July 5, 2016

Tamara Syrek Jensen, J.D.
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-14-15
Baltimore, MD 21244-1850

Re: Proposed decision memorandum on gender reassignment surgery for Medicare beneficiaries with gender dysphoria (Administrative File CAG #00446N)

Submitted via email

Dear Ms. Syrek Jensen,

We are writing to comment on the proposed decision regarding whether the Centers for Medicare & Medicaid Services (CMS) should issue a new National Coverage Determination (NCD) regarding gender reassignment surgery (GRS). Like you, we believe that all Medicare beneficiaries, including transgender individuals, should have access to high-quality coverage and care, and we appreciate your attention to this issue.

The proposed decision memo, in seeking to answer the question of whether there is sufficient evidence to conclude that GRS improves health outcomes for Medicare beneficiaries with gender dysphoria, asserts that the evidence is inadequate to support this conclusion. We acknowledge that a new NCD for GRS may not be warranted at this time, given that NCDs are relatively rare for Medicare procedures. It is also the case that widespread coverage exclusions regarding this care, many of which were lifted only recently, have limited the extent of research regarding the full scope of surgical procedures that may be medically necessary as part of gender transition.

However, we have grave concerns regarding flaws in the analysis that CMS cites to support its proposed decision and the degree to which that decision could seriously undermine access to coverage for medically necessary health care services for transgender Medicare beneficiaries and other transgender individuals. We therefore respectfully urge you to revise the decision to clarify that Medicare coverage for GRS is available in appropriate cases and to ensure that the decision does not conflict with recent advances in transgender health, including the 2014 decision by the U.S. Department of Health and Human Services (HHS) Departmental Appeals Board overturning Medicare’s ban on coverage for GRS.

Specifically, in light of the available evidence and the consensus of major medical associations regarding transition-related care, we believe the final decision must include the following points:

- The established medical consensus is that GRS is a safe, effective, and medically necessary treatment for many individuals with gender dysphoria, and for some individuals with severe dysphoria, it is the only effective treatment.

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1 We are aware that various medical experts who specialize in transgender health care are submitting detailed comments about the specific and widespread flaws in CMS’s analysis of the scientific literature, and we do not repeat those points here. Rather, this comment is intended to explain that, in light of those flaws, the final decision must be drastically revised.
• Previous HHS findings support this consensus and indicate that the Standards of Care maintained by the World Professional Association for Transgender Health can satisfy Medicare’s “reasonable and necessary” criterion for determining GRS coverage on a case-by-case basis.
• Medicare does cover transition-related care, including GRS in appropriate cases, and CMS’s decision to not issue an NCD at this time must not be interpreted to the contrary or used in any way to inappropriately restrict access to coverage for transgender Medicare beneficiaries or other transgender individuals.
• Other legal standards beyond the NCD process—particularly the nondiscrimination protections codified in Section 1557 of the Affordable Care Act—also apply to Medicare coverage for GRS and other care related to gender transition.
• More research is needed on the health care needs of transgender individuals, but a Medicare coverage protocol that supports “coverage with evidence development” will not be issued at this time.

Below we discuss each of these points in more detail.

The established medical consensus is that GRS is safe, effective, and medically necessary for some individuals with gender dysphoria, and for some individuals with severe dysphoria, it is the only effective treatment.

A transgender person is an individual whose gender identity or expression is different from the sex they were assigned at birth. According to 2016 estimates, there are at least 1.4 million transgender people living in the United States. Like anyone, transgender individuals need preventive care to stay healthy and acute care when they become sick. Unfortunately, transgender individuals frequently face barriers to quality health care, such as harassment in health care settings, substandard care, and outright refusals of care. As a result of these barriers and other forms of discrimination, the transgender population as a whole experiences significant health disparities that include high incidence of HIV infection, elevated tobacco and other substance use, frequent exposure to abuse and violence, and a prevalence of suicidal ideation almost nine times higher than among the non-transgender population.

Many transgender people need medical treatment to help them physically transition from their assigned birth sex to the sex with which they identify. The medical diagnosis that is frequently associated with a need for this treatment is “gender dysphoria,” which refers to the clinically significant distress experienced by transgender individuals as a result of a profound misalignment between their gender identity and their assigned sex at birth. Gender dysphoria is described in the fifth edition of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and is recognized as a serious medical condition by the World

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Health Organization\textsuperscript{5} and every U.S. court that has considered the question.\textsuperscript{6} According to the standards of care maintained by the World Professional Association for Transgender Health (WPATH), treatment for gender dysphoria may include gender reassignment surgeries, hormone therapy, and mental health counselling, though the WPATH standards emphasize that treatment must be individualized for each patient on the basis of their clinical history and the judgment of their health care provider.\textsuperscript{7} Major medical associations—including the American Medical Association, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the Endocrine Society, and the American Congress of Obstetricians and Gynecologists, among others—agree that treatment for gender dysphoria is medically necessary.\textsuperscript{8}

In a 2008 resolution, for example, the American Medical Association affirmed that mental health counselling, hormone therapy, and GRS are effective, safe, and medically necessary treatments for individuals diagnosed with gender dysphoria.\textsuperscript{9} The resolution further emphasizes that, without appropriate medical treatment, gender dysphoria can have consequences that include “clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death.”\textsuperscript{10} As such, access to treatment for gender dysphoria, including GRS, is frequently a matter of life or death for transgender individuals.

Previous HHS findings support this consensus and indicate that the WPATH Standards of Care can satisfy Medicare’s “reasonable and necessary” criterion for determining GRS coverage on a case-by-case basis.

Previous findings from the HHS Departmental Appeals Board (DAB) have already determined that a widespread medical consensus has established GRS as a “reasonable and necessary” treatment for gender dysphoria in appropriate cases.

In May 2014 the DAB invalidated NCD 140.3, which denied Medicare coverage of all “transsexual surgery,” on the grounds that it was based on an outdated record from 1981 that was not complete or adequate to support the determination that transsexual surgery had not been shown to be effective.\textsuperscript{11} In its ruling, the DAB cited expert testimony stating that “there are numerous long-term follow-up studies on surgical treatment demonstrating

\begin{itemize}
    \item \textsuperscript{5} World Health Org., \textit{International Statistical Classification of Diseases and Related Health Problems}, \url{http://apps.who.int/classifications/icd10/browse/2010/en/#F64}.
    \item \textsuperscript{7} World Prof. Ass'n for Transgender Health, \textit{Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People} (2012).
    \item \textsuperscript{9} Am. Med. Ass'n House of Delegates, \textit{Removing Financial Barriers to Care for Transgender Patients}, H-185.950 (Res. 122; A-08) (2008), \url{http://www.tgender.net/taw/ama_resolutions.pdf}.
    \item \textsuperscript{10} \textit{Id.}
    \item \textsuperscript{11} Dept of Health \\& Human Servs., NCD 140.3, Transsexual Surgery (Docket No. A-13-47) (2013), \url{http://www.hhs.gov/dab/decisions/dabdecisions/ncd1403.pdf}.
\end{itemize}
that surgeries are effective and have low complication rates," and noted that CMS did not challenge this testimony.  

The ruling also stated that, contrary to the NCD's assertion that GRS is "experimental" and "controversial," current evidence "indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism."  

The DAB noted that CMS guidance to contractors indicates that such a consensus may be sufficient to establish that a particular treatment is reasonable and necessary for purposes of Medicare coverage: "While the guidance states a 'preference' for '[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies...,,' it also includes as evidence meeting that standard, '[g]eneral acceptance by the medical community (standard of practice), as supported by sound medical evidence...." According to the ruling, "[r]egardless of whether the new evidence here meets the first option for meeting the evidentiary standard set forth in the guidance (and CMS does not assert that it does not), it clearly meets the second option." 

In January 2016 the HHS Medicare Appeals Council ("the Council"), which is part of the DAB, issued a ruling that a Medicare Advantage plan's decision to deny coverage for GRS to a transgender Medicare beneficiary did not comport with Medicare’s “reasonable and necessary” criterion. In its ruling, the Council echoed the 2014 DAB ruling in noting that the WPATH Standards of Care have "attained widespread acceptance" and emphasized that both the plan and the enrollee’s physicians had recognized the “authority” of the WPATH Standards. The Council therefore concluded that these standards are “reasonable guidelines to determine medical necessity in this case” and found that, inasmuch as the enrollee “satisfies all of the WPATH clinical requirements for gender reassignment surgery...the requested vaginoplasty is medically reasonable and necessary for treatment of this enrollee's gender dysphoria under Section 1862(a)(1)(A) of the [Social Security] Act and is covered under existing CMS guidance.”

Though this case involved only one individual, the Council expressly framed its ruling as an example of how it will adjudicate claims for GRS on a case-by-case basis in the absence of an NCD. Furthermore, inasmuch as the Council's ruling in this case constitutes a statement of HHS’s opinion on the “widespread acceptance” of the WPATH Standards and the degree to which its guidelines for GRS can satisfy Medicare's “reasonable and necessary” test, this ruling and its approach to the WPATH Standards deserve significant deference. We therefore strongly urge CMS to state in the decision or in other guidance to Medicare contractors, as well as to Medicare Advantage plans and Medicare providers, that previous HHS findings on this issue indicate that the WPATH Standards of Care are reasonable guidelines to use in determining medical necessity and coverage for GRS on a case-by-case basis.

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13 Id.  
14 Id. note 12 at *20.  
15 Id. (citations omitted).  
16 Id.  
17 Id. (citations omitted).  
18 Id. at *9.  
19 Id.  
20 Id. at *13.  
21 Id. at *18.
Medicare does cover transition-related care, including GRS in appropriate cases, and CMS’s decision to not issue an NCD at this time must not be interpreted to the contrary or used in any way to inappropriately restrict access to coverage for transgender Medicare beneficiaries or other transgender individuals.

We are concerned that the proposed decision adopts an unnecessarily broad scope that could be read as a statement that Medicare does not cover GRS procedures for the treatment of gender dysphoria. Such an interpretation would be out of step with the previous HHS findings that GRS is “reasonable and necessary” in appropriate cases, and it will also negatively affect the health and wellbeing of transgender Medicare beneficiaries.

The proposed decision states that “CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary.” We do not believe that this is an appropriate framing of the question in light of the DAB’s existing ruling that the medical consensus—by itself—is sufficient to establish that GRS is reasonable and necessary. Rather, the only question before CMS is whether the evidence is of sufficient quality to support a finding that an NCD is the most appropriate means of providing GRS to Medicare recipients with gender dysphoria. We agree with the conclusion that an NCD is not warranted at this time and that “[t]he case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule.”

The scope of the proposed decision, however, substantially exceeds the specific question of whether an NCD is the most appropriate method of providing GRS to Medicare beneficiaries with gender dysphoria.

We have no doubt that CMS intended the broad scope of its analysis to help advance the field of transgender medicine by highlighting areas in need of additional research. However, in presenting a sweeping assessment of studies looking at the entire transgender population—and in drawing conclusions on the basis of an analysis that we believe has serious flaws—the proposed decision reads as a repudiation of GRS as an effective treatment for any transgender individual.

The breadth of this assessment is not required by the laws governing the NCD process. Under 42 U.S.C. 1395y(l)(3)(C) and guidance published at 78 Fed. Reg. 48164-01 (Aug. 7, 2013), a final decision memo must include only (a) summary of public comments and response to those comments, and (b) the scientific basis of CMS’s coverage determination. There is thus no requirement for the decision to include any information or analysis that is not directly relevant to explaining the “scientific basis” for CMS’s ultimate decision. In fact, including extraneous information could be actively misleading by giving the impression that the extraneous information also informed the “scientific basis” for the decision. If CMS determines that none of the studies for a given medical procedure provide sufficient analysis of the Medicare population, there is no basis for providing additional information, analysis, or critiques about other aspects of the relevant studies.

Similarly, there is no need to include information, analysis, or critiques about all studies relating to a medical condition if those studies do not strictly form the basis for evaluating the effectiveness and safety of the procedure in question. As such, we strongly urge you to limit the scope of the decision to noting that a preponderance of the available evidence specific to GRS does not include the Medicare population. In this situation, the logical conclusion is that an NCD is not warranted at this time because it is more appropriate to continue to assess the medical necessity of GRS procedures for Medicare beneficiaries on an individual basis, with guidance from the WPATH Standards or other relevant expert standards in the field of transgender medicine.

In addition to overgeneralizing from the lack of information available about the Medicare population, the proposed decision also fails to make clear distinctions between GRS and other treatments for gender dysphoria, such as hormone therapy. The proposed decision notes in passing merely that “the specific role for various surgical procedures is less well understood than the role of hormonal intervention,” without any further clarification that the analysis applies only to surgical procedures. While we are aware that CMS intentionally focused this analysis on GRS, the lack of any other guidance from CMS about Medicare coverage for care related to gender transition makes it very likely that this proposed decision will be interpreted as the definitive statement of what Medicare does or does not cover. Given the decision’s broad dismissal of the evidence related to GRS and its relative silence about any other aspects of transition-related care, we are deeply concerned that the decision will be used as evidence that Medicare does not cover any care related to gender transition—with predictable negative consequences not only for transgender Medicare beneficiaries but also those with coverage from other payers.

CMS indicates that the purpose of the proposed decision is to maintain the status quo regarding the availability of coverage for gender reassignment under Medicare. This perspective, however, fails to address the fact that the status quo for many transgender Medicare beneficiaries is a lack of coverage. A moderated online group for transgender Medicare beneficiaries with more than 2,600 members, for example, provides numerous examples of denials, confusion, and misinformation related to what Medicare covers for care related to gender transition:

- “I’m so upset with Medcare [sic] until I’m ready to just die, I found out that it will not pay for my Top surgery, not [sic] matter how much I try it seems that I’m always hitting this damn wall...I’m so tired of hitting that wall. So now I sit here crying and trying to think what to do, and I’m about to my witts [sic] end.” (October 2015)
- “The surgeon replied to my request: Jaime in our insurance department called Medicare and this is what they said—National Coverage Determination is no longer valid, an appeal invalidated the coverage for transgender surgery. They have no idea when it might be reinstated. So with that being said there’s no way we can submit this as gender reassignment. It will get denied and you will be responsible for everything.” (November 2015)
- “Got a call from [hospital]. Surgeries are on hold. They have not been paid from four cases. They are in the process of trying to figure things out with Medicare. Not the best news for me.” (December 2015)
- “The reason [for denial of bilateral mastectomy/chest reconstruction for a transgender man] is that the surgeons know that there is no National Coverage Determination, i.e. written policy on the part of Medicare. There hasn’t been one since the ban was dropped...many surgeons are waiting for written policy.” (April 2016)
- “I am disabled and on SSDI with Medicare. While I am fortunate to have had a career that puts me on the upper ranges of SSDI, and my wife works (17 years and she is just getting to $13 an hour) we don’t have the kind of money we can throw at electrolysis for a surgical site on me. It’s a prerequisite for surgery, there are no Medicare billing electrolysis technicians who I’ve found, and it’s a lengthy process that requires in the $1000’s to complete. If I don’t find a way to get the funding for the electrolysis I very well will be shut off from obtaining the care I need. If I’ve got it bad, I can’t imagine the unobtainable nightmare it must be for those fighting poverty.” (June 2016)

One of the group’s moderators provides the following summary of what he describes as common problems:

- Surgeons can’t get preauthorization, so they won’t schedule surgery. Even though original Medicare pays

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23 Original posts on file with the Center for American Progress and available upon request.
24 Quotes are lightly edited and condensed for clarity.
after the procedure, these surgeons won’t take a chance on Medicare since there is nothing in writing to say Medicare will cover it. They will do it for other established surgeries, but surgeries related to gender reassignment are “taboo.”

- Providers’ offices say that Medicare does not cover transition-related services because they do not know about the 2014 DAB ruling rescinding NCD 140.3.
- Providers refuse to accept Medicare’s low reimbursement rates.
- Providers do not know what codes they need to use to bill Medicare for GRS.
- Transgender Medicare beneficiaries call Medicare’s call center and are regularly told the call center representatives can’t say whether GRS is covered; call center representatives don’t inform callers that procedures are being covered on a case-by-case basis.

The problem of ongoing denials of coverage for care related to gender transition is not restricted to Medicare. As of June 2016, for instance, 18 state Medicaid programs and 40 state-selected Essential Health Benefit (EHB) benchmark plans for 2017 still explicitly ban coverage for care related to gender transition.²⁵ This status quo is changing, but even in the short time the proposed decision has been public, numerous advocacy organizations have received reports of payers and regulators seizing on it as justification for attempts to limit access to transition-related care.²⁶ While we understand that CMS cannot be responsible for the actions of other payers and regulators, we strongly urge you to ensure that the decision is clearly restricted to the Medicare population and clarifies that coverage for GRS is available under Medicare on a case-by-case basis. We also encourage CMS to publish additional guidance for Medicare contractors, Medicare Advantage plans, Part D prescription drug plans, and providers, clarifying that physician services and prescription drugs related to gender transition—such as mental health counseling and hormone therapy—are broadly considered reasonable and necessary under Medicare guidelines.

Other legal standards beyond the NCD process also apply to Medicare coverage for GRS and other care related to gender transition.

As you know, ACA Section 1557 prohibits any health program or entity receiving federal funds from discriminating on a variety of bases, including sex. HHS released a final rule in May 2016 clarifying that these sex protections extend to gender identity and sex stereotypes, meaning that they specifically include transgender individuals.²⁷ The final rule explicitly states that covered entities can no longer categorically exclude all services related to gender transition, and they cannot make coverage decisions in a manner that results in discrimination against a transgender individual—such as denying coverage for mental health services related to gender transition while covering them for depression, among many other examples. The final rule also requires health care providers to provide medically necessary health care services to transgender individuals, as long as those services are within the provider’s scope of practice and are provided to non-transgender individuals. Section 1557

²⁵ Analysis on file with the Center for American Progress and available upon request.
²⁶ Information on file with the Center for American Progress and available upon request.
applies to all plans sold by any issuer who participates in federal health care programs such as Medicare or federally supported programs such as Medicaid. Covered entities that violate Section 1557’s requirements are potentially subject to both administrative remedies and private lawsuits.

It is beyond the scope of the NCD process and the proposed decision memo to provide substantial guidance to contractors and other Medicare stakeholders on their legal obligations with regard to coverage for gender transition services under Section 1557. We believe, however, that CMS would do these stakeholders a disservice by failing to take the opportunity to reiterate that, in the absence of an NCD, Medicare contractors, Medicare Advantage plans, and Part D prescription drug plans must ensure that they are making coverage determinations in a nondiscriminatory manner. This involves eliminating categorical exclusions for transition-related care, as well as using medical necessity criteria that conform to the latest WPATM Standards of Care or other accepted standards in the field of transgender medicine and that do not inappropriately limit access to health care services for transgender individuals, including GRS and other services related to gender transition.

**More research is needed on the health care needs of transgender individuals, but a Medicare coverage protocol that supports “coverage with evidence development” (CED) will not be issued at this time.**

We appreciate CMS’s support for more research regarding the treatment options available to transgender individuals with gender dysphoria. As you know, these treatment options are lifesaving for transgender individuals who need specific health care services to live authentic lives in bodies that reflect their true identity. We agree that more research is needed around the health care needs of transgender individuals and look forward to working with CMS and research entities such as the National Institutes of Health and the Patient-Centered Outcomes Research Institute to enhance the number and quality of studies in the field of transgender medicine.

In the meantime, however, we strongly caution against instituting a CED protocol for Medicare coverage of GRS. While we recognize that CMS policy allows use of the CED process in a wide range of situations, a CED protocol would unnecessarily restrict access to care for transgender individuals. Outcomes research can be conducted without designating only a limited number of sites or providers where treatment can be received. Moreover, despite welcome advances such as the Section 1557 final rule, transgender individuals continue to face widespread discrimination, harassment, and even violence in aspects of everyday life as mundane as trying to access public restrooms. In the health care context, the long history of mistreatment of transgender patients at the hands of medical professionals leads many transgender individuals to be wary of the medical field and sometimes to avoid seeking health care entirely. Potential study participants may thus have well-founded concerns about a policy that makes access to Medicare coverage for transition-related health care contingent on being enrolled in a formal medical research study. While a CED protocol would be a well-intentioned effort to advance the field of transgender medicine, in practice it would raise serious concerns for participants and would severely restrict the availability of lifesaving health care services for transgender individuals.

**Conclusion**

Thank you again for your dedication to the health and wellbeing of transgender individuals and for your invitation to provide public comment on the proposed NCD decision. We strongly support CMS in clarifying the circumstances under which GRS and other care related to gender transition is available under Medicare, and we

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29 Lambda Legal, *supra* note 3.
appreciate your concern for doing so in a way that reflects the best current standards in the field, does not hinder access to medically necessary care in a discriminatory manner, and does not conflict with previous HHS findings on this matter. We look forward to continuing to work with you to ensure that the final decision is appropriate in scope and clear that coverage for GRS and other care related to gender transition is available under Medicare despite the lack of an NCD. Please do not hesitate to contact Kellan Baker at the Center for American Progress at kbaker@americanprogress.org or (805) 390-2309 with any questions or concerns about these comments.

Sincerely Yours,

Organizational Signatories:

ACLU LGBT Project
AIDS Foundation of Chicago
Basic Rights Oregon
Brave Space, LLC
Callen-Lorde Community Health Center
Campus Pride
Center for American Progress
Center for Medicare Advocacy, Inc.
Conceptions Consulting
DGLHue
Equi Institute
Fair Wisconsin
Family Equality Council
Fenway Health
Fenway Institute
FORGE, Inc.
GLBTQ Legal Advocates and Defenders
GLMA: Health Professionals Advancing LGBT Equality
Human Rights Campaign
Justice in Aging
Lambda Legal
Legacy Health
Lesbian Health Initiative of Houston
lgbtQ&A Diversity and Inclusion Consulting
MassEquality
Mount Sinai Health System
National Alliance of State & Territorial AIDS Directors
National Black Justice Coalition
National Center for Lesbian Rights
National Center for Transgender Equality
National LGBTQ Task Force
Oregon Health and Sciences University
OutFront Minnesota
PFLAG National
RAD Remedy
Raising Women’s Voices – NY
San Francisco AIDS Foundation
Stonewall Columbus
Trans Pride Initiative
Transcend Legal
Transgender Law Center
Transgender Legal Defense & Education Fund
University of California at San Francisco
Whitman-Walker Health
Woodhull Freedom Foundation
World Professional Association for Transgender Health

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