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

Chief Executive Officer
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April 15, 2022

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Via email: Sherrette.funn@hhs.gov

RE: Information Request HHS 42 CFR subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects (0937-0166)

Dear Secretary Becerra:

On behalf of the American College of Obstetricians and Gynecologists, representing more than 62,000 physicians and partners dedicated to advancing women's health and the health of individuals seeking obstetric and gynecologic care, 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 is 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.

Background

According to data from the National Center for Health Statistics, female sterilization has consistently been one of the top two most frequently utilized methods of contraception since 1982.[1] Use of sterilization varies among certain subgroups of women. It is most common among Black and Latina women, women aged 35 or older, never-married women, women with two or more children, women living below 150 percent of the federal poverty level (FPL), women with less than a college education, and women living outside of a metropolitan area.[2] Sterilization is also most common among those who are uninsured or rely on public insurance including Medicaid.[3] In addition, male sterilization (i.e., vasectomy) is an equally effective but often underutilized method of contraception.[4]

Throughout U.S. history, the use of sterilization has been significantly complicated by the tension between the needs of those who desire sterilization to control their family size, those who desire sterilization but were unable to access it as a result of systemic inequities, and those who desire fertility but were sterilized without their knowledge or consent.[5] An ethical and equitable approach to the provision of sterilization must promote access for those who wish to use sterilization as a method of

contraception, but at the same time safeguard against coercive or otherwise unjust uses of the procedure and ensure availability of alternative contraceptive methods.[6] As with any personal health care decision, patient autonomy and informed consent in reproductive decision-making is paramount and should not vary based on insurance status or insurance type. Data suggest, however, that unfulfilled sterilization requests – particularly in the postpartum period prior to hospital discharge – are more common among beneficiaries of Medicaid.[7]

ACOG is committed to encouraging and upholding policies and action to assure that everyone has the right to decide whether to have children, the number and spacing of their children, and to have the information, education, and access to health services to make these choices. [8] Sterilization is the most common method of contraception in the United States among contraceptive users aged 15-49, representing nearly 28 percent of all female contraceptive users in 2018.[9] 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 beneficiaries of Medicaid and other federally funded 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, 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, including in cases of post-partum tubal ligations the entire admission for labor and delivery.

To mitigate these concerns, we urge HHS to evaluate current approval processes governing coverage of sterilization for beneficiaries of Medicaid and other federally funded programs and update the policies to improve access, eliminate procedural barriers, and facilitate informed decision-making. It is with these goals in mind that we submit the following comments on the ICR.

Barriers to Care

Federal rules require a signed consent form for beneficiaries of Medicaid or other federally funded health programs for all sterilization procedures.[10] The 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. These requirements, even with exceptions, continue to be obstacles and often results in cancelled procedures or unnecessary multiple surgical encounters. Administrative issues related to definitions and process too often result in individuals being denied reproductive health care. According to findings from Zite, Wuellner, and Gilliam, administrative barriers around the sterilization consent form are the most common reason for unfulfilled sterilizations among women still desiring to undergo the procedure at hospital discharge.[11] When looking at postpartum sterilization after cesarean section, the evidence is overwhelming that issues with the sterilization consent form are causing delays in care.

Waiting Period

The immediate postpartum period following vaginal delivery or the time of cesarean delivery is an ideal time for patients who have given informed consent to perform sterilization because of technical ease and convenience for both the patient and the physician.[12] Yet only 50 percent of pregnant persons who request postpartum sterilization during prenatal contraception counseling actually undergo the procedure.[13,14] Several studies have found that beneficiaries of Medicaid have greater difficulty in

receiving a desired postpartum sterilization than privately-insured patients. [15,16,17,18] Evidence suggests that many persons experiencing poverty 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.[19] Pregnant persons who receive Medicaid based on their pregnancy are at-risk of losing their health insurance coverage 60 days from the end of pregnancy.[20] Beneficiaries of 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.

There are wide reaching implications for individuals who are denied desired sterilizations. In one study, 47 percent of beneficiaries of Medicaid who requested sterilization because they had reached their desired family size experienced a pregnancy in the next year after they were denied the procedure due to a problem with their sterilization consent form or the waiting period.[21] Another study found that the current sterilization consent form and process has resulted in up to 62,000 unfulfilled requests for postpartum sterilization, 10,000 abortions, and 19,000 unintended births in the subsequent year.[22] Further, in the aforementioned study by Morris et al., among patients who did not receive sterilization at time of cesarean delivery, 15.5 percent had a subsequent pregnancy within the study period.[23] Each of these patients who did not receive their desired sterilization and experienced a subsequent pregnancy had Medicaid coverage at the time of their index pregnancy.[24] During the early months of the COVID-19 pandemic, one third of women reported delaying or canceling a visit to a health care provider for sexual and reproductive health care because of the pandemic.[25] The public health emergency exacerbated many of the existing barriers to accessing a desired sterilization procedure. Some states deemed sterilization an elective procedure and postponed this time sensitive procedure.[26] Additionally, a lack of guidance on the consent process through telemedicine platforms for this form caused barriers to care.[27]

While the original intent of the required 30-day waiting period was to protect people on Medicaid from unwanted sterilization, this policy creates an unnecessary barrier for individuals desiring the procedure. Policies that have forced waiting periods have roots in paternalism and undermine an individuals' agency and autonomous decision-making abilities.[28] The waiting period for sterilization has been shown to work against individual autonomy by causing delays and obstructing access to care, and to be discriminatory when applied to marginalized groups.[29] Individuals on Medicaid are disproportionally experiencing barriers to their desired form of birth control because of the mandatory waiting period.[30] **ACOG strongly urges CMS reconsider the mandatory waiting period for the sterilization procedure as it is unnecessarily creating a barrier to care.**

Definitions

While the federal regulations at 42 CFR Subpart F of §441 allow for the standard 30-day waiting period for a sterilization procedure to be decreased to 72 hours in the case of extenuating circumstances such as ''premature delivery" or ''emergency abdominal surgery," the regulation does not provide definitions of these terms. Research confirms that, in the absence of standardized definitions from the federal government, states are creating their own definitions and applying the policy inconsistently both within and across jurisdictions.[31] A recent study, which explored the attitudes, beliefs, and interpretations of individual state Medicaid agency employees regarding the sterilization consent form, found that only 11 states provide additional clarification regarding definitions of "premature delivery" and/or "emergency abdominal surgery."[32]

Nine states counted ‘‘any day before the expected delivery” as a premature delivery so long as the sterilization consent form was signed 30 days prior to the expected delivery date.[33] Five states considered premature delivery to be in the purview of the physician or other delivering provider, basing coverage of the sterilization procedure ‘‘solely on the physician’s certification.”[34] One state reported a gestational age cutoff, using ACOG’s ‘‘preterm labor” definition of 37 weeks gestation.[35] Two states made determinations on a case-by-case basis in order to take individual circumstances into account but did not have any specific definitional guidelines in place.[36]

To meet the definition of “emergency abdominal surgery” for the purposes of an exception to the waiting period, eight states reported the procedure must be unplanned and medically necessary.[37] In addition, eight states had a case-by-case review of written explanations on the sterilization consent form.[38] Examples of emergency abdominal surgeries covered as an extenuating circumstance in the past included appendectomy, cholecystectomy, ovarian cystectomy for a ruptured cyst, removal of ectopic pregnancy, cesarean delivery for placenta accreta with severe hemorrhage, removal of metastatic abdominal cancer, and splenectomy in the case of a ruptured spleen. The researchers encountered one state that provided a list of procedures that were covered and not covered, while another state covered any procedure so long as ‘‘the abdomen [was] open and access [was] visualized.”[39] **ACOG requests that HHS define ‘‘premature delivery” and ‘‘emergency abdominal surgery,” consistent with evidence-based clinical guidance to ensure equitable implementation across jurisdictions.**

Supporting the Informed Consent Process

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 material 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 obstetrician-gynecologist and the patient to facilitate the patient's autonomy in the process of making ongoing choices.[40] As such, ACOG firmly believes that informed consent should be looked on as an important conversation and documentation process. In the case of sterilization, the physician performing a sterilization has the responsibility of ensuring that the patient is properly counseled concerning the material risks, benefits, intended permanence, and reversable alternatives to sterilization.[41]

Increased Administrative Burden

As previously mentioned, there are several challenges with the current sterilization consent policy and with the form itself. The waiting period, appropriately-dated forms, and denials for reimbursement from Medicaid programs result in cancelled procedures, repeat visits, increased costs to the hospital and the patient, and the increased risk of an unintended pregnancy. **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. 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.

Readability and Comprehension Challenges

Studies have shown the current sterilization consent form to be difficult to read and understand, creating additional barriers for individuals seeking a sterilization procedure. The form is written at a ninth grade reading level, exceeding the recommended level for patient education and informed consent materials.[42] Inaccessible reading levels also present a significant barrier for people with intellectual, developmental, and cognitive disabilities. A study tested a plain language version of the form and found improved understanding among study participants of the permanent nature of the procedure, the time limits associated with the form, and the availability of nonpermanent contraceptive options that are as effective as sterilization.[43] When asked which form they preferred, an overwhelming majority (94 percent) of study participants preferred the plain language version over the standard Medicaid version.[44]

As currently drafted, the sterilization consent form also 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.[45] Supported decision-making gives an individual with a disability a chance to consult with a person of their choosing to make an informed decision. Recognizing supported decision-making agreements would also be consistent with the regulatory requirements for informed consent.[46] **We encourage HHS to consider changes to the form for improved readability and supported decision making.**

Interpreter's Statement

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." This attestation is in conflict with the National Council on Interpreting in Health Care ethics, which advises interpreters to refrain from personal involvement and maintain their role as a conduit for the content and spirit of the original message.[47]

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.[48] 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.[49] 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 and remove the patient comprehension as an attestation for the interpreter.**

Ethical sterilization care requires access to the procedure without undue burden, and also protections from unjust or coercive practices.[50] To reiterate our initial request, **ACOG requests HHS to evaluate current approval processes governing coverage of sterilization for beneficiaries of Medicaid and other federally funded programs and update the policies to improve access, eliminate procedural barriers, and facilitate informed decision-making**. **Additionally, the current consent form is set to expire on April 22nd, 2022. ACOG urges CMS to extend the expiration date of the current form as well as provide guidance to state Medicaid agencies as soon as possible on using the current form past the April 22nd expiration date.**

ACOG Recommendations:

- Reconsider the mandatory waiting period for the sterilization procedure as it is unnecessarily creating a barrier to care.
- Define ‘‘premature delivery” and ‘‘emergency abdominal surgery,” consistent with evidence-based clinical guidance to ensure equitable implementation across jurisdictions.
- Develop processes to integrate the sterilization consent form into EHR technology and strengthen information sharing between health systems**.**
- Consider changes to the form for improved readability and supported decision-making.
- Amend the interpreter statement to cover language interpretation versus translation, remove the patient comprehension as an attestation for the interpreter.
- Evaluate current approval processes governing coverage of sterilization for beneficiaries of Medicaid and other federally funded programs and update the policies to improve access, eliminate procedural barriers, and facilitate informed decision-making.
- Extend the current expiration date so that the form can be modified appropriately and updated guidance provided to state Medicaid programs.

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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 Taylor Platt, Manager, Health Policy, at tplatt@acog.org or 202-314-2359.

Sincerely,

Maureen G. Phipps, MD, MPH, FACOG
Chief Executive Officer

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