



California Healthcare Interpreting Association
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September 16, 2018

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

Via email: Sherrette.funn@hhs.gov

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

Dear Secretary Azar:

We are submitting this letter on behalf of CHIA, California Health Care interpreting association. The California Healthcare Interpreting Association is dedicated to improving the quality and availability of language services in the delivery of health care.

We thank you 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. 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. 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.ⁱ While the need for the Form continues, the Form itself has remained unchanged for over 40 years.ⁱⁱ 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, 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.ⁱⁱⁱ The Form's text is written at a ninth grade reading level, which exceeds the recommended level for patient education and informed consent materials.^{iv} 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 study tested a low-literacy version of the Form and found improved understanding of the permanent nature of the procedure, the time limits associated with the form, and the availability of long-acting reversible contraceptive options which are as effective as sterilization.^v When asked which form they preferred, an overwhelming majority (94%) of study participants preferred the low-literacy version.^{vi}

In addition, we 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.

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." This requirement falls well beyond the role of a language interpreter. 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.^{vii} This circumscribed role of an interpreter is further recognized by the two organizations that certify health care interpreters, the Certification Commission for Healthcare Interpreters and the National Board of Certification for Medical Interpreters. Both organizations test candidates to ensure their knowledge of the ethics and practice standards governing interpreters.^{viii} 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.

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.^{ix} 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.^x An interpreter would not "translate" the information regarding sterilization but rather "interpret" the information orally. 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. But the statement seems to refer to the oral communication of information between the

individual obtaining informed consent from the patient and patient; it does not involve an individual creating a written translation of the English document in another language.

Further, the Form does not adequately address the accessibility needs of people with disabilities and should be inclusive of sign language and other communication methods. For example, individuals fluent in American Sign Language may have trouble reading written English due to differences in grammar structure. Other individuals may use simplified signs and will need an interpreter who works regularly with them and understands their modifications. Deaf Blind people will 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 _____(insert language); or
___interpreted a summary of the form into _____(insert language) or an alternative format as communicated by the person obtaining the consent to the individual to be sterilized.

II. 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, with disabilities, and with limited English proficiency. 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.

III. Conclusion

Thank you for the opportunity to comment. If you have any questions or need any additional information, please contact Tatiana Foerster, CHIA President at president@chiaonline.org or Don Schinske, Executive Director at dschinske@chiaonline.org.

Sincerely,

[REDACTED]

[REDACTED]

ⁱ 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>.

ⁱⁱ 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).

ⁱⁱⁱ 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).

^{iv} *Id.*

^v 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).

^{vi} *Id.*

^{vii} 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>.

^{viii} 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>.

^{ix} 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.

^x *Id.*