OBAMA-BIDEN TRANSITION PROJECT

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Access to Transgender Health Care under Medicare

Issue

Many transgender people are denied access to necessary medical care related to gender transition under Medicare.

Short Answer

The Centers for Medicare and Medicaid Services ("CMS") should revise its National Coverage Determinations to ensure that individuals have access to medically-necessary treatments related to gender transition and to remove any barriers to health care related to conditions associated with an individual's pre-transition gender.

Background

Medicare is one of the largest health insurance programs in the country and is the primary health insurer for approximately 44 million individuals. The policies established by CMS, the federal agency within the U.S. Department of Health and Human Services ("HHS") responsible for overseeing this program, also wield significant, indirect influence over other public and private health care coverage.

CMS's coverage decisions are based on the scope of the statutes and regulations enacted as part of, or pursuant to, the Social Security Act ("SSA") as well as existing clinical literature. Although the U.S. Food and Drug Administration is responsible for determining whether a new treatment is "safe and effective," Medicare coverage policies directly determine whether an item or service is "reasonable and necessary for the diagnosis and treatment of illness or injury"[1] and effective and efficient such that it should be available to all Medicare beneficiaries.

Those transgender people who undergo medical treatments related to gender transition, under the direction and supervision of health care professionals, nonetheless encounter numerous barriers to coverage under the Medicare program. First, CMS has issued an NCD excluding "sexual reassignment surgery" from Medicare coverage by categorizing the surgery as cosmetic.[2] This categorical exclusion not only denies coverage for medically-necessary treatment to Medicare beneficiaries, but also signals to a range of public and private health insurers that it is permissible to exclude such coverage in their own programs.

Second, coverage for long-term hormone therapy, also medically necessary for many who undergo gender transition, is not clearly available to Medicare recipients. Hormone therapy is not categorically included or excluded from the definition of a drug covered under Medicare's "Part D" prescription drug benefit. Thus, it could be covered to the extent it is prescribed for a "medically

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[1] Social Security Act (SSA) § 1862(a)(1)(A), *codified at* 42 U.S.C. § 1395y(a)(1)(A).

[2] The NCD contains a description of the surgery, explaining that it "is the culmination of a series of procedures . . . . For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses." CTRS. FOR MEDICARE & MEDICAID SERVS., National Coverage Determination § 140.3 (CIM § 35-61), Transsexual Surgery, http://www.cms.hhs.gov/transmittals/downloads/R131CIM.pdf.

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accepted" indication (where "medically accepted" indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being). However, if hormone therapy is prescribed "for cosmetic purposes,"[3] it would not be covered. Should eligibility for coverage be established, a second level of analysis is required to determine whether the medication regimen is covered under the formulary of the private entity which administers a particular Medicare beneficiary's Part D Plan. Due to the degree of discretion left to Part D Plan provider, and a lack of clear direction from CMS, it is unclear whether, from plan to plan, a transgender Medicare beneficiary will have coverage for medically-necessary hormone therapy.

Third, transgender Medicare beneficiaries who have undergone gender transition, and successfully modified the gender marker in their Social Security records[4], are at risk of being denied coverage for treatment of medical conditions, associated with their pre-transition gender, for which they remain at risk. Currently, the SSA, implementing regulations and NCDs limit access to screening mammography and cervical cancer screenings to women and prostate cancer screenings to men.[5] As a result, transgender Medicare beneficiaries –many of whom are in age groups at high risk for breast, cervical and prostate cancer– may be denied access to critical preventative care because they have transitioned.

Recommendation

The Secretary of HHS should instruct the Administrator of CMS to review all relevant clinical data and revise NCDs regarding sexual reassignment surgery and access to breast, cervical and prostate cancer screenings to remove barriers to treatment for transgender Medicare beneficiaries. CMS should issue an NCD indicating that hormone therapy as part of gender transition is a necessary, "medically accepted" use of drugs that must be covered by all Part D Plans.

Authority

The SSA does not specify what items and services are eligible for Medicare coverage, but rather lists categories of coverable items and services (such as diagnostic services and surgical procedures) and delegates to the Secretary of HHS the authority to make determinations about whether a specific item or service within these categories can be covered.[6] CMS assesses whether to extend coverage to an item or service through National Coverage Determinations ("NCDs"), which are issued by the Office of Clinical Standards and Quality. CMS staff physicians typically issue the final decision on each health care item and service, although public input is sought and outside technology assessments may be requested.[7] Objective scientific data and well-documented clinical studies receive the most weight in coverage decisions.[8]

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[3] SSA § 1927(d)(2).
[4] SEE ISSUE PAPER ON SSA GENDER MARKER CHANGE
[5] *See* SSA §§ 1861(jj) and 410.34(a)(2) (regarding mammography); SSA §§ 1861(nn), 410.56(b)(1), and CMS Nat'l Coverage Determination for Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer 210.2 (regarding cervical cancer screenings); and SSA §§ 1861(oo) and 410.39 (regarding prostate cancer screenings).
[6] *See generally* CTRS. FOR MEDICARE AND MEDICAID SERVS., Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003).
[7] *Id.* *See also* CTRS. FOR MEDICARE AND MEDICAID SERVS., *Medicare Coverage Determination Process*, http://www.cms.gov/DeterminationProcess/01_overview.asp.
[8] *Id.* Note that Medicare claims are adjudicated by government contractors – fiscal intermediaries or program carriers – that have the authority to establish their own policies for coverage and reimbursement of items and services, so long as

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such policies are not inconsistent with an NCD and so long as they are developed with public comment. These "Local Medical Review Policies" (LMRPs), which must be based on scientific and clinical information with an emphasis on peer-reviewed literature, may affect beneficiary access.