

September 17, 2018

**Via email:** [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov)

The Honorable Alex Azar, Secretary  
Department of Health and Human Services  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: Information Collection Request on Consent for Sterilization Form (0990–New–60D)

Dear Secretary Azar:

The National Health Law Program (NHeLP) and the undersigned organizations thank the Department of Health and Human Services (HHS) for the opportunity to respond to its Agency Information Collection Request regarding the Consent for Sterilization Form (OMB No. 0937-0166) set to expire on December 31, 2018. Our organizations are committed to advancing the reproductive health, rights, and justice of people with low incomes, people of color, LGBTQ individuals, people with disabilities, and people with substance use disorders. We support the continued use of the Consent for Sterilization Form (“Form”) and offer the following comments to improve clarity and enhance the quality and utility of the information collected through the Form.

## **I. The Necessity and Utility of the Information Collection**

The consent requirement was created to protect people from coercive sterilization practices. The United States has an ugly history of forcibly sterilizing low-income people, and particularly targeting low-income women, women of color, immigrant women, and women with disabilities to advance eugenics principles. Some sterilizations occurred without the woman’s knowledge or consent while under anesthesia or during labor, while other women were misinformed or not counseled on the permanent nature of sterilization.<sup>1</sup> In other cases, immigrant, Native American/American Indian, and low-income women were threatened with deportation or the withholding of public benefits or health treatment, or the removal of their children if they did not consent to sterilization.<sup>2</sup>

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<sup>1</sup> Alexandra Minna Stern, *Sterilized in the Name of Public Health: Race, Immigration, and Reproductive Control in Modern California*, 95 AM. J. PUBLIC HEALTH, 1128-38 (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449330/>.

<sup>2</sup> See Sally J. Torpy, *Native American Women and Coerced Sterilization: On the Trail of Tears in the 1970s*, 24 AM. INDIAN CULTURE AND RESEARCH J., 1-22 (2000), <https://www.law.berkeley.edu/php->

Additionally, based on inaccurate and misguided assumptions about disability, over 60,000 disabled men and women were deemed “unfit to reproduce” and involuntarily sterilized in state institutions across the country.<sup>3</sup> Established by regulation, the Medicaid Consent for Sterilization policy was, and remains, a much-needed protection against these practices.<sup>4</sup> Any changes to the Form must comply with the underlying regulation that established the 30-day consent period and authorized the Form.<sup>5</sup>

The deeply troubling practice of coerced sterilization continues today and affects women with substance use disorders, disabilities, or incarcerated women in particular. Within the last two years, judges in Tennessee and Oklahoma offered reduced sentences to people with substance use disorders if they underwent sterilization, calling into question the ability of defendants to provide consent free of coercive influence.<sup>6</sup> In 2015, prosecutors in Nashville included sterilization in plea deals with several women with mental health diagnoses or substance use disorders.<sup>7</sup> Further, from 2005 to 2013, prison officials and medical staff authorized sterilizations of incarcerated women in California—many of whom were women of color—without obtaining informed consent.<sup>8</sup> For people with disabilities, sterilization practices raise a host of issues, many of which have historical and civil rights implications.<sup>9</sup>

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[programs/centers/crri/zotero/loadfile.php?entity\\_key=QFDB5MW3](https://programs/centers/crri/zotero/loadfile.php?entity_key=QFDB5MW3). See also Elena Gutierrez, *FERTILE MATTERS: THE POLITICS OF MEXICAN-ORIGIN WOMEN’S REPRODUCTION*, Univ. of Texas Press (2009), at 44.

<sup>3</sup> Stern, *supra* note 1.

<sup>4</sup> 42 C.F.R. § 441.257.

<sup>5</sup> An exception to the 30-day consent period exists in cases of premature delivery or emergency abdominal surgery. See 42 CFR § 441.253(d).

<sup>6</sup> See Tom Jackman, *Judge Suggests Drug-Addicted Woman Get Sterilized Before Sentencing, and She Does*, WASHINGTON POST (Feb. 8, 2018), <https://wapo.st/2w7g7CE>. See Derek Hawkins, *Tenn. Judge reprimanded for offering reduced jail time in exchange for sterilization*, WASHINGTON POST (Nov. 21, 2017) <https://wapo.st/2N91q8H>. Jessica Lusenhopp, *We Were Guinea Pigs: Jailed Inmates Agreed to Birth Control*, BBC NEWS (Aug. 18, 2017), <https://www.bbc.com/news/world-us-canada-40955288>.

<sup>7</sup> Sheila Burke, *Nashville Prosecutors Require Sterilization as Part of Plea Deals*, AP (March 29, 2015), <https://bit.ly/2Lm59y7>.

<sup>8</sup> The California State Auditor found that out of 144 tubal ligations performed on inmates, at least 39 were performed without lawful consent. See Cal. State Auditor, Report 2013-120, *Sterilization of Female Inmates: Some Inmates Were Sterilized Unlawfully and Safeguards Designed to Limit Occurrences of the Procedure Failed*, 36 (June 2014), <https://www.auditor.ca.gov/reports/summary/2013-120>.

<sup>9</sup> For example, see Autistic Self Advocacy Network, Letter to Washington State Patterns Forms Committee (2018), <https://autisticadvocacy.org/wp-content/uploads/2018/02/Letter-from-Undersigned-Organizations-to-Commissioner-Rebekah-Zinn.pdf>.

These cases demonstrate why sterilization consent practices, including the Form used for Medicaid-funded sterilization procedures, remain vital and necessary even as they could be improved.

## **II. Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected**

42 C.F.R. § 441.258 defines the Form's content, signature, and certification requirements for states to receive federal financial reimbursement for the procedure. Recent CMS guidance documents reinforced these consent requirements as a condition for federal reimbursement.<sup>10</sup> While the need for the Medicaid Consent for Sterilization policy and Form continues, the Form itself has remained unchanged for over 40 years.<sup>11</sup> We offer the following recommendations to enhance the quality, utility, and clarity of the consent process for people with disabilities, individuals with limited English proficiency, LGBTQ individuals, and people with low literacy levels who want to undergo sterilization.

### *Readability Challenges*

Studies have shown that the Form is difficult to read and understand.<sup>12</sup> The Form is written at a ninth grade reading level, which exceeds the recommended level for patient education and informed consent materials.<sup>13</sup> The Form's lack of readability is a serious concern because sterilization has life-altering consequences for the women who undergo the procedure. A recent National Institutes of Health-funded research project found that women of color and women with low incomes were less likely to understand that sterilization is a permanent procedure.<sup>14</sup> Another study tested a low-literacy version of the Form and found improved understanding of the permanent nature of the

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<sup>10</sup> CMS, FREQUENTLY ASKED QUESTIONS MEDICAID FAMILY PLANNING SERVICES AND SUPPLIES (Jan. 11, 2017), <https://www.medicaid.gov/federal-policy-guidance/downloads/faq11117.pdf>. See also CMS, Dear State Health Official Letter Re: Medicaid Family Planning Services and Supplies (June 14, 2016)(SHO #16-008), <https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf>.

<sup>11</sup> The "Consent to Sterilization" form was created in 1976 through regulation. Dana Block-Abraham, Kavita S. Arora, et al, *Medicaid Consent to Sterilization Forms: Historical, Practical, Ethical, and Advocacy Considerations*, 58 CLINICAL OB. AND GYN. at 412, (June 2015).

<sup>12</sup> N.B. Zite & L.S. Wallace, *Medicaid-Title XIX Sterilization Consent Form: Is it Readable?*, 74 CONTRACEPTION, 180 (2016). See also Nikki B. Zite, Sandra J. Philipson, & Lorraine S. Wallace, *Consent to sterilization section of the Medicaid-Title XIX Form: Is it Understandable?*, 75 CONTRACEPTION, 256-260 (2007).

<sup>13</sup> *Id.*

<sup>14</sup> Wes Venteicher, *Sterilization Among Low-income Women Target of New Pitt study*, TRIBUNE REVIEW (Sept. 1, 2017), <https://triblive.com/local/alleggheny/12682263-74/sterilization-among-low-income-women-target-of-new-pitt-study>.

procedure, the time limits associated with the form, and the availability of long-acting reversible contraceptive options that are as effective as sterilization.<sup>15</sup> When asked which form they preferred, an overwhelming majority (94%) of study participants preferred the low-literacy version.<sup>16</sup>

We also recommend HHS consider the font type, font size, line spacing, and column width of the Form to improve its overall visual readability. HHS should also consider accessibility requirements for individuals with disabilities when modifying the Form. Depending on the disabled individual's needs and preferences, accessibility may mean providing auxiliary aids and services or alternative format materials such as large print, Braille, audio, digitally navigable formats, or sign language videos with captions.<sup>17</sup>

### *Issues with the Interpreter's Statement*

Individuals with limited English proficiency and disabilities may also face barriers to understanding the Form. While the Form includes an interpreter's statement, the text is confusing and inaccurate. For example, the interpreter statement includes the following declaration: "To the best of my knowledge and belief he/she understood this explanation." Asking an interpreter to attest that a patient understands a form or understands statements made by a medical provider seeking the patient's informed consent violates the ethics and standards of practice that an interpreter must follow. According to the National Council on Interpreting in Health Care, an interpreter cannot speak to the level of understanding of a person for whom they interpret. Rather, an interpreter serves as a conduit handling language and can only attest that they accurately interpreted the information to the best of their knowledge and ability.<sup>18</sup> The two organizations that certify foreign language interpreters, the Certification Commission for Healthcare Interpreters and the National Board of Certification for Medical Interpreters both endorse this circumscribed role of an interpreter. Both organizations test candidates to ensure their knowledge of the ethics and practice standards governing interpreters.<sup>19</sup>

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<sup>15</sup> N.B. Zite & L.S. Wallace, *Use of Low-literacy Informed Consent Form to Improve Women's Understanding of Tubal Sterilization: A Randomized Controlled Trial*, 1117 *Ob Gyn*. 1160-66 (2011).

<sup>16</sup> *Id.*

<sup>17</sup> See 42 C.F.R. § 438.10 for further guidance on how Medicaid forms must be made readily accessible for people with disabilities.

<sup>18</sup> National Council on Interpreting in Health Care, *A National Code of Ethics for Interpreters in Healthcare* at 15 (2004),

<http://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Code%20of%20Ethics.pdf>.

<sup>19</sup> For more information, see Certification Commission for Healthcare Interpreters, <http://cchicertification.org/certifications/preparing/>; National Board of Certification for Medical Interpreters, <https://www.certifiedmedicalinterpreters.org/candidate-handbook>.

The Interpreter’s Statement also misuses the term “translated.” Translation refers to the conversion of written text into a corresponding written text in a different language.<sup>20</sup> Translation involves different skills and abilities than interpretation, which is a process of understanding and analyzing a spoken or signed message and re-expressing that message faithfully, accurately, and objectively in another language, taking the cultural and social context into account.<sup>21</sup> There are several methods of interpreting, including sight translation, which involves an interpreter reading text in one language and delivering an oral rendition of the text in another language.

Further, the Form does not adequately address the accessibility needs of people with disabilities, and should include sign language and other communication methods. For example, individuals fluent in American Sign Language may have trouble reading written English due to differences in grammatical structure. Other individuals may use simplified signs and require an interpreter who works regularly with them and understands their modifications. Deaf-Blind people need tactile signs.

As such, we recommend HHS amend the interpreter statement to cover language interpreting in a foreign language, sign language, and other communication methods.

**Current language:**

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in \_\_\_\_\_ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

**RECOMMENDATION:** We recommend HHS revise the interpreter statement as follows:

I have accurately interpreted the information that was presented orally by the person obtaining this consent to the individual to be sterilized. As requested by the person obtaining consent, I have also:  
\_\_\_ sight translated the consent form into \_\_\_\_\_ (Specify Language) \_\_\_\_\_; or  
\_\_\_ interpreted a summary of the form into \_\_\_\_\_ (Specify Language) \_\_\_\_\_ or an alternative format as communicated by the person obtaining the consent to the individual to be sterilized.

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<sup>20</sup> Mara Youdelman, NHeLP, *What’s in a Word? A Guide to Understanding Interpreting and Translation in Health Care* (2010), <http://www.healthlaw.org/issues/health-disparities/whats-in-a-word-a-guide-to-understanding-interpreting-and-translation-in-health-care-full-guide#.W4 - hOhKjIU>.

<sup>21</sup> *Id.*

### *Need for Gender Inclusive Language*

We recommend HHS amend the “he/she” pronouns used in the Form to more accurately reflect the nonbinary nature of gender identity. Gender identity and expression are fluid, and adopting more inclusive language will help enhance the utility and quality of the consent process for transgender, gender nonconforming, and gender non-binary individuals seeking sterilization. As such, one option is to use the singular pronoun “they” and “their” in place of “he/she” and “his/her,” respectively.

### *Recognizing Supported Decision Making*

As currently drafted, the Form appears to have an either/or definition of mental competence, and does not indicate that an individual can use a supported decision making process for help with understanding the information contained in the Form.<sup>22</sup> Supported decision making gives an individual with a disability a chance to consult with a person of their choosing to make an informed decision. Such arrangements are validated by a supported decision making agreement. These agreements are becoming widely recognized and accepted as a reasonable accommodation, and the Form should be modified to reflect this option. Recognizing supported decision making agreements would also be consistent with the regulatory requirements for informed consent.<sup>23</sup>

### *Other Technical Corrections*

Finally, the Form contains some typos, grammatical errors, and inaccuracies that should be corrected:

<b>Section</b>	<b>Current language</b>	<b>Explanation</b>
Consent to Sterilization	“I, _____, hereby consent of my own free will to be sterilized ...”	Fill-in-the-blank should direct the patient to enter their name.
	“I am at least 21 years of age and was born on: ___Date___”	Fill-in-the blank should be clarified and direct the patient to enter “Date of Birth.” The sentence is also missing a period.
	“You are requested to supply the following information, but it is not	The request for race/ethnicity should explain why the data is

<sup>22</sup> For more information about supported decision making, see National Resource Center for Supported Decision Making website at [www.supporteddecisionmaking.org](http://www.supporteddecisionmaking.org).

<sup>23</sup> 42 C.F.R. § 441.257(a)(2) requires “suitable arrangements [a]re made to insure that the information... [is] effectively communicated to any individual who is blind, deaf, or otherwise handicapped.”

	required: ( <i>Ethnicity and Race Designation</i> )( <i>please check</i> )”	being collected, and reiterate the confidential nature of the information collection. We also recommend the inclusion of a fill-in-the-blank option. Also, the purpose of the text contained inside the first parenthetical (“Ethnicity and Race Designation”) is unclear, and should be struck. In addition, the text in the second parenthetical (“please check”) should be modified to allow the patient to check all of the race/ethnicity categories that apply.
	See comments above, under “Issues with the Interpreter’s Statement.”	See comments above, under “Issues with the Interpreter’s Statement.”
Interpreter’s Statement	“Before <u>    (Name of Individual)    </u> signed the consent form, I explained to him/her the nature of sterilization operation...”	Insert “the” before “sterilization operation.”
Statement of Person Obtaining Consent	Use of “him/her” and “he/she”	See comments above, under “Need for gender inclusive language.”

**III. The Use of Automated Collection Techniques or Other Forms of Information Technology to Minimize the Information Collection Burden**

Health information technology (health IT) has transformed the way patients, providers, and health care plans manage patient information and deliver health care. While health IT has the potential to improve the efficiency, clarity, and cost effectiveness of the paper-based approach currently in use, HHS’ notice does not provide enough information about what health IT techniques the agency may consider for implementation for us to provide specific comments.

At a minimum, we urge HHS to consider the literacy, readability, and accessibility impacts of any health IT integration of the Form on people with low literacy, people with disabilities, and limited English proficient individuals. As such, we recommend HHS always provide Medicaid patients with the option to use the current paper-based approach or a health IT-based approach. HHS must also effectively protect the confidentiality of patients' records and ensure patients can maintain the right to determine who can obtain information about their sterilization procedure.

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Given the long history and continuation of abusive and coercive sterilization practices in the U.S., the undersigned organizations recommend that HHS revise the Form and engage with the communities the policy impacts. Our recommendations will improve states' and providers' ability to meet the regulation's consent requirements, and equip Medicaid enrollees considering voluntary sterilization to make a more informed decision.

Thank you for the opportunity to comment. If you have any questions or need any additional information, please contact Priscilla Huang ([huang@healthlaw.org](mailto:huang@healthlaw.org)) or Candace Gibson ([gibson@healthlaw.org](mailto:gibson@healthlaw.org)) at the National Health Law Program.

Sincerely,

National Health Law Program  
ACT for Women and Girls  
American Atheists  
American Civil Liberties Union  
American Medical Women's Association  
Asian & Pacific Islander American Health Forum  
Asian Americans Advancing Justice - Los Angeles  
California Latinas for Reproductive Justice  
California Women's Law Center  
Center for Reproductive Rights  
Center on Reproductive Rights & Justice  
Disability Rights Education and Defense Fund  
Equality California  
FORGE, Inc.  
In Our Own Voice: National Black Women's Reproductive Justice Agenda  
Jacobs Institute of Women's Health  
Legal Action Center  
Medical Students for Choice  
NARAL Pro-Choice America  
National Asian Pacific American Women's Forum (NAPAWF)  
National Center for Lesbian Rights

National Council of Jewish Women  
National Equality Action Team (NEAT)  
National Family Planning & Reproductive Health Association  
National Institute for Reproductive Health (NIRH)  
National Latina Institute for Reproductive Health  
National LGBTQ Task Force  
National Network of Abortion Funds  
National Organization for Women  
National Partnership for Women & Families  
National Women's Health Network  
National Women's Law Center  
Nevada County Citizens for Choice  
Planned Parenthood Federation of America and Planned Parenthood Action Fund  
Population Connection  
Positive Women's Network - USA  
Power to Decide  
SIA Legal Team  
URGE: Unite for Reproductive & Gender Equity  
Western Center on Law and Poverty