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

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

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1751-P; Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

The American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners in women's health, appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the CY 2022 Medicare Physician Fee Schedule (MPFS) and the Quality Payment Program (QPP). As physicians dedicated to providing quality care to women, ACOG appreciates the agency's willingness to continue seeking input from the physician community to implement sound policies for Medicare, both in terms of expanding access to Medicare telehealth services and implementation of changes to the office/outpatient Evaluation and Management services. Below are recommendations to further improve beneficiaries' access to quality health care services.

Section II.B. Practice Expense [Relative Value Units] RVUs

CMS is proposing to update the practice expense (PE) clinical labor pricing for CY 2022 using the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from Bureau of Labor Statistics (BLS) wage data. Since the BLS survey of wage data does not cover all the staff types contained in the direct PE database, CMS cross-walked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. CMS is also considering the use of a 4-year transition to implement the clinical labor pricing update. The multi-year transition may alleviate the fluctuating increases and decreases in payment caused by the pricing update and promote payment stability. **ACOG supports the use of BLS wage data to use as a basis for clinical labor pricing, but also recommends utilizing the median as the more accurate middle of the data and using a fringe benefits multiplier reflective of physician practice.**

ACOG is disappointed that the demonstrated increases in clinical labor costs are not effectively recognized in this proposal. More specifically, due to the practice expense formula and the method the budget neutrality adjustments were applied, many services with demonstrated increased direct expenses will experience decreases in payment. ACOG urges CMS to work with the American Medical Association (AMA) RVS Update Committee (RUC) on the most effective way to implement clinical labor updates, including partnering with the AMA on the upcoming Physician Practice Information Survey

(PPIS) survey. After corrections and updates are made to the clinical labor proposal, **ACOG supports a four-year transition**, due to the significant shifts to individual services that will result from the proposal.

ACOG Recommendations

- Finalize the use of BLS wage data as a basis for clinical labor pricing.
- Utilize the median, instead of the mean, to inform the update.
- Utilize a fringe benefits multiplier reflective of physician practice.
- Finalize a four-year transition plan for clinical labor pricing update.

Section II.D. Telehealth and Other Services Involving Communications Technology

ACOG appreciates the expanded flexibilities made possible by CMS to increase access to telehealth services throughout the COVID-19 pandemic, including the addition of Category 3 to the Medicare Telehealth Services List. **ACOG supports extending this category of services through 2023 in order to facilitate continuity of care for recipients and data collection to inform future proposals.**

CMS is proposing to revise the regulatory definition of "interactive telecommunications system" to permit the use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home. Mental illness is often a leading cause of pregnancy-related deaths and plays a significant role in our country's maternal mortality crisis. In a study of 14 state Maternal Morbidity and Mortality Review Committees (MMRCs), researchers found that mental health conditions were the underlying cause of 8.8 percent of pregnancy-related deaths.[1] This study recommended several solutions to improve these preventable deaths, including to expand telehealth services for increased access to care.[2] ACOG continues to advocate for advancing maternal health from all angles, including strengthening telehealth policies such as remote patient monitoring to reach more patients.[3] **ACOG supports revising the regulatory definition of "interactive telecommunications system" to permit use of audio-only communications technology for mental health telehealth services as indicated by CMS**. Expanding this definition will give patients who may not possess audio-visual technology, have digital literacy skills, or do not feel comfortable utilizing video due to the sensitive nature of mental health information more readily available access to vital mental health services.

The expanded telehealth flexibilities included in this proposal also serve as an opportunity to enhance outreach for mental health treatment. Additionally, the proposal of a new modifier for audio-only mental health services will provide useful insight on utilization through the data collected. For similar reasons, **ACOG supports CMS's proposal to allow opioid treatment programs (OTPs) to provide counseling and therapy services via audio-only communication after the COVID-19 public health emergency (PHE)**. ACOG and many of our medical specialty counterparts have been working to reduce burdens against obtaining treatment for opioid and substance use disorder (SUD). [4] With these proposals finalized, we believe such changes will help promote better access to opioid and SUD treatment.

While ACOG applauds CMS for extending the flexibilities in Section II.D. through the end of the PHE, we believe that these changes should be made permanent and reimbursed at parity with the respective in-person services.[5]

ACOG Recommendations

- Extend Category 3 Telehealth Services List through CY 2023.
- Finalize revising the regulatory definition of "interactive telecommunications system" to include audio-only communications technology.
- Finalize the proposal to allow opioid treatment programs to provide counseling and therapy services via audio-only communication after the COVID-19 PHE.

Section II.E. Valuation of Specific Codes

In CY 2022, the RUC resurveyed the complex care management (CCM) code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes (99X21, 99X22, 99X23, 99X24, and 99X25) each with a base code and an add-on code for a total of 10 new codes. The RUC recommended values for these 10 codes and CMS is proposing to accept the RUC recommendations for the CCM code family. **ACOG thanks CMS for this proposal and agrees with finalizing the RUC recommendations for the new CCM code family**.

Section II.J. Vaccine Administration Services

In April 2021, ACOG surveyed the Immunization Administration codes (90460, 90461, 90471, 90472, 90473, 90474, G0008, G0009 and G0010) for RUC consideration. RUC recommendations were then forwarded to CMS in May 2021. ACOG urges CMS to use the RUC recommendations to value these services based on the resource-based relative value scale (RBRVS) principles.

ACOG objects to the reliance on Medicare data from the Outpatient Prospective Payment System (OPPS) in establishing relative values for the MPFS. Section 4505 of the Balanced Budget Act of 1997 requires CMS to:

1. Utilize, to the maximum extent practicable, generally accepted cost accounting principles which recognize all staff, equipment, supplies and expenses, not just those which can be tied to specific procedures and use actual data on equipment utilization and other key assumptions, and
2. Consult with organizations representing physicians regarding methodology.

Any proposal to use the relativity of hospital charge data to determine the relativity of practice costs within a physician office is not consistent with these statutory provisions. **ACOG reiterates the request that CMS use RUC recommendations to determine RVUs for the MPFS.**

ACOG Recommendations

- Utilize the RUC recommendations to determine RVUs for the MPFS.

Section III.A.4. Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs

In the CY 2020 final rule, CMS finalized allowing Transitional Care Management (TCM) services to be billed concurrently with 14 codes previously considered to overlap TCM. ACOG was appreciative of the finalization of this proposal. Now in the CY 2022 proposed rule, CMS is proposing to extend this allowance of billing TCM services furnished for the same beneficiary during the same service period, provided all requirements for billing each code are met to rural health centers (RHCs) and federally

qualified health centers (FQHCs). **ACOG agrees with this proposal to allow concurrent billing of TCM services for RHCs and FQHCs in alignment with previous updates.**

ACOG Recommendations

- Finalize the proposal to allow concurrent billing of TCM services for RHCs and FQHCs.

Section III.G. Removal of Select National Coverage Determinations

In the CY 2021 final rule, it was established that rulemaking would be utilized to solicit comments related to outdated National Coverage Determinations (NCDs). ACOG supports the continuation of CMS's proposal to change this into a rule-making process to ensure that stakeholders' input is considered through public comment for any NCD reconsideration or removal. As such, ACOG has reviewed relevant NCDs for potential retirement for CMS's consideration:

Relevant NCDs Suggested for Retirement

NCD Section	Title	Justification
140.1	Abortion	ACOG recommends the removal of this NCD based on the age of the policy.
230.16	Bladder Stimulators (Pacemakers)	This NCD was put into effect on 10/7/1996 and is outdated. Medical terminology and evidence has changed significantly since 1996 and as such warrants removal of this determination.
230.11	Diagnostic Pap Smears	This NCD is redundant of another NCD (190.2) and should be removed.
220.6.14	FDG PET for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers	This NCD was replaced by NCD 220.6.17 and should be removed.
220.6.10	FDG PET for Breast Cancer	This NCD was replaced by NCD 220.6.17 and should be removed.
140.9	Gender Dysphoria and Gender Reassignment Surgery	Per the NCD, it was determined that no NCD is appropriate at this time and no updated policy has been put into effect. ACOG questions if this NCD meets the statutory definition as noted in 1862(l) or 1869(f) of the Act.
220.13	Percutaneous Image-Guided Breast Biopsy	This NCD is unnecessary as Medicare Administrative Contractors (MACs) can decide what types of palpable lesions can be biopsied.
230.2	Uroflowmetric Evaluations	This NCD is unnecessary and can be determined by MACs.

ACOG Recommendations

- Continue usage of comment solicitation through rulemaking for removal of NCDs.
- Consider removal of the identified NCDs.

Section III.J. Medicare Shared Savings Program

In 2021, CMS proposed and finalized many substantial and significant changes to reporting requirements for accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). ACOG believed the impact of COVID-19 and the PHE on practices and physicians would have downstream effects on adaptions to these changes. This sentiment remains unchanged. As such, **ACOG applauds CMS for allowing ACOs to continue reporting through the Web Interface in 2022 and 2023.** Delaying electronic clinical quality measures (eCQM) and Merit-based Incentive Payment System (MIPS) clinical quality measure (CQM) reporting until 2023 is appreciated; however, ACOG remains concerned that the resource needs of COVID-19 have limited attention to the MSSP. Therefore, ACOG **requests that CMS consider delaying eCQM reporting requirements to 2025.** Given the recent National Association of Accountable Care Organizations survey showing that a large majority of ACOs do not have the infrastructure in place to report eCQM/MIPS CQM data and the lingering effects of COVID-19 and its variants, delaying these types of significant and costly changes is in the best interest of practices, physicians, and the patients they care for.[6]

CMS is also seeking comment on how ACOs can utilize their resources to ensure that patients, regardless of racial/ethnic group, geographic location and/or income status, have access to equal care and how ACOs can improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare. ACOG appreciates CMS's focus on health disparities and improving care for all patients, regardless of race, location, or socioeconomic status. ACOG is committed to changing the culture of medicine and addressing bias and racism in health care.[7] Data exist that implicate health disparities for women, especially pregnant women.[8] [9] [10] One way to promote quality care while addressing disparities is through the development and appropriate utilization of quality measures. While ACOs are required to report on quality measures, they can find further benefits of the quality reporting through the stratification and risk adjustment of measures. Risk adjustment promotes a fair and accurate comparison of healthcare outcomes across organizations and providers.[11] Risk stratification refers to reporting separate outcomes for different groups.[12] Both of these tools can be applied to existing measures to further extrapolate the impact of measurement on targeted groups, including those that would likely experience higher levels of health disparities. However, not all quality measures are currently risk adjusted. Therefore, **CMS should seek to promote the use of risk adjustment in quality measure development and maintenance and promote such quality measure usage by ACOs in practice.**

CMS is also seeking comments and recommendations on how to encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives. ACOG believes any participation in value-based purchasing programs or similar initiatives should be optional. Additionally, such programs should include assistance for physicians and practices to provide patients support to address social determinants of health. Models that employ downside risk-based contracts should not be considered; instead, financial incentives that can support the complexities of care management for vulnerable patients need to be available. Therefore, **ACOG recommends that CMS include financial incentives without downside risk to encourage voluntary participation.**

Finally, CMS is seeking comments on the role of specialists in ACOs. An existing resource that CMS should consider for informing how to include specialists in ACOs is the Core Quality Measures Collaborative (CQMC) cross-cutting workgroup tasked with managing measures for specialty providers in ACOs. This coalition group of healthcare leaders work to facilitate cross-payer alignment of measures by developing core measure sets to assess quality of care.[13] Their expertise would be beneficial in identifying the role of specialists in ACOs.

ACOG Recommendations

- Continue reporting through the CMS Web Interface through CY 2023.
- Delay eCQM/MIPS CQM reporting until CY 2023.
- Promote the use of risk adjustment in quality measures for ACOs.
- Keep participation in ACOs optional.
- Include financial incentives for physicians that provide care to vulnerable patients through ACOs.
- Consult with the CQMC regarding specialist participation.

Section III.L. Medicare Diabetes Prevention Program (MDPP)

ACOG strongly support the proposal to waive the provider enrollment Medicare application fee of $599 for all organizations enrolling in Medicare as MDPP suppliers that submit an application on or after January 1, 2022. This waiver would be implemented to extend beyond the COVID-19 Emergency Declaration Blanket Waiver and is expected to increase MDPP supplier enrollment. This fee often poses a significant barrier for physicians who are seeking to prevent and treat patients with diabetes, including diabetes mellitus. Diabetes mellitus affects over 30 million women in the United States, yet studies show that approximately one in four women are unaware of their disease.[14] Without high costs of enrolling in the Medicare Diabetes Prevention Program, more patients can gain control of their disease and ultimately improve women's health outcomes.

ACOG Recommendations

- Finalize the proposal waiving the $599 provider enrollment Medicare application fee as MDPP suppliers submitting an application on or after January 1, 2022.

Section III.O. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As health care professionals dedicated to serving the full scope of patients' needs, ACOG is encouraged by CMS' proposals to enhance policies surrounding opioid use disorder (OUD) treatment services. Drug overdose is a leading cause of maternal mortality and policymakers must ensure that lack of access to care does not discourage pregnant and breastfeeding individuals from seeking care for OUD.[15] **ACOG supports the creation of a new G-code for a take-home supply of higher dose naloxone hydrochloride nasal spray product, to allow for this treatment to be covered by Medicare in opioid treatment programs (OTPs).**

In addition, we support the proposal for a new modifier to track utilization of audio-only communication, so long as it does not prove burdensome for patients or physicians and it does not interfere with the use of other modifiers on the claim. Tracking such claims data separately from audio/visual communication will be critical in demonstrating the need for future updates to the OTP benefit regarding audio-only interactions. **In summary, CMS should permanently allow audio-only services, finalize the inclusion of a new modifier for audio-only communications, and ensure any changes to billing does not result in undue burdens for physicians**.

We applaud CMS's proposal to allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as any additional counseling or therapy that is billed using the add-on code,

using audio-only telephone calls rather than via two-way interactive audio/video communication technology following the end of the PHE. However, ACOG believes this option should be available to all patients receiving OUD treatment services, and that the wording "not available to the beneficiary" be removed from the proposed regulatory language. Privacy is of utmost concern for many beneficiaries, including those in OTPs and/or experiencing intimate partner violence (IPV). This continues to be a significant public health problem in the country, with the Centers for Disease Control and Prevention (CDC) reporting that over one-third of women (36.4% or 43.5 million) experienced psychological aggression by an intimate partner during their lifetime.[16] Often, the abuser progressively isolates the woman from family and friends and may deprive her of food, money, transportation, and access to health care, making access a matter of a patient safety and physical security.[17] [18] This is further compounded by the emergence of the COVID-19 pandemic, with women experiencing IPV sheltering at home with their abusers. The United Nations have reported that there has been a global surge in IPV accompanying the COVID-19 stay-at-home and lockdown orders.[19] In these circumstances, telehealth communications with their physicians may be the only points of contact available to women experiencing IPV. Maintaining as many telehealth communication options as possible for women experiencing IPV is critical and their privacy and safety should be a primary concern when developing telehealth policies.

CMS is also proposing to require that physicians document the rationale for utilizing audio-only communication and, for additional therapy and services add-ons, certify that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because the beneficiary did not have access to two-way audio/video communications technology. However, CMS is not clear on how and in what form this certification would be accepted. In the proposal, CMS is indicating that these provisions are being recommended in order to promote program integrity, minimize patient safety concerns, and ensure that beneficiaries have access to the most appropriate form of care. The use of audio-only communications and technologies is critical to expanding access to care in populations that otherwise may have difficulty accessing necessary treatments. While gains have been made in digital technology adoption throughout the country, many Americans still lack access to critical digital infrastructures that would facilitate use of audio-visual communication technology.[20] [21] [22] Little research exists on the utilization of audio-only telehealth visits and the impacts of such services on quality of care, but there is clear need of alternatives to audio-visual communication technologies that are not accessible to all beneficiaries. Further burdening physicians to unclearly certify and document the rationales for utilizing audio-only technologies can lead to access issues for beneficiaries that may otherwise require these services. **ACOG requests that CMS remove these burdensome reporting requirements for audio-only telehealth visits to facilitate and promote expanded access to care for all beneficiaries.**

ACOG Recommendations

- Finalize the creation of a new G-code for higher dose naloxone hydrochloride nasal spray.
- Finalize the new modifier for audio-only communications.
- Remove burdensome reporting and documentation requirements for audio-only telehealth visits.

Section III.P. Updates to the Physician Self-Referral Regulations

In the proposed rule, CMS is proposing to permit the use of the exception for COVID-19 vaccines even when they are not subject to CMS-mandated frequency limits. Given to continuing impact of the COVID-19 PHE on practices, physicians, and patients, ensuring that life-saving vaccines are available to Medicare beneficiaries is critical. Frequency limits typically are required for a preventive test, immunization or vaccine to be an exception from physician self-referral law's referral and billing prohibitions. By removing this requirement for COVID-19 vaccines, CMS in ensuring that there is no impediment on vaccine availability for beneficiaries. This remains important as variants emerge in the patient population and potential booster vaccinations are required for many patients. **ACOG agrees with CMS's application of this exception and for not requiring CMS-frequency limits for the COVID-19 vaccine to be included within this exception.**

ACOG Recommendations

- Finalize the proposal to not require CMS-frequency limits for the COVID-19 vaccine as part of the physician self-referral exceptions.

Section III.Q. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act)

CMS is proposing to further delay the electronic prescribing for controlled substances (EPCS) compliance date from January 22, 2022 to January 1, 2023 due to the continued effects of the COVID-19 PHE. The benefits of EPCS are broad and far-reaching, but its transition is not without logistical and administrative burdens practices and physicians may not be able to tackle currently. As discussed in prior sections, the impact of the COVID-19 PHE has left practices and physicians with less financial resources and capital to invest in technology-based infrastructures, including EPCS systems and training. As such, **ACOG agrees with CMS further delaying the EPCS compliance date to January 1, 2023.**

ACOG Recommendations

- Finalize the further delay of the EPCS compliance date to January 1, 2023.

Section IV. Updates to the Quality Payment Program

CMS is proposing to begin voluntary reporting of MIPS Value Pathways (MVPs) in PY 2023, with a transitionary period between PY 2023 and 2027 where participation in MVPs would remain voluntary. In 2028, it is proposed to sunset the traditional MIPS program. ACOG appreciates the continued effort to make MVP participation optional for clinicians when the included measures and activities within the MVP are applicable and available to their practice. We strongly believe that MVPs should be optional and that the eligibility criteria that is established for the MIPS program should also apply to MVPs. Clinicians that do not meet the eligibility threshold for traditional MIPS should not be mandated to participate in MVPs, even if they are relevant to their clinical practice. However, requiring MVPs and sunsetting the traditional MIPS program by 2028 is an unrealistic and burdensome timeline for practices and physicians to adhere. It is unclear whether the MVPs developed by this deadline will be relevant to practices and physicians already participating in the MIPS program, making their MVP participation even more difficult. Without stakeholder input in the development process and expectations on the types of

MVPs queued for future development, it will be difficult for practices and physicians to facilitate their transition to MVPs and set the necessary infrastructure for reporting. **ACOG cautions CMS against setting a firm deadline with which to sunset the traditional MIPS program and require MVP participation.**

CMS is also proposing voluntary subgroup reporting of MVPs beginning in CY 2023, with multispecialty groups required to form subgroups to report MVPs by CY 2025 and beyond. While ACOG supports the option for subgroup MVP reporting, we caution CMS against requiring individual clinicians that practice in a multi- or single-specialty setting to report MVPs on their own. We recognize that patients often desire information about their individual clinician and that MIPS measures often do not provide that level of data. However, individual reporting requirements are likely to significantly increase the burden of MIPS participation and discourage participation in MIPS and other value-based models. We strongly urge CMS to continue to focus on reducing the burden of MIPS participation throughout MVP implementation. As such, **ACOG strongly opposes mandatory subgroup reporting in CY 2025 and beyond.**

By 2025, CMS aims to move to digital quality measurement in their quality reporting and value-based purchasing programs. Within this movement, CMS is seeking input on various components related to the development, maintenance, and implementation of digital quality measures. There are varying concerns with this transition to digital quality movement. First, there has been little guidance from CMS on how digital quality measures are defined, how they are different from current quality measures and eCQMs, how they will be developed and maintained, and how practices should be implementing these measures in their workflows. Without answers to these questions, it is increasingly difficult for affected parties to plan for a successful transition to digital quality measurement, with a CY 2025 deadline incredibly unrealistic. Second, this transition is expected to take place simultaneously with the transition to MVPs. Time and resources around improving the MIPS quality reporting program should be focused on one effort. CMS should consider delaying a transition to digital quality measures until MVPs have been fully realized and tested and the traditional MIPS program has been retired. Third, many specialties lack the ability to report regular quality measures to begin with and moving towards even more resource- and technology-heavy measures will be difficult. Furthermore, CMS should place a focus on creating more high-value, patient-centered, outcome-based quality measures instead of transitioning to digital quality measures. Overall, **ACOG strongly opposes moving forward with a CY 2025 transition deadline for digital quality measures and suggests CMS identify a way to streamline digital quality measurement and MVPs without creating undue and unnecessary burdens on physicians and practices.**

In the 2020 final rule, CMS finalized the 2023 MIPS performance threshold to be 60 points, an increase of 15 points from the 2022 threshold of 45 points. For the 2024 MIPS payment year, CMS is proposing to further increase the performance threshold to 75 points. While this is consistent with the 15-point increases of the previous three years, it does not consider the tremendous burden and strain the COVID-19 PHE has placed on physicians and practices. As such, **ACOG recommends CMS delay further increasing the PY 2024 performance threshold increase of 15 points until after the COVID-19 PHE due to the significant impact of the PHE on physicians and practices.**

ACOG Recommendations

- Do not finalize mandatory subgroup reporting in CY 2025 and in the future.
- Do not finalize a CY 2025 transition deadline for digital quality measurement.
- Delay increasing the PY 2024 performance threshold increase 75 points until after the COVID-19 PHE.

Section VII.C. Changes in Relative Value Unit (RVU) Impacts

In this rule, CMS is proposing to update the CY 2022 conversion factor to 33.5848, a 3.75 percent decrease from the CY 2021 conversion factor of 34.8931. This is especially concerning as CMS has failed to keep pace with inflation in setting annual Medicare payments and maintaining budget neutrality requirements. As such, **ACOG strongly opposes this reduction in the conversion factor and suggests implementing practices and provisions to promote investments in obstetrics and gynecology, and the practice of medicine as a whole**.

ACOG Recommendations

- Do not finalize the CY 2022 reduction in the conversion factor.

Thank you for your time and consideration. Should you have any questions about our comments, please contact Erin Lambie Alston, Policy Strategist at elambie@acog.org.

Sincerely,

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Chief Executive Officer
American College of Obstetricians and Gynecologists (ACOG)

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