



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

**Vice President, Health Policy**

Barbara S. Levy, MD  
e-mail: [blevy@acog.org](mailto:blevy@acog.org)

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Alex M. Azar II  
Secretary  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Donald W. Rucker, MD  
National Coordinator for Health Information  
Technology  
Office of the National Coordinator for Health  
Information Technology  
U.S. Department of Health and Human Services  
330 C St SW, Floor 7  
Washington, DC 20201

**Re: RIN 0955-AA01; 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program**

Dear Secretary Azar and Dr. Rucker:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing over 58,000 physicians and partners dedicated to advancing women's health, I am pleased to offer these comments on the Office of the National Coordinator for Health Information Technology's (ONC) Interoperability, Information Blocking, and the ONC Health IT Certification Program notice of proposed rule-making (NPRM) implementing certain provisions from the 21<sup>st</sup> Century Cures Act. We believe that the technological advances and interoperability efforts underway have the potential to improve care quality and coordination across our health care system. However, to realize the true potential of electronic health records (EHRs) and other health IT improvements, obstetrician-gynecologists (ob-gyns) and other health care providers need to be engaged as equal partners throughout the development and implementation processes. ACOG appreciates ONC's efforts to both improve patients' access to their health information and ameliorate the administrative burden experienced by ob-gyns and other physicians. We look forward to working with ONC to build a more interoperable health IT ecosystem that prioritizes women's unique health care needs while reducing administrative burdens on physicians.

**General Comments**

ACOG has a unique perspective in the arena of digital health platforms, as we are currently working with an application developer to create the Comprehensive Women's Health Record, an application integrated with EHR platforms. We are constantly advocating to reduce the administrative burden ob-gyns experience every day. The Comprehensive Women's Health Record consists of well-woman, obstetrics, and gynecology modules that match the ob-gyn providers' workflow, provide clinical decision support at the point of care, and seamlessly interchange electronic health information (EHI) with providers' EHRs. Simply put, it is designed to facilitate evidence-based, patient-centered care while reducing the number of clicks required to document patient encounters. With these goals in mind,

ACOG strongly supports efforts within the Department of Health and Human Services (HHS) to require the adoption of open application programming interfaces (APIs), and believes that this proposal, if finalized, will lead to the development of other applications like the Comprehensive Women's Health Record that will drastically improve the experience of both patients and women's health providers. ACOG also shares in the agency's goals of advancing interoperability and achieving complete access to health information for patients.

ACOG appreciates ONC's efforts to address excessive fees and other anti-competitive behaviors by EHR vendors. We note, however, that physicians and other health care providers are the only entities that cannot recoup the costs of implementing the United States Core Data for Interoperability (USCDI) and Application Programming Interfaces (APIs). ACOG recognizes that EHR developers must be able to recover the costs incurred to develop, implement, and upgrade their platforms so they can be in compliance with current regulations. Physicians and other healthcare professionals, however, should not bear the burden of those costs. We believe that it is ONC's responsibility to ensure that those fees do not lead to high costs and unintended consequences for patients and their health care providers.

This proposal has significant implications on the privacy and security of patients' health information. ONC proposes to dramatically increase the accessibility of patients' EHI and has failed to include provisions to protect this valuable, sensitive information. While we agree that the ability to easily share information will improve care coordination and reduce unnecessary duplication of tests and other services, the risks of a patient's health information being inappropriately shared, viewed, and used without the patient's explicit consent will also increase substantially. In the absence of policies that require EHR and app developers to take steps to protect patients, developers are unlikely to implement privacy and security features into their products. Patients are likely to withhold sensitive clinical information from their ob-gyns and other women's health providers once they determine that they cannot control what is being shared across the health care system. For instance, a patient may not disclose his or her history of substance use, which may have a significant impact on a physician's medical decision making and the patient's subsequent treatment plan. We believe it is ONC's responsibility to ensure that health IT regulations preserve the physician-patient relationship. **Data segmentation at the element level is critical for protecting patient privacy in an interoperable system. ACOG strongly urges ONC to improve access and affordability of data segmentation software for all physicians and other health care providers.** Ob-gyns have specifically emphasized the importance of segmenting data for patients who have reported intimate partner violence.

Recent reports also indicate that, given the incentives to monetize EHI, third-party applications pose a significant risk to patients. Employers and corporations have a vested interest in accessing as much information as possible about the individuals they employ, cover, or aim to do business with. However, patients may not be aware that the third-party applications they are using to track their meals, pregnancies, or chronic conditions are selling the data they collect to other interested parties. Further, if they perceive those apps to be connected to their physicians or health plans, as they likely will be under this proposal, patients are likely to believe that the information they record is protected by HIPAA and other privacy laws. ACOG is extremely concerned that ONC has not sufficiently protected the privacy and security of patients' EHI under this proposal. As the agency compiles its final rule, **ACOG firmly**

**believes that ONC should work with us and all other relevant stakeholders to ensure that patient privacy and data security are made a priority.**

### **Deregulatory Actions for Previous Rulemakings**

#### *§170.556(c). Removal of Randomized Surveillance Requirements.*

ONC proposes to change the requirement that ONC-Authorized Certification Bodies (ONC-ACBs) *must* conduct in-the-field, randomized surveillance to specify that ONC-ACBs *may* conduct in-the-field, randomized surveillance. The proposal also removes the accompanying regulatory specifications related to randomized surveillance. ACOG agrees that the benefits of randomized surveillance do not outweigh the time commitment required by physicians, and that reactive surveillance is a better use of both ONC-ACBs' and physicians' resources. We applaud the agency for taking action to reduce provider burden and recommend adoption of this proposal.

#### *§170.102. Removal of Certain 2015 Edition Certification Criteria*

ONC proposes to remove the following certification criteria from the 2015 Edition:

- problem list
- medication list
- medication allergy list
- drug formulary and preferred drug list checks
- smoking status
- patient-specific education resources
- Common Clinical Data Set Summary (CCDS) Record – create and receive
- secure messaging certification criteria

ACOG commends ONC for proposing to remove the above requirements and subsequently update them to current standards in the USCDI. We believe these changes will lead to improved patient care, allow for the proliferation of more automated solutions, and improve interoperability overall. We recommend ONC adopt this proposal.

#### *Recognition of Food and Drug Administration Processes (FDA) and Request for Information on the Development of Similar Independent Program Processes*

ONC proposes to establish a process that would provide health IT developers who can document successful certification under the FDA Software Pre-Certification Pilot Program, with exemptions to the ONC Health IT Certification Program requirements for testing and certification of health IT. The agency also seeks comments on whether the ONC should establish new regulatory processes tailored toward health IT. Under these new processes, the agency would first look at the IT developer rather than primarily at the health IT presented for certification. ACOG supports the proposal to establish a streamlined process for EHR certification. We believe that removing burdensome certification requirements will allow developers to focus on innovation and lead to more usable and interoperable EHRs. As ONC streamlines the certification process, ACOG encourages ONC to prioritize patient privacy,

data security, and reduction of administrative burden. Without pressure from ONC, developers will not be incentivized to protect patients and health care providers.

**ACOG Recommendations:**

- Finalize the proposal to remove the randomized surveillance requirements for ONC-ACBs.
- Finalize the proposal to remove problem list, medication list, medication allergy list, drug formulary and preferred drug list checks, smoking status, patient-specific education resources, Common Clinical Data Set Summary (CCDS) Record – create and receive, as well as secure messaging certification criteria from the 2015 Edition.
- Establish a streamlined process for EHR certification while prioritizing patient privacy, data security, and the reduction of administrative burden.

**Updates to the 2015 Edition Certification Criteria**

***§170.213. United States Core Data for Interoperability***

*USCDI 2015 Edition Certification Criteria*

ONC proposes to remove the Common Clinical Data Set (CCDS) definition and its references from the 2015 Edition, replace it with the USCDI standard, and adopt USCDI Version 1 (v1). ACOG supports the proposal to require all certified health IT systems to comply with the USCDI v1. We urge ONC to prioritize efforts to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion. Accordingly, on page 6, we recommend that ONC work with ACOG and other stakeholders to include both "gender" and a Reproductive Health data class in the next version of the USCDI.

The agency also proposes that developers with certified health IT would have to update that health IT to the comply with these proposals and provide the updated version to all of their customers who currently have certified health IT no later than 24 months after the effective date of this rule. ACOG supports this proposal but urges ONC to extend the effective date to ensure that EHR developers have sufficient time to incorporate new standards and test new software before implementing it in EHRs. Several more months are required thereafter for software updates to be installed and operational in physician practices and other health care settings. We agree that developers should have to provide updated health IT to all of their customers, but we are concerned that rushing those updates could lead to frustration among both patients and providers.

*Pediatric Vital Signs*

ONC requests comment on the inclusion of the following pediatric vital signs in the USCDI v1:

- head occipital-frontal circumference for children less than 3 years of age
- BMI percentile per age and sex for youth 2-20 years of age
- weight for age per length and sex for children less than 3 years of age
- reference range/scale or growth curve

ACOG supports the inclusion of pediatric vital signs in the USCDI v1 and **recommends that ONC add “gestational age at birth” to the list above.** The impact of gestational age on pediatric health outcomes later in childhood is well documented. We believe making this valuable information standard and readily available to physicians and other health care providers would lead to improved patient care.<sup>i,ii</sup>

#### *Clinical Notes*

ONC proposes to include the following clinical note types for both inpatient and outpatient settings in the USCDI v1 as a minimum standard: Discharge summary, history & physical, progress note, consultation note, imaging narrative, laboratory report narrative, pathology report narrative, and procedures, and seeks comment on whether to include additional note types as part of the standard. ACOG applauds ONC for including all eight of these note types in the minimum standard. This will protect many physicians from incurring unnecessary additional costs. ACOG recommends that ONC finalize this proposal.

#### *Provenance*

The USCDI v1 also includes a provenance data class, and ONC requests comment on the inclusion of the following three data elements to delineate this new data class: the author, the time, and the author’s organization. ACOG believes that provenance, or information about who created data and when, is essential to ensuring patient safety and reducing medical errors, and we support the inclusion of provenance as a data class in the USCDI v1. Since APIs facilitate the aggregation of data from multiple sources, these three data elements will be important for assuring patient safety as APIs become more commonly used. **ACOG urges ONC to ensure that future provenance data elements also identify when data was deleted and by whom.** Our members have reported that this information is also important for patient safety and will be essential as API technology proliferates and allows other providers, and possibly patients, to write data into the EHR via a third-party application. We agree that ONC should adopt the industry consensus for provenance in the USCDI once it becomes available.

#### *Unique Device Identifier(s) for a Patients Implantable Device(s)*

ONC requests comment on whether they should add the unique device identifier (UDI) implementation guide as a requirement for adoption to meet the requirements for the UDI USCDI Data Class. ACOG recommends adding the UDI implementation guide to the requirements for the UDI USCDI Data Class. We believe that successful exchange of the device lot or batch number, serial number, manufacturing date, expiration date, and distinct identification code would be beneficial to patients. ONC should require vendors to keep up with the innovation that has occurred to improve these functions. In women’s health specifically, UDIs would allow physicians and other health care providers to quickly identify what type of long-acting reversible contraception (LARC) device or urinary incontinence device a woman has in the case that a device is recalled or becomes known to cause certain serious side effects. Therefore, UDI data fields should be made standard to improve patient care.

#### *Include Gender and Reproductive Health Information in the USCDI*

ACOG recommends, in addition to the existing data element “sex,” **ONC include the data element “gender,” in the USCDI.** Providers have repeatedly indicated that they need to be able to document a patient’s sex along with their gender identity. Recording both data elements could help eliminate payment denials for transgender and other patients who may have unique health care needs for a person of their sex. Additionally, transgender individuals are at a much higher risk for cardiovascular disease, mental illness, violence, Human Immunodeficiency Virus (HIV), and many other conditions.<sup>iii,iv,v,vi</sup> Documenting both gender identity and sex will allow physicians and other health care providers to screen for and more adequately prevent these adverse outcomes, as well as provide more clinically appropriate care to their patients. To improve care quality and coordination, ACOG urges ONC to include “gender” in the USCDI.

Sexual and reproductive health is an important component of preventive care for both men and women. For instance, clinical guidance recommends that both men and women receive STI screening and counseling to prevent STIs.<sup>vii,viii</sup> Recent evidence indicates that there has been a sharp increase in sexually transmitted infections (STIs) in recent years. Chlamydia, gonorrhea, and syphilis are all curable with antibiotics, but are often undiagnosed and untreated. All three of these infections can lead to serious and costly adverse health effects, including infertility, ectopic pregnancy, stillbirth, and increased risk for Human Immunodeficiency Virus (HIV).<sup>ix,x</sup> Including a Reproductive Health Data class in the USCDI would facilitate the standardization of reproductive health data and, when patients have consented, allow physicians to share this important information more easily. Therefore, to improve physicians’ and other health care providers’ ability to prevent, diagnose, and treat STIs and their sequelae, ACOG recommends that a *Reproductive Health* data class be added to the USCDI.

Increasing the interoperability of reproductive health data would also contribute to the administration’s recently announced initiative to end the HIV epidemic.<sup>xi</sup> In 2017, 38,739 people were diagnosed with HIV in the United States. Heterosexual women accounted for 16% of HIV diagnoses, significantly higher than heterosexual men, who accounted for 7% of diagnoses. While diagnoses for all other groups decreased, HIV diagnoses for some Hispanic/Latino men increased by 12%, and diagnoses of African American men remained stable in 2017.<sup>xii</sup> Preexposure prophylaxis (PrEP) is highly effective in preventing the transmission of HIV, however only 4.7% of PrEP users in 2016 were women and 13.1% were Hispanic.<sup>xiii</sup> If standardized reproductive health information were available, ob-gyns and other health care providers would be able to easily determine patients who are at higher risk for contracting HIV and recommend they take PrEP. Standardized documentation of these risk factors will also allow EHR software and applications to detect high-risk patients and notify the provider that they should screen for PrEP eligibility, as well as facilitate insurance coverage of PrEP for those patients who choose to initiate it. In short, the inclusion of a *Reproductive Health* data class could increase the use of PrEP among high-risk populations, and therefore could lead to a significant reduction in HIV transmission across the country.

**ACOG urges ONC to include a Reproductive Health data class with the following data elements in the USCDI to ensure that reproductive health information can be easily shared among providers.**

- **Sexual activity**
- **Contraceptive method at intake**

- **Pregnancy intent**
- **Menopause status**
- **Pregnancy status at intake**
- **Date of last menstrual period**
- **Age at menarchy**

We strongly believe that ONC should work with ACOG and other stakeholders to implement this and all future expansions of the USCDI. ACOG stands ready to work with ONC and health IT developers to ensure that, as these important data elements are included in the USCDI, the needs of women and their health care providers are met.

*Create a New Name for the New Edition with USCDI*

In this proposed rule, ONC did not propose a new name for this updated 2015 Edition. ACOG is concerned that this will create confusion as all providers/practices and vendors update their contract agreements, since they will not be able to clearly decipher which version of the 2015 Edition they have or are agreeing to implement – the CCDS or USCDI v1 version. To ameliorate this issue, ACOG strongly recommends that ONC finalize a new name for this 2015 Edition.

**ACOG Recommendations:**

- Adopt the proposal to remove the CCDS from the 2015 Edition and replace it with the USCDI.
- Finalize the proposal to adopt USCDI v1.
- Prioritize efforts to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI’s expansion.
- Finalize the proposals to require developers with certified health IT to update such health IT software to the proposed revisions, and provide the updated certified health IT to all their customers who have previously certified health IT.
- Extend the effective date of the final rule by at least 12 months to ensure that developers and end users have significant time to implement, test, and learn to use new systems.
- Add “gestational age at birth” to the list of pediatric vital signs to be included in the USCDI v1.
- Finalize the proposal to include the eight listed note types in the USCDI v1 standard.
- Include the following three data elements to delineate data in the provenance data class: the author, the time the note was generated, and the author’s organization.
- Ensure that provenance data elements are operationalized in the EHR so that they also indicate who deleted data and when.
- Add the unique device identifier (UDI) implementation guide as a requirement for health IT to adopt in order to meet the requirements for the UDI USCDI Data Class.
- Add “gender” to the USCDI.
- Add a *Reproductive Health* data class with the following data elements to the USCDI:
  - Sexual activity

- Pregnancy intent
- Menopause status
- Pregnancy status at intake
- Date of last menstrual period
- Age at menarche
- Create a new name for the 2015 Edition with the USCDI v1 standard to distinguish it from the 2015 Edition with the CCDS standard.

### **§170.205. Clinical Quality Measures**

ONC proposes to remove the Health Level-7 (HL7) Quality Reporting Document Architecture (QRDA) standard requirements from the 2015 Edition Clinical Quality Measures (CQMs) – report criterion. However, the agency would require that certified health IT support the CMS QRDA Implementation Guides (IGs). ACOG agrees that it would be beneficial for developers, and possibly providers, to only support one form of the QRDA standard instead of two. However, the HL7 QRDA standard undergoes a rigorous review process through the HL7 standards development organization (SDO) which allows for input from subject matter experts and key stakeholders through public comment. While the CMS QRDA IGs are also subject to a public comment period, it is not supported by an SDO. If CMS QRDA IGs are going to be the only minimum standard, ACOG recommends working with an SDO or other organization to sufficiently support updating and using CMS QRDA IGs.

ONC also proposes to adopt the latest CMS QRDA IGs at the time of final rule publication, if this proposal is finalized. ACOG agrees that ONC should adopt the latest CMS QRDA IGs to support the latest electronic CQM specifications.

#### **ACOG Recommendations:**

- Adopt the proposal to remove the HL7 QRDA standard requirements from the 2015 Edition Clinical Quality Measures (CQMs) – report criterion, but require that health IT certified to the criterion support the CMS QRDA Implementation Guides (IGs).
- Engage an SDO to conduct a rigorous review process on the CMS QRDA IGs, including input from subject matter experts and key stakeholders through public comment.
- Finalize the proposal to adopt the latest CMS QRDA IGs at the time of final rule publication.

### **§170.315 Electronic Health Information Export**

ONC proposes to adopt a new 2015 Edition certification criterion for EHI export, which would require that all EHI produced and electronically managed in a developer’s technology should be made readily available for export as a standard capability of certified health IT for the following two specific use cases:

1. Enable the export of EHI for a single patient upon a valid request from that patient or a user on the patient’s behalf.

2. At a customer's request, provide a complete export of all EHI that is produced or managed by means of the developer's certified EHI.

ACOG shares in ONC's goal to ensure that patients can easily access their EHI, and we appreciate the agency's efforts to eliminate anti-competitive and coercive practices by developers. However, we are concerned that, given the limited scope of the USCDI, this proposal is infeasible. Physicians and other health care providers will not be able to reliably export patient health information that is not standardized in the USCDI. In this proposed rule, ONC defines EHI to be virtually any electronic information that relates to a patient's care or condition. Given this scope, ACOG is also concerned about the privacy and security of patients' information.

If finalized, this proposal would also require providers to share patients' health information with any individual that claims to be working on the patient's behalf. ONC then fails to propose any requirements to ensure that those requesting patients' information actually are working on behalf of the patient or have the patient's consent to access this information. The agency later seeks comment on who should be able to use a technology application to request access to a patient's EHI. ACOG firmly believes that only a patient, their health care provider, or their authorized representative should be able to request their health information using a technology application, such as a patient portal or app. The data transferred should only include the information that the patient has approved and **should not contain information that the patient chooses to keep confidential.**

ACOG is particularly concerned that payers could claim to be working on behalf of their enrollees and use this requirement to demand that health care providers give them access to their enrollees' entire health record without the enrollee's express consent. We believe it would be inappropriate for the staff of payers to be able to read clinical notes detailing a woman's visit with her ob-gyn or any other health care provider. As mentioned previously, ACOG believes that this proposed rule, if finalized without changes, will result in broad commoditization and commercialization of patient data. We strongly recommend that ONC protect patients' privacy and security by amending this proposal.

ONC should instead limit its definition of EHI to just the data elements represented by the USCDI, and therefore limit this proposal to require that developers enable the export the data elements represented by the USCDI upon a valid request. Patients and their authorized representatives requesting their own health information would be excepted – providers and developers would still be compelled to give a patient any health information that they request.

**ACOG Recommendations:**

- Constrain the definition of EHI, and therefore the scope of this proposal, to just the data elements represented by the USCDI.
- Except patients and their authorized representatives, as they should be given access to their entire health record when requested.
- Amend the proposal to read "Enable the export of EHI for a single patient upon a valid request from that patient, their health care provider, or an authorized representative."
- Allow only a patient or their authorized representative to request their EHI using a technology application, such as a patient portal or application.

## **§170.315 Data Segmentation for Privacy and Consent Management**

ONC proposes to remove the current 2015 Edition Data Segmentation for Privacy (DS4P) criteria, and replace it with three new criteria that would support a more granular approach to privacy tagging data and consent management. **ACOG strongly believes that data segmentation is essential for the protection of women’s EHI, and we support a more granular approach.** Certain notes and data elements specific to women’s health should not be released unless specific permission from the patient is obtained. For example, segmenting data at the element level would protect individuals who have experienced intimate partner violence, sexual assault, and other sensitive experiences that disproportionately affect women. This would also allow ob-gyns and other women’s health providers to maintain confidentiality of documentation related to care for sexually transmitted infections (STIs), pregnancy, substance use disorder, or other conditions that, if shared, could endanger women or make them more vulnerable to discrimination. However, providers are not currently able to tag these types of data elements for privacy or keep track of which elements patients have consented to sharing.

Data segmentation and consent management software currently exist, but these functions are very costly to implement in many EHRs. ONC should work with CMS, EHR developers, and other stakeholders to make data segmentation technologies accessible and affordable to all physicians and other health care providers, including independent and small practices. As it becomes easier to share data, ACOG believes it is imperative that granular data segmentation standards be included in the USCDI. It is our understanding that FHIR-enabled Consent2Share (C2S) APIs provide both physician and patient-facing services and the infrastructure to segment data and manage consent. **We support requiring C2S in Base EHR certification and encourage ONC to increase C2S adoption.** We are also aware that there is no longer funding to continue this important work. **ACOG recommends ONC coordinate with Substance Abuse and Mental Health Services Administration (SAMHSA) to establish a public-private project to advance C2S.**

ONC also seeks comment regarding certification to the “consent management for APIs” criteria that should only be available in conjunction with the “standardized API for patient and population services” criteria when both of these criteria are aligned to one version of the FHIR standard. ACOG firmly believes that developers should be allowed to certify the “consent management for APIs” criteria even without current standards alignment. While it may take FHIR some time to instantiate many discrete clinical observations for more granular data segmentation, those elements may be made available in non-FHIR APIs. During this time, patients should be able to control whether or not they want to share those elements at a very granular level. Therefore, developers should be able to certify the consent management criteria in a non-FHIR data sharing environment.

### ACOG Recommendations:

- Finalize the proposal to remove the current 2015 Edition DS4P criteria and replace it with three new criteria that would support a more granular approach to privacy tagging data and consent management.

- Ensure that API implementation is accompanied by affordable and accessible data segmentation and patient consent management software that allows providers to segment data at a granular level, as well as manage patient consent related to segmentation.
- Require C2S in Base EHR certification in future editions and increase C2S adoption.
- Coordinate with SAMHSA to advance C2S.
- Allow for certification of the “consent management for APIs” criteria for those developers interested in doing so even without alignment with current FHIR standards.

## **Health IT for the Care Continuum**

### *Approach to Health IT for the Care Continuum and the Health Care of Children*

ACOG supports the Health IT for the Care Continuum Task Force Recommendations for voluntary certification of health IT for pediatric care. We are particularly supportive of Recommendation 8: Associate maternal health information and demographics with newborn. Linking maternal and neonatal health information is a vital step in implementing meaningful value-based maternity care models. Current methods for linking these data are complex, burdensome, and unreliable. As a result, most value-based maternity care models are unable to associate neonatal outcomes with prenatal care, and therefore cannot fully appreciate the impact of this care on health care costs or outcomes.

ONC should consult ob-gyns and other women’s health providers to ensure that the appropriate data elements for the care of adolescent women and girls are included in health IT certified for pediatric care. We are interested in and ready to serve as a resource to ONC to ensure that pediatric EHRs are designed to meet the unique needs of adolescent women and girls.

ACOG agrees with ONC that the proposal to support a more granular approach to data segmentation and consent management would be applicable to ob-gyns and other women’s health providers who wish to limit the sharing of a minor’s reproductive and sexual health EHI. It would also allow all providers to segment information about child abuse and other sensitive situations to protect children and adolescents. In future, when a woman’s health information can be easily linked to her neonate’s, data segmentation will be required if the mother does not remain the child’s legal guardian throughout their childhood. ACOG again urges ONC to ensure that granular data segmentation technology is affordable and accessible to all providers, including pediatric and women’s health providers. We strongly believe that, as EHI is shared more freely, the capability to segment data will become increasingly important.

### *Request for Information on Health IT and Opioid Use Disorder Prevention and Treatment*

ACOG recognizes that the efficient exchange of EHI for patients with substance use disorder (SUD) could help physicians and other health care providers coordinate care across settings, particularly for those patients undergoing medication assisted treatment (MAT). This improved care coordination could benefit ob-gyns, certified nurse midwives (CNMs), family physicians, and other providers that care for pregnant women with SUD. However, we caution that making this data more freely available may put mothers and other caregivers seeking treatment for SUD at greater risk for prosecution. In an

environment where patients' EHI is easily accessed and shared via an open API, a patient's SUD information will not be sufficiently protected by current consent and privacy laws. This could lead to serious unintentional consequences, as patients may choose not to disclose their substance use or forego treatment for fear of prosecution. In order to protect their patients, ob-gyns and other women's health care providers may also opt not to record sensitive information in the EHR, which could lead to incomplete records.

To prevent this situation, open API implementation should be accompanied by affordable data segmentation and patient consent management software. We commend ONC for proposing that granular data segmentation capabilities be part of FHIR standards in the future, and strongly recommend the agency ensure these capabilities become accessible to all providers in both FHIR and non-FHIR environments in the interim.

## **Application Programming Interfaces**

### **Proposed Adoption of FHIR DSTU2 Standard**

ONC proposes to adopt the HL7 FHIR standard, specifically the FHIR Draft Standard for Trial Use (DSTU) 2 (known as FHIR Release 2) as a baseline standard requirement. However, given that other FHIR release versions are available, ONC requests comment on the options that it could pursue for a final rule. **ACOG recommends that ONC require the adoption of FHIR Release 4.** This is the first normative version, and ACOG believes that, by the time the final rule goes into effect, FHIR Release 4 will be widely supported while other versions may be outdated.

ACOG applauds ONC's proposal to require health IT developers to implement API technology. We believe that this proposal represents a significant step towards achieving interoperability. However, we do not believe that 24 months from the publication date of the final rule will give vendors and providers/practices sufficient time to successfully implement open APIs. Past experience indicates that EHR vendors will need between 18-24 months to develop this technology, and physicians and hospitals will need another 12 months thereafter to get in the installation queue. **To ensure that the major changes in this proposal are implemented safely and effectively, ACOG strongly recommends that ONC extend its proposed timeline by 12 months or, at the very least, provide physicians additional implementation time beyond the 24-month deadline.** If ONC continues along the proposed timeline, which we strongly recommend against, ACOG recommends that ONC finalize the proposal to require the adoption of FHIR Release 2. We do not believe FHIR Release 4 will be widely supported at the proposed date of implementation.

### **Conditions of Certification**

#### *Permitted Fees*

ACOG appreciates ONC's efforts to prohibit EHR developers from charging providers burdensome fees related to API technology. We are concerned, however, that ob-gyns and other providers will still incur

significant costs due to the proposed permitted fees. For instance, developers' current contracts with providers and health systems do not include the cost of system updates that will be required to support API functionality. While large hospitals and health systems may be able to afford the fees that developers are permitted to charge to update their EHR platforms, physician practices, particularly those that are small or see a high proportion of underserved patients, will not. Since the proposed permitted fees allow developers to charge fees related to development, deployment, and upgrade of API technology, ob-gyns and other health care providers are likely to incur ongoing significant fees as ONC updates the API standard. ACOG is concerned the proposed fee structure will ultimately designate physicians as the default revenue stream for EHR vendors and app developers.

Additionally, ONC proposes to allow developers to charge usage-based fees to ob-gyns and other providers to recover the costs that would typically be incurred supporting API interactions at increasing volumes. While ONC indicates that these fees cannot include costs incurred that facilitate a patient's ability to access, exchange, or use their electronic health information, the agency allows developers to charge providers whose patients use API technology at a high volume. Physicians and other health care providers themselves may increase the volume, and therefore the cost, of API technology if they are regularly using it to document or coordinate patients' care. Since providers cannot be reimbursed for the costs they incur related to APIs, these permitted fees will result in an unaffordable increase in all providers' overhead costs. **Accordingly, ACOG strongly recommends that ONC adopt a tiered usage-based fee structure in which physicians would not be charged for exchanging data in compliance with federal requirements.** For instance, ONC could establish categories where the technology requirements designate the fees.

- A "no fee" category would limit API Technology Suppliers from charging API Data Providers or API Users any fees for exchanging data in compliance with federal requirements (e.g., costs associated with health information exchange, patient access, reporting quality measures, and data segmentation for privacy). Since all API Technology Suppliers will be certified by ONC, any API Technology Supplier-to-API Technology Supplier connections would also be in the "no fee" category.
- An "at cost" category would allow API Technology Suppliers to charge API Data Providers or API Users the cost of interfacing APIs with a non-API Technology Supplier's commercial technology (e.g., commercial lab systems, commercial picture archiving and communication systems (PACS), commercial data analytics services).
- A "cost plus reasonable profit" category would allow API Technology Suppliers to charge API Data Providers or API Users a reasonable profit when conducting legitimate custom API development or creating custom apps (e.g., creating proprietary mappings for technology unique to a health system or establishing connections with non-commercially available technology.)

For the "at cost" and "cost plus reasonable profit" categories, API Technology Suppliers should be restricted from implementing health IT in non-standard ways that unnecessarily increase the costs, complexity, and other burden of accessing, exchanging, or using EHI. We do not expect all scenarios will

be addressed by this approach; however, we believe a clearer and more approachable fee structure will better empower physicians to be informed consumers of technology. We believe this also establishes fair and equitable fee structure for all parties involved.

### *Transparency, Openness, and Pro-competitive Requirements*

ACOG applauds the proposed Conditions of Certification which require API developers to make specific business and technical documentation freely accessible and promote an open and competitive marketplace. ACOG particularly appreciates the removal of EHR contract “gag clauses,” which block physicians from discussing EHR concerns. We agree that a transparent, non-discriminatory environment will drive market competition among developers and lead to interoperable application overlays that match physicians and other health care providers’ workflow and have a more intuitive interface. ACOG recommends that ONC finalize these proposals.

#### **ACOG Recommendations:**

- Adopt the HL7 FHIR standard, specifically the FHIR Draft Standard for Trial Use (DSTU) 4 (known as FHIR Release 4) as a baseline standard requirement.
- Require the implementation of API technology to be accompanied by granular data segmentation and patient consent management capabilities.
- Extend the proposed timeline for API implementation or, at the very least, provide physicians additional implementation time beyond the 24-month deadline.
- Adopt a tiered usage-based fee structure in which physicians would not be charged for exchanging data in compliance with federal requirements.
- Finalize the proposed Conditions of Certification which require API developers to make specific business and technical documentation freely accessible and promote an open and competitive marketplace.

### **Information Blocking**

#### *Definition of Electronic Health Information (EHI)*

ONC’s proposed definition of EHI includes all information about a patient that relates, or may in the future relate, to their care. ACOG recommends that ONC constrain its definition of EHI to just the data elements represented by the USCDI for specified actors. The agency’s expansive proposed definition for EHI would make providers and other actors responsible for sharing information that is not standardized and, therefore, cannot be easily shared. ACOG is concerned that ob-gyns and other health care providers will be forced to resort to faxing patients’ medical records, claims records, and other information that is contained in the proposed definition of EHI. To ameliorate this issue, EHI should only include the data elements in the USCDI. ONC should then focus on implementing and expanding the USCDI through the proposed pathways with input from stakeholders. This would ensure that ob-gyns and other health care providers are not legally responsible for sharing information that cannot be easily exchanged.

#### *Practices that May Implicate the Information Blocking Provision*

ACOG is strongly against the practice of information blocking. While we agree that inappropriate instances of information blocking must be eliminated to foster a competitive health IT marketplace, ACOG strongly believes that ONC's proposed definition of information blocking fails to implement the 21<sup>st</sup> Century Cures Act as Congress intended.

The proposed definition of information blocking is extremely broad and subjective. The definition for EHI includes all types of information related to a patient, most of which is not included in the USCDI, and therefore cannot be shared easily. It also includes subjective terminology, including "timely" and "unreasonable" throughout the proposed exceptions and sub-exceptions. The resulting uncertainty will likely lead to costly investigations and legal proceedings for all health care providers, even if they are not found to have violated the information blocking provision.

The proposed burden of proof for information blocking is unreasonable. Each time a health care provider chooses not to share a patient's EHI, they will have to look up which exception(s) they may qualify for and determine whether or not they satisfy all of the criteria under those exceptions. Next, physicians and other health care providers will have to document their justification and how they met each criterion. It is unclear where this justification would be documented. It would be inappropriate for this information to be recorded in a patient's EHR, since it is not EHI, nor is it relevant to their care. This will create yet another administrative burden for an already over-burdened population of health care providers. For each information blocking exception, **ACOG recommends that ONC clarify that a physician's professional judgment will never be considered information blocking.** This, coupled with aligning information blocking and EHI requirements with USCDI and certified APIs, will reduce the overall complexity of ONC's proposal.

ONC's interpretation of the 21<sup>st</sup> Century Cures Act creates an assumption that any physician who withholds data is guilty of information blocking, and ACOG strongly believes that this is in direct conflict with HIPAA's minimum necessary requirement. In the preamble, ONC provides the following example of a practice that would be considered information blocking: "a health system incorrectly claims that the HIPAA Rules or other legal requirements preclude it from exchanging EHI with unaffiliated providers." Given this, as well as how complicated the conditions of the proposed sub-exceptions are, some physicians may find it easier to comply by simply disclosing all the information they have. This requires ob-gyns and other providers to make decisions that directly violate the minimum necessary standard, which states they should make reasonable efforts to limit the use or disclosure of protected health information to the minimum necessary to accomplish the intended purpose.<sup>xiv</sup> In drafting the 21<sup>st</sup> Century Cures Act, Congress deferred to HIPAA. This proposal would violate one of its major provisions. To ameliorate this issue, ACOG recommends ONC clarify that physicians providing the minimum necessary information to an actor (even a covered entity) will not be considered in violation of the information blocking provisions, without having to go through the exercise of meeting the requirements of the sub-exception.

ACOG is concerned that, as proposed, the information blocking provisions will lead to payers demanding more information from ob-gyns and other health care providers than they need. Private payers are already implementing programs to gain complete access of provider EHRs in the name of reducing

administrative burden. Women trust their ob-gyns and other women’s health care providers with personal information and allow them to record details of their medical appointments with the understanding that this information is confidential.<sup>xv</sup> They have not consented for their insurance company, which is typically closely associated with their employer, to have complete access to their personal health information. Any federal proposal that extends access, exchange, or use of EHI must make sure the patient continues to be the primary authority in designating rights to their data.

#### *§171.201 Proposed Exception: Preventing Harm*

ONC proposes to establish an exception to the information blocking provision for practices that are reasonable and necessary to prevent harm to a patient or another person. The agency further proposes that, in order to qualify for this exception, a practice must be responding to one of the following risks that is cognizable under this exception:

1. Risk of corrupt or inaccurate data being recorded or incorporated in a patient’s EHR
2. Risk of misidentifying a patient or patient’s EHI
3. Determination by a licensed health care professional that the disclosure of EHI is reasonably likely to endanger life or physical safety

The agency requests comment on whether these categories of harm capture the full range of safety risks that might arise directly from accessing, exchanging, or using EHI, as well as whether ONC should consider other types of patient safety risks related to data quality and integrity concerns. ACOG appreciates ONC’s efforts to ensure that ob-gyns and other women’s health care providers are not penalized or disincentivized from protecting patients’ safety. However, we strongly recommend that ONC amend the third cognizable risk to include all types of abuse, not just physical. The Department of Health and Human Services (HHS) Office on Women’s Health indicates that women experience physical, sexual, verbal, emotional, financial, and elder abuse, along with intimate partner violence, harassment, stalking, and sexual coercion.<sup>xvi</sup> ACOG guidance indicates that women are disproportionately affected by violence and abuse, and recommends that ob-gyns and other women’s health providers screen for violence and abuse.<sup>xvii,xviii,xix,xx</sup> As physicians dedicated to promoting the health and wellbeing of women, ACOG strongly believes that all types of violence and abuse should be included in the preventing harm exception. Ob-gyns and other health care providers must be able to protect and promote patients’ overall wellbeing, not just prevent physical harm.

#### **Patient Privacy and Data Security**

If patients access their health data—some of which could contain family history and could be sensitive—through a smartphone, they must have a clear understanding of the potential uses of that data by app developers. Most patients will not be aware of who has access to their medical information, how and why they received it, and how it is being used (for example, an app may collect or use information for its own purposes, such as an insurer using health information to limit/exclude coverage for certain services, or may sell information to clients such as to an employer or a landlord). Recent reports indicate that pregnancy, smoking cessation, and depression apps are collecting data from users and selling it to their employers, Google, and Facebook.<sup>xxi,xxii</sup> We predict that these types of apps will proliferate as APIs are

implemented across the health care system and patients increasingly access their health data on smartphones.

The downstream consequences of data being used in this way may ultimately erode a patient's privacy and willingness to disclose information to his or her physician. ONC's proposal requires API usage without requiring that the API technology include privacy controls. The technological capability to implement privacy controls exists, so by failing to implement them, the agency is making a deliberate policy decision not to prioritize privacy.

We believe that ONC has the responsibility to provide patients with a basic level of privacy and app transparency—especially since some apps deliberately hide their actions and make it difficult for patients to learn about or control their data. ACOG urges ONC to take the following steps to ensure patient data are accessed, exchanged, and used pursuant with the goals outlined in the 21<sup>st</sup> Century Cures Act and the desires expressed by patients.

As part of an API Technology Supplier's certification, **ONC should require APIs check an app's attestation to:**

- **Industry-recognized development guidance;**
- **Transparency statements and best practices; and**
- **The adoption of a clearly written model notice to patients.**

One possible method to accommodate this would require an EHR vendor's API to check for three "yes/no" attestations from any consumer-facing app. For example, 1) An app developer could choose to assert conformance to [Xcertia's Privacy Guidelines](#).<sup>1</sup> 2) An app developer could attest to the Federal Trade Commission's (FTC) [Mobile Health App Developers: FTC Best Practices](#) and the [CARIN Alliance Code of Conduct](#). 3) An app developer could attest to adopting and implementing [ONC's Model Privacy Notice](#). These could be viewed as value-add services as proposed by ONC. The app could be acknowledged or listed by the health IT developer in some special manner (e.g., in an "app store," "verified app" list). We would urge EHR vendors to also publicize the app developers' attestations; ONC could require a vendor to do so as a prerequisite to product certification.

We do not believe that requiring an API check for an app developer attestation would be a significant burden on API Technology Suppliers. We recognize that a "yes" attestation would not ensure apps implement or conform to their attestations. However, we firmly believe this will provide a needed level of assurance to patients and would be greatly welcomed by users. **We also believe this could act as a "bookend"—placing app developers between ONC health IT certification requirements (which would be imposed by API Technology Suppliers), and FTC's enforcement of unfair and deceptive practices. In other words, an app developer would be strongly motivated to attest "yes" and to act in line with their attestations.**

### Supplemental Notice of Proposed Rulemaking

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<sup>1</sup> Both the [Food and Drug Administration \(FDA\) and ONC participate on the board of Xcertia](#), a multi-stakeholder effort to develop guidelines and recommendations for medical app development.

**ACOG also recommends that ONC consider issuing a Supplemental Notice of Proposed Rulemaking (SNPRM) to seek further comments on the information blocking provisions in the proposed rule.** We applaud Congress' intent in section 4004 of the Cures Act to eradicate practices that unreasonably limit the access, exchange and use of electronic health information for authorized and permitted purposes which in turn have frustrated care coordination and improvements in health care quality and efficiency as well as inhibited the transition to a learning health system. That said, Part 171 of the proposed rule introduces a number of new definitions and terminologies, including such definitions as "electronic health information," "use," and "health information network" (HIN) that require additional clarification from ONC before the entire rule is finalized given the significant economic impact of this rule. ACOG recommends ONC clarify whether clinical registries are included in the definition of a HIN, and if so, how the information blocking requirements will apply to registries. Most specialty society registries collect deidentified health information and are therefore not in a position to exchange information with patients or providers.

Furthermore, a number of regulatory and deregulatory actions on the Office of Management and Budget's Unified Agenda await regulatory action, including changes to the 42 CFR Part 2 regulation, potential modernization of HIPAA to support and remove barriers to coordinated care, as well as enactment of TEFCA, all of which have immediate implications for Part 171 of this proposed rule.

ONC is requiring that physicians comply with all detailed and complex information blocking provisions without knowing the potential appropriate disincentives. ONC deferred to future rulemaking as to the potential penalties for physicians. Asking physicians to comply with an unfunded mandate without knowing the penalties is unfair. It is not our intent to slow ONC's implementation of Title IV of the Cures Act as mandated by Congress. However, issuance of an SNPRM would enable ONC to propose additional clarifications to the information blocking rule and seek feedback on its proposals to address identified concerns before finalizing the information blocking section of this proposed rule. We also believe that issuance of a SNPRM would provide ONC with the desired flexibility, if it so chooses, to finalize certain aspects of the rule while concurrently issuing a SNPRM on Part 171.

**Should ONC choose not to issue a SNPRM, ONC should extend the effective date of the final rule by at least twelve months in order for physicians to have the necessary time to fully digest and implement changes in their business practices, policies, and procedures.** This is necessary to help physicians and patients fully understand the implications of the Administration's policies and ensure actors have time to seek clarifying feedback from HHS' agencies on a myriad of questions without fear of penalties.

**ACOG Recommendations:**

- Limit the definition of EHI to just those data elements that are in the USCDI.
- Clarify that physicians providing the minimum necessary information to an actor (even a covered entity) will not be considered in violation of the information blocking provisions, without having to go through the exercise of meeting the requirements of the sub-exception.

- Clarify that ob-gyns and other providers will never be considered information blocking if they are using their professional judgment to protect their patients’ rights or privacy, without having to walk through the steps of the sub-exception.
- Amend the third cognizable risk in the proposed exception for Preventing Harm to include all types of abuse, not just physical.
- To promote patient privacy and data security, require APIs check an app’s attestation to:
  - Industry-recognized development guidance;
  - Transparency statements and best practices; and
  - The adoption of a model notice to patients.
- Issue a SNPRM to seek further comments on the information blocking provisions of the proposed rule, including the definition of HIN.

### Price Transparency RFI

ONC seeks comment on behalf of all of HHS on the implications of including price information in EHI, and therefore requiring it to be published on an open API. **ACOG is strongly supportive of price transparency but we do not believe that price information should be included in the definition of EHI.** ACOG agrees that, in some instances, making price information more transparent could help patients make informed decisions about their care. Given the recent evidence regarding “surprise” or “balance” billing within the healthcare system, we believe increasing price transparency would benefit patients and their health care providers.<sup>xxiii</sup> Research also indicates that women make the majority of health care decisions on behalf of their families.<sup>xxiv</sup> Increased transparency in health care prices would not only allow women to make more informed decisions about their families’ health care, but also reduce the amount of time they are required to spend shopping for health care. Ob-gyns and other providers would also benefit from price transparency, as they would be able to more accurately discuss the cost of various treatment options with patients, along with the clinical benefits. Accordingly, ACOG supports using open APIs to make accurate price information more easily accessible.

However, ACOG is concerned that much of this information will be irrelevant and confusing for patients, leading to unintended consequences. For instance, telling patients how much a health plan pays a provider for a service does not give them valuable information about their own costs or the quality of that care. Health plans would need to provide patients with resources to explain how each price impacts them, including whether they’ve met their deductible, copays/coinsurance, drug rebates, and a variety of other benefits that vary between patients and their health care providers. In women’s health specifically, health plans would have to clearly communicate that women in Medicaid or ACA-compliant plans will not incur cost sharing for contraception or contraceptive counseling, even though some forms of contraception have a high list price. As HHS ramps up its important efforts to make prices more transparent, the agency should emphasize the importance of clearly and accurately reporting patients’ individualized out-of-pocket costs.

ACOG urges HHS to aggressively pursue alternative avenues to reduce the cost of health care and prescription drugs. While price transparency efforts may aid patients and providers in making health care decisions, these efforts are unlikely to significantly lower the cost of health care.

*ONC asks whether prices that are included in EHI should reflect all out-of-pocket costs such as deductibles, copayments, and coinsurance (for insured patients).*

While we do not believe that any price information should be included in the definition of EHI, ACOG believes that any prices being communicated to patients must include all out-of-pocket costs. Patients' out-of-pocket costs have a direct impact on whether or not they choose to seek care, medication adherence, and their ability to afford health care services and prescription drugs.<sup>xxv,xxvi</sup> For these reasons, we believe any price transparency efforts should focus on accurately representing out-of-pocket costs to the patient.

*ONC asks whether prices that are included in EHI should include a reference price as a comparison tool such as the Medicare rate and, if so, what the most meaningful reference would be.*

ACOG firmly believes that it would be inappropriate to use the Medicare rate as a reference price. There is substantial evidence to indicate that Medicare payments do not cover the cost of providing care.<sup>xxvii</sup> The 2019 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Medicare Trustees Report) found that, given the upcoming Medicare payment freeze, Medicare payment amounts are not expected to keep pace with the projected 2.2 percent per year increase in physician costs.<sup>xxviii</sup> We believe the agency would be misleading patients by using the Medicare rate, which does not cover the cost of care, as a reference price.

We would like to reiterate our request that EHI be defined to only include information in the USCDI. Price information is not in the USCDI and therefore there is not a standardized way to transmit this information to patients or between providers

*ONC inquires whether price information be available on public web sites so that patients can shop for care without having to contact individual providers/practices, and if so, who should be responsible for posting such information. Additionally, the agency asks how the public posting of pricing information through API technology would help advance market competition and the ability of patients to shop for care.*

ACOG believes that health plans should provide plan enrollees or their designees with complete information regarding plan benefits and real-time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs. Since health plans contract with physicians and other health care providers and control individuals' benefits, they are in the best position to provide this information. Additionally, under CMS's companion interoperability proposal, health plans will be responsible for implementing open APIs, and therefore they should work with vendors to facilitate price transparency through their APIs.

While ACOG believes that making prices publicly available may increase market competition and the ability for some patients to shop for some services, we do not believe this will have a major impact on the affordability of health care overall. If prices are posted publicly, health plans will not be able to personalize cost information according to individual benefits, and therefore the public prices may not

accurately reflect patients' costs. It is unlikely patients will be able to shop for emergency services or choose the health care providers on call during an emergency care episode.

### **Request for Information on Disincentives for Providers**

ONC requests information on disincentives or whether modifying disincentives already available under existing HHS programs and regulations would provide for more effective deterrents to information blocking. ACOG wishes to reiterate that ob-gyns are strong advocates for the free exchange of EHI when that exchange is safe, secure, private, and appropriate. Health care providers do not restrict the free flow of patient's EHI for malicious purposes, and therefore there is no need for additional or modified disincentives. Instead, HHS should work to ensure that ob-gyns and other health care providers are able to share patients' EHI easily, privately, and securely when they feel it is safe to do so. **If HHS is concerned about providers restricting the flow of patients' EHI due to privacy and security concerns, then the agency should incentivize health IT and EHR developers to implement granular data segmentation capabilities in a way that will be accessible and affordable to all physicians.**

### **Patient Matching Request for Information**

ACOG believes that expanding efforts to improve patient matching are essential to our shared goals of advancing interoperability. Without being able to match patients' records across health systems and health care providers, we will not be able to achieve the comprehensive patient medical record that ONC is envisioning. ACOG recommends that ONC and CMS support piloting of various patient matching methods, including the use of patient-empowered solutions, demographic data standardization, and referential matching. Given this proposal's focus on open API technology, phone number validation and smart phone application solutions could be within reach. Whichever patient matching efforts and solutions ONC and CMS choose to support, these agencies must ensure that patients' data will be secure, and that costs of implementing those solutions are not passed onto patients or providers.

*ONC seeks input on what additional data elements could be defined to assist in patient matching as well as input on a required set of elements that need to be collected and exchanged.*

ACOG supports the standardization of data elements, and we are prepared to work with ONC to ensure that women's health needs and appropriate care guidelines are included throughout the standardization process. We believe that further standardization of data elements would reduce the semantic differences between organizations and facilitate successful patient matching. We also recommend that ONC consult specialty societies to ensure that standardized data elements are medically appropriate. Before requiring the use of new standardized elements, they should be piloted in clinical care settings and deemed successful by a variety of stakeholders.

ACOG believes that the process for standardizing data elements and updating standards must allow for the testing and incorporation of new elements. For instance, some evidence indicates that email addresses could become useful for patient matching, while Social Security numbers may be captured less in the future.<sup>xxix</sup> ONC should ensure that any requirements for standardized elements do not restrict innovation and future pilots.

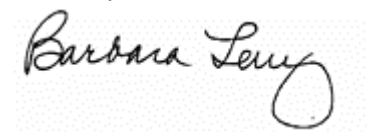
*ONC seeks comment on potential solutions that include patients through a variety of methods and technical platforms in the capture, update, and maintenance of their own demographic and health data, including privacy criteria and the role of providers as educators and advocates.*

As open APIs are implemented across health plans, ACOG believes that using patient generated data could improve patient matching. Patients who are accessing their EHR, provider directories, and claims data through a third-party application could also use that application to submit demographic information for a visit with a new provider, or when demographic data changes. We note that this would require implementation of an API that supports bidirectional data exchange, while the current proposal focuses on one way data exchange – from the EHR to the API. Again, ACOG emphasizes the importance of developing and piloting smart phone-based solutions for patient matching in clinical care settings with front-line physicians. Any patient matching solution that is implemented will have to be thoughtfully incorporated into clinical workflows to ensure that it does not increase the administrative burden on patients or providers.

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ACOG applauds ONC’s continued efforts to improve interoperability and patient access to their health information. We look forward to working with ONC, CMS, and the rest of the administration to strengthen the privacy and security of patients’ health information and reduce provider administrative burden. If you have any questions, please contact Meredith Yinger, Health Policy Analyst, at [myinger@acog.org](mailto:myinger@acog.org) or 202-863-2544.

Sincerely,



Barbara S. Levy, MD, FACOG, FACS  
Vice President, Health Policy

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<sup>i</sup> Boyle EM, Poulsen G, Field DJ, Kurinczuk JJ, Wolke D, Alfirevic Z et al. Effects of gestational age at birth on health outcomes at 3 and 5 years of age: population based cohort study *BMJ* 2012; 344 :e896

<sup>ii</sup> Berry MJ, Foster T, Rowe K, Robertson O, Robson B, Pierse N. Gestational Age, Health, and Educational Outcomes in Adolescents. *Pediatrics* Nov 2018, 142 (5) e20181016; DOI: 10.1542/peds.2018-1016

<sup>iii</sup> Irwig MS. Cardiovascular health in transgender people. [Rev Endocr Metab Disord](#). 2018 Sep;19(3):243-251. doi: 10.1007/s11154-018-9454-3

<sup>iv</sup> Baker KE. Findings From the Behavioral Risk Factor Surveillance System on Health-Related Quality of Life Among US Transgender Adults, 2014-2017. *JAMA Intern Med*. Published online April 22, 2019. doi:10.1001/jamainternmed.2018.7931

<sup>v</sup> Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts, 2017. *MMWR Morb Mortal Wkly Rep* 2019;68:67–71.

DOI: <http://dx.doi.org/10.15585/mmwr.mm6803a3>

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- <sup>vi</sup> Baral, SD et al. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. *The Lancet Infectious Diseases*. 2012 Dec;13(3):214:222. Retrieved from: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(12\)70315-8/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(12)70315-8/fulltext)
- <sup>vii</sup> The adult well-male examination. American Academy of Family Physicians. *Am Fam Physician*. 2018;98(12):729-737.
- <sup>viii</sup> Well-woman visit. ACOG Committee Opinion No. 755. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2018;132:e181–86.
- <sup>ix</sup> New CDC analysis shows steep and sustained increases in STDs in recent years. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Centers for Disease Control and Prevention. U.S. Department of Health and Human Services. 2018 <https://www.cdc.gov/nchhstp/newsroom/2018/press-release-2018-std-prevention-conference.html>
- <sup>x</sup> Sexually transmitted disease surveillance 2017. Division of STD Prevention. Centers for Disease Control and prevention. U.S. Department of Health and Human Services. 2018. Retrieved from: [https://www.cdc.gov/std/stats17/2017-STD-Surveillance-Report\\_CDC-clearance-9.10.18.pdf](https://www.cdc.gov/std/stats17/2017-STD-Surveillance-Report_CDC-clearance-9.10.18.pdf)
- <sup>xi</sup> Azar, A. Ending the HIV epidemic: a plan for America. Department of Health and Human Services. 2019. Retrieved from: <https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html>
- <sup>xii</sup> HIV in the United States and Dependent Areas. Centers for Disease Control and Prevention. U.S. Department of Health and Human Services. 2019. Retrieved from: <https://www.cdc.gov/hiv/statistics/overview/ataglance.html>
- <sup>xiii</sup> Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV Preexposure Prophylaxis, by Race and Ethnicity — United States, 2014–2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1147–1150. DOI: <http://dx.doi.org/10.15585/mmwr.mm6741a3external icon>.
- <sup>xiv</sup> 45 CFR 164.502(b), 164.514(d)
- <sup>xv</sup> Examining the health care needs and preferences of women ages 18 to 44. PerryUndem Research/Communication. 2017. Retrieved from: [https://www.plannedparenthood.org/uploads/filer\\_public/31/28/312868ed-0dcf-48a2-b146-03087fccff02/perryundem\\_research\\_july\\_2017.pdf](https://www.plannedparenthood.org/uploads/filer_public/31/28/312868ed-0dcf-48a2-b146-03087fccff02/perryundem_research_july_2017.pdf)
- <sup>xvi</sup> U.S. Department of Health & Human Services. Office on Women’s Health. Retrieved from: <https://www.womenshealth.gov/relationships-and-safety/other-types>
- <sup>xvii</sup> Intimate partner violence. Committee Opinion No. 518. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;119:412–7.
- <sup>xviii</sup> Elder abuse and women’s health. Committee Opinion No. 568. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2013;122:187–91.
- <sup>xix</sup> Sexual assault. ACOG Committee Opinion No. 777. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2019;133:e296–302.
- <sup>xx</sup> Human trafficking. Committee Opinion No. 507. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:767-70.
- <sup>xxi</sup> Harwell D. Is your pregnancy app sharing your intimate data with your boss? *Washington Post*. 2019. Retrieved from: [https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?utm\\_term=.9957679a8795](https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?utm_term=.9957679a8795)
- <sup>xxii</sup> Siegel R. Smoking and depression apps are selling your data to oogle and Facebook, study finds. *Washington Post*. 2019. Retrieved from: [https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?utm\\_term=.9957679a8795](https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?utm_term=.9957679a8795)
- <sup>xxiii</sup> Chartock B, Garmon C, Schutz S. Consumer’s responses to surprise medical bills in elective situations. *Health Affairs* 2019;38:3.
- <sup>xxiv</sup> U.S. Department of Labor. General facts on women and job based health. Washington, DC: U.S. Department of Labor, 2005. Retrieved at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/women-and-job-based-health.pdf>
- <sup>xxv</sup> Dalton VK, Carlos RC, Kolenic GE, et al. The impact of cost sharing on women’s use of annual examinations and effective contraception. *Obstet Gynecol* 2018;219:93.e1-13.
- <sup>xxvi</sup> Karter AJ, Parker MM, Solomon MD, et al. Effect of Out-of-Pocket Cost on Medication Initiation, Adherence, and Persistence among Patients with Type 2 Diabetes: The Diabetes Study of Northern California (DISTANCE). *Health Serv Res*. 2018;53(2):1227–1247. doi:10.1111/1475-6773.12700

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<sup>xxvii</sup> Underpayment by Medicare and Medicaid Fact Sheet. American Hospital Association. 2019. Retrieved from: <https://www.aha.org/system/files/2019-01/underpayment-by-medicare-medicaid-fact-sheet-jan-2019.pdf>

<sup>xxviii</sup> U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. 2019 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Retrieved from: <https://www.cms.gov/Research-StatisticsData-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Trustees-Reports-Items/2016-2019.html>

<sup>xxix</sup> PEW Charitable Trusts. Enhanced patient matching is critical to achieving full promise of digital health records. 2018. Retrieved from: <https://www.pewtrusts.org/en/research-and-analysis/reports/2018/10/02/enhanced-patient-matching-critical-to-achieving-full-promise-of-digital-health-records>