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

January 4, 2021

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

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Box 8016, Baltimore, MD 21244-8016

Re: [CMS-9123-P**]; Proposed Rule, Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications**

Dear Secretary Azar and Administrator Verma:

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) notice of proposed rulemaking, CMS-9123-P, that proposes several initiatives to encourage interoperability, improve care coordination, and reduce administrative burdens. We also appreciate the ability to provide information in response to the requests for information.

While ACOG appreciates CMS' efforts to both improve patients' access to their health information and reduce the administrative burden experienced by obstetrician-gynecologists in delivering essential health care, we are disappointed in the time frame provided by the agency to respond to the proposed rules and to provide information in response to the requests for information. CMS issued its notice of proposed rulemaking and requests for information on December 10, 2020 and requested a response by January 4, 2021. This period —inclusive of multiple federal holidays and weekends—is not sufficient to be able to provide comprehensive responses to the many important issues raised by the rules and the request for information. We endeavor here to provide some information that we hope is helpful to CMS and respectfully request that the agency extend the time for response so that we can address the proposed rules and requests for information more comprehensively.

Obstetrician-gynecologists provide a range of services for women across the lifespan. In an informal survey of ACOG members, ACOG found that prior authorization for services has been noted as one of

the top drivers of job dissatisfaction and administrative burden. Often those reviewing requests for the authorization of services are not specialists in obstetrics or gynecology and therefore do not understand the complexities of the conditions or the range of treatments available. Additionally, gynecologic surgeons find prior authorizations for surgery frustrating; it is not uncommon for imaging to miss issues or there to be anatomical differences that require change at the time of surgery, which renders the current authorization invalid. ACOG appreciates that HHS and CMS are looking to technology to remedy some of the issues with prior authorization. However, it is important to stress that ACOG members work with very sensitive patient information, and the attention to secure, safe transmission of patient health data is of utmost importance. **ACOG supports and appreciates any efforts to ensure safe, seamless record sharing that protects patients and reduces physician burden.**

Response to the Proposed Rules

Prior Authorization Access through APIs

CMS proposes to require payers to make pending and active prior authorization decisions and related documentation and forms available for patient access in order to promote patient-centered, shared decision making. Specifically, CMS proposes to require payers impacted by the proposed rule (ie, state Medicaid and CHIP Fee-for-Service [FFS] programs, Medicaid managed care plans, CHIP managed care entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges) to provide patients access to information regarding prior authorization decisions, documentation and forms through the Patient Access API no later than one business day after the physician or qualified health professional initiates the request or if there is a change in status of the prior authorization. This information would also be available through the Provider Access API and the Payer-to-Payer Access API. The prior authorizations include those that are active and those in review status, but not those that are denied or expired. Additionally, prior authorizations for prescription medications are not included.

ACOG appreciates the proposal requires payers to make the prior authorization status available to all stakeholders. However, **ACOG believes that the Patient Access API and Provider Access API should include denied authorizations and authorizations for prescription medications**.

A 2018 audit performed by the HHS Office of the Inspector General (OIG) found that 75% of appeals Medicare Advantage Organization (MAO) denials between 2014-2016 were overturned at the first level of appeal.[1] The study further found that the reasons for overturning the original denial included an incorrect original decision, additional information (eg, lab or diagnostic tests) was available to support the care, or that a referral to the provider was not included in the original documentation.[2] Denials due to documentation could be recognized and mitigated quickly with stakeholder access to denied authorizations and a clear description of the reason for denial. The engagement of the patient at the denial and appeal stage could help provide additional information and expedite authorization decisions. **ACOG strongly recommends that denied prior authorizations are made available to all stakeholders so that patients and physicians can respond, and necessary care is not delayed or dropped.**

Additionally, the prior authorization access should include prescription medication authorizations as soon as possible. Many prescription medication authorizations are annual and are subject to changing payer policies and drug formularies.[3] Payers will also require documentation that substantiates the

medication is being used as approved by the Food and Drug Administration (FDA) and is not being prescribed for non-indicated (off-label) conditions.[4] In 2019 the OIG studied Medicare Part D denials and found 73% of appeals for denied coverage was overturned at the first review.[5] In 2017, almost half of Part D contractors were cited for misclassifying the coverage request, which resulted in the inability to appeal the denial.[6] It is imperative that payers are held accountable to all aspects of health care, and prescription medication coverage should not be excluded. **ACOG strongly urges that prescription medication prior authorization information is included in the stakeholder APIs**.

Patient Access API and Data Privacy

ACOG appreciates that CMS is addressing stakeholder and public concerns for privacy and security measures for the Patient Access API. To date, CMS has not required that payers request a privacy policy attestation from third-party application developers when the application connects to an API. CMS proposes that payers must establish, implement, and maintain a process for third-party application developers to attest to certain privacy provisions. CMS is also requesting comment regarding whether the third-party should have a blanket attestation to all privacy provisions or a separate attestation for each provision, and how that is clearly communicated with the patient.

ACOG has considerable concerns regarding the privacy of health data. Patients share sensitive information with their obstetrician-gynecologist related to sexual health, pregnancy, substance abuse, and intimate partner violence. Recent reports also indicate that, given the incentives to monetize electronic health information, third-party applications pose risks to patients' privacy.[7,8] If there are not known safety measures in place, patients may withhold sensitive clinical information from their doctor once they determine that they cannot control what is being shared across the health care system. **ACOG strongly urges CMS to adopt an approach that best ensures third-party application developers have only that information necessary for providing quality health care.** Additionally, **ACOG requests that CMS finalize the proposal that health plans and health insurance issuers provide enrollees with information about the potential privacy and security risks associated with sharing information with third-party applications**.

Provider Access API and Participation

CMS is requesting comments related to physician (and other qualified health professionals) access to patient data through a Provider Access API. Specifically, CMS requests input regarding an opt-in or opt-out process for patients and physicians, and the role of patients in process. Additionally, CMS indicates they do not want to be too prescriptive and requests input on whether payers should develop their own policies and processes.

Many states have developed consent policies in the development of the health information exchanges.[9] ACOG recommends that CMS establish baseline requirements that reduce administrative burden on physicians and allow equitable access to patient records. This may include consistency with current state consent requirements. Requirements should also require the payers to collect the patient's permission at the time of eligibility determination, in order to minimize the number of communication requests that require patient response. Medicaid eligibility determination provides the opportunity for payers to explain all of the patient's rights and responsibilities. Additionally, the opt-in process should allow the physician, qualified health care professional, or ancillary staff to consult with the patient during a

patient visit to obtain the necessary permissions. This will ensure the physician has access to the information necessary to provide comprehensive, coordinated care. **ACOG recommends that CMS be mindful of existing state policies and that CMS finalize processes that prioritize patient safety and that prevent commercial payers from being the gatekeeper of patient records.**

Prior Authorization

CMS is proposing requirements that would ease electronic information exchange between physician offices and payers and takes into consideration the clinical workflow in the prior authorization process. Specifically, CMS proposes to require payers to:

- Include a list of covered items and services that require prior authorization, along with the documentation requirements;
- Develop Document Requirement Lookup Service (DRLS) APIs that could be integrated with a provider's electronic health record (EHR) to allow providers to electronically locate prior authorization requirements for each specific payer from within the provider's workflow;
- Develop Prior Authorization Support (PAS) APIs that offer physicians the ability to send the prior authorization requests and receive responses in the existing workflow;
- Provide clear, specific reasons for denied prior authorization requests;
- Make prior authorization decisions within 72 hours for urgent requests and 7 calendar days for standard requests;
- Publicly report data about their prior authorization process, including metrics of prior authorization requests approved, denied, and ultimately approved after appeal, and average time between submission and determination; and
- Include gold-carding programs that relieve certain providers of prior authorizations as a factor in quality star ratings.

Consistent with the findings of the American Medical Association, informal surveys of ACOG members indicate one of the leading causes of job dissatisfaction and stress is managing prior authorizations. **ACOG supports the proposed measures that assist physicians and staff with the prior authorization process and require clarity and transparency from payers**. In addition to the proposed requirements, **CMS should consider including prescription drug prior authorizations and take steps to implement the 2019 OIG recommendations that include improving electronic communication and reduce inappropriate coverage denials**.[10]

The 2018 Medicare Advantage Organization OIG report indicated about 1 million preauthorization requests were denied, resulting in a denial rates of 4 percent.[11] The Council for Affordable Quality Healthcare (CAQH) 2019 CAQH Index found that the moving to web portal prior authorizations could save physician offices nationwide approximately $355 million a year.[12] These data support use of electronic prior authorization; however, they also call into question the need of prior authorization at the current levels of use. **ACOG is supportive of gold-carding programs that relieves compliant physicians of prior authorization requirements, and strongly encourages CMS to implement a gold-carding requirement across payers.**

Post-Service Claim Denials for Services with Prior Authorization

CMS is requesting comment on methods to mitigate claim denials that have an approved prior authorization, as this will be addressed in future rulemaking.

Obstetrician-gynecologists provide surgical services for conditions such as endometriosis, incontinence, fibroid embolization, biopsies, repair of hernias in the pelvic area, and fallopian tube disease and obstructions. While advanced imaging provides details of the disease progression or anatomical dysfunction, it is not uncommon for an obstetrician-gynecologist to discover the procedure authorized is not appropriate at the time of surgery. For example, CPT codes 58553 and 58354 are the laparoscopic with vaginal hysterectomy, but differ based on the size of the uterus, which is unknown until the uterus is removed and weighed. For endometriosis, the definitive diagnosis is based on the lesions removed at surgery, and serum markers or imaging studies do not provide the detail found at the laparoscopy. Given this, **ACOG requests that CMS evaluate post-service claim denials, authorization and appeals for surgical services, and consider mechanisms that ensure payment is not denied or delayed for surgical services.**

Additional Comments Regarding Prior Authorization

ACOG has been working with private payers to share the harms of burdensome authorization requirements. In particular, ACOG has advocated for private payors to reduce burdensome prior authorization requirements for services that have been determined necessary regardless of condition or risk. For example, patients symptomatic of bacterial vaginosis should receive direct and DNA-probe testing for diagnosis and treatment without prior authorization requirements.[13] As another example, non-invasive prenatal testing (NIPTs) should be offered to all pregnant patients regardless of risk.[14] Lab tests, diagnostic tests and procedures that are standard for a condition or population should not require review and prior authorization by payers. While ACOG has been able to get traction with private payors on some of these issues, much work remains to be done across the specialty of obstetrics and gynecology as well as all medical care. **ACOG encourages CMS to work with physician specialty societies to determine which lab tests, diagnostic tests and procedures should never require prior authorization**.

Payer-to-Payer Access API

ACOG appreciates that CMS recognizes the impact coverage instability and patient cycling on and off Medicaid coverage has on the utilization of health care (i.e., higher emergency department use) and the negative consequences instability has on patient health. As CMS noted in the proposed rule, the smooth flow of electronic health records has the potential to help reduce this cycling (also referred to as "churn") in the Medicaid program, therefore increasing access to care without barriers and lowering general health care costs associated with churn. ACOG believes this is especially relevant for pregnant patients and appreciates the efforts of CMS to provide seamless transition from payer-to-payer through a separate API. **ACOG recommends that CMS move forward with the Payer-to-Payer Access API in a way that promotes secure record sharing and helps reduce Medicaid churn.**

ACOG is focused on encouraging states and Congress to extend coverage to Medicaid-enrolled pregnant patients from the current 60-day requirement to 12 months of coverage after delivery. Adoption of this

policy, either through waivers or state plan amendments, will protect pregnant patients from loss of coverage when they need it most. Nearly 70 percent of women report experiencing at least one physical problem during the 12-month postpartum period.[15] One in seven women experience symptoms of postpartum depression in the year after giving birth, and evidence suggests women with substance use disorder are more likely to experience relapse and overdose 7-12 months postpartum.[16,17] According to new research from the Urban Institute examining access and affordability challenges facing uninsured new mothers, almost one-third of women who lost Medicaid coverage and became uninsured in the postpartum period were obese before their pregnancy, and 18 percent reported either gestational diabetes or pregnancy-related hypertension – conditions that require ongoing monitoring and treatment after giving birth.[18] In addition, about one-third of the women who lost coverage were recovering from a cesarean section and just over one-quarter reported being depressed sometimes, often, or always in the months after giving birth.[19]

Extending coverage to 12 months after delivery not only will bring about positive changes in health care outcomes, but it also saves costs. Studies have shown that improved health care outcomes reduce costs. [20] Reducing churn in the Medicaid program has also been found to lower monthly per capita spending and can help reduce administrative costs.[21] By providing 12 months of continuous coverage after the end of pregnancy, states can create administrative efficiencies and therefore cost savings by conducting a mother's redetermination at the same time as her infant's instead of doing two separate redeterminations at different times.[i]

ACOG recommends that CMS encourage the reduction of churn in the Medicaid program by approving Medicaid state waivers for the extension of postpartum coverage beyond 60 days.

ACOG Recommendations to the Proposed Rule:

ACOG recommends that CMS:

- Take efforts to ensure safe, seamless record sharing that protects patients and reduces physician burden.
- Include denied authorizations and authorizations for prescription medications in the Patient Access and Physician Access APIs.
- Adopt an approach for sharing patient information to third-party applications that best ensures third-party application developers have only that information that is necessary for providing quality health care.
- Finalize the proposal that health plans and health insurance issuers provide enrollees with information about the potential privacy and security risks associated with sharing information with third-party applications.
- Ensure all regulations place patient safety as the priority and prevent payers from being the gatekeeper of patient records.
- Finalize measures that assist physicians and staff with the prior authorization process and require clarity and transparency from payers.

[i] Under Sec. 1902(e)(4), "A child born to a woman eligible for and receiving medical assistance under a State plan on the date of the child's birth shall be deemed to have applied for medical assistance and to have been found eligible for such assistance under such plan on the date of such birth and to remain eligible for such assistance for a period of one year."

- Consider including prescription drug prior authorizations and take steps to implement the 2019 OIG recommendations that include improving electronic communication and reduce inappropriate coverage denials
- Encourage gold-carding programs across payers.
- Evaluate post-service claim denials, authorization and appeals for surgical services, and consider mechanisms that ensure payment is not denied or delayed for surgical services.
- Work with physician specialty societies to determine which lab tests, diagnostic tests and procedures should never require prior authorization.
- Move forward with the Payer-to-Payer Access API in a way that promotes secure record sharing and helps reduce Medicaid churn.
- Approve Medicaid waivers that reduce churn for postpartum women by extending coverage beyond the 60-day statutory requirement.

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Response to Request for Information (RFI)

CMS posed several questions regarding data segmentation, implementation and technical processes for segmenting the health record for sharing. CMS also recognized the importance of social determinants of health and how that information is collected, documented and shared in electronic records. ACOG is pleased that CMS is considering the concerns of commenters in related proposed rules and RFIs on these topics and we appreciate that CMS is seeking additional clarification. However, as noted at the outset of our correspondence, we are also discouraged that the timeline CMS provided for responding to the proposed rule and the RFI –a time frame of just over two weeks inclusive of federal holidays and weekends— is not inadequate. In order for stakeholders and the public to respond more comprehensively to these important issues, **ACOG encourages HHS and CMS to extend response time so additional research and perspective may be provided**. ACOG endeavors to provide some information response to the requests below.

Methods for Enabling Patients and Providers to Control Sharing of Health Information (A)

ACOG has provided comment to prior year interoperability proposed rules to share our concerns with sharing patient health information.[22] As previously mentioned, patients of obstetrician-gynecologists share sensitive information with their physicians, and at times, information that should not be accessed by potentially abusive family members. It is imperative that data sharing is secure and only information that is necessary for the payment of clinical care is provided to payers. Data segmentation is required to ensure the privacy and safety of patients. Therefore, APIs that allow payer access to the entire health record are unnecessary and provide additional risk for data breech and inappropriate use of personal health data. **As CMS considers comments regarding implementation and technology, ACOG urges that CMS assign priority to software that integrates data segmentation and patient consent.** Software should allow patients to choose which data are shared and allow physicians to continue to protect the sensitive information needed to provide comprehensive, respectful, patient-centered care. Additionally**, ACOG requests that any costs of implementing data segmentation software not be passed on to physician practices or patients.**

Accelerating the Adoption of Standards Related to Social Risk Data (F)

As CMS recognizes in the RFI, social and physical conditions not captured by diagnostic codes significantly affect health outcomes. Physical conditions such as lack of access to safe housing, clean drinking water, nutritious food, safe neighborhoods contribute to poor health. Socio-political conditions such as institutional racism; police violence targeting people of color; gender inequity; discrimination against lesbian, gay, bisexual, transgender, queer, or questioning (LGBTQ) individuals; poverty; lack of access to quality education and jobs that pay a livable wage; and mass incarceration all shape behavior and biological processes that ultimately influence individuals' health and the health of communities.[23,24,25]

Social determinants of health serve as a risk indicator for pregnant and postpartum women. Approximately 2.3 million people (2.2 percent of all U.S. households) live in low-income, rural areas that are more than 10 miles from a supermarket.[26] This can often cause severe limitations in access to nutritious foods for pregnant and breastfeeding women and can contribute to poorer health outcomes for women and children. Less formal education, lower health literacy, unplanned pregnancies, and poor transportation have all been associated with late initiation of prenatal care.[27] Additionally, lack of child and other dependent care can reduce a pregnant person's ability to initiate and attend prenatal appointments.[28] Prenatal care initiation in the first trimester was lower for women in rural areas compared with suburban areas.[29] And for women of color, it is important to acknowledge that institutionalized racism and other forms of discrimination are social determinants of health.[30,31]

Also, as noted by CMS, tools have been developed to assist health care professionals in screening for some conditions, such as food insecurity and housing instability, and incorporate these questions into electronic medical records. [32] A referring clinician's ability to provide referrals to housing or food services while patents are in the clinic further paves way for opportunities to address some of these issues.[33] The key issue we hear from ACOG members is the lack of resources and time to address the complex social issues.

Payment models outside of the fee-for-service system have been more successful and collecting and sharing social determinants of health. The per-patient-per-month payment allows the pregnancy medical home to address social determinants of health and other needs through care management and coordination. Some models also provide bonus payments to practices for completing certain tasks, such as a risk assessment. For example, North Carolina's Medicaid program is home to the only state-wide pregnancy medical home model in the country.[34,35] Hundreds of practices participate in this model, including many practices located in rural areas of the state. In North Carolina, practices commit to the following for all pregnancy medical home enrollees: performing a thorough risk screening, providing face-to-face care management services, maintaining a specific nulliparous term singleton vertex (NTSV) cesarean delivery rate, and completing a postpartum visit within 60 days of delivery. Case managers also assist women in meeting social needs, such as housing, nutritious food, and support for behavioral health. Women who are enrolled in the medical home model have lower rates of infants with low birth weight and cesarean deliveries, as well as higher postpartum visit attendance rates than women who do not participate. North Carolina also estimates that the program reduced the cost of prenatal care. Other pregnancy medical home models have been shown to reduce unnecessary cesarean deliveries, increase postpartum visit attendance, and achieve other positive birth outcomes.[36, 37, 38, 39]

ACOG encourages CMS to engage physicians that participate in maternal medical home models, oncology payment models, and primary care payment models to understand how information is collected and shared. Importantly, CMS should study the time and resources necessary not only for

the collecting and sharing of data, but also the work required to mitigate the effects of social determinants on health outcomes.

ACOG Recommendations to the RFI:

ACOG recommends that CMS:

- Reissue the RFI and extend the response time so additional research and perspective may be provided .
- Assign priority to software that integrates data segmentation and patient consent.
- Ensure that any costs of implementing data segmentation software is not passed on to physician practices or patients.
- Engage physicians that participate in maternal medical home models, oncology payment models, and primary care payment models to understand how social determinants of health information is collected and shared.
- Study the time and resources necessary for the work required to mitigate the effects of social determinants on health outcomes.

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We appreciate the opportunity to comment on the Prior Authorization proposed rule and to provide information in response to CMS' Request for Information. We hope you have found our comments helpful, and we look forward to working with CMS to advance interoperability efforts that promote the health and well-being of women and their health care professionals. Should you have any questions, please contact me at lsatterfield@acog.org, or Emily Eckert at eeckert@acog.org.

Sincerely,

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Senior Director, Health Economics & Practice Management

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