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February 12, 2021

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Utah 1115 Primary Care Network Demonstration Waiver
Amendment Request: In Vitro Fertilization and Genetic Testing
for Qualified Conditions

To Whom It May Concern:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and under-served people. We appreciate the opportunity to provide these comments on Utah's application.

Utah is requesting a waiver to restrict coverage of in vitro fertilization (IVF) services and preimplantation genetic diagnosis (PGD) for Medicaid-enrolled individuals who: (1) have been diagnosed by a physician as having a genetic trait associated with one of five specified conditions; and (2) intend to get pregnant with a partner who also has been diagnosed by a physician as having a genetic trait associated with the same condition. The State estimates that with these criteria in place, only 50 individuals per year will receive IVF and PGD through the Medicaid program.

IVF and PGD are services that are used in combination by prospective parents to avoid having children with specific

genetic disorders. IVF and PGD include a number of discrete services, including genetic counseling, stimulation of ovaries to produce eggs, harvesting eggs, fertilizing the eggs in a Petri dish, allowing the eggs to grow from a single cell into 8-cell embryos, storing such embryos until biopsies can genetically test each embryo, and then transferring unaffected embryos to the uterus. IVF and PGD are generally used when the prospective parents screen positive for a genetic variation or are otherwise aware that either: (1) both parents carry a recessive genetic variation connected with an inheritable genetic condition; or (2) one parent is affected by a condition that is an autosomal dominant condition. State Medicaid programs should cover IVF and PGD services for all enrollees who need them in a non-discriminatory manner.

As described in detail below, we recommend that the Department of Health & Human Services (HHS) deny Utah’s application. First and foremost, Utah did not submit a complete application with a sufficient level of detail to allow for meaningful comment. Second, Utah’s proposal does not comply with the requirements of § 1115 of the Social Security Act – it is not likely to assist in promoting the objectives of the Medicaid Act and does not propose an actual experiment.¹ And finally, Utah’s proposal is at best arbitrary, and at worst motivated by the discriminatory motive of trying to avoid providing medical assistance to people with disabilities.

I. Utah Did Not Submit a Complete Application

While Utah has labeled its request an amendment to the Primary Care Network (PCN) project, the State is seeking permission to implement a new project. The proposal would apply to the entire Medicaid population (as opposed to the distinct population groups covered through the PCN project).² In addition, the purported “experiment” that Utah is proposing is unrelated to the “experiment” currently underway. Thus, HHS should treat the request as an application for a new project.

The request does not meet the federal requirements for a complete application. Utah has not provided a sufficient level of detail to “ensure a meaningful level of public input.”³ For example, Utah has requested a waiver of the freedom of choice requirement (42 U.S.C. § 1396a(a)(23)),

¹ 42 U.S.C. § 1315(a).

² *Utah 1115 Primary Care Network Demonstration Waiver Amendment Request: In Vitro Fertilization and Genetic Testing for Qualified Conditions*, 2 (2021), <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ut-primary-care-network-pa13.pdf> [hereinafter “Application”].

³ 42 U.S.C. § 1315(d)(A), (C); 42 C.F.R. §§ 431.408(a), 431.412(a).



but did not explain for what purpose.⁴ The application indicates that the IVF and PGD will initially be provided on a fee-for-service basis but that the State may later transition delivery of the services to managed care by using the authority in § 1396n(b) or requesting an amendment to the project.⁵ This leaves the public with no idea why the State is seeking a waiver of § 1396a(a)(23). Is Utah planning to require beneficiaries to receive these sensitive services from a particular provider or set of providers of its choosing? If so, this would raise serious concerns. The decision to undergo IVF and PGD can be a difficult, deeply personal decision, and it is essential that enrollees be able to choose a provider with whom they are comfortable.

The application also leaves other critical questions unanswered. For example, to be eligible to receive IVF and PGD, individuals must: (1) have been diagnosed by a physician as having a genetic trait associated with one of the five specified conditions; and (2) intend to get pregnant with a partner who also has been diagnosed by a physician as having a genetic trait associated with the same condition. However, the application does not indicate whether Utah covers or will start to cover the genetic screening and testing that could be needed to obtain that diagnosis. That testing can cost hundreds of dollars or more, depending on the condition. If Utah does not cover the screening and testing – for both the individuals who intend to get pregnant and for their partners, who may or may not be enrolled in Medicaid – very few (if any) individuals will be eligible to receive the services. Furthermore, the application does not indicate why those five conditions are specifically being targeted, nor why the proposal applies the same eligibility criteria for the conditions that are inherited via an autosomal recessive pattern and those that are inherited via an autosomal dominant pattern.

The answers to these questions are crucial to helping the public understand the nature and scope of the proposed project. Because the application did not include enough information to allow the public to offer full and meaningful comment, it should not have been deemed complete. We ask HHS to require the State to submit an application that adheres to the federal requirements and to provide an additional comment period on that proposal.

⁴ Application at 3.

⁵ *Id.*



II. The Project Does Not Comply With the Requirements of § 1115

To be approved pursuant to § 1115, Utah's project must:

- propose an “experiment[], pilot or demonstration,”
- waive compliance only with requirements in 42 U.S.C. § 1396a,
- be likely to promote the objectives of the Medicaid Act, and
- be approved only “to the extent and for the period necessary” to carry out the experiment.⁶

The core purpose of Medicaid is to enable states to furnish medical assistance to individuals who are unable to meet the costs of necessary medical care.⁷ As explained below, Utah's proposal is inconsistent with the provisions of § 1115.

A. Utah's Proposal Does Not Promote the Objectives of the Medicaid Act.

While Utah has framed its application as a request to cover additional services, it is in fact a request to restrict coverage of Medicaid services that should be provided to all individuals who need them. IVF and PGD services fall within the categories of care and services described in the Medicaid Act.⁸ Utah is seeking a waiver of the comparability requirement to allow it to limit coverage of those services to individuals who: (1) have a genetic trait associated with one of five listed conditions (and whose partners share that genetic trait); and (2) are between ages 18 and 35. Utah is also seeking to limit coverage of the services to once per lifetime. And, as noted above in Section I, it is not clear whether Utah will cover the initial genetic screening and testing that some individuals will need to access the services.⁹

Utah could claim that without the waiver, it will not cover genetic testing or IVF at all. Even assuming that the State could continue to exclude coverage of the services without violating

⁶ 42 U.S.C. § 1315(a).

⁷ *Id.* § 1396-1.

⁸ *See id.* §§ 1396d(a) (defining medical assistance); 1396a(a)(10) (requiring states to cover certain categories of services and giving them the option to cover others).

⁹ It appears as though Utah is not currently covering those services. *See* Utah Div. of Medicaid & Health Fin., *Utah Medicaid Provider Manual, Physician Services Manual*, 17 (2021), [PhysicianServices.pdf \(utah.gov\)](#) (excluding coverage of genetic testing “for screening purposes only” and when “performed solely for the purposes of genetic counseling, family planning, or health screening”).



the Medicaid Act, it does not follow that the project promotes coverage. As courts have held, the relevant baseline for determining if a proposed § 1115 project increases coverage is not no coverage at all, but rather coverage that complies with the requirements of the Medicaid Act.¹⁰ When evaluating Utah’s proposed project against that baseline, it is clear that it will not provide additional coverage. And, as described in Section III below, the way in which Utah is seeking to restrict coverage is discriminatory.

B. Utah Has Not Proposed an Experiment.

Section 1115 allows HHS to waive some requirements of the federal Medicaid Act so that states can test novel approaches to furnishing medical assistance to low-income individuals, if such waivers comply with certain statutory requirements. Thus, in order for HHS to approve a § 1115 demonstration, the demonstration must propose a genuine experiment of some kind. That is, it must include a stated hypothesis and a way to measure whether that hypothesis is correct. Furthermore, the experiment must be designed to evaluate a new idea or way of addressing problems faced by enrollees; it is insufficient that the state seeks to test whether modifications via § 1115 will save the state funds.¹¹ According to Congress, “States can apply to HHS for a waiver of existing law to test a unique approach to the delivery and financing of services to Medicaid beneficiaries ... contingent upon development of a detailed research methodology and comprehensive evaluation for the demonstration.”¹²

Utah has failed to propose a legitimate experiment. Utah’s application includes one single hypothesis—that the amendment “will decrease Medicaid expenditures associated with the conditions identified in this demonstration.”¹³ Utah is not testing a unique approach to delivery and financing of services to enrollees. Instead, the proposed hypothesis and the associated measures only seek to determine if the project will reduce costs to the State. What is more, there is a disconnect between the single hypothesis and the waivers that Utah seeks. The State has not articulated any experiment associated with restricting coverage of IVF and PGD services to a subset of enrollees for whom it is medically appropriate. Because Utah has not

¹⁰ See, e.g., *Stewart v. Azar*, 366 F. Supp. 3d 125, 154 (D.D.C. 2019)

¹¹ See *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011) (finding that if the “purpose of [a Section 1115] waiver application [i]s to save money,” the application does not satisfy Section 1115); *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994) (holding that Section 1115 “was not enacted to enable states to save money or to evade federal requirements but to test out new ideas”).

¹² H.R. Rep. No. 3982, pt. 2 at 307-08 (1981).

¹³ Application at 2.



articulated a new idea and proposed a valid way to measure such idea, HHS should not approve this proposal.

III. Utah's Proposal Is Discriminatory.

Utah's proposal is discriminatory for at least two reasons. First, Utah fails to explain why it proposes to restrict IVF and PGD to individuals who are carriers for five specific conditions. The proposal limits IVF and PGD to a subset of individuals who may desire it and for whom it is medically appropriate, without any reasonable explanation. Second, the expressly stated purpose of the application is to reduce costs to the State by avoiding the obligation to pay for treatment and services for people with five specific conditions, based on the presumption that parents will choose not bear offspring with the any of those genetic conditions. Essentially, Utah suggests that if children with significant medical conditions are not born, Utah will save money.

Decisions regarding the use of genetic testing in conjunction with assisted reproduction are intensely personal, private decisions. Prospective parents must have the right to make informed, personal decisions, including the decision to use genetic testing or other screening in conjunction with reproductive technologies. However, it is naïve to suggest that such decisions exist separate and apart from social, political, and economic constructs. Thus, when the government intervenes in some way to facilitate the use of such technologies for a limited subset of individuals, it is incumbent to remain vigilant that the policies or practices do not promote selection based on racism, sexism, or in this case, ableism.

At best, Utah's proposal discriminatorily restricts services to an arbitrary subset of individuals; at worst, it is designed to allow Utah to facilitate avoiding the birth of children with conditions that are perceived to be particularly expensive to treat.

The proposal arbitrarily discriminates because Utah provides no information about why certain conditions are targeted and others are not. For example, Utah does not propose to cover IVF and PGD for conditions with extremely poor prognoses, such as Tay-Sachs, but does propose to cover IVF and PGD for myotonic dystrophy, which is associated some physical disability and with individuals with milder symptoms living a fairly normal lifespan.¹⁴

¹⁴ Genetic and Rare Diseases Information Center, Myotonic Dystrophy (last visited Feb. 2, 2021), <https://rarediseases.info.nih.gov/diseases/10419/myotonic-dystrophy>.



Alternatively, Utah’s proposal may be designed to facilitate avoiding the birth of children with conditions that are perceived to be costly. For example, the proposal allows for potential parents to avoid having a child with spinal muscular atrophy, one form of which is treatable by a one-dose gene therapy that costs \$2.1 million.¹⁵ Another treatment for spinal muscular atrophy, Spinraza, can cost up for \$4 million over a decade.¹⁶ Other conditions, such as cystic fibrosis, are associated with rising costs as the average lifespan of individuals with CF continues to increase, and newly approved pharmaceutical treatments can cost more than \$300,000 per year.¹⁷ Again, however, even this appears arbitrary. For other targeted conditions, such as myotonic muscular dystrophy, there is no known pharmaceutical treatment and treatment is aimed at managing the symptoms via relatively traditional interventions, supports and services.¹⁸

The very lack of any reasonable explanation for why certain conditions were selected, accompanied by the explicit statement that the State wants to reduce the costs associated with providing treatment, services, and supports for children that have these conditions, raises serious questions regarding Utah’s motivations. Therefore, the application should not be approved.

IV. Conclusion

The Secretary should not approve Utah’s requested demonstration amendment. In general, NHeLP supports efforts to expand reproductive services to Medicaid beneficiaries. However, Utah’s request is incomplete, fails to comply with the requirements of § 1115, and is discriminatory.

¹⁵ Katie Thomas, This New Treatment Could Save the Lives of Babies. But It Costs \$2.1 Million, *N. Y. Times* (May 24, 2019), <https://www.nytimes.com/2019/05/24/health/zolgensma-gene-therapy-drug.html>.

¹⁶ *Id.*

¹⁷ Andrew Joseph, New Vertex Cystic Fibrosis Drug Approved, Expanding Treatments to 90% of Patients, *Stat*, (Oct. 21, 2019), <https://www.statnews.com/2019/10/21/new-vertex-cystic-fibrosis-drug-approved-extending-treatments-to-90-of-patients/>.

¹⁸ *Supra* note 14 (noting that there is no cure or specific treatment for myotonic dystrophy, but that physical activity, orthopedic supports, durable medical equipment, pain management, and regular cardiac monitoring and interventions are common).



We appreciate your consideration of our input. If you have questions about these comments, please do not hesitate to contact us.

Sincerely,



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