The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Vice President, Health Policy
[redacted]

September 17, 2018

Alex M. Azar II
Secretary, Department of Health and Human Services
Health Resources and Services Administration
200 Independence Avenue SW
Washington, DC 20201

RE: HHS–OS–0937–0166: HHS 42 CFR Subpart B: Sterilization of Persons in Federally Assisted Family Planning Projects

Dear Secretary Azar:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 58,000 physicians and partners in women's health, I am pleased to offer the following comments in response to the Department of Health and Human Services' (HHS) Information Collection Request (ICR) on 42 CFR Subpart B: Sterilization of Persons in Federally Assisted Family Planning Projects. Female sterilization is safe, efficacious, and is an important strategy in our Nation's ongoing effort to improve birth outcomes by reducing rates of unintended and rapid repeat pregnancies. As physicians dedicated to providing quality care to women, ACOG has long been concerned that the current processes and required documentation for sterilization procedures interfere with our patients' ability to access care, particularly those who receive health coverage through Medicaid or other federally-financed programs.

ACOG believes all women have a right to pursue and to prevent pregnancy.[1] Sterilization is the second most common method of contraception in the United States, representing nearly 22 percent of all female contraceptive users in 2014.[2] Sterilization can also result in reproductive injustice, as it has at various points throughout the history of the United States.[3,4] Obtaining informed consent for sterilization is medically and ethically necessary, and is already standard practice in obstetrics and gynecology; however, the current federally-mandated sterilization consent form and the 30-day waiting period create serious logistical barriers. Too often, these barriers prevent Medicaid patients and women who receive health care coverage through other federally-financed programs from receiving desired sterilizations. Ensuring that a signed and appropriately-dated copy of the form is available at the time of the procedure can be difficult for obstetrician-gynecologists (ob-gyns), health care institutions, and patients. If the signed form is not immediately available, hospitals are often unwilling to allow sterilizations to take place because reimbursement may be denied, not only for the sterilization, but also for other services delivered concomitantly.

To mitigate these concerns, we urge HHS to overhaul the federal rules governing coverage of sterilization for Medicaid patients and other publicly-insured women to improve access,

eliminate procedural barriers, and facilitate women's informed decision-making. Further, we do not believe that HHS has accurately calculated the burden of this ICR because it has only estimated the burden on patients and has not considered the burden on ob-gyns and other medical staff responsible for ensuring that the form is signed and available at the time of the procedure or on medical practices and institutions. It is with these goals in mind that we submit the following comments on the ICR.

Informed consent is and must remain a central tenet of the sterilization consent policy.

Informed consent is central to the practice of obstetrics and gynecology and is considered the standard of care. Informed consent for any procedure requires a detailed discussion of the risks, benefits and alternatives specific to that procedure, with adequate time devoted to ensuring patient understanding. This process includes a mutual sharing of information over time between the ob-gyn and the patient to facilitate the patient's autonomy in the process of making ongoing choices.[5] As such, ACOG firmly believes that informed consent should be looked on as a process rather than a mere signature on a form.

In the case of sterilization, the physician performing a sterilization has the responsibility of ensuring that the patient is properly counseled concerning the risks and benefits of the procedure. As a part of this process, the patient should receive comprehensive and individualized counseling on reversible alternatives to sterilization.[6] In addition, the procedure's intended permanence should be stressed, as well as the possibility of future regret. An estimate of the procedure's failure rate and risk of ectopic pregnancy should also be provided. Above all else, it is essential for the patient to be given the opportunity to discuss all relevant issues with her physician and to ask questions.

ACOG is concerned that the consent form itself does not actually document informed consent, largely because of the literacy level at which it is written. According to the National Assessment of Adult Literacy, nearly 93 million American adults have basic or below basic literacy skills.[7,8] In addition, one-third of U.S. adults have trouble reading and acting on health-related information.[9] Researchers evaluated the federally-mandated sterilization consent form and found that it was written at a ninth-grade reading level and provided little useful information on the risks and benefits of sterilization for women seeking this service.[10] We are concerned that the reading level of the form is too high for many patients to comprehend. Indeed, numerous studies have indicated that more patients comprehend patient education materials that are written at lower grade reading levels.[11] To mitigate this concern, we urge HHS to rewrite the form at a more appropriate reading level and engage in focus group testing to ensure that it provides meaningful, informed consent.

ACOG is also concerned that the interpreter's statement on the existing sterilization consent form may create additional barriers for individuals with limited English proficiency. 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.[12]

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.[13] 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.[14] 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. We recommend HHS amend the interpreter statement to cover language interpretation versus translation. Additionally, we urge HHS to make the form available in multiple languages to eliminate the need for interpretation services whenever possible.

The current sterilization consent policy creates barriers to care for low-income women, leading to increased health risks and greater risk of unintended pregnancies.

Federal rules require a signed consent form for women, as well as men, enrolled in Medicaid or covered by other federally-financed health programs for all sterilization procedures.[15] This consent form must be signed at least 30 days before the procedure for a health care provider or health care facility to be reimbursed, and it remains valid for 180 days. If a woman goes into premature labor or needs emergency abdominal surgery, the 30-day waiting period may be waived if the form was signed at least 72 hours prior to the procedure. While these exceptions exist, the administrative difficulties of ensuring that a signed, appropriately-dated form is on record and physically present at the time of the procedure continues to be an obstacle and often results in cancelled procedures or multiple surgical encounters – increasing both cost and risk.

ACOG considers the immediate postpartum period following vaginal delivery or the time of cesarean delivery the ideal time to perform sterilization because of technical ease and convenience for both the patient and the physician.[16] Yet only 50 percent of women who request postpartum sterilization during prenatal contraception counseling actually undergo the procedure.[17,18] Several studies have found that women on Medicaid have greater difficulty in receiving a desired postpartum sterilization than privately-insured women.[19,20,21,22] Women on Medicaid who choose an immediate postpartum sterilization but have not signed the required form 30 days earlier must return for a second medical procedure, which places them at unnecessary medical risk.

Evidence suggests that many lower-income women struggle to return to an outpatient facility for alternative methods of contraception until the sterilization can be scheduled due to logistical and economic challenges, such as a lack of paid sick leave or child care, as well as fluctuating insurance coverage.[23] Indeed, women who receive Medicaid based on their pregnancy are at risk of losing their health insurance coverage 60 days from the end of pregnancy.[24] Many of these women may not be able to obtain their desired sterilization within that timeframe. Another issue that can occur is women who believe that they have been sterilized when in fact they have not. This is especially likely when a delivery is particularly high-risk, and the focus is on addressing a

medical emergency, not an elective procedure. Post-procedure, it may not be clear to the patient that they did not receive the requested sterilization. These patients may leave the hospital without any method of contraception because they believe that they received their desired sterilization. Each of these barriers put women at increased health risk, including risk of rapid repeat pregnancy, and increased costs for the health care system.

While the original intent of the sterilization consent policy may have been to protect low-income women and other marginalized groups from being sterilized against their will, it has created a two-tiered system of access where low-income women cannot fully exercise their reproductive autonomy. Indeed, women with private insurance who desire sterilization are generally not required to follow this difficult process or sign a consent form at least 30 days in advance to obtain the procedure. This is true for all sterilizations, including those outside the postpartum period. These differences based on the type of insurance a patient has must be addressed to establish equitable access to sterilization for all women.

The current sterilization consent policy places excessive burden on ob-gyns, and too often results in claim denials and increased uncompensated care costs.

As previously mentioned, there are several challenges with the current sterilization consent policy and with the form itself. A number of these challenges add to the administrative and operational burden placed on ob-gyns and other women's health care providers. We do not believe that the current estimate accurately captures the burden associated with this ICR. We urge HHS to recalculate the estimated burden to include the impact on ob-gyns and other health care providers who are tasked with obtaining informed consent from patients, as well as medical staff who file and make the signed form available at the time of the procedure, not just the impact on patients.

For example, if a signed, appropriately-dated form is not immediately available at the time of service, some hospitals are unwilling to allow the procedure to take place because reimbursement may be in jeopardy. There are concerns not just with reimbursement for the sterilization procedure itself, but also the charges related to labor and delivery when a postpartum sterilization is performed because some state Medicaid programs deny all maternity and sterilization claims if the form is not adequately completed. As noted above, federal rules allow ob-gyns to waive the 30-day waiting period in some clinical circumstances if the form has been signed in the last 72 hours. However, the added challenge of having a signed copy of the form on hand in a medical emergency on the labor and delivery unit or surgical suite can render this waiver moot since hospitals may be unwilling to allow sterilization if there is a possibility that there will be no reimbursement. This can result in cancelled procedures, further burdening the patient by not administering their preferred contraceptive method and requiring a second surgical procedure over a paperwork error and increasing costs to the federal and state governments.

Women seeking sterilization, but who are unable to receive one at their desired time, must choose an alternative contraceptive method and reschedule their sterilization procedure before their consent form expires. During this time, they are at greater risk of an unintended pregnancy, which has a host of financial costs, not to mention health risks. Some of these expenditures stem from the increased cost of providing maternity care relative to the cost of a sterilization

procedure, a greater number of newborns that will be enrolled in federal assistance programs, and poorer birth outcomes that are more expensive to treat. For women who want an immediate postpartum sterilization but cannot get one at the time of delivery, the rescheduled procedure will add further costs because there may be an additional facility fee and anesthesia costs incurred for the sterilization procedure.

Moving forward, ACOG urges HHS to develop processes to integrate the sterilization consent form into electronic health record (EHR) technology. Integrating the information into an EHR would help mitigate some of the concerns with having the form "on hand" to provide sterilization for women covered by federally-financed health programs. For example, having this information in the medical record and accessible to all clinicians involved in a patient's care would result in fewer cancelled procedures or multiple procedures attributed to a lost or incomplete consent form. This would directly benefit the patient by helping to guarantee access to their preferred method of contraception at the desired time without the extra red tape. Additionally, we encourage HHS to continue its ongoing work to strengthen information sharing between health systems. By linking inpatient and outpatient EHR systems, further concerns about documentation "following the patient" could be reduced.

Overhauling the existing sterilization consent policy will require an interdisciplinary approach that engages multiple stakeholders.

While HHS is, at present, only seeking comment on the sterilization consent form, ACOG does not believe that merely revising the form is sufficient to reduce the systemic inequities that the federal policy imposes on women with federally-financed coverage and to eliminate this unnecessary interference with the provision of high-quality, desired care and patient autonomy. We, therefore, urge HHS to overhaul the existing policy and attendant form in its entirety by undertaking formal rulemaking. Ethical sterilization care requires access to the procedure for women who request it, without undue burden, but it also requires protections from unjust or coercive practices, particularly for low-income women and other marginalized groups.[25] Negotiating these ethical nuances will be challenging and requires engagement of multiple stakeholders to meet the needs of all women. If HHS is unwilling to facilitate rulemaking at this time, at minimum, the sterilization consent form should be revised to a more linguistically-appropriate document that can be integrated into EHRs and that promotes shared decision-making between ob-gyns and our patients.

ACOG Recommendations:

- Rewrite the sterilization consent form to ensure comprehension at an appropriate reading level.
- Amend the interpreter statement to focus on interpretation versus translation and make the sterilization consent form available in multiple languages.
- Recalculate the estimated burden of the sterilization consent form to include the impact on ob-gyns, other health care providers, medical staff, and health care institutions.
- Develop processes to integrate the sterilization consent form into existing inpatient and outpatient electronic health records and make these systems interoperable.

- Undertake formal rulemaking to overhaul in its entirety the federally-mandated sterilization consent form and related waiting period for sterilizations in federally-financed programs. Extend the current form's expiration date for a maximum of twelve months while rulemaking is conducted.

Thank you for the opportunity to comment on the Information Collection Request on 42 CFR Subpart B: Sterilization of Persons in Federally Assisted Family Planning Projects. We hope you have found our comments useful, and we look forward to the opportunity to work collaboratively with HHS to improve women's health care. Should you have any questions, please contact [redacted]

Sincerely,

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