UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BAGLY, *et al.*,	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-cv-11297-PBS
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
Defendants.	)	

RESPONSE TO PLAINTIFFS' OPPORTUNITY TO SUPPLEMENT THE RECORD IN SUPPORT OF THEIR STANDING

As the Government has explained, the Department of Health and Human Services is reconsidering the challenged rule and intends to engage in a new rulemaking to ensure that the Section 1557 regulations are consistent with the Biden Administration's commitment to equity and to expanding access to coverage and care for underserved communities. Nevertheless, federal courts have jurisdiction to resolve legal disputes over agency rulemakings only if the plaintiffs can demonstrate standing as of the date they filed suit. At this point, almost all of the rule challenged in this case has been in effect for nearly a year. But Plaintiffs have not been able to demonstrate how the rule has resulted in cognizable injury to them—or how injury was imminent when they filed suit. In their supplemental filing dated June 17, 2021, Plaintiffs seek almost exclusively to rely upon the experiences of nonparty participants in the healthcare system, without demonstrating the necessary link to an injury to Plaintiffs themselves. The only Plaintiff offering any evidence of *some* concrete injury that was imminent at the outset of the litigation in July 2020 is Indigenous Women Rising ("IWR"), but IWR fails to carry its burden to demonstrate that it suffered an injury caused by the 2020 Rule that can be redressed by the relief it seeks. There is thus no occasion for the Court to consider the merits of Plaintiffs' challenge.

I. BACKGROUND AND LEGAL STANDARDS

On June 19, 2020, the United States Department of Health and Human Services ("HHS") promulgated a final rule making modifying regulations implementing Section 1557 of the Affordable Care Act. *See* Nondiscrimination in Health and Health Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) ("2020 Rule"). The effective date of these modifications was August 18, 2020. *Id*.

Between August and October 2020, two district courts enjoined several provisions of the 2020 Rule from taking effect. *See Asapansa-Johnson Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. Aug. 17, 2020) (staying the 2020 Rule's repeal of the Section 1557 regulatory definition of discrimination "on the basis of sex"); Order, *Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-01630-JEB, ECF No. 55 (D.D.C. Sept. 2, 2020) (enjoining enforcement of the 2020 Rule's incorporation of the religious exemption contained in Title IX into Section 1557 regulations and of the repeal of the definition of "on the basis of sex" insofar as it includes discrimination on the basis of sex stereotyping); *Asapansa-Johnson Walker v. Azar*, No. 1:20-cv-02834-FB-SMG, 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020) (staying "the repeal of 45 C.F.R. § 92.206," which requires covered entities to treat individuals consistent with their gender identity).

The balance of the 2020 Rule went into effect on August 18, 2020, including a modification to the scope of entities subject to Section 1557, the repeal of former 45 C.F.R. § 92.207's explicit examples of discriminatory practices in the provision and administration of health related insurance and replacement with a general prohibition on discrimination, modifications to legal standards for enforcement of Section 1557 violations, modifications to the standards regarding meaningful access to programs or activities by limited English proficient persons, a determination not to take a position by rule regarding whether Section 1557 encompasses discrimination on the basis of association, and conforming amendments to related regulations. In their Amended Complaint, Plaintiffs challenged *all* of the 2020 Rule's modifications to Section 1557 regulations. Recognizing that the allegations in their Amended Complaint alone were insufficient to support

their standing, Plaintiffs filed thirteen evidentiary declarations in support of their standing on November 18, 2020, *see* ECF No. 27, "much as they would for a summary judgment motion," *see Torres-Negron v. J&N Records, LLC*, 504 F.3d 151, 163 (1st Cir. 2007). Introducing that evidence converted the Rule 12(b)(1) motion into a factual one and forfeited any argument on Plaintiffs' part that the Court's subject matter jurisdiction inquiry should be limited to the four corners of their Amended Complaint. *See id*. at 163 (explaining that "the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case" on a Rule 12(b)(1) motion) (quotation omitted).

Recognizing that "common sense dictates that a court can and should consider the activities of the plaintiff during and after the time that the complaint is filed in order to assess [how imminent an alleged] future injury" was at the outset of the litigation, *see Nat'l Sec. Couns. v. CIA*, 898 F. Supp. 2d 233, 262 (D.D.C. 2012), on June 3, 2021, the Court permitted Plaintiffs an opportunity to supplement the record, including through submission of concrete evidence to substantiate their allegations of injuries imminent in July 2020. *See* Transcript of Hearing on Defendants' Motion to Dismiss (hereinafter "Mot. Hr'g Tr.") at 78:19-19; *see also id*. at 44:24-25 ("I think they are claiming imminent injury. It's just they felt precluded from supplementing."). Plaintiffs submitted additional evidence on June 17, 2021, *see* ECF No. 56, when most of the challenged provisions of the 2020 Rule had been "effective . . . for about [ten] months. . . . [D]uring those [ten] months, it was possible to measure any injury to the [Plaintiffs'] interests" or "measure projected future injury" that was allegedly imminent at the outset of the litigation. *See Massachusetts v. HHS*, 923 F.3d 209, 219 (1st Cir. 2019).

II. PLAINTIFFS' SUPPLEMENTAL MATERIALS CONFIRM THEY LACK STANDING

Plaintiffs' submissions lack evidence to substantiate their allegations that they faced imminent harm in July 2020 traceable to the 2020 Rule. Because "[a]llegations of possible future injury" are not sufficient, *see Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quotation

and emphasis omitted), Plaintiffs' speculation in the Amended Complaint did not plausibly allege standing, *see United States v. AVX Corp.*, 962 F.2d 108, 115, 116-17 (1st Cir. 1992). And Plaintiffs' failure to produce any concrete evidence to substantiate their speculation of imminent harm—now that most of the regulation has been in effect for nearly a year—makes clear that they did not face concrete, particularized, and personal imminent injury stemming from the regulatory provisions that they sought to challenge. *See Equal Rights Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1141-42 (D.C. Cir. 2011) (denying *Havens* standing where plaintiff did "not spell out when it engaged in" the alleged "counteraction programs" which would have had to be "actual or imminent at the time it filed suit"). On the now-supplemented record, "the extent to which the challenged [provisions] . . . perceptibly impede the plaintiffs' mission-orientated activities [still] seems difficult to measure, or, in other words, are imperceptible." *See Nat'l Fair Hous. All. v. Carson*, 330 F. Supp. 3d 14, 46 (D.D.C. 2018).[1]

Defendants agree with Plaintiffs that "the Court should analyze their standing as of the time of the filing of the complaint." ECF No. 56 at 1. But no Plaintiff alleged an actual or ongoing injury due to any provision of the challenged regulation at that time. Instead, the parties dispute whether any Plaintiff faced an *imminent* injury due to each of HHS's 2020 changes to its Section 1557 regulations at that time. *See* ECF No. 27 at 9.[2]

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[1] In *Equal Means Equal v. Ferriero*, --- F.4d ---, 2021 WL 2659061 (1st Cir. June 29, 2021), the First Circuit recently held that "an organization cannot establish [*Havens*] standing . . .when the service impaired is pure issue advocacy," nor can an organization "adopt a mission so that the organization expressed an interest in the subject matter of the case, and then spend its way into having standing." *Id.* at *4 (first quoting *PETA v. U.S. Dep't of Ag.*, 797 F.3d 1087, 1093-94 (D.C. Cir. 2015) and then quoting *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 288 (3d Cir. 2014)). That holding undermines the organizational Plaintiffs' advocacy-related injuries here.

[2] The Supreme Court analyzes the standing inquiry based on the time "when the suit was filed." *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 569 n.4 (1992); *see also Friends of the Earth, Inc. v. Laidlaw Env. Servs. Inc.*, 528 U.S. 167, 180 (2000) ("we have an obligation to assure ourselves that [plaintiff] had Article III standing at the outset of the litigation"). But it is immaterial whether the inquiry focuses at the time of the original Complaint or the Amended Complaint here.

Although the legal standard looks to the date of the complaint, "common sense dictates that a court can and should consider the activities of the plaintiff during and after the time that the complaint is filed in order to assess [how imminent] such a future injury" was at the outset of the litigation. *See Nat'l Sec. Couns.*, 898 F. Supp. 2d at 262. And during the past ten months, "it was possible to measure any injury to the [Plaintiffs'] interests" or "measure projected future injury" in July 2020. *See Massachusetts*, 923 F.3d at 219. But Plaintiffs have been unable to show, with evidence, that they faced anything more than speculative future injury at the outset of the litigation.

Plaintiff CrescentCare highlights this broader failure. Plaintiffs have argued that CrescentCare has standing to press its claims that HHS invalidly and arbitrarily construed the term "health program or activity" in Section 1557 (resulting in a narrower scope of covered entities). Plaintiffs did not allege that CrescentCare had suffered ongoing injury due to this construction by the time of the Amended Complaint. *See* ECF No. 27 at 28. Instead, they claimed that the provision "*will* reduce the reimbursements that Plaintiff Healthcare Facilities will receive for the care that they provide" at a future time. *See* ECF No. 27 at 26 (citing Am. Compl. ¶¶ 237, 241) (emphasis added). Plaintiffs submitted evidence from two declarants associated with CrescentCare with personal knowledge of the organization's operations—Alice Riener and Noel Twilbeck—both dated November 17, 2020. ECF No. 27-7 at p. 13 ("Riener Decl."), ECF No. 27-12 at p. 18. By that time, the rule had been in effect for three months, but neither declaration included concrete facts demonstrating that CrescentCare had experienced the reduction in reimbursements that it had alleged as imminent in July 2020. Instead, Riener merely asserted that the rule "*will* also cause CresentCare to lose revenue" at some hypothetical future time. *See* Riener Decl. ¶ 18 (emphasis added); *see also id*. ¶¶ 19-21. Finally, after the Court invited CrescentCare to supplement the record with concrete evidence of actual or ongoing injuries, on June 17, 2021, after the rule had been in effect for about ten months, CrescentCare submitted no evidence that it has experienced or is experiencing the feared reduction in typical reimbursements. CrescentCare's alleged injuries were not imminent at the outset of the litigation; if the injuries had been imminent, Plaintiffs would

have suffered injury—and introduced evidence to that effect—from some point over the past ten months.

The other Plaintiffs' efforts to establish standing to challenge each of the 2020 Rule's provisions fail for similar reasons. The Court should therefore dismiss the Amended Complaint for lack of standing.

A. The Keith Declaration and Associated Materials are Not Evidence of any Plaintiff's Injury, Let Alone One Fairly Traceable to Anything in the 2020 Rule

Without evidence that particular Plaintiffs have experienced actual injuries, Plaintiffs seek to rely on data about the industry as a whole. Plaintiffs submitted one organization's analysis of "1,386 silver marketplace [insurance] plan options from 176 insurers in the 36 states that use HealthCare.gov." ("Out2Enroll Report"). *See* Declaration of Katie Keith ¶ 10, ECF No 51-1 ("Keith Decl."). The analysis reports that four of these insurers—Bright Health, United Healthcare, Alliance, and MercyCare—include a benefit design that the report describes as including "broad" transgender-related exclusions for thirteen 2021 silver marketplace plans in eight states. *See* ECF No. 56-1 at 14-15.[3] But Plaintiffs have failed to show *personal* injury from any of these four insurers' plans: there is no evidence that any Plaintiff has experienced or is experiencing a decrease in reimbursement as a result of any of these four insurers' policies. And Plaintiffs have not demonstrated that it is substantially likely that any of these plans' transgender subscribers will turn to any of the particular Plaintiff organizations for uncompensated care—instead of taking no action or some other action—in such numbers as to perceptibly impair the Plaintiff organizations' ability to provide services. Indeed, no Plaintiff "serves as the [default] 'secondary payor'" for gender-affirming care for any transgender subscribers of any of these four insurers. *See Massachusetts*, 923 F.3d at 218.

Even if Plaintiffs had made the necessary showing of injury, they haven't made the equally necessary showing of a direct nexus between these policies and any aspect of the 2020 Rule.

[3] In order to illuminate the record for comparison purposes, Defendants attach the 2020 Marketplace Plan Compliance with Section 1557 Out2Enroll Report as Exhibit 1.

Because the Out2Enroll Report only analyzes silver marketplace plans, Plaintiffs have not carried their burden to "identify, articulate, and substantiate" their theory of how the Report provides evidence to support their standing to challenge the 2020 Rule's construction of the scope of covered entities.[4] *See Nat'l Exch. Carrier Ass'n v. FCC*, 253 F.3d 1, 4 (D.C. Cir. 2001).

Moreover, because Plaintiffs have not demonstrated that these benefit designs are permissible under the 2020 Rule in light of the Supreme Court's landmark decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), Plaintiffs have failed to demonstrate a concrete causal link between these four insurers' benefit designs and the 2020 Rule's replacement of former 45 C.F.R. § 92.207's explicit examples of discriminatory health insurance practices with a general prohibition on discrimination. Even assuming that the 2020 Rule "had 'encouraged'" these benefit designs, Plaintiffs do not establish causation as a matter of Article III standing. *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41-42 (1976). "The text of the 2020 Rule prohibits discrimination on the grounds prohibited by Title IX," *see Washington v. HHS*, 482 F. Supp. 3d 1104, 1114, (W.D. Wash. 2020), and HHS explained that the 2020 Rule did not "preclude application of the [Supreme] Court's construction" of civil rights statutes as prohibiting gender identity discrimination, 85 Fed. Reg. at 37,168; *see also* 84 Fed. Reg. at 27,857 (declining to take certain policy positions by rule "[b]ecause of the likelihood that the Supreme Court will be

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[4] Section 1557 covers "any health program or activity, any part of which is receiving Federal Financial assistance, including credits, subsidies, or contracts of insurance[.]" 42 U.S.C. § 18116(a). The 2020 Rule construed this provision to govern certain entities providing healthcare and "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37,244-45 (42 C.F.R § 92.3(b)-(c)). But Section 1557 also covers "any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA]." 42 U.S.C. § 18116(a).

The Out2Enroll report relates to silver marketplace plans offered "in the individual market in states that use Heathcare.gov." *See* Keith Decl. ¶ 7, ECF No. 56-1. "These plans remain subject to [the 2020 Rule] because they are sold on the Exchanges established under Title I of the ACA (*see* § 92.3(a)(3) of this final rule)." *See* 85 Fed. Reg. at 37,170; *see also id*. at 37,174 (Qualified Health Plans "would be covered by the rule because it is a program or activity administered by an entity established under Title I (i.e., an Exchange), pursuant to § 92.3(a)(3).").

addressing the issue in the near future"). Consistent with the preamble language and President Biden's Executive Order 13988, on May 10, 2021, HHS issued a Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments Act of 1972. *See* ECF No. 50. In that Notification, HHS explained that the HHS Office for Civil Rights ("OCR") "will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. This interpretation will guide OCR in processing complaints and conducting investigations[,]" including those in covered benefit designs. *See id*. at 3.

B. The Cited Cigna Policy is Not Evidence of any Plaintiff's Injury, Let Alone One Fairly Traceable to Anything in the 2020 Rule

Plaintiffs' argument fares no better with respect to their discussion of Cigna as a "prominent example of an insurance company that has [purportedly] changed coverage policies." ECF No. 56 at 2. This alleged change does not establish standing. First, Plaintiffs have not shown that Cigna's purported change is harming them in any way. Plaintiffs assert that they have "patients enrolled in Cigna plans." *See* ECF No. 56 at 4 & n.3. But even if they have Cigna patients, Plaintiffs have failed to show that Cigna patients (1) will seek from them the type of surgical care purportedly excluded, and (2) that such care will be uncompensated. That Plaintiffs might some day have to provide uncompensated care to a Cigna subscriber "without any description of concrete plans, or indeed even any specification of *when* the some day will be—do[es] not support a finding of the 'actual or imminent' injury that [Supreme Court] cases require." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992).

Indeed, Plaintiffs can only speculate that the Cigna plan limits coverage for any Plaintiff's hypothetical future patients in light of the exceptive language Cigna uses. Specifically, Cigna's

2021 Medical Coverage Policy explains that "some benefit plans may expressly cover some or all of the procedures listed below for gender reassignment surgery."[5]

Second, even if Plaintiffs had made the necessary showing of injury, they haven't made the equally necessary showing of a direct nexus between the Cigna policy and any aspect of the 2020 Rule. Plaintiffs provide no evidence that these benefit designs are policy choices that have been taken *because* of anything in the 2020 Rule. *See Massachusetts*, 923 F.3d at 224 n.9. A copy of Cigna's policy on treatment for gender dysphoria with an effective date of April 2018 appears to include a similar benefit design, suggesting that Cigna included it "even before" the 2020 Rule, *see id.*; *see also* Medical Coverage Policy: Treatment of Gender Dysphoria, Cigna 4 (April 15, 2018) (attached as Exhibit 2).

An examination of the cited Cigna policy document shows that it provides coverage for significant types of gender affirming care. For example, it covers gender reassignment surgery procedures, including female to male reconstructive genital surgery, female to male reconstructive chest surgery, male to female reconstructive chest surgery, and male to female reconstructive genital surgery. *See* 2021 Cigna Policy at 3-4. Plaintiffs fail to explain how Cigna's current coverage for gender affirming care is fairly traceable to the 2020 Rule. Plaintiffs cannot establish causation merely by pointing to the 2016 Rule because that rule explicitly allowed for benefit designs not to cover all medically necessary health services related to gender transition: under the 2016 Rule (and the 2020 Rule) covered insurance "issuers are not required to cover all medically necessary services. Moreover, [HHS] do[es] not affirmatively require covered entities to cover any particular treatment[.]" Nondiscrimination in Health Programs and Activities, Final Rule, 81 Fed. Reg. 31,376 31,435 (May 18, 2016). In the 2016 Rule's preamble, HHS "reject[ed] commenters' suggestion that the rule require[s] covered entities to provide coverage for all medically necessary health services related to gender transition regardless of the scope of their coverage for other

[5] Medical Coverage Policy: Treatment of Gender Dysphoria, Cigna 4 (May 18, 2021), available at https://perma.cc/UY3K-KNXG ("2021 Cigna Policy").

conditions." *Id*. The former explicit "prohibition in § 92.207(b)(4) on categorically limiting coverage for all health services related to gender transition is intended to prevent issuers from placing categorical, arbitrary limitations or restrictions on coverage for *all* gender transition-related services, such as by singling out services related to gender transition for higher co-pays; it is not intended to prevent issuers from placing nondiscriminatory limitations or restrictions on coverage under the plan." *Id*. (emphasis added).

To be sure, the failure to cover such services must be "evidence-based and nondiscriminatory," *id*., but Plaintiffs have not attempted to meet their burden in establishing those as faults with the Cigna policy.

In sum, Plaintiffs have not shown that Cigna made substantive changes to its benefit design in light of the 2020 Rule. And as a result, they also have not shown that Cigna would likely change its benefit design if this Court issued an order vacating the 2020 Rule's construction of the scope of covered entities or its replacement of 45 C.F.R. § 92.207 with a general prohibition on discrimination. Plaintiffs therefore have not shown that such an order would likely redress any plausible injury that might be caused by Cigna's benefit design. *See California v. Texas*, 141 S. Ct. 2104, 2115 (2021).

C. Evidence that Two Insurers Provide Taglines in Spanish, Tagalog, Chinese, and Navajo is Not Evidence of any Plaintiff's Injury and Undermines Plaintiffs' Standing Arguments

No Plaintiff has provided any evidence substantiating a claim of *personal* imminent harm at the outset of the litigation in July 2020 due to the 2020 Rule's modifications to the standards regarding meaningful access to programs or activities by limited English proficient persons. For example, in September 2020, Plaintiff CrescentCare alleged that the 2020 Rule "will [imminently] burden the resources of the organizations that provide healthcare to . . . [limited English proficient ("LEP")] people." Am. Compl. ¶ 242. *See* ECF No. 27 at 37. In November 2020, a CrescentCare declarant speculated that the rule "will cause CrescentCare financial harm through an increase in non-reimbursable costs" at some hypothetical future time. *See* Riener Decl. ¶ 20 (cited at ECF No.

27 at 37). In lieu of concrete evidence to substantiate those assertions, Plaintiffs submitted evidence of two insurers—one in Alabama and one in Arkansas—that continue to provide taglines[6] in their summaries of benefits only in Spanish, Tagalog, Chinese, and Navajo. *See* ECF No. 56 at 4-5 (citing *Arkansas Blue Cross and Blue Shield: Silver Plan 1 PPO Summary of Benefits and Coverage* (2021), available at https://perma.cc/T2CJ-HVTF; *Bright Health: Silver 4200 Summary of Benefits of Coverage* (2021), available at https://perma.cc/P3BG-MKQ9).

But whether New Orleans-based CrescentCare serves an unspecified number of patients from Arkansas and Alabama, *id*. at 5, "is simply not enough" to "support a finding of the 'actual or imminent' injury that [is] require[d]." *Lujan*, 504 U.S. at 564. CrescentCare has not provided evidence to demonstrate that (1) subscribers of these Alabama and Arkansas insurers are turning to it for care, (2) those subscribers are LEP, (3) those subscribers speak languages other than Spanish, Tagalog, Chinese, and Navajo, (4) those subscribers are likely encountering difficulties because they lack a tagline in their language, (5) these insurers are not likely compensating CrescentCare for their subscribers' care and (6) those subscribers exist in sufficient numbers to perceptibly impair CrescentCare's ability to provide services. CrescentCare's "generalities" leave these matters "open to surmise" and "cannot survive a motion to dismiss." *See AVX Corp.*, 962 F.2d at 117.[7]

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[6] Taglines are "short statements written in non-English languages that indicate the availability of language assistance services free of charge." 81 Fed. Reg. at 31,468 (former 45 C.F.R. § 92.4).

[7] Although Plaintiffs' two cited insurers no longer appear to provide the notice of nondiscrimination in the cited communications, the record is silent as to the manner in which these insurers may continue to provide the notice to consumers. They continue to post the notice on their website along with other important notices. *See* https://www.arkansasbluecross.com/ (link to "Non-discrimination notice" in bottom-left corner); https://www.arkansasbluecross.com/docs/librariesprovider6/member-forms/other-forms/non-discrimination-notice.pdf?sfvrsn=acd179fd_0 (Non-Discrimination Notice); https://brighthealthcare.com/individual-and-family/resource/care-partners/al-bbpa (link to "Notice of Nondiscrimination" at bottom under "Individual Resources"); https://cdn1.brighthealthplan.com/docs/commercial-resources/2021-section-1557-notice.pdf (Non-Discrimination Notice). But they may also include it in other mailings to their subscribers.

D. IWR's Injuries are Not Fairly Traceable to any Provision of the 2020 Rule

IWR is the only Plaintiff to provide evidence that in the ten months since the 2020 Rule took effect, it allegedly experienced some injury that was arguably imminent at the outset of the litigation. Specifically, IWR provides statements about an increase in funding requests to its Abortion Fund, which it states has never turned away a client due to lack of funds. Declaration of Rachael Lorenzo ¶¶ 3, 7, ECF No. 56-2 ("Second Lorenzo Decl."). But IWR has "failed to show how this injury is directly traceable to" the 2020 Rule's construction of the scope of entities covered by Section 1557. *See California*, 141 S. Ct. at 2117.

The only facts Plaintiffs provide about why IWR is receiving increased calls do not relate to increased Abortion Fund expenditures;[8] IWR Co-Founder Lorenzo states that "[s]ome callers" who are merely asking for "basic information about abortion care and pregnancy options . . . report that [the Indian Health Service ("IHS")] and other providers refuse to give them the information that they need to access an abortion." Second Lorenzo Decl. ¶ 5. But IHS has not changed any policy or practice as a result of the changes in the 2020 Rule implementing Section 1557 of the ACA, *see* Declaration of Dr. Greggory Woitte ("Woitte Decl.") ¶¶ 7-11 (attached as Exhibit 3), and Plaintiffs provide no evidence that other formerly covered entities associated with IWR's callers have changed a policy or practice in light of the 2020 Rule's modifications to the scope of covered entities. Finally, Plaintiffs provide no evidence that any such policy change is, in turn, responsible for the increased Abortion Fund expenditures. Nothing in the 2016 Rule required covered entities to provide notice about abortion care and pregnancy options.[9]

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[8] IWR provides no evidence that the increased call volume itself—now only about ten callers in a week—has "perceptibly impaired [its] ability to provide . . . services." *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). Only the significantly increased Abortion Fund expenditures could arguably be considered such a perceptive impairment "with the consequent drain on the organization's resources" required to distinguish the interest from IWR's "abstract social interests[.]" *See id.*; *see also Equal Means Equal*, --- F.4d ---, 2021 WL 2659061, at *4.

[9] The 2016 Rule's Notice Requirements, formally codified at 45 C.F.R. § 92.8, can be found at 81 Fed. Reg. 31,469

The information Plaintiffs have provided does not indicate that the 2020 Rule has led more persons to seek IWR services. IWR offers Abortion Fund grant "recipients many benefits that have nothing to do with" anything that would stem from IHS's status as a covered entity under Section 1557 of the ACA. *See California*, 141 S. Ct. at 2117. "IWR's Abortion Fund helps Indigenous people pay for abortion care by paying clinics for a portion of the procedure and by providing [IWR] clients the necessary funds to cover lodging, gas, food, childcare, and other related travel expenses." Declaration of Rachael Lorenzo ¶ 4, ECF No. 27-6 ("First Lorenzo Decl."). "Given these benefits, neither logic nor intuition suggests that the [mere] presence" of HHS's new regulation excluding IHS from the scope of covered entities "would lead an individual to [seek funding from IWR] programs that its absence would lead them to ignore." *See California*, 141 S. Ct. at 2118. Moreover, "IWR's Abortion Fund is open to all Indigenous people in the United States and Canada who . . . are seeking an abortion in the United States" and IWR makes no effort to account for the likelihood that state policies or other factors that have nothing to do with the 2020 Rule are driving the increased demand for IWR's funding services. *See* First Lorenzo Decl. ¶ 4. Indeed, a major global pandemic has been taking place throughout the last year which itself has reduced access to healthcare services while healthcare providers have been overwhelmed with COVID-19 patients. *See, e.g.*, Declaration of Ellen LaPointe ¶ 29, ECF No. 27-4. "It would require far stronger evidence than [IWR] has offered here to support their counterintuitive theory of standing, which rests on a 'highly attenuated chain of possibilities.'" *California*, 141 S. Ct. at 2119 (quotation omitted).[10]

"To consider the matter from the point of view of another standing requirement, namely, redressability, makes clear that" there is no evidence that IWR's injury is fairly traceable to the

[10] Plaintiffs have erroneously relied on *Department of Commerce, et al, v. New York, et al.*, 139 S. Ct. 2551 (2019), for the proposition that they can speculate as to the purportedly predictable effect of government action on third parties. *See* Mot. Hr'g. Tr. at 20:1-3. But as the Supreme Court recently clarified, the *Commerce* "plaintiffs relied not only on 'the predictable effect of Government action on the decisions of third parties' but also on comprehensive studies, rather than mere 'speculation.'" *California*, 141 S. Ct. at 2119 (quoting *Commerce*, 139 S. Ct. at 2565-66).

scope of federal entities covered by the 2020 Rule. *See California*, 141 S. Ct. at 2115. "To determine whether an injury is redressable, a court will consider the relationship between 'the judicial relief requested' and the 'injury' suffered." *Id*. (quoting *Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984)). Here, IWR seeks an order vacating the Rule's construction of the scope of federal entities covered by Section 1557. Am. Compl. at p. 106. But that relief would only have an implication for IWR's Abortion Fund expenditures if, in light of the vacatur, IHS would be likely to revert to a policy or practice it had in place prior to the effective date of the 2020 Rule, which, in turn, would be likely to lead to decreased calls and requests for funds from IWR. But because IHS has done nothing differently in light of the 2020 Rule's scope of covered entities, *see* Woitte Decl. ¶¶ 7-11, an order vacating this portion of the rule would have no impact on IHS operations, and there is no reason to believe that IWR would see a reduction in call volume or Abortion Fund expenditures, *see Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 939-40 (D.C. Cir. 2004) (analyzing similar standing problems in the context of a challenge to Title IX guidance).

Contrast IWR's failure to establish traceability or redressability with *Massachusetts*, 923 F.3d at 224. In that case, "the Commonwealth ha[d] demonstrated that it is highly likely that at least three [specific] employers in the Commonwealth"—Autocam Medical Devices, Hobby Lobby Stores, and Cummins-Allison Corporation—"will use the [challenged] expanded [contraceptive coverage requirement] exemptions[.]" *Id*. The Commonwealth demonstrated that if these three entities implemented a new policy—namely, declining to provide their employees contractive coverage—as would be permitted under the challenged regulation, the Commonwealth would be directly harmed in its capacity as secondary payor for contraceptive coverage under MassHealth. *Id*. Accordingly, a court order vacating or enjoining the challenged regulation would directly result in those three employers continuing to provide employees contraceptive coverage and the Commonwealth's imminent harm—absorbing those costs as the default MassHealth secondary payor—would be redressed. Here, Plaintiffs establish no similar IHS policy change.

Accordingly, no IHS action is substantially likely because of a court order vacating this provision of the rule, so there is no reason that vacatur would impact IWR Abortion Fund expenditures.

E. Evidence of Certain Pregnancy-Related Coverage Exclusions is Not Evidence of any Plaintiff's Injury, Let Alone One Fairly Traceable to Anything in the 2020 Rule

Plaintiffs also gesture toward a number of health plans that purportedly do not provide pregnancy-related coverage for non-spousal dependent children. *See* ECF No. 56 at 6-7. But no Plaintiff has shown that it has been harmed by any of these policies. CrescentCare may well "provide[] healthcare services, including" certain types of pregnancy-related care, ECF No. 56 at 7, but there is no evidence that CrescentCare is experiencing less advantageous third-party reimbursement for medically necessary healthcare services than it had been receiving in the past. And the cited pregnancy-related coverage has nothing to do with the gender identity-related injuries that Plaintiffs alleged in the Amended Complaint or argued in response to HHS's motion to dismiss.

Moreover, Plaintiffs provide no evidence that these benefit designs are *new* policy choices that have been taken *because* of anything in the 2020 Rule. *See Massachusetts*, 923 F.3d at 224 n.9. In fact, it has been reported that these type of benefit designs may have been widespread long before the 2020 Rule. *See* Megan Leonhardt, *This 24-year-old mistakenly thought her health insurance covered her pregnancy—and 4.2 million others like her may be at risk*, CNBC.com, Nov. 26, 2019 (attached as Exhibit 4).[11]

In addition, Plaintiffs fail to identify any nexus between any challenged provision of the 2020 Rule and these benefit designs. To be sure, the 2020 Rule narrows the scope of insurers that are covered by Section 1557, but Plaintiffs admit that all of these plans continue to be "subject to Section 1557" under the 2020 Rule. *See* ECF No. 56 at 6. Moreover, since one district court "stay[ed] the repeal of the 2016 definition of discrimination on the basis of sex" from the Code of Federal Regulations, *see Asapansa-Johnson Walker*, 480 F. Supp. 3d 430, these policies could not

[11] Available at https://www.cnbc.com/2019/11/26/when-your-insurer-does-not-cover-your-maternity-costs.html

have been caused by HHS's decision not to define "on the basis of sex" by rule. And in any event, as described *infra* at 16-17, impermissible pregnancy discrimination in benefit design continues to be prohibited under the 2020 Rule even if the *Asapansa-Johnson Walker* court lifted its preliminary injunction. *See* 85 Fed. Reg. 37,177 ("The Department will enforce vigorously Section 1557's prohibition on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design.").

III. CONTRARY TO PLAINTIFFS' ALLEGATIONS, PREGNANCY-RELATED DISCRIMINATION IS PROHIBITED UNDER THE 2020 RULE

Plaintiffs are wrong to argue that the 2020 Rule permits pregnancy-related discrimination by covered entities. During the motion hearing, the Court asked undersigned counsel: "Is it the position of HHS that discrimination on the basis of sex includes pregnancy-related discrimination?" Mot. Hr'g Tr. at 21:13-15. The answer is yes; Section 1557 provides that "an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination" by certain covered entities. 42 U.S.C. § 18116(a). HHS's decision not to include a definition of "on the basis of sex" in Section 1557 regulations does not narrow the scope of sex discrimination prohibited by the statute. In the preamble to the 2020 Rule, HHS explained that "[u]nder this final rule, the Department will interpret Section 1557's prohibition on sex-based discrimination consistent with Title IX and its implementing regulations." 85 Fed. Reg. at 37,192. HHS's Title IX implementing regulations have long required that federal funding recipients "treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom in the same manner and under the same policies as any other temporary disability with respect to any medical or hospital benefit, service, plan or policy which such recipient administers, operates, offers, or participates in . . . ." 45 C.F.R. § 86.40(b)(4); *see also id.* § 86.21(c)(2) (admissions); *id.* § 86.57(b) (marital or parent status). Nothing in the 2020 Rule has any effect on those longstanding Title IX regulations implementing the statute that Congress referenced in Section 1557.

Plaintiffs point to a November 6, 2020, letter from OCR to the National Women's Law Center advising the organization that it declined to investigate certain allegations of discrimination. ECF No. 56 at 8. But agencies enjoy wide prosecutorial discretion in addressing individual complaints in light of the "many variables involved in the proper ordering of its priorities." *See Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985). Because the letter does not state that HHS declined to investigate *because* sex discrimination excludes pregnancy-related discrimination, it is not probative of the answer to the Court's question.

What is more, Plaintiffs' reference to the letter serves only to highlight their lack of standing in this case as they may not invoke their "interests in enforcement" of Section 1557 by HHS as a basis of standing to seek vacatur of any part of the 2020 Rule. *See Diamond v. Charles*, 476 U.S. 54, 64 (1986). Plaintiffs cannot "compel [HHS] to enforce [its Section 1557 regulations] . . . because 'a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.'" *Id*. (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973)).

Title IX, and therefore Section 1557, prohibits discrimination on the basis of sex, including pregnancy-related discrimination. Removing an express mention of pregnancy discrimination from the Section 1557 regulations did not alter the scope of pregnancy discrimination the statutes prohibit.

IV. PLAINTIFFS LACK STANDING TO CHALLENGE THE 2020 RULE PROVISIONS ENJOINED FROM TAKING EFFECT BEFORE OCTOBER 2020

Plaintiffs continue to lack standing to challenge the 2020 provisions that were enjoined before taking effect. While Plaintiffs are in no better position now than they were earlier in this case to provide evidence to support their counterintuitive theories of standing with respect to the provisions of the 2020 Rule that other district courts have enjoined from taking effect, their allegations of injury from those changes have always been speculative. *See Washington*, 482 F. Supp. 3d at 1112-21. Moreover, Plaintiffs' failure to provide evidence of concrete injury due to

any other provision of the 2020 Rule is probative of the fact that injuries from these changes were always speculative.[12]

Even if this Court disagrees or views "the constitutional standing issue to be a close one" (which it is not), "prudential reasons alone provide adequate basis" to dismiss these claims, *see McInnis-Misenor v. Me. Med. Ctr.*, 319 F.3d 63, 70, 73 (1st Cir. 2003), especially in light of events occurring since the change in presidential administrations. These events have strengthened Defendants' motion to dismiss for lack of prudential ripeness.[13] There is a likelihood that the several provisions of the 2020 Rule that have not taken effect because of nationwide preliminary injunction orders issued by other courts may never become effective.

Fitness. "[I]f a plaintiff's claim, though predominately legal in character, depends on future events that may never come to pass, or that may not occur in the form forecasted, then the claim is unripe." *Id*. (quoting *Ernst & Young v. Depositors Econ. Prot. Corp.*, 45 F.3d 530, 537 (1st Cir. 1995)). Here, (in addition to the typical reasons that all of Plaintiffs' pre-enforcement claims seeking review of the regulations are unripe under standard administrative law principles, *see* ECF No. 22 at 24-30), "HHS has determined that it intends to initiate a [new] rulemaking proceeding on Section 1557[,]" which "will provide for the reconsideration of many or all of the changes to existing Section 1557 regulations that Plaintiffs challenge here." ECF No. 49 at 2. Simultaneously, the courts that have issued preliminary injunctions have stayed proceedings "pending the new

[12] Due to the similarities between the repeal of the definition of "on the basis of sex," which has been enjoined, and the conforming amendments to related regulations, which have not, Plaintiffs failure to produce any evidence of injuries fairly traceable to the latter change over the last ten months is especially probative as to lack of imminent injury due to the 2020 Rule's repeal of the regulatory definition of "on the basis of sex."

[13] This case is one of five pending before various district courts challenging the 2020 Rule's provisions. *See* ECF No. 51 at 3-4. On that basis alone, this Court is "well equipped" with discretion to dismiss this case without prejudice. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967) ("A court may even in its discretion dismiss a declaratory judgment or injunctive suit if the same issue is pending in litigation elsewhere."); *see also Black Warrior Riverkeeper, Inc. v. U.S. Army Corps. of Engr's*, 781 F.3d 1271, 1290 (11th Cir. 2015) ("Undeniably, vacatur is equitable relief.") (quotation omitted).

administration's review of . . . the rule being challenged" during which time HHS "will continue to adhere to" the preliminary injunction orders. *See, e.g.*, Joint Motion for a Stay Proceedings, *Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-01630-JEB, ECF No. 70 (D.D.C. Feb. 12, 2021), granted, Feb. 16, 2021. Accordingly, there is a substantial likelihood that the preliminary injunction orders will remain effective until HHS completes a new rulemaking proceeding that may well render Plaintiffs' claims moot. Plaintiffs are seeking an advisory opinion about the validity of provisions of a rule that may never take effect (let alone harm any of them, if it ever did take effect). *See Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25, 39 (D.D.C. 2012) (Boasberg, J.) (holding that "a challenge to final regulations that Defendants have promised to amend" was not ripe for review even *without* preliminary injunctions).

Hardship. The hardship analysis for prudential ripeness is more stringent for plaintiffs than the standing analysis and "focuses on 'direct and immediate' harm [from delay]. It is unconcerned with wholly contingent harm." *See McInnis-Misenor*, 319 F.3d at 73. Here, *at least* with respect to the preliminarily enjoined provisions of the 2020 Rule, there can be no suggestion that Plaintiffs could suffer hardship from delay if this Court were to issue a dismissal without prejudice to refiling in the event the preliminary injunctions are dissolved or HHS's anticipated rulemaking proceeding does not address Plaintiffs' policy concerns with the 2020 Rule. *See Belmont Abbey Coll.*, 878 F. Supp. 2d at 41 ("If Plaintiff is displeased by the ultimate regulations, it may certainly renew its suit at that time. All the Court holds here is that [plaintiff] has no basis to proceed now.").

CONCLUSION

For the foregoing reasons, Plaintiffs' supplemental evidence has failed to demonstrate that at the time they filed this suit they faced imminent injury fairly traceable to any provision of the 2020 Rule that they challenge. This Court should grant Defendants' motion and dismiss the Amended Complaint.

Dated: July 15, 2021

Respectfully submitted,

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EXHIBIT 1

Summary of Findings:
2020 Marketplace Plan Compliance with Section 1557

To assess the degree to which insurers complied with Section 1557 of the Affordable Care Act for the 2020 plan year, Out2Enroll collected and analyzed 1,057 silver marketplace plan options from 161 insurers in 38 states. This report briefly summarizes the methodology used and the results of this analysis.

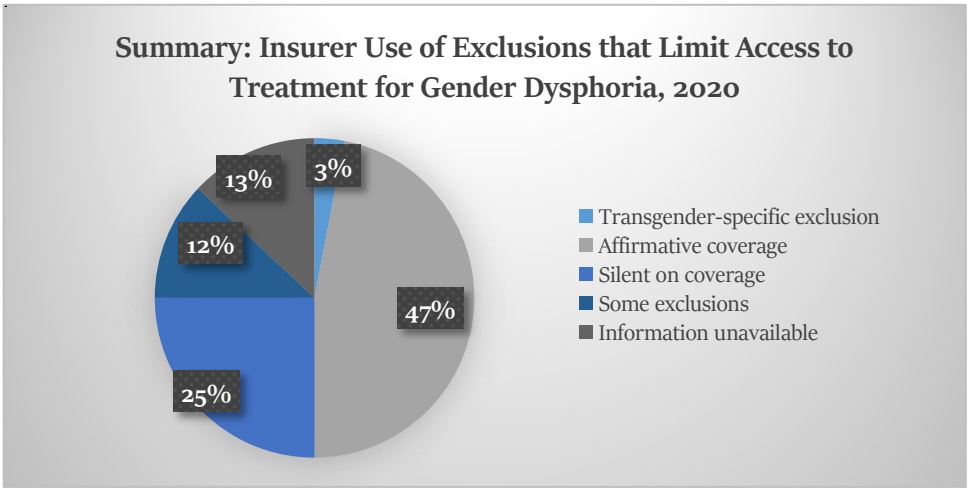
Summary of Findings

- **For the fourth year in a row, the vast majority of insurers did not use transgender-specific exclusions.** Most insurers (97% studied) did not include transgender-specific exclusions in their 2020 silver marketplace plans. This is the highest percentage of insurers recorded since Out2Enroll began conducting this analysis for the 2017 plan year; the percentage is high even though there are many more insurers participating in the marketplace than in prior years. Only plans from five insurers—AdventHealth and Health First Health Plans in Florida, Medical Mutual in Ohio, Sendero Health in Texas, and Common Ground in Wisconsin—continued to have discriminatory transgender-specific exclusions.

- **More insurers than ever before affirmatively stated that medically necessary treatment for gender dysphoria was covered.** Nearly half of insurers (47% studied) incorporated plan language that stated that all or some medically necessary treatment for gender dysphoria would be covered by the plan. This percentage has increased every year (the 2017 plan year (18.5%), 2018 plan year (28%), and 2019 plan year (41%)) with more insurers including affirmative coverage language each year. An additional 25% of insurers were silent about the coverage of treatment for gender dysphoria: these insurers did not affirmatively state that such care is covered but also did not have other broad exclusions that could deny access to medically necessary care.

- **Far fewer insurers had exclusions that would limit access to medically necessary treatment for gender dysphoria.** Only 12% of insurers did not include transgender-specific exclusions but completely excluded a procedure commonly used to treat gender dysphoria or incorporated potentially overbroad definitions of excluded "cosmetic" care. This is down significantly from 2019 (24.8%), 2018 (24%), and 2017 (55.5%).

- **Consumers continue to find it challenging to obtain and review certificates of coverage.** Although plan documents were more available than in prior years, Out2Enroll could not access plan documents from 22 insurers (13% studied) to assess their coverage of treatment for gender dysphoria. This lack of access will continue to present challenges to transgender consumers when assessing coverage options.



Methodology

In October and November 2019, Out2Enroll reviewed 2020 silver plans sold through HealthCare.gov in 38 states. Plans were identified using the 2020 Plan Attributes PUF files, which include plan- and insurer-level information for certified qualified health plans from states participating in the federally facilitated marketplace. Out2Enroll limited its review to silver plans because these plans have historically been the most popular. Out2Enroll excluded dental-only plans, SHOP plans, cost-sharing reduction variation plans, off-marketplace plans, and child-only plans from its review. Once identified, Out2Enroll located each plan's Summary of Benefits and Coverage and Certificate of Coverage to assess whether the plan included 1) an exclusion with a transgender-specific reference; 2) an exclusion with a procedure commonly used in treatment for gender dysphoria; or 3) an exclusion for cosmetic or reconstructive services that would affect access to treatment. In total, Out2Enroll analyzed a record number of 1,057 silver marketplace plan options from 161 insurers in 38 states. This information was compiled into state-specific guides for transgender consumers and is available at: out2enroll.org/2020-cocs.

Findings

Most insurers have removed discriminatory transgender-specific exclusions in compliance with Section 1557 of the Affordable Care Act; however, some marketplace plans continue to include exclusions that limit access to medically necessary treatment for gender dysphoria. Of the plans reviewed from 161 insurers in 38 states, five insurers in four states—AdventHealth and Health First Health Plans in Florida, Medical Mutual in Ohio, Sendero Health in Texas, and Common Ground in Wisconsin—continued to use discriminatory transgender-specific exclusions. The language of these exclusions varies but all were categorical exclusions of treatment for gender dysphoria, including, for instance, hormone therapy, mental health services, and surgical procedures.

These exclusions must be addressed. However, the vast majority of insurers (97% studied) removed transgender-specific exclusions from their 2020 silver marketplace plan options. This analysis, which includes every state using HealthCare.gov, suggests that insurers continue to adjust their marketplace plan options in light of gender identity nondiscrimination protections under Section 1557.

Affirmative coverage for the treatment of gender dysphoria. In a significant shift from prior years, nearly half of insurers (47% studied) incorporated language indicating that all or some medically necessary treatment for gender dysphoria would be covered by the plan. This is up significantly from the 2017 plan year when Out2Enroll began this annual analysis and only 18.5% of insurers included affirmative coverage language. This language does, however, vary significantly by insurer and, in some cases, among the same insurer offering coverage in different states. Some insurers included extensive information on the coverage of gender dysphoria while others noted simply that the plan covers the medically necessary treatment of gender dysphoria.

About 12% of insurers did not include transgender-specific exclusions but excluded a transition-related procedure, or incorporated broad "cosmetic" exclusions that would likely deny access to medically necessary treatment for gender dysphoria. This approach, especially in the absence of affirmative coverage for the treatment of gender dysphoria, continues to be problematic for transgender consumers (but is much lower than the 55.5% of insurers with partial exclusions that Out2Enroll observed in 2017).

An additional 25% of insurers were silent about the coverage of treatment for gender dysphoria. While these insurers did not affirmatively state that transition-related care is covered, the plans did not have broad exclusions that would likely automatically access to medically necessary treatment for gender dysphoria. Where a plan is silent about coverage, transgender consumers should expect that their medically necessary health care needs will be

covered in accordance with plan rules and protocols. A full summary of the plan language is available here: https://drive.google.com/drive/u/2/folders/1SSprlNG41BYbrs_1kgaQA_F5bkeXniVc.

Conclusion

Although some gaps remain in the nondiscriminatory coverage of medically necessary treatment for gender dysphoria, insurers that offer marketplace plans continue to make significant progress in complying with Section 1557. To better ensure that transgender people have a minimal level of access to medically necessary treatment, Out2Enroll 1) urges insurers to affirmatively state in their plan documents that medically necessary treatment for gender dysphoria is covered; and 2) urges state and federal insurance regulators to encourage the use of affirmative coverage language and closely review plan documents to ensure compliance with state and federal gender identity nondiscrimination requirements.

STATE-LEVEL SUMMARY OF INSURER APPROACHES TO TRANS EXCLUSIONS, 2020

State	Affirmative Coverage	Broad Exclusion	Some Exclusions	Silent	Unavailable
AK	Premera			Moda Health Plan	
AL				Blue Cross Blue Shield of Alabama, Bright Health	
AR	Ambetter, Blue Cross Blue Shield of Arkansas				
AZ	Ambetter, Cigna, Oscar			Blue Cross Blue Shield of Arizona, Bright Health	
DE				Highmark	
FL	Ambetter, Blue Cross Blue Shield of Florida, Cigna, Florida Health Care Plans, Molina, Oscar	AdventHealth, Health First Health Plans		Bright Health	
GA	Ambetter, Oscar		Anthem, CareSource	Kaiser Permanente	Alliant
HI	Hawaii Medical Service Association			Kaiser Permanente	
IA	Medica			Wellmark	
IL	Ambetter, Cigna, Health Alliance			Blue Cross Blue Shield of Illinois, Quartz	
IN			CareSource	Ambetter	
KS	Ambetter, Cigna, Medica, Oscar				Blue Cross Blue Shield of Kansas
KY			Anthem, CareSource		
LA			Blue Cross Blue Shield of Louisiana	Christus Health Plan	Vantage
ME	Harvard Pilgrim Health Care		Anthem		Community Health Options
MI	Blue Cross Blue Shield Blue Care Network of Michigan, McLaren, Meridian, Molina, Oscar, Physicians Health Plan Michigan				Priority Health, Total Health Care
MO	Ambetter, Cigna, Medica, Oscar		Anthem		Cox Health Plans, WellFirst
MS	Ambetter, Molina				
MT	Montana Health Co-Op, Pacific Source			Blue Cross Blue Shield of Montana	
NC	Blue Cross Blue Shield of North Carolina, Cigna			Ambetter, Bright Health	
ND	Blue Cross Blue Shield of North Dakota, Medica, Sanford Health				
NE	Medica			Bright Health	
NH	Ambetter, Harvard Pilgrim Health Care		Anthem		
NJ					AmeriHealth New Jersey, Horizon Blue Cross Blue Shield of New Jersey, Oscar

NM	Blue Cross Blue Shield of New Mexico, Molina, New Mexico Health Connections, True Health				
OH	Ambetter, Oscar, Paramount Health Care	Medical Mutual	Anthem, CareSource	Molina	AultCare Health Plans, SummaCare
OK	Medica			Blue Cross Blue Shield of Oklahoma, Bright Health	
OR	BridgeSpan Health, Kaiser Permanente, Moda Health Plan, Pacific Source, Providence Health Plan				
PA	Ambetter, Highmark Blue Cross Blue Shield, Independence Blue Cross, Oscar			Capital Blue Cross, UMPC Health Plan	Geisinger Health Plan
SC	Molina		Blue Cross Blue Shield of South Carolina	Ambetter, Bright Health	
SD	Sanford Health				Avera
TN	Cigna, Oscar			Ambetter, Bright Health	Blue Cross Blue Shield of Tennessee
TX	Ambetter, Molina, Oscar	Sendero Health Plan	Community Health Choice, First Care Health Plans	Christus Health Plan, Blue Cross Blue Shield of Texas	
UT	Molina		University of Utah Health Plans	BridgeSpan, Cigna, SelectHealth	
VA	CareFirst, Oscar		Anthem, Virginia Premier	Cigna, Kaiser Permanente, Piedmont Community Health Plan	Optima
WI	Medica, Molina	Common Ground	Network Health	Arise Health Plan, Children's Community Health Plan, Dean Health Plan, HealthPartners, Security Health Plan	Mercy Care, Prevea, Quartz
WV	Highmark Blue Cross Blue Shield		CareSource		
WY				Blue Cross Blue Shield of Wyoming	

EXHIBIT 2

Medical Coverage Policy

Effective Date..... 4/15/2018
Next Review Date..... 3/15/2019
Coverage Policy Number 0266

Treatment of Gender Dysphoria

Table of Contents

Related Coverage Resources

Blepharoplasty, Reconstructive Eyelid Surgery, and Brow Lift
Breast Reconstruction Following Mastectomy or Lumpectomy
Dermabrasion and Chemical Peels
Endometrial Ablation
Infertility Services
Male Sexual Dysfunction Treatment: Non- pharmacologic
Panniculectomy and Abdominoplasty
Preventive Care Services
Reduction Mammoplasty
Rhinoplasty, Vestibular Stenosis Repair, and Septoplasty
Redundant Skin Surgery
Speech Therapy

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Coverage for treatment of gender dysphoria, including gender reassignment surgery and related services, is subject to the terms, conditions and limitations of the applicable benefit plan and may be governed by state and/or federal mandates. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

Unless otherwise specified in a benefit plan, the following conditions of coverage apply for treatment of gender dysphoria and/or gender reassignment surgery and related procedures, including all applicable benefit limitations, precertification, or other medical necessity criteria.

SERVICES MEDICALLY NECESSARY

Medically necessary treatment for an individual with gender dysphoria may include ANY of the following services, when services are available in the benefit plan:

- Behavioral health services, including but not limited to, counseling for gender dysphoria and related psychiatric conditions (e.g., anxiety, depression)
- Hormonal therapy, including but not limited to androgens, anti-androgens, GnRH analogues, estrogens, and progestins.
- Laboratory testing to monitor prescribed hormonal therapy
- Age-related, gender-specific services, including but not limited to preventive health, as appropriate to the individuals biological anatomy (e.g., cancer screening [e.g., cervical, breast, prostate]; treatment of a prostate medical condition)
- Gender reassignment and related surgery (see below).

Gender Reassignment Surgery

Gender reassignment surgery (see Table 1) is considered medically necessary treatment of gender dysphoria when the individual is age 18 years or older and when the following criteria are met:

- **For initial mastectomy:** one letter of support from a qualified mental health professional.

  NOTE: The Women's Health and Cancer Rights Act (WHCRA), 29 U.S. Code § 1185b requires coverage of certain post-mastectomy services related to breast reconstruction and treatment of physical complications from mastectomy including nipple-areola reconstruction.

- **For hysterectomy, salpingo-oophorectomy, orchiectomy:**
  - documentation of at least 12 months of continuous hormonal sex reassignment therapy AND
  - recommendation for sex reassignment surgery (i.e., genital surgery) by two qualified mental health professionals with written documentation submitted to the physician performing the genital surgery. (If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both [for example, if practicing within the same clinic] are required.

- **For reconstructive genital surgery:**
  - documentation of at least 12 months of continuous hormonal sex reassignment therapy AND
  - recommendation for sex reassignment surgery (i.e., genital surgery) by two qualified mental health professionals with written documentation submitted to the physician performing the genital surgery. (If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both [for example, if practicing within the same clinic] are required AND
  - documentation the individual has lived for at least 12 continuous months in a gender role that is congruent with their gender identity.

Table 1: Gender Reassignment Surgery

Procedure	CPT / HCPCS codes (This list may not be all inclusive)
Initial mastectomy*, nipple-areola reconstruction (related to mastectomy or post mastectomy reconstruction)	19303, 19304, 19350
Hysterectomy and salpingo-oophorectomy	58150, 58260 58262 58291, 58552, 58554, 58571, 58573, 58661
Female to male reconstructive genital surgery which may include any of the following:	55980

Vaginectomy**/colpectomy Vulvectomy Metoidioplasty Phalloplasty Penile prosthesis (noninflatable / inflatable), including surgical correction of malfunctioning pump, cylinders, or reservoir Urethroplasty /urethromeatoplasty	57110 56625 58999 58999 54400, 54401, 54405, C1813, C2622 53430, 53450
Orchiectomy	54690
Male to female reconstructive genital surgery, which may include any of the following: Vaginoplasty**, (e.g, construction of vagina with/without graft, colovaginoplasty) Penectomy Vulvoplasty, (e.g., labiaplasty, clitoroplasty, penile skin inversion) Repair of introitus Coloproctostomy	55970 57291, 57292, 57335 54125 56620, 56805 56800 44145, 55899

***Note: Please reference the Cigna Medical Coverage Policy 0152 Reduction Mammoplasty for conditions of coverage related to breast reduction.**

****Note: For individuals considering hysterectomy/salpingo-oophorectomy, orchiectomy, vaginectomy or vaginoplasty procedures a total of 12 months continuous hormonal sex reassignment therapy is required. An additional 12 months of hormone therapy is not required for vaginectomy or vaginoplasty procedures.**

NOT MEDICALLY NECESSARY SERVICES

Gender reassignment surgery is considered not medically necessary when the applicable medical necessity criteria for the procedure(s) has not been met.

Each of the following is excluded under many benefit plans and/or considered not medically necessary as part of gender reassignment for preservation of fertility (see Table 2):

Table: 2 Excluded and/or Not Medically Necessary- Fertility Preservation

Procedure	CPT/HCPCS Code
Cryopreservation of embryo, sperm, oocytes	89258, 89259, 89337
Procurement of embryo, sperm, oocytes	S4030, S4031
Storage of embryo, sperm, oocytes	89342, 89343, 89346, S4027, S4040

EXPERIMENTAL /INVESTIGATIONAL/UNPROVEN SERVICES

Each of the following is considered experimental, investigational or unproven as part of gender reassignment for the preservation of fertility (see Table 3):

Table:3 Experimental, Investigational or Unproven - Fertility Preservation

Procedure	CPT/HCPCS Code
Cryopreservation of immature oocytes	0357T
Cryopreservation of reproductive tissue (i.e.,	89335, 0058T

ovaries, testicular tissue)	
Storage of reproductive tissue (i.e., ovaries, testicular tissue)	89344
Thawing of reproductive tissue (i.e., ovaries, testicular tissue)	89354

COSMETIC SERVICES

Each of the following services (see Table 4) is considered cosmetic and/or not medically necessary for the purpose of improving or altering appearance or self-esteem related to one's appearance, including gender specific appearance for an individual with gender dysphoria:

Table 4: Cosmetic and/or Not Medically Necessary

Procedure	CPT/HCPCS Code
Abdominoplasty	15847
Blepharoplasty	15820, 15821, 15822, 15823
Breast augmentation with implants	19324, 19325, 19340, 19342, C1789
Calf implants	17999
Cheek/malar implants	17999
Chin/nose implants	21210, 21270, 30400, 30410, 30420, 30430 30435, 30450
Collagen injections	11950, 11951, 11952, 11954
Electrolysis	17380
Face/forehead lift	15824, 21137, 15825, 15826, 15828, 15829
Facial bone reduction (osteoplasty)	21209
Hair removal/hair transplantation	15775, 15776, 17380
Insertion of testicular prosthesis	54660
Jaw reduction	21120, 21121, 21122, 21223, 21125, 21127
Laryngoplasty	31599
Mastopexy	19316
Neck tightening	15825
Nipple/areola reconstruction (unrelated to mastectomy or post mastectomy reconstruction)	19350
Pectoral Implants	L8600, 17999
Removal of redundant skin	15830, 15832, 15833, 15834, 15835, 15836 15837, 15838, 15839
Replacement of tissue expander with permanent prosthesis testicular insertion	11970
Rhinoplasty	21210, 21270, 30400, 30410, 30420, 30430, 30435, 30450
Scrotoplasty	55175, 55180
Skin resurfacing (e.g., dermabrasion, chemical peels)	15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793
Suction assisted lipoplasty, lipofilling, and/or liposuction	15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879
Testicular expanders, including replacement with prosthesis, testicular prosthesis	11960, 11970, 11971, 54660
Thyroid reduction chondroplasty	31750
Voice modification surgery	31599, 31899
Voice therapy/voice lessons	92507

Overview

This Coverage Policy addresses treatment of gender dysphoria. Gender dysphoria is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and the person's assigned sex at birth (World Professional Association for Transgender Health, [WPATH], 2012).

General Background

The causes of gender dysphoria and the developmental factors associated with them are not well-understood. Treatment of individuals with gender dysphoria varies, with some treatments involving a change in gender expression or body modifications. The term "transsexual" refers to an individual whose gender identity is not congruent with their genetic and/or assigned sex and usually seeks hormone replacement therapy (HRT) and possibly gender-affirmation surgery to feminize or masculinize the body and who may live full-time in the crossgender role. Transsexualism is a form of gender dysphoria. Other differential diagnoses include, but are not limited to, partial or temporary disorders as seen in adolescent crisis, transvestitism, refusal to accept a homosexual orientation, psychotic misjudgments of gender identity and severe personality disorders (Becker, et al., 1998). Individuals that are transsexual, transgender, or gender nonconforming (i.e., gender identity differs from the cultural norm) may experience gender dysphoria.

Treatment of gender dysphoria is unique to each individual and may or may not involve body modifications. Some individuals require only psychotherapy, some require a change in gender roles/expression, and others require hormone therapy and/or surgery to facilitate a gender transition.

Behavioral Health Services

Licensing requirements and scope of practice vary by state for healthcare professionals. WPATH has defined recommended minimum credentials for a mental health professional to be qualified to evaluate or treat adult individuals with gender dysphoria. In addition to general licensing requirements, WPATH includes a minimum of a Master's or more advanced degree from an accredited institution, an ability to recognize and diagnose coexisting mental health concerns, and an ability to distinguish such conditions from gender dysphoria. Mental health professionals play a strong role in working with individuals with gender dysphoria as they need to diagnose the gender disorder and any co-morbid psychiatric conditions accurately, counsel the individual regarding treatment options, and provide psychotherapy (as needed) and assess eligibility and readiness for hormone and surgical therapy. For children and adolescents, the mental health professional should also be trained in child and adolescent developmental psychopathology.

Once the individual is evaluated, the mental health professional provides documentation and formal recommendations to medical and surgical specialists. Documentation for hormonal and/or surgery should be comprehensive and include the extent to which eligibility criteria have been met (i.e., confirmed gender dysphoria, capacity to make a fully informed decision, age ≥ 18 years or age of majority, and other significant medical or behavioral health concerns are well-controlled), in addition to the following:

- individual's general identifying characteristics
- the initial and evolving gender, sexual and psychiatric diagnoses
- details regarding the type and duration of psychotherapy or evaluation the individual received
- the mental health professional's rationale for hormone therapy or surgery
- the degree to which the individual has followed the standards of care and likelihood of continued compliance
- whether or not the mental health professional is a part of a gender team

For breast surgery WPATH Standards of Care Version 7 require one referral from a qualified mental health professional, as defined above. For genital surgery WPATH requires two referrals from qualified mental health professionals indicating criteria for surgery has been met. In contrast, the Endocrine Society Clinical Practice Guidelines (Hembree, et al., 2009) recommend both an endocrinologist responsible for endocrine transition therapy and a mental health professional certify the individual is eligible and meets WPATH criteria for gender reassignment surgery.

Psychiatric care may need to continue for several years after gender reassignment surgery, as major psychological adjustments may continue to be necessary. Other providers of care may include a family physician or internist, endocrinologist, urologist, plastic surgeon, general surgeon and gynecologist. The overall success of the surgery is highly dependent on psychological adjustment and continued support.

After diagnosis, the therapeutic approach is individualized but generally includes three elements: sex hormone therapy of the identified gender, real life experience in the desired role, and surgery to change the genitalia and other sex characteristics.

Hormonal Therapy

For both adults and adolescents, hormonal treatment for gender dysphoria must be administered and monitored by a qualified healthcare practitioner as therapy requires ongoing medical management, including physical examination and laboratory evaluation studies to manage dosage, side effects, etc. Lifelong maintenance is usually required.

Adults: Prior to and following gender reassignment surgery, individuals undergo hormone replacement therapy, unless medically contraindicated. Biological males are treated with estrogens and anti-androgens to increase breast size, redistribute body fat, soften skin, decrease body hair, and decrease testicular size and erections. Biological females are treated with androgens such as testosterone to deepen voice, increase muscle and bone mass, decrease breast size, increase clitoris size, and increase facial and body hair. In both sexes hormone replacement therapy (HRT) may be effective in reducing the adverse psychologic impact of gender dysphoria. Hormone therapy is usually initiated upon referral from a qualified mental health professional or a health professional competent in behavioral health and gender dysphoria treatment specifically. Twelve months of continuous hormone therapy (gender appropriate) is required prior to hysterectomy and salpingo-oophorectomy and orchiectomy.

Adolescents: Puberty-suppressing hormones (e.g., GnRH analogues) for adolescents may be provided to individuals who have reached at least Tanner stage 2 of sexual development. The Endocrine Society supports puberty suppression and has developed criteria for a subset of individuals who fulfill and meet eligibility readiness for gender reassignment (Hembree, et al., 2009). WPATH clinical recommendations also support puberty suppression (WPATH, 2012) for a similar subset of individuals. Consistent with adult hormone therapy, treatment of adolescents involves a multidisciplinary team, however when treating an adolescent a pediatric endocrinologist should be included as a part of the team. Pre-pubertal hormone suppression differs from hormone therapy used in adults and may not be without consequence; some pharmaceutical agents may cause negative physical side effects (e.g., height, bone growth).

Gender Reassignment Surgery

The term "gender reassignment surgery," also known as sexual reassignment surgery, gender confirming surgery or gender affirmation surgery, may be part of a treatment plan for gender dysphoria. The terms may be used to refer to either the reconstruction of male or female genitalia specifically, or the reshaping by any surgical procedure of a male body into a body with female appearance, or vice versa.

Performing gender reassignment surgery prior to age 18, or the legal age to give consent, is not recommended. Gender reassignment surgery is intended to be a permanent change (non-reversible), establishing congruency between an individual's gender identity and physical appearance. Therefore, a careful and accurate diagnosis is essential for treatment and can be made only as part of a long-term diagnostic process involving a multidisciplinary specialty approach that includes an extensive case history; gynecological, endocrine and urological examination, and a clinical psychiatric/psychological examination.

Twelve months of continuous hormone therapy is required prior to irreversible genital surgery. In addition, prior to surgery the individual identified with gender dysphoria must undergo a "real life experience," in which he/she adopts the new or evolving gender role and lives in that role for at least 12 continuous months as part of the transition pathway. This process assists in confirming the person's desire for gender role change, ability to function in this role long-term, as well as the adequacy of his/her support system. During this time, a person would be expected to maintain their baseline functional lifestyle, participate in community activities, and provide an indication that others are aware of the change in gender role.

Other Associated Surgical Procedures

Services Otherwise Medically Necessary: Age appropriate gender-specific services that would otherwise be considered medically necessary remain medically necessary services for transgender individuals, as appropriate to their biological anatomy. Examples include (but are not limited to):

- for female to male transgender individuals who have not undergone a mastectomy, breast cancer and cervical cancer screening
- for male to female transgender individuals who have retained their prostate cancer screening or treatment of a prostate condition.

Reversal of Gender Reassignment: Gender reassignment surgery is considered an irreversible intervention (WPATH, 2012). Although infrequent, surgery to reverse a partially or fully completed gender reassignment (reversal of surgery to revise secondary sex characteristics), may be necessary as a result of a complication (i.e., infection) or other medical condition necessitating surgical intervention.

Fertility Preservation: Both hormone therapy and gender reassignment surgery limits fertility, and individuals should be informed of sperm preservation options and other cryopreservation services prior to starting hormone therapy. Reproductive options should also be discussed prior to surgery for individuals who are of child-bearing age. However, procedures aimed at preservation of fertility (e.g., procurement, cryopreservation, and storage of sperm, oocytes and/or embryos) performed prior to gender reassignment surgery are considered not medically necessary. Please refer to the applicable benefit plan document for terms, conditions, and limitations, and applicable Cigna Medical Coverage Policy for conditions of coverage.

Cosmetic Procedures: Various other surgical procedures may be performed as part of gender reassignment surgery. Although WPATH does not define medical necessity criteria for masculinization and feminization procedures, referral by a qualified mental health professional is recommended. When performed as part of gender reassignment surgery such procedures, aimed primarily at improving personal appearance (i.e., masculinization, feminization), are performed to assist with improving culturally appropriate male or female appearance characteristics and are therefore considered cosmetic and are not medically necessary. Please refer to the applicable benefit plan document for terms, conditions, and limitations, and applicable Cigna Medical Coverage Policy for conditions of coverage.

Professional Society/Organization

WPATH Clinical Guidelines: The World Professional Association for Transgender Health (WPATH) promotes standards of health care for individuals through the articulation of "Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People" (WPATH, 2012, Version 7). WPATH standards of care are based on scientific evidence and expert consensus and are commonly utilized as clinical recommendations for individuals seeking treatment of gender disorders.

Endocrine Society Guidelines: In 2009 the Endocrine Society published a clinical practice guideline for endocrine treatment of transsexual persons (Hembree, et al., 2009). As part of this guideline, the endocrine society recommends that transsexual persons consider genital sex reassignment surgery only after both the physician responsible for endocrine transition therapy and the mental health professional find surgery advisable; that surgery be recommended only after completion of at least one year of consistent and compliant hormone treatment; and that the physician responsible for endocrine treatment medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery.

Use Outside of the US: Several other countries including the United Kingdom offer treatment options for individuals with gender dysphoria. Treatments are similar to those offered in the United States.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Intersex Surgery: Male to Female

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
55970†	Intersex surgery; male to female
	†Includes only the following procedures:
44145	Colectomy, partial; with coloproctostomy (low pelvic anastomosis)
54125	Amputation of penis; complete
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54690	Laparoscopy, surgical; orchiectomy
55899††	Unlisted procedure, male genital system
56620	Vulvectomy simple; partial
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state

††Note: **Considered medically necessary when used to report Coloproctostomy.**

Intersex Surgery: Female to Male

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
55980†	Intersex surgery, female to male
	†Includes only the following procedures:
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19350††	Nipple/areola reconstruction
53430	Urethroplasty, reconstruction of female urethra
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
56625	Vulvectomy simple; complete
57110	Vaginectomy, complete removal of vaginal wall
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;

	with removal of tube(s) and/or ovary(s)
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58999†††	Unlisted procedure, female genital system (nonobstetrical)

††**Note: Considered medically necessary when performed as part of a mastectomy or breast reconstruction procedure following a mastectomy.**

†††**Note: Considered medically necessary when used to report metoidioplasty with phalloplasty.**

ICD-10-CM Diagnosis Codes	Description
F64.0	Trans-sexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Generally Excluded/Not Medically Necessary:

CPT®* Codes	Description
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89337	Cryopreservation, mature oocyte(s)
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen
89346	Storage (per year); oocyte(s)
S4027	Storage of previously frozen embryos
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit
S4040	Monitoring and storage of cryopreserved embryos, per 30 days

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
89335	Cryopreservation, reproductive tissue, testicular
89344	Storage (per year); reproductive tissue, testicular/ovarian
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian
0058T	Cryopreservation; reproductive tissue, ovarian
0357T	Cryopreservation; immature oocyte(s)

Considered Cosmetic and/or not medically necessary when performed as a component of gender reassignment, even when coverage for gender reassignment surgery exists unless subject to a coverage mandate:

CPT®* Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy, forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity

15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999†	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19316	Mastopexy
19324	Mammaplasty, augmentation; without prosthetic implant
19325	Mammaplasty, augmentation; with prosthetic implant
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19350††	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599†††	Unlisted procedure, larynx
31750	Tracheoplasty; cervical
31899††††	Unlisted procedure, trachea, bronchi
40799†††††	Unlisted procedure, lips
54660	Insertion of testicular prosthesis (separate procedure)
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual

HCPCS Codes	Description
C1789	Prosthesis, breast (implantable)
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
L8600	Implantable breast prosthesis, silicone or equal

†**Note: Cosmetic and/or not medically necessary when used to report calf, cheek, malar or pectoral implants or fat transfers performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

††**Note: Cosmetic and/or not medically necessary when not performed as part of a mastectomy or breast reconstructive procedure.**

†††Note: **Cosmetic and/or not medically necessary when used to report laryngoplasty performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

††††Note: **Cosmetic and/or not medically necessary when used to report voice modification surgery performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

†††††Note: **Cosmetic and/or not medically necessary when used to report lip reduction/enhancement performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

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EXHIBIT 3

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BOSTON ALLIANCE OF GAY, LESBIAN BISEXUAL AND TRANSGENDER YOUTH (BAGLY), *et al.,*	)	
Plaintiffs,	)	
v.	)	C.A. No. 1:20-cv-11297-PBS
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,	)	
Defendants.	)	

DECLARATION OF DR. GREGGORY WOITTE

I, RADM Greggory Woitte, M.D., FACOG, Assistant Surgeon General, U.S. Public Health Service, Acting Chief Medical Officer for the Indian Health Service make the following declaration in accordance with 28 U.S.C. § 1746 with respect to the above captioned matter.

1. I am the Acting Chief Medical Officer for the Indian Health Service ("IHS").

2. The Chief Medical Officer (CMO) is IHS's lead expert on medical and public health topics, giving technical advice and guidance to the IHS Office of the Director and IHS staff throughout the country on American Indian and Alaska Native health care policies and issues. The CMO provides national leadership for the clinical and community-based health programs of the agency, and serves as the primary liaison and advocate for IHS health professionals.

3. I am a Fellow of the American College of Obstetricians and Gynecologists.

4. This declaration is based upon my knowledge, information obtained from other individuals employed by IHS, and information obtained from IHS records.

5. IHS is an agency within the Department of Health and Human Services that is

responsible for providing federal health services to American Indians and Alaska Natives. The agency is the principal federal health care provider and federal health advocate for these populations, and it provides a comprehensive health service delivery system.

6. I have knowledge of IHS's policies and practices.

7. Since August 2020, IHS has not affirmatively adopted any new policy or practice on the assumption that IHS was no longer within the scope of entities covered by section 1557 of the Patient Protection and Affordable Care Act (ACA)(42 U.S.C. § 18116).

8. Since August 2020, IHS has not adopted any policy or practice that affirmatively authorizes discrimination that was prohibited by the 2016 regulations implementing section 1557 of the ACA (81 Fed. Reg. 31,375 (May 18, 2016)).

9. Since August 2020, IHS has not adopted any policy or practice that affirmatively removes protections against discrimination that was prohibited by the 2016 regulations implementing section 1557 of the ACA (81 Fed. Reg. 31,375 (May 18, 2016)).

10. IHS did not make any changes to any of its policies or practices based on HHS's 2020 final rule (85 Fed. Reg. 37,160 (June 19, 2020)) implementing section 1557 of the ACA.

11. IHS's policies set forth in the Indian Health Manual on abortion (Part 3, Chapter 13, Section 14, Abortion Services), emergency contraception (Part 1, Chapter 15, Emergency Contraception), and family planning (Part 3, Chapter 13, Section 12, Family Planning Services) have not been changed, amended, or rescinded since the 2020 final rule implementing section 1557 of the ACA (85 Fed. Reg. 37,160 (June 19, 2020)) became effective.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: July __1___, 2021

Oklahoma City, Oklahoma

Greggory J. Woitte -S

Digitally signed by Greggory J. Woitte -S
Date: 2021.07.01 08:21:36 -05'00'

RADM Greggory Woitte, M.D., FACOG
Acting Chief Medical Officer for the
Indian Health Service

EXHIBIT 4

How this millennial family makes a living traveling in their RV

Kate Hudson on privilege, misconceptions and being a Hollywood entrepreneur

Use the 5(successfu

SPEND

This 24-year-old mistakenly thought her health insurance covered her pregnancy—and 4.2 million others like her may be at risk

Published Tue, Nov 26 2019•10:02 AM EST Updated Tue, Nov 26 2019•10:02 AM EST

Megan Leonhardt
@MEGAN_LEONHARDT

Bethany* is like many first-time mothers preparing for the arrival of her baby, attending childbirth classes and setting up the nursery — "really just a large closet more than an actual room," she says — with finds from Facebook Marketplace.

"My husband will hold up the newborn size outfits and announce he doesn't believe it, nobody can be this small," the 24-year-old says, adding she and her husband always knew they wanted kids.

But while the couple planned to have a baby, they weren't expecting it to be so expensive. Despite Bethany's best intentions, only a small fraction of her pregnancy-related health-care costs are covered by her insurance company.

They learned the upsetting news at their very first doctor's appointment. "When we found out [about the pregnancy], I scheduled an OB-GYN visit to figure out next steps with prenatal care," Bethany says. It was a pretty typical visit. The office drew blood and ran tests, and her doctor spent time talking to the couple about what to expect during the pregnancy.

What Bethany didn't expect: Learning her insurance company wouldn't cover the vast majority of her medical expenses during her pregnancy. And getting a $3,000 bill for a single OB-GYN visit.

Bethany and her husband had no idea insurance was going to be an issue, since she's insured through her parents' plan. But it turns out that was the problem. Bethany says her Michigan-based insurer, ASR Health Benefits, said her mother's health insurance plan doesn't cover maternity care for adult dependents and only paid a portion, about $1,000, of that initial OB-GYN bill that it deemed "prenatal care." ASR did not respond to multiple requests by CNBC for comment and clarification of its policies.

"It feels misogynistic to me," Bethany says. A 20-year-old woman may need multiple ultrasounds during her pregnancy and end up paying thousands out-of-pocket. Meanwhile, should her 23-year-old brother need an ultrasound to treat a tendon tear, his care typically would be covered.

Twenty/20

Maternity coverage is still way too complicated

Bethany married her college sweetheart a year and a half ago. But because her husband has had a few different jobs since graduating, most of which were contract positions with lackluster benefits, Bethany opted to stay on her mom's insurance. Young adults can remain on their parents' insurance until they're 26, regardless of marital status.

It seemed ideal: Her parents have had some health issues in recent years, which meant they always hit their deductible. They had no idea about the dependent exemptions until it was too late, Bethany says.

In hindsight, it would be more affordable if Bethany was unmarried and therefore had a lower household income so she could claim Medicaid benefits, or if she taken out her own policy through a marketplace. While there are some federal laws that protect maternity rights, Bethany falls into a loophole.

For years, federal laws have stipulated that employers need to cover maternity care for their employees and their spouses. But there are no laws that specifically state companies have to cover maternity care for adult children because, until the ACA passed in 2009, most employer-based health insurance plans cut off coverage when the children legally became adults or upon college graduation.

The ACA changed the rules, allowing dependent children to stay on their parents' health insurance plans until the age of 26. The law also blocked insurers from turning away pregnant women and stipulated that maternity care was an "essential health benefit."

> **There are all these disparate puzzle pieces fitting together and not fitting together.**
>
> **Julie Stich**
> THE INTERNATIONAL FOUNDATION OF EMPLOYEE BENEFIT PLANS

On the surface, it seems like that should have solved everything. But the ACA's essential health benefit stipulations apply only to individual health-care plans sold through the marketplaces and those offered by small employers (less than 50 employees), which is only a small percentage of plans. The bulk of Americans, 49%, get their health insurance through their employers, according to the Kaiser Family Foundation. Yet large employer plans (those with more than 50 employees) are not required to comply with the essential health benefit requirements.

Also exempt from these restrictions (unless mandated by the state law) are employers who opt to offer a self-insured (self-funded) health plan, says Julie Stich, vice president of content for the International Foundation of Employee Benefit Plans. These self-insured health plans may be run and handled by an insurance carrier, but

the company is ultimately responsible for paying out on claims, instead of paying the insurer a premium.

"There are all these disparate puzzle pieces fitting together and not fitting together," Stich tells CNBC Make It. Even many student health plans provided by colleges and universities, especially if they are self-funded, do not offer comprehensive maternity coverage, according to Young Invincibles, an organization focused on policy needs for younger Americans. It's estimated that about 3 million young people are covered by these types of health-care plans, according to the Centers for Medicare and Medicaid Services.

Making it even more complicated is the fact that maternity care is not an all-or-nothing scenario in most cases. Some maternity care costs, termed "prenatal services," are routinely covered by insurers, even if the woman is an adult dependent. These covered costs generally include prenatal vitamins, as well as screenings for STDs, anemia, gestational diabetes, Rh incompatibility and preeclampsia. However, other routine tests and services are not, including chromosomal screenings, ultrasounds and copays for office visits, which can make budgeting and planning a challenge, to say the least.

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This isn't a rare occurrence

Bethany is far from the only young woman facing these circumstances. "This is not an anomaly; this happening pretty consistently," says Dorianne Mason, director of health equity and reproductive rights and health at the National Women's Law Center.

Currently about 4.2 million women ages 19 to 25 have coverage as dependents on their parent's employer insurance plan, according to an analysis of 2019 Census data performed by New York University professors Ougni Chakraborty and Sherry Glied on behalf of the Commonwealth Fund for CNBC Make It.

In the U.S., the average woman has her first child at age 26, but many women get pregnant much earlier. Almost half of women with some college education have children before 25, while the median age for women with a high school diploma or less to have their first child is just 24, according to the Pew Research Center.

CNBC Make It reached out to the biggest insurance companies in the country to see if their employer-based plans included maternity care coverage for adult dependents. Cigna and Humana did not respond to queries. Beyond asking for clarification of the request, Anthem and UnitedHealthcare did not either.

Aetna and Blue Cross Blue Shield said they could not provide that information, and neither company would confirm nor deny they had employer-based plans that excluded this coverage.

The insurance industry's trade group, America's Health Insurance Plans, told Make It in a statement that "specific coverage and benefits are going to vary depending on the employer, the insurance provider, the individual and the plan they choose," and added it did not have specific data or statistics on this.

Carrying the cost

Across the country, the hospital bill for vaginal delivery costs an average of $30,570, according to estimates from the independent nonprofit organization FAIR Health. Women who undergo a C-section delivery stay in the hospital an average of three days and are typically billed $47,360. Depending on the mother's insurance plan, she'll likely pay out-of-pocket for some portion of the bill.

But the health-care expenses for Bethany and women in her situation start well before labor and delivery. Beyond that first OB-GYN appointment, women generally have another seven to 12 appointments during a normal pregnancy.

On average, the cost for doctor's visits range from about $90 to $500 per appointment, according to research site ValuePenguin. But then each additional service, such as ultrasounds, is billed separately and can range from $100 to $2,500 for special tests like amniocentesis.

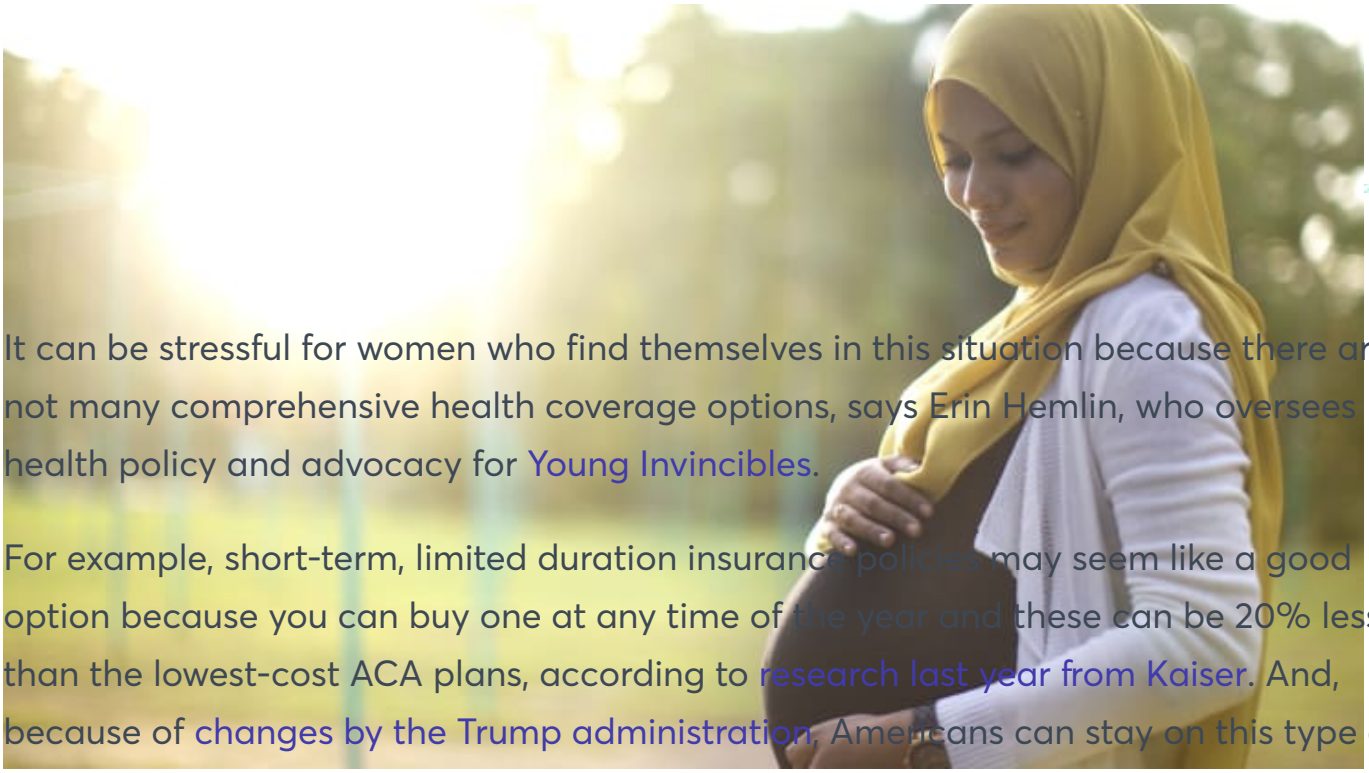
When Bethany discovered that her mother's plan wasn't going to cover all of her pregnancy costs, Bethany knew she needed to find a new provider — and fast. "I jettisoned my old OB-GYN, called around and found a practice that lets me self-pay for about $500 a visit, not including some labs and stuff like ultrasounds," she says.

Since April, she's been seeing the doctor about once a month, but now that she's closer to her due date, the visits have been bumped up to twice a month, and $1,000 out-of-pocket.

> **I know this is stereotypical, but I feel like we're kind of being punished for doing everything 'right' — we're married, financially responsible.**
>
> **Bethany**

Bethany has also been trying to negotiate her $3,000 bill from the initial doctor's visit, but says "they've been a brick wall about it." She finds the whole process "unfair" because the insurance company typically doesn't pays sticker price.

Additionally, she's unable to take advantage of uninsured rates sometimes offered by doctors because technically, she has insurance. "My current OB-GYN is affiliated with a hospital that has an automatic 20% discount for uninsured patients, but they told me they won't give me the discount since I have insurance, as far as they are concerned."



It can be stressful for women who find themselves in this situation because there are not many comprehensive health coverage options, says Erin Hemlin, who oversees health policy and advocacy for Young Invincibles.

For example, short-term, limited duration insurance policies may seem like a good option because you can buy one at any time of the year and these can be 20% less than the lowest-cost ACA plans, according to research last year from Kaiser. And, because of changes by the Trump administration, Americans can stay on this type of insurance for up to three years.

But Hemlin says a majority of these plans don't actually cover maternity care either. Of the 24 short-term health-care plans offered by big online providers, Kaiser found none offered maternity coverage.

Meanwhile, Medicaid and hospitals' charity care programs have income caps based on household size and state residency. Even those who do qualify for these programs may face huge bills. Under ACA, non-profit hospitals are required to provide free or discounted care to low-income patients, but about half, 45%, sent bills to patients who would otherwise qualify, Kaiser found. Some of that medical debt is later written off, but other hospitals have sent unpaid medical bills to collections, according to Kaiser.

"I know this is stereotypical, but I feel like we're kind of being punished for doing everything 'right' — we're married, financially responsible," Bethany says. "The result is not qualifying for Medicaid or assistance from the hospital."

Many times, it's up to the individual to do the research and fight for coverage. For those who are denied coverage for prenatal services, but believe they should be covered, the National Women's Law Center has a hotline and email service called Cover Her that women can call to get help.

After months of fighting with her insurance and paying $7,500 out of pocket for care, Bethany signed up for an individual Obamacare plan during open enrollment this month. The plan will go into effect January 1, 2020, so ideally Bethany's labor and delivery costs will be covered. It's going to a close call: She's due the first week of January.

"We are hoping like crazy she waits," Bethany says.

** Subject asked to be identified with a pseudonym to protect her privacy*

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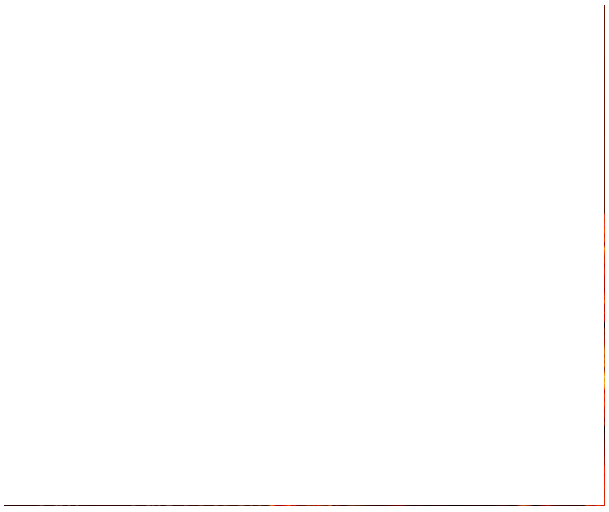

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