH, Constance She

DOH WPATH Care, OHSU

See Constance Sept. 2015, ECF

OHSU

Centers ("CMS").

CMS Coverage

Contractors

Court Williams' report has no bearing on the question of the medical necessity of specific treatments of gender dysphoria in minors.

Apart from Dr. Williams, defendant primarily relies on the testimony of a representative of the Donohue.a affirms that, in deciding that no treatments for gender dysphoria in minors were medically necessary, the relied on the Standards of the Hayes report, the report, "studies and journal articles related to [the] topic," and guidelines prepared by the Endocrine Society. Declaration of Donohue dated 11, 9, No. 88. As explained above, the Hayes report and the report are inadmissible hearsay. Defendant has not produced any of the "studies and journal articles related to [the] topic" and, on the present record, they would also be inadmissible hearsay. Defendant's own

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After full briefing on the present motions, defendant also submitted a proposed decision memorandum issued by the for Medicare & Medicaid Services The memorandum proposes to maintain the status quo regarding Medicare coverage of gender reassignment surgeries, namely, that will not issue a National Determination and instead leave coverage determinations to local Medicare Administrative on an individual claim basis. It bases this proposal on the conclusion that there is insufficient evidence to determine whether coverage of gender reassignment surgery by Medicare

would be beneficial and asks for further studies to be conducted on the issue. This document is of little relevance to the present inquiry and the

gives it little weight. The proposed decision memorandum is not a binding document and is primarily a literature review of studies that are inadmissible hearsay. Most importantly, it focuses on Medicare recipients, i.e. individuals 65 years and older, a necessarily significantly different population than members of the Age Subclass.

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30(b)

See Christopher 2015, ECF Olson,

Christopher 2015, ECF

Christopher 2015, ECF

Care

See Care

Care

2504.1]

Care "[c]hest (6) testimony concerning the contents of these absent studies is inadmissible hearsay.

That leaves the WPATH Standards of Care and the guidelines prepared by the Endocrine Society, each of which raise a genuine dispute over whether surgeries are medically necessary treatments for minors with gender dysphoria. Both sides, as well as plaintiffs' experts, rely on these texts, and the Court concludes they are sufficiently authoritative to allow their admissibility under Fed. R. Evid. 803(18). Expert Report of Jack Drescher, M.D., P.C., Declaration of J. McNamara dated Aug. 28,

Ex. 22 at 11, No. 74; Expert Report of Johanna M.D., Declaration of J. McNamara dated Aug. 28, Ex. 27 17, 22, 25, No. 74; Expert Report of Nicholas Gorton, MD, DABEM, Declaration of J. McNamara dated Aug. 28, Ex. 38 at 3, No. 74. As a general matter, the WPATH Standards of encourage treatment of minors with gender dysphoria and even warn of the consequences of delaying treatment. WPATH Standards of at 21. However, the WPATH Standards of state that

[g] eni tal surgery should not be carried out until [] patients reach the legal age of majority to give

consent for medical procedures in a given country [18, under N.Y. Public Health Law§ . The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention. Id. at 21. The WPATH Standards of do state that surgery in FtM patients could be carried out earlier." Id. The

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"[w]e

2015 ECF

Court

U.S.C. "Comparability

Court

Cosmetic Cosmetic

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U.S.C. (10) Circuit "[the Comparability Endocrine Society guidelines state that suggest deferring surgery until the individual is at least 18 years old." Declaration of John Gasior dated Aug. 28, Ex. 15 at 4 2.6,

No. 83. These materials create a genuine dispute of material fact that must be resolved at trial: what surgeries are medically necessary treatments for minors with gender dysphoria? As such, the denies both parties' motion for summary judgment on plaintiffs' Availability Provision claims against the Age Exclusion with respect to surgeries.

Sixth, on plaintiffs' second claim, for violations of 42

§ 1396a(a)(10)(B) (Medicaid's Provision"), the denies defendant's motion for summary judgment with respect to the Exclusion, grants plaintiffs' motion with respect to the Exclusion, and grants defendant's motion in part and denies plaintiffs' motion with respect to the Age Exclusion. The Provision requires that medical assistance made available to any [categorically needy] individual

. shall not be less in amount, duration, or scope than the medical assistance made available to any other such [categorically needy] individual." 42 § 1396a (a) (B) (i). The Second has explained that

Provision] prohibits discrimination among individuals with the same medical needs stemming from

different

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Shah, Cir. 2016)

Cosmetic DOH

See Plaintiffs' Set Christopher

2015, ECF

State Program Physician Procedure Code, 2015 "Physician's

See Counter-Statement Plaintiffs' Statement Pursuant ECF

Cosmetic

Physician's medical conditions." Davis v. 821 F.3d 231, 258 (2d

. With respect to the Exclusion, there is no genuine dispute that covers the cosmetic surgeries excluded by § 505.2(1) for individuals with diagnoses other than gender dysphoria. Defendant claims that there is a dispute over which cosmetic surgeries are covered for other diagnoses. However, defendant's position is belied by his own admissions that New York's Medicaid program covers breast reconstruction, facial feminizing surgery, chondrolaryngoplasty, electrolysis, and body sculpting procedures. Defendant's Responses to First of Requests for Admission, Declaration of J. McNamara dated Aug. 28, Ex. 4 at 14-15, No. 74. In addition, defendant does not contest that the New York Medicaid Version, (the

Manual") which contains billing instructions for physicians regarding treatments covered by Medicaid, contains billing instructions, including billing codes, for essentially all the cosmetic procedures. Defendant's Response and

to of Material Facts to Local Rule 56.1 154, 155, No. 87. The one item barred by the Exclusion which is not addressed in some form by defendant's admissions, the Manual, or both is "drugs to promote hair growth or loss," barred by§

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505.2

Plaintiffs' Pursuant

Provision

Plaintiffs' Statement Pursuant

Provision "[the Provision]

2016) (1) (4) (v) (f). Neither side presents evidence particularly addressed to this item. Moreover, as discussed above, there is no dispute that the cosmetic procedures and services barred by the Cosmetic Exclusion can be medically necessary. Defendant's Response and Counter-Statement to Statement of Material Facts to Local Rule 56.l 138, ECF No. 87. Accordingly, the Court grants plaintiffs' motion for summary judgment on their Comparability claims with respect to the Cosmetic Exclusion, except with respect to drugs promoting hair growth or loss, and denies the corresponding part of defendant's motion.

With respect to the Age Exclusion, there is no dispute that the cosmetic and gender reassignment surgeries sought by plaintiffs are covered by New York's Medicaid program. See supra (discussing coverage of cosmetic procedures); Defendant's Response and Counter-Statement to of Material Facts to Local Rule 56.1 188, ECF No. 87 (defendant admitting that New York provides Medicaid coverage of the components of gender reassignment surgeries). However, this is not the end of the Comparability inquiry. The Second Circuit has stated that Comparability prohibits discrimination among individuals with the same medical needs stemming from different medical conditions." Davis v. Shah, 821 F.3d 231, 258 (2d Cir. (emphasis added). Thus, the

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Comparability Provision

Otherwise,

Comparability

Subclass

Comparability

Court

Comparability Provision

Compendia Comparability

Compendia Comparability

See Counter-Statement Statement ECF

Compendia

incorporates a medical necessity requirement. any categorically needy individual, regardless of medical need for a procedure, could seek coverage of a procedure provided to other categorically needy recipients under the Provision. As discussed above, it is disputed whether the surgeries sought by the Age members are medically necessary for individuals under 18. This question must be resolved at trial with respect to plaintiffs'

Provision claims as well as their Availability Provision claims. Accordingly, the denies both parties' motions for summary judgment on plaintiffs'

claims with respect to surgeries. With respect to hormone therapies, defendant argues that the

Requirement blocks plaintiffs' Provision claims. Plaintiffs respond that the Requirement does not apply to their Provision claims because defendant provides hormone therapies to other categorically needy individuals with gender dysphoria, even though all uses of hormones to treat gender dysphoria lack FDA support. Defendant's Response and to Plaintiffs'

of Material Facts Pursuant to Local Rule 56.1 226, No. 87. Plaintiffs' argument points to a tension within the Medicaid Act between the Requirement (and§ 1396r-8 (k) (3) 's

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Supreme Court

Corley United States, U.S. (2009)

Comparability Court

Compendia Comparability Compendia

Compendia

Comparability definition of a "covered outpatient drug") and the Comparability Provision. The has identified as "one of the most basic interpretive canons, that '[a] statute should be construed so that

effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.'"

v. 556 303, 314 (internal quotation marks omitted) (alteration in original) In this case, defendant's reading of the Medicaid Act would render the

Provision inoperative. Accordingly, the adopts a reading that gives both the Requirement and the Provision force: although defendant may, under the Requirement, exclude coverage of uses of hormone therapies without FDA or support to all categorically individuals with gender dysphoria, nonetheless, if defendant does cover unapproved uses of hormone therapies for some categorically needy individuals with gender dysphoria, under the Provision, he must then cover unapproved uses of hormone therapies for all categorically needy individuals with gender dysphoria. Essentially, the provisions work together to present defendant with an "all-or-nothing" choice: he can either cover hormone therapies for gender dysphoria or not, but he cannot cover them selectively.

Defendant argues that, as a factual matter, he has chosen not to cover unapproved hormone therapies at all. He claims that

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Compendia. See Sept. 2015, ECF 103.

Compendia See

30(b) Constance Christopher 2015,

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Olson, Christopher

2015, 50 ECF Court

Compendia. has a policy in place to deny coverage of all drug uses not covered in the Medicaid Declaration of Norman P. Ostrove dated 18, Ex. 66, No. Plaintiffs respond that defendant fabricated this policy for purposes of the present litigation and, to the extent it was a bona fide policy, it has been selectively enforced, such that New York does cover drug uses that lack FDA or support in some circumstances. id. (showing a prominent "DRAFT" watermark on defendant's policy); (6)

Deposition of Donohue, Declaration of J. McNamara dated Aug. 28, Ex. 19 at 142:15-23, 162:22-163:3. Because the has conflicting evidence before it, the provenance of defendant's policy and whether it has been consistently enforced cannot be resolved on summary judgment and must be dealt with at trial. Relatedly, the

notes that§ 505.2(1) states that "payment is available for medically necessary hormone therapy . for the treatment of gender dysphoria . . for individuals 18 years of age or older." Although plaintiffs have offered uncontroverted expert testimony that no uses of hormone therapy to treat gender dysphoria (for adults or minors) have been approved by the FDA, see Deposition of Johanna M.D., Declaration of J. McNamara dated Aug. 28, Ex. at 214:18-21, No. 74, the cannot discern from the present record whether hormone therapies for adults are listed in the Medicaid If they are not,

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9 Pubertal

Stage the language of§ 505.2(1) approving hormone therapy for adults would fly in the face of defendant's alleged policy limited coverage to uses with Compendia support. However, the question of whether hormone therapies for adults with gender dysphoria are listed in the Medicaid Compendia must be resolved at trial. In addition, if the Compendia Requirement does not defeat plaintiffs' Comparability claims against the Age Exclusion, the parties need also address at trial which types of hormone therapies defendant has covered for adults. In particular, it is not clear from the present record if pubertal suppressants for individuals 18 years or older have been or ever would be covered under§ 505.2(1) .

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Depending on the resolution of this factual question, it is possible that plaintiffs' Comparability claims would only survive the Compendia Requirement with respect to cross-sex hormones and not with respect to pubertal suppressants.

Even assuming that the Compendia Requirement is not a bar to plaintiffs' Comparability claims for hormone therapies for minors - i.e. that the factual disputes discussed above are resolved in

plaintiffs' favor - to prevail on their Comparability

claims, plaintiffs would still need to show that pubertal suppressants and cross-sex hormones are medically

suppressants are typically administered when individual reaches Tanner II, the second of five stages of puberty.

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See Shah, Cir. 2016). Plaintiffs'

See Olson, Sept.

Christopher ECF

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See WPATH SOC

Olson,

50 necessary for minors. Davis v. 821 F.3d 231, 258 (2d

experts report that the use of cross-sex hormones and pubertal suppressants for minors with gender dysphoria is safe, effective, and medically necessary. Expert Report of Johanna M.D., Declaration of Christopher J. McNamara dated Aug. 28, 2015, Ex. 27 15-20, ECF No. 74; Expert Report of Nicholas Gorton, MD, DABEM, Declaration of

J. McNamara dated Aug. 28, 2015, Ex. 38 at 16-18, No. 74. Defendant claims that hormone therapies for minors with gender dysphoria are experimental and that there is no medical consensus that they are safe and effective. However, as discussed above in the context of the factual dispute over surgeries for minors with gender dysphoria, much of what defendant has offered in support of his position is inadmissible hearsay and defendant's sole expert witness did not opine on the efficacy of treatments for individuals with gender dysphoria. The non-hearsay

Standards of and Endocrine Society guidelines endorse the use of hormone therapies to treat gender dysphoria in minors.

at 18-20; Declaration of John Gasior dated Aug. 28, 2015, Ex. 15 at 11-17, ECF No. 83. Nonetheless, the Court concludes that there is a genuine factual dispute over the safety and efficacy of hormone

therapies for minors with gender dysphoria because of the lack of FDA or Medicaid Compendia

Deposition of Johanna M.D., Declaration of Christopher J.

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Comparability

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Compendia,

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Care ("ACA"), U.S.C. Court

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20 U.S.C. 504

U.S.C. See U.S.C.

20 U.S.C. Section 504

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See Order 2015, ECF approval. The lack of regulatory approval means that this issue must be resolved at trial. Accordingly, the denies both parties' motions for summary judgment on plaintiffs'

Provision claims. The trial must resolve the following two questions with respect to these claims: first, what treatments, including surgeries or hormone therapies, are medically necessary for the treatment of gender dysphoria in minors? does have a bona fide policy to exclude coverage of drug uses not listed in the Medicaid and to what extent has this policy been applied consistently in the context of the provision of hormone therapies to treat individuals with gender dysphoria?

on plaintiffs' fifth claim,

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for violations of § 1557 of the Affordable Act 42 § 18116, the

denies defendant's motion for summary judgment in part and grants it in part. § 1557 of the incorporates the standards of, among other statutes, Title IX of the Education Amendments of 1972, § 1681, and § of the Rehabilitation Act of 1973, 29 § 794. 42 § 18116. Title IX forbids discrimination on the basis of sex. § 1681. prohibits discrimination on the basis of disability. 29 §

McNamara dated Aug. 28, Ex. at 190:22-191:3, ECF No. 74.

The Court previously dismissed plaintiffs' third and fourth claims. dated June 29, No. 46. Plaintiffs did not move for summary judgment on their fifth claim.

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U.S.C. 705(20) "disability" U.S.C. "a

"major 794. claim that§ 505.2(1) discriminates against them on the basis of sex and disability.

The grants defendant's motion for summary judgment with respect to plaintiffs' disability discrimination claims. Section states that

[n] o otherwise qualified individual with a disability in the States, as defined in section of this title, shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. 29 § 794. Section (F) states that the purposes of section[] 794 of this title, the term 'individual with a disability' does not include an individual on the basis of . gender identity disorders not resulting from physical impairments." 29 § (F). Even if this carveout did not apply here, 29 § (B) incorporates the definition of given in 42 § 12102: physical or mental impairment that substantially limits one or more major life activities of such individual" with life activities includ[ing], but . not

limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working." Defendant argues that plaintiffs have failed to produce any significant evidence that all

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Summary

Services ("HHS")

"on "gender individuals with gender dysphoria are limited in the performance of major life activities, such that gender dysphoria can be identified as a disability. Deposition of Johanna

M.D., Declaration of John Gasior dated Aug. 28, 2015, Ex. 12 at 109:3-110:6 think that gender dysphoria can be disabling. I don't know that I would call it a disability."), ECF No. 83. Plaintiffs do not oppose defendant's arguments. Memorandum of Law in Opposition to Defendant's Motion for Judgment at 23-25, ECF No. 95. Accordingly, the Court grants defendant's motion for summary judgment and dismisses plaintiffs' disability discrimination claim.

The Court denies, however, defendant's motion for summary judgment with respect to plaintiffs' sex discrimination claim. Defendant originally argued that plaintiffs' sex discrimination claim failed because gender dysphoria was not a proxy for sex within the meaning of the ACA, § 505.2(1) did not treat individuals with gender dysphoria differently from other individuals, and Title IX, as incorporated into the ACA, does not allow disparate impact claims. However, on May 18, 2016, the Department of Health and Human promulgated regulations explaining that the ACA's ban on discrimination the basis of sex" includes discrimination on the basis of identity." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31467 (May 18, 2016). The regulation defines

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HHS "gender identity" as "an individual's internal sense of gender" and states that "[a] transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth." Id. It sets forth the following rules:

[a] covered entity [defined as an entity that operates a health program or activity, any part of which receives Federal financial assistance] shall not, in providing or administering health-related insurance or other health-related coverage (4) Have or implement a categorical coverage exclusion or limitation for all heal th services related to gender transition; or (5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual. Id. at 31472. The supplementary information published with the rule stated that "[the of Civil Rights] interprets 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation." Id. at

After publication of this regulation, the Court received supplemental briefing from the parties. In his supplemental briefing, defendant argued that§ 505.2(1) does not run afoul of the ACA or the recent regulation because it does not implement a categorical exclusion on treatments of gender dysphoria and allows coverage of medically necessary procedures. As explained above, § 505.2(1) does categorically ban medically necessary treatments for gender dysphoria. Accordingly, the Court

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Support Summary denies defendant's motion for summary judgment on plaintiffs' sex discrimination claim.

Eighth, on plaintiffs' sixth claim, for violations of 42

§§ 1396a(a) (43), 1396d(r) (Medicaid's Provision"), the denies both parties' motions for summary judgment. The

Provision requires states to or arrang[e] for the provision of [early and periodic screening, diagnostic, and treatment services, described at § 1396d(r)] in all cases where they are requested" for Medicaid recipients under 21 and

for . . corrective treatment the need for which is disclosed by such child health screening services." 42 § 1396 (a) (43) 1396d(r) defines early and periodic screening, diagnostic, and treatment services to include a range of screening services, as well as health care, diagnostic services, treatment, and [other medical assistance] to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the

plan." 42 § 1396d(r). The parties agree that the Provision requires states to provide all medically necessary care to Medicaid recipients under 21, although states may elect not to cover experimental treatments. Memorandum of Law in of Defendant's Motion for Judgment at 17-18,

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Support Plaintiffs' Summary

EPSDT Provision

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EPDST Provision. "[a] State

U.S.C. EPDST Provision EPSDT

State U.S.C. ECF No. 82; Memorandum of Law in of Motion for Judgment at 19-21, ECF No. 76.

As discussed above, there is a genuine dispute over whether the surgeries sought by plaintiffs are medically necessary and not experimental. Accordingly, the Court denies both parties' motions for summary judgment on plaintiffs' claims with respect to surgeries.

With respect to the hormone therapies sought by plaintiffs, defendant argues that the Compendia Requirement bars plaintiffs'

claims because there is no FDA or Compendia support for hormone therapies as treatments for gender dysphoria in minors. However, the Compendia Requirement does not extend to the

The Compendia Requirement states that may exclude or otherwise restrict coverage of a covered outpatient drug if . the prescribed use is not for a medically accepted indication." 42 § 1396r-8 (d) (1) (B) (i). However, the

defines services, which states are required to provide, to include "necessary health care, diagnostic services, treatment, and [other medical assistance] to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the plan." 42 § 1396d(r) (5) (emphasis added). Accordingly, the coverage carveout offered by the Compendia Requirement does not lessen a state's

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EPSDT Provision

EPSDT Provision

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ESPDT EPDST Provision burden under the to provide all medically necessary care.

Because they survive the Compendia Requirement in full, plaintiffs' claims directly present the factual questions that are only contingently presented by plaintiffs' Comparability claims, namely, whether hormone therapies are medically necessary to treat gender dysphoria in minors. As discussed above, because of the lack of regulatory approvals, there are genuine disputes over whether hormone therapies, both cross-sex hormones and pubertal suppressants, are safe, effective, and medically necessary for minors with gender dysphoria. Accordingly, the Court denies both parties' motions for summary judgment on plaintiffs' claims. The question to be resolved at trial on the claims is also presented by plaintiffs' other claims, namely, what treatments, including surgeries or hormone therapies, are medically necessary for the treatment of gender dysphoria in minors?

In sum, for the foregoing reasons, the Court denies defendant's motion for reconsideration, denies defendant's motion to decertify the plaintiff class, denies defendant's motion for summary judgment in part and grants it in part, and denies plaintiffs' motion for summary judgment in part and grants it in part. This case will proceed to trial to determine (1) what treatments are medically necessary for individuals under 18 with

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July£, 2016 gender dysphoria and (2) to what extent has consistently followed a bona fide policy of limiting coverage of drug uses to those listed in the Medicaid Compendia in the context of treatments for gender dysphoria. The parties are directed to jointly telephone Chambers by no later than July 8, to schedule a trial date.

The Clerk of Court is directed to close documents numbered 77, 79, and 81 on the docket of this case.

ORDERED. Dated: New York, New York

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