American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

May 31, 2019

Re: RIN 0955-AA01

Don Rucker, M.D.
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 Street, SW
Washington, DC 20201

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

Dear Dr. Rucker:

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On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the Office of the National Coordinator (ONC) for Health Information Technology's proposed rule that, among numerous proposals, implements certain provisions of the 21st Century Cures Act, advances interoperability, and supports the access, exchange, and use of electronic health information (EHI).

ACEP supports the Trump Administration's commitment to eliminating barriers that impede our ability to provide the best possible care to our patients. Emergency physicians play a critical role in our health care system, serving as the safety net in our communities. However, in general, it is challenging for us to provide comprehensive care to patients who arrive in our emergency departments (EDs) without a medical record that we can easily access. In many cases, we see patients with acute conditions who we have never seen before and may not be able to communicate due to their health condition. We deal with life and death situations and must make near-instantaneous critical decisions about how to treat our patients with limited information. Therefore, we are eager to work with hospitals toward the goal of interoperable EHRs that will open the door to more comprehensive patient information sharing across sites of care. Linking disparate EHRs will allow us to make more informed decisions and will significantly enhance timely communication with patients, community physicians, and other caregivers. To that end, we support policies that promote our ability to receive and exchange information about our patients.

ACEP believes that both this proposed rule and the companion proposed rule released by the Centers for Medicare & Medicaid Services (CMS) are steps in the right direction to reduce information barriers and improve access to data. **However, as emphasized later on in our comments, we are very concerned about the additional burden being placed on providers, from investing in and adopting new technology to**

understanding all of the new definitions and exceptions around information blocking. Furthermore, we believe that ONC and CMS did not sufficiently address some of the data and privacy concerns that come with increased sharing of EHI. Although the Office of Civil Rights (OCR) issued a request for information on HIPAA, which included questions about what changes to make to support interoperability[1], the ONC and CMS proposed rules do not propose or seek comment on any modifications. **Given the magnitude of changes encompassed in these rules, ONC and CMS should publish interim final rules rather than final rules to allow additional opportunity for stakeholder comment. We also recommend that ONC and CMS delay any disincentives and/or penalties until two years after implementation of the rule to allow all stakeholders to have time to address any unforeseen challenges.**

Finally, while we support the goal of increasing price transparency, we urge ONC and the Department of Health and Human Services (HHS) overall to think about the unique nature of emergency care before establishing any new requirements. For example, ONC and HHS must factor in laws such as the Emergency Medical Treatment and Labor Act (EMTALA) when thinking about how far in advance of care patients should reasonability expect to receive price information.

With these principles in mind, we offer the following comments on specific proposals.

Privacy and Security of Data

In the rule, ONC proposes a broad definition of EHI that can be made available on open Application Programming Interfaces (APIs). EHI includes extremely sensitive data elements that are included in a patient's medical record, and therefore, all the data need to be secured and protected appropriately. ACEP recognizes that we are entering into a whole new world in terms of data sharing and consumer access to their healthcare information and that it is even more essential now to protect that information after the initial encounter. As the ways in which information can be exchanged continue to grow, we believe that privacy and security laws need to be updated and extended to cover all possible types of data-sharing. That is why we were surprised that no changes to HIPAA were proposed even though the OCR specifically asked what modifications were needed to support efforts to prohibit information blocking in the recent Request for Information.[2]

As more and more third-party applications obtain data from open APIs, we need to think extremely carefully about how to ensure patient information is protected and that these third-parties do not engage in any deceptive practices that could potentially jeopardize the privacy and security of the data. Some third-party applications may not be covered entities under HIPAA. Therefore, they are regulated by the Federal Trade Commission (FTC), which has the authority to investigate and take action against unfair or deceptive trade practices. Even though the EHI may not be under the control of a HIPAA-covered entity, it deserves at least the same protections as it receives under HIPAA. Third-party applications can use data for a variety of purposes, and we think it will be extremely difficult for patients to truly understand what aspects of their information are being shared and with whom. In fact, some studies suggest that current applications, like Facebook and Google, share information without the individual's knowledge or informed consent.[3] As the health IT applications ecosystem continues to evolve, patients need to be provided clear guidance and information about what they agree to when signing into an application and that their personal information could be at risk. We are also concerned

[1]Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 Fed. Reg. 64305 (December 14, 2018).
[2] Ibid.
[3] Huckvale K, Torous J, Larsen ME, Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation, JAMA Netw Open. 2019;2(4):e192542. doi:10.1001/jamanetworkopen.2019.2542.

that providing patients with unfiltered data may be overwhelming and incomprehensible without the proper context and medical expertise to interpret the information. Payer data is often error-prone, and we believe that the burden may fall on the physician to identify and remedy the errors within the data patients receive through the third-party applications. Therefore, we encourage the FTC to put out strong guidance or regulations clearly articulating what are and are not acceptable uses of the data, using HIPAA privacy and security rules as a guiding benchmark. ONC should also commit to working with the FTC on that additional guidance.

We also encourage ONC to go even further to ensure that consumers are protected and that they truly understand how their data are being used. ONC should consider requiring EHR vendor's APIs to answer basic questions about how the third-party application plans to use the data. Consumers should have access to the answers on this questionnaire before using the third-party application. That way, even if the third-party application has a data use agreement that they require consumers to agree to, there will be another mandatory safeguard in place to ensure that consumers understand all the potential uses of their data once a third-party application retrieves all of it from the EHR vendor's API.

Trusted Exchange Framework and the Common Agreement (TEFCA)– Request for Information

ONC requests comment on whether health IT developers should be required to participate in the TEFCA in order to assure people that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. ACEP believes that ONC should enforce broad adherence to the TEFCA, particularly because of its strong privacy and security requirements. In the second draft of the TEFCA, ONC states "In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape."[4] This principle aligns with our previously stated request that the Administration establish strong privacy and security regulations for third-party applications, using HIPAA as a guide.

Updates to the 2015 Edition Certification Criteria

This rule proposes to update the 2015 Edition of Certified EHR Technology (CEHRT) through the removal, revision, and addition of new certification criteria. In general, ACEP is concerned about the burden associated with upgrading EHR systems to meet the new technology requirements outlined in the rule. Many providers are still in the process of adapting to their 2015 Edition CEHRT. Adding another set of requirements may be daunting—and potentially expensive, since providers may have to pay for another upgrade.

ONC proposes to establish the U.S. Core Data for Interoperability (USCDI) as the standard for interoperability. However, in both this rule and the companion CMS rule, ONC and CMS do not standardize the clinical vocabulary within the USCDI. This lack of standardization could place a burden on physician organizations to define clinical terms in a common way that would support interoperability. Clinicians will need to ensure they accurately and consistently capture all of this additional information, for fear of being classified as someone who engages in "information blocking," and possibility incurring any associated penalties.

[4] Office of the National Coordinator (ONC) for Health Information Technology, "The Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2," 19 April, 2019, https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf.

Under ONC's proposal, the USCDI would replace the Common Clinical Data Set (CCDS) definition in the 2015 Edition of CEHRT. USCDI Version 1 includes the same data classes referenced by the CCDS definition, but also includes new required data classes and data elements, including clinical notes. ACEP requests clarification regarding the "Imaging Narrative" as part of the new clinical notes data class. ONC should determine if the current category of "Laboratory" may be expanded to include all "Diagnostic Tests," as many of these tests can and are sent to another provider for completion. This may allow for better technical ways to transmit and document both the imaging orders and results – and/or allow for a link to where the results are stored outside of the primary health record.

Further, ACEP believes that imaging tests should be added to USCDI Version 1. Emergency physicians frequently evaluate patients who have had imaging completed at another facility, and information regarding prior imaging has the potential to substantially improve the safety and quality of patient care. For example, knowing that a patient with undifferentiated chest pain of potentially cardiac origin had a stress echocardiogram completed at another facility several weeks prior and was discharged could potentially reduce the likelihood of repeat testing and a costly hospitalization. While it would be ideal to *access* images and radiology reports, the inclusion of just even basic information regarding imaging orders (what test was done and when)—has tremendous potential to avoid potentially duplicative and costly imaging, as well as the patient safety risks associated with excess radiation. We feel that the inclusion of whether an imaging test was done would not add substantial burden beyond the inclusion of laboratory testing.

Overall, ACEP recognizes that the data classes and elements include in the USCDI will be updated over time. We urge ONC to establish and follow a transparent and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

Electronic Prescribing Criterion

ACEP supports ONC's proposal to remove the current 2015 CEHRT electronic prescribing (e-Rx) SCRIPT standard and replace it with an updated criterion, NCPDP SCRIPT 2017071. The revised criterion aligns with relevant CMS programs, including Part D e-prescribing requirements. In fact, NCPDP SCRIPT 2017071 becomes mandatory for Medicare Part D electronic scripts starting on January 1, 2020. We appreciate this effort by ONC to harmonize technology standards with program-specific requirements.

Health IT for the Care Continuum

In the rule, ONC seeks comment on policies that would use health IT to help address opioid use disorder (OUD) prevention and treatment. To truly help improve care for patients with OUD, ACEP believes that ONC should adopt new EHR certification criteria that require EHRs to integrate Prescription Drug Monitoring Programs (PDMPs) into their existing capabilities. In general, we support effective and interoperable PDMPs that push prescription data to emergency physicians, rather than requiring them to sign into and pull the data from the PDMP separately. Currently, not all states have optimally functional PDMPs, resulting in highly variable usability and trustworthiness. Some states have not made commitments to make their PDMPs state-of-the-art, and as a result, they are cumbersome, and may not contain real-time or reliable data. In addition, patients may cross state lines for care, and not all states are part of InterConnect, which shares interstate information about dispensed prescriptions. One approach to consider would be replacing the piecemeal state-based PDMPs with a highly functional national system, as contemplated by the National All Schedules

Prescription Electronic Reporting Act (NASPER). Finally, we believe that ONC can also take action by requiring all PDMPs to be interoperable and to include specific standards, such as privacy and security protocols that protect patient-sensitive information.

Information Blocking

The 21st Century Cures Act defines practices that constitute information blocking when conducted by a health care provider or a health information technology developer, exchange, or network. The Act also calls on the HHS Secretary to identify, through notice and comment rulemaking, "reasonable and necessary" activities that do not constitute information blocking. In this rule, ONC proposes seven reasonable and necessary activities that would qualify as exceptions to the information blocking definition. These proposed exceptions include:

1) Preventing Harm
2) Promoting the Privacy of EHI
3) Promoting the Security of EHI
4) Recovering Costs Reasonably Incurred
5) Responding to Requests that are Infeasible
6) Licensing of Interoperability Elements on Reasonable and Non-Discriminatory Terms
7) Maintaining and Improving Health IT Performance

ACEP has general comments on all the exceptions as well as specific comments on each exception.

General Comments on the Seven Exceptions

ACEP appreciates the examples ONC provides both in the rule and supporting materials that highlight how providers can qualify for these exceptions, but believes that ONC needs to produce even more educational materials and sub-regulatory guidance that attempt to explain the exceptions using real-world examples. Understanding how the information-blocking provisions will affect providers in their daily practice will prove to be extremely complicated. Each exception or information blocking claim will be reviewed subjectively and based on the facts and circumstances of each case. It will be extremely burdensome to make sure physicians are covering all of their bases to defend themselves in any type of information blocking claim against them. Not only are the information blocking provisions and exceptions complicated in and of themselves, but the provisions also overlap with existing HIPAA regulations, and it will be unclear what information a clinician is permitted versus required to share to receive an exception. For example, a requirement to exchange all EHI with any requestor for nearly any purpose may force physicians to compromise the "minimum necessary" standard in HIPAA. ACEP supports maintaining HIPAA's minimum necessary standard, which generally requires physicians to share the minimum amount of information necessary to accomplish the intended purpose of the disclosure.

For those clinicians who do not understand the complexity of the information blocking provisions and how they intersect with longstanding HIPAA regulations, they will inevitably lean towards not sharing the information or oversharing. In all, ONC should simplify the information-blocking exception requirements, and not set up a system that could potentially penalize clinicians who are using their best clinical judgment and acting in good faith to protect their patients' rights to privacy. ONC should also remove the burdensome requirements for physicians to document their decision-making associated with qualifying for information blocking exceptions or sub-exceptions.

Specific Comments on the Seven Exceptions

Preventing Harm

ACEP agrees with how ONC defines "harm" in this exception. The definition includes corrupt or inaccurate data being recorded or incorporated into a patient's EHR, as well as the misidentification of a patient's EHI. However, as described below in our general comments, we are concerned about the burden of proof that would fall on providers who want to use this exception. There could be a lot of borderline situations where it may or may not be appropriate to use this exception. ONC even states that some known inaccuracies in data may not be sufficient justification to withhold the entire electronic record. Therefore, understanding when it would be permissible to pursue this exception would be merely a judgement call for different actors. If ONC decides to finalize the exception, we recommend that ONC issue sub-regulatory guidance to clarify when it is appropriate to use this exception and when actors have sufficient grounds to withhold EHI.

Promoting the Privacy of EHI

While ACEP supports the goal of protecting the privacy of EHI, we are concerned by the complexity of this exception and the ability for providers to fully understand and meet all of its requirements and preconditions (sub-exceptions). The exception and sub-exceptions assume that stakeholders understand all the nuances of HIPAA. HIPAA is tremendously complex, and in many cases, covered entities are afraid to release any information out of fear of breaching data, violating HIPAA, and receiving a penalty. This exception will only add to their confusion.

On top of that, HIPAA represents a floor in terms of legal requirements. States are allowed to impose stricter laws and regulations governing privacy and security. Other regulations, such as 42 CFR Part 2 also need to be considered. HHS is in the process of updating 42 CFR Part 2 regulations. Accordingly, we suggest waiting until this rulemaking has been completed and 42 CFR Part 2 has been updated to comply with HIPAA prior to moving forward with workarounds and carveouts. Not only would systems likely require an update, but this would add extensive administrative burden.

With respect to 42 CFR Part 2, we note that there is an exception built in for emergency services, which allows information to be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained. This is another policy that emergency physicians have to factor in as they try to piece together and understand all the different data privacy and security laws and regulations.

If ONC decides to finalize this exception as written, the office needs to work with OCR on effective educational materials that will help health care providers and other covered entities understand what is and is not permissible under federal and state privacy laws.

Promoting Security of EHI

As with the proposed exception to promote the privacy of EHI, ACEP supports ONC's efforts to promote the security of EHI. However, we would like to reiterate our above comments related to HIPAA and other

privacy and security laws and regulations. We remain concerned that EHR vendors and others will use the safeguarding of information as an excuse not to share data out of fear of violating HIPAA.

Proposed Exception: Recovering Costs Reasonable Incurred

ACEP supports ONC's proposal to limit an actor's ability to charge fees to the recovery of costs reasonably incurred to provide access, exchange, or use of EHI based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. We believe that unreasonably high fees charged by EHR vendors are a major impediment to the exchange of information between EHRs and providers. We further support ONC's efforts to prohibit the charging of fees based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor. We are concerned, however, that EHR vendors may attempt to use this proposed exception as a loophole to continue to charge unreasonably high fees.

Responding to Requests that are Infeasible

Under this proposed exception, an actor could state that he/she is unable to provide access, exchange, or use of EHI because the request is infeasible. We appreciate that some requests for EHI could impose a substantial burden on actors, and therefore agree with this exception. However, ONC, when finalizing the exception, should consider how to treat these exceptions in emergencies. Emergency physicians provide care twenty-four hours a day, seven days a week, and 365 days a year in EDs across the country. We understand that it would be unreasonable to expect to receive information on a patient at 1 AM on a Sunday from a non-ED provider. However, at the same time, we must consider the consequences of not giving that treating emergency physician the information he or she needs as soon as possible to provide the best possible care to the patient.

Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

ACEP supports ONC's proposal to require actors to negotiate with requestors in a reasonable and non-discriminatory fashion to identify any interoperability elements that are needed and offer an appropriate license with reasonable and non-discriminatory terms. However, we are concerned that the ability to charge reasonable royalties to license interoperability elements may present an opening for EHR vendors to charge unreasonably high fees for exchanging information with provider groups. As a result, we urge ONC to require actors to disclose the methodology behind their fees.

Maintaining and Improving Health IT Performance

ACEP supports an actor's ability to make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the practice is for a period of time no longer than necessary and implemented in a consistent and non-discriminatory manner. ACEP urges ONC to require that, if feasible, actors provide advance notice that health IT will be temporarily unavailable in order to perform maintenance or improvements.

Enforcement

The 21st Century Cures Act gives the HHS Office of Inspector General (OIG) the responsibility of investigating claims of information blocking and establishes referral processes to facilitate coordination with other relevant

agencies, including ONC, OCR, and the FTC. ACEP understands that ONC and OIG may coordinate their respective enforcement activities, as appropriate, by sharing information about claims or suggestions of possible information blocking or false attestations. However, with multiple agencies having some enforcement authority, there are going to be turf disputes and differences in interpretation. Therefore, ACEP urges ONC to more specifically address how it plans to coordinate with the OIG to enforce the information blocking provisions of the Cures Act. We also request that ONC clarify the circumstances under which ONC will coordinate its review of a claim of information blocking with the OIG versus deferring to the OIG to lead a review of such a claim.

Disincentives for Health Care Providers – Request for Information

ONC requests information on different disincentives for information blocking and if modifying disincentives already available under existing HHS programs and regulations would serve as more effective deterrents. The proposed rule specifically notes that, per the 21st Century Cures Act, duplicative penalty structures related to information blocking should not be imposed on providers. ACEP notes that the Promoting Interoperability (PI) category of the Merit-based Incentive Payment System (MIPS) already includes a requirement that clinicians attest to three statements around information blocking. If such an attestation does not occur, then the clinician will not be successful in this category and receive points—increasing the chances that he or she receives a downward payment adjustment (i.e. a penalty) under MIPS. Thus, it appears that most clinicians already have a disincentive for not engaging in information blocking. **Given the language in the Cures Act around not duplicating penalties, we believe that ONC should not institute additional penalties.**

Networks and Exchanges

The 21st Century Cures Act defines practices that constitute information blocking when conducted by a health care provider, a health information technology developer, or health information exchange or network. Since these terms are not specified in statute, ONC proposes definitions in the proposed rule. ONC defines a Health Information Exchange (HIE) as an individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes. In addition, ONC specifically states, "For example, an HIE might facilitate or enable the access, exchange, or use of EHI exclusively within a regional area (such as a RHIO), or for a limited scope of participants and purposes (such as a ***clinical data registry*** [emphasis included] or an exchange established by a hospital-physician organization to facilitate Admission, Discharge, and Transfer (ADT) alerting)."[5]

We believe that it is inappropriate to include clinical data registries in the definition of HIEs because registries serve a fundamentally different purpose from these other entities. While HIEs are primarily just facilitators of information exchange between a number of providers and organizations, clinical data registries serve to collect and analyze data to identify best practices and improve patient care. Furthermore, as a medical association that owns and operates a clinical data registry, we are extremely concerned about the unintended consequences of including clinical data registries in the definition of a health information exchange. While we are committed not to engage in data blocking, under the proposed rule, registries would be held to a much higher standard than health care providers. As alluded to above, under the law and this proposed rule, health care providers are subject to "disincentives" if they have engaged in data blocking. However, HIEs may be subject to civil monetary penalties of up to $1 million. Thus, if ONC finalizes this definition, clinical data registries owned and operated by medical associations such as ours would be at risk for exorbitantly high fines. Even the potential

[5] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, 84 Fed. Reg. 7513 (March 4, 2019).

for receiving a fine that large may make some registry owners decide to terminate their registries. **We, therefore, urge ONC not to finalize the definition of HIE as proposed and to explicitly remove clinical data registries from the definition in the final rule.**

Price Transparency

Overview

ONC seeks comment on the implications of including price information within the scope of EHI for purposes of information blocking. In addition, HHS overall is seeking comments on the "technical operational, legal, cultural, environmental and other challenges to creating price transparency within healthcare."[6]

Before responding to some of the specific questions and concepts that ONC and HHS more broadly raise, ACEP would like to point out some factors and principles of transparency that are unique to emergency medicine. Like you, we strongly believe that a patient's concern should be focused on receiving the appropriate care, rather than choosing their care based on cost. In the ED, minutes and seconds matter and emergency physicians are often required to exercise their best clinical judgment quickly. Patients who have life-threatening illnesses and injuries obviously cannot shop around for the "lowest cost" provider.

Furthermore, in delivering acute care, knowing what patients' total out-of-pocket costs will be before they are diagnosed and stabilized is nearly impossible until a proper course of medical care and progression is followed. A large proportion of emergency care involves the acute diagnosis, treatment, and stabilization of diffuse and undifferentiated clinical conditions. For example, two of the most common patient presentations are "chest pain" and "abdominal pain." These initial symptoms have a large range of ultimate diagnoses and require a large variety of patient-specific lab tests, radiology exams, and other interventions. This is very different from being able to figure out total costs for an urgent care patient with a small, clean, superficial laceration or a sore throat. Further complicating the issue is the fact that emergency care is billed in two separate components, the facility fee, and the professional fee. Therefore, patients must sort through costs included in at least two different bills, each of which may have different cost-sharing obligations associated with it.

The Emergency Medical Treatment and Labor Act (EMTALA)

Another major factor that affects price transparency for emergency care is EMTALA. This cornerstone law guarantees access to emergency medical care for everyone, regardless of insurance status or ability to pay. The requirements of EMTALA are mandatory and are unaffected by in-network or out-of-network insurance status or payment considerations. EMTALA stipulates that a hospital may not place any signs in the ED regarding the prepayment of fees or payment of co-pays and deductibles which can have the chilling effect of dissuading patients from "coming to the emergency department." To do so could lead patients to leave prior to receiving a medical screening examination and stabilizing treatment without regard to financial means or insurance status, which is a fundamental condition for satisfying EMTALA, and one of the most foundational principles of important patient protection that was enacted three decades ago. If we attempt to provide pricing information to patients prior to stabilizing them, not only would that be an EMTALA violation, but it could also potentially cause the patient's health to deteriorate since it could delay the patient from receiving critical care. The last

[6] 84 Fed. Reg. 7514 (March 4, 2019).

thing we want to do is put our patients in a position of making life-or-death health care decisions based on costs.

Once again, we appreciate your focus on improving price transparency for the benefit of our patients. Please find our comments on the specific concepts raised below.

Patients' Right to Price Information within a "Reasonable" Time in Advance of Care

ONC asks a series of questions about how to define "reasonable" when thinking about how far in advance of care patients should reasonability have a right to receive price information. In the context of emergency care, ONC asks how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization.

As highlighted above, EMTALA forbids hospitals from posting any signs in hospital EDs regarding payment and does not allow physicians or other medical or administrative staff from discussing fees or payment of co-pays and deductibles prior to stabilization. ACEP believes that insurers should provide information to consumers about the potential costs of seeking care under their particular coverage. Providers can participate by helping patients interpret their cost-sharing responsibilities (of note not during the emergency but rather at a non-emergent time such as upon purchase of a policy), but the onus should be on insurers to make these costs transparent to patients. We believe that patients today truly do not understand their "high deductible" health plans, and there is a dearth of information on "co-insurance," "deductibles," and "co-pays."

While providers and hospitals may be able to provide raw pricing information upfront to patients, without accompanying information from insurers concerning the manner and methodology the insurer has utilized to adjudicate the patient's benefits; little can be achieved in the form of true transparency. This information from insurers is an essential component of transparency. Further, knowing that an insurer paid a member benefit 'at the usual and customary benefit level consistent with the member/patient's plan benefits' is not acceptable. Rather, the insurer must define in specific terms and plain English the manner and methodology utilized by the insurer to adjudicate the patient's plan benefits, notwithstanding an assertion by the insurer that the information is proprietary or confidential—which, more often than not, is an all too frequent insurer response. This often provides the patient with a cryptic response and a limited understanding of what they're ultimately responsible for. Therefore, placing this responsibility exclusively on the shoulders of the hospital, physician, or patient is unfair and of little use in satisfying the objective of CMS' present request for true transparency.

With respect to acute unscheduled emergency care, patients have the right to know from their insurers in advance if the physician treating them is in-network and, as required by the Affordable Care Act, should pay the same cost-sharing if they receive care from an out-of-network clinician that they would have paid to an in-network physician. Insurers must meet appropriate network adequacy standards that include adequate patient access to care, including access to hospital-based physician specialties.

ACEP also has some suggestions of actions private plans can take to increase transparency. First, we believe that insurers should more clearly convey beneficiary plan details, such as printing the deductible on each insurance card. This can help patients understand the limits of their insurance coverage and reduce the surprise when they later get a bill. Second, as stated above, insurers should explain a patient's rights related to emergency care in plain, easy-to-understand clear language.

Information Useful to Reduce or Prevent Surprise Billing

If price information is eventually included in EHI, ONC asks whether that information would be useful in subsequent rulemaking that the Department may consider in order to reduce or prevent surprise medical billing, such as requirements relating to:

- The provision of a single bill that includes all health care providers involved in a health care service, including their network status;
- The provision of a binding quote reasonably in advance of scheduled care (that is, non-emergent care) or some subset of scheduled care, such as for the most "shoppable" services;
- Ensuring that all health care providers in an in-network facility charge the in-network rate; and
- Notification of billing policies such as timely invoice dates for all providers and facilities, notwithstanding network status, the due date for invoice payments by the prospective patient's payers and out-of-pocket obligations, date when unpaid balances are referred for collections, and appeals rights and procedures for patients wishing to contest an invoice.

ACEP believes that more must be done to protect patients and their families from unexpected high medical bills and provide greater stability and transparency in these encounters. That is why ACEP released a proactive *Framework for Protecting Patients When Emergency Care is Out-of-Network*[7] in January 2019 that lays out a proposed federal approach for addressing surprise billing for emergency patients. As part of our framework, we suggest a number of ways to expand patient protections in order to truly take patients out of the middle of billing disputes between payers and providers. We believe insurers should be required to pay all cost-sharing for emergency care directly to the provider. Insurers can then collect back these amounts from the patient. This ensures patients only have a single point of contact for emergency medical billing and payment and will no longer receive and have to reconcile multiple, confusing bills and explanation of benefits (EOBs) that result from the many providers that are often involved in a single emergency episode.

Provision of a Single Bill

ACEP **strongly opposes** requiring health care services to be included in a single bill, which could involve bundling payments together for all health providers involved in an emergency episode and relying on hospitals to appropriately distribute them. While the Center for Medicare & Medicaid Innovation (CMMI) has tested bundled payments for certain common conditions with predictable treatment protocols and outcomes such as hip and knee replacements under the Bundled Payment for Care Improvement (BPCI) Advanced Initiative, it would be extremely difficult for insurers to develop an accurate bundled payment for unscheduled and unpredictable emergency care episodes. As discussed above, many people come to the ED with acute, undifferentiated conditions that may necessitate a broad range of services, tests, and procedures conducted by a range of providers. Patients could also wind up receiving care at other parts of a hospital or end up being transferred to another facility. Thus, it would be almost impossible in some cases to determine which services should be included in the episode. Developing a system to sort this out would be extremely complex. It would represent another administrative cost to insurers, hospitals, and providers and could, in fact, lead to higher overall health care prices. Hospitals in rural areas could be especially hard hit, as they already have difficulty ensuring adequate staffing of EDs.

[7] ACEP's Framework is available at: https://acep.org/globalassets/new-pdfs/advocacy/acep-framework-for-addressing-oon-emergency-care.pdf.

Furthermore, the idea that a bundling model would reduce costs to the system relies on the presumption that somehow hospitals will be more effective at negotiating a contract with physician staffing groups than the insurers have been, to date. Adding in the complexity these new contracts between hospitals and physician groups would entail (given the need to define the episodes as we describe above), we will likely see such an administrative burden and disruption to all impacted parties that there could have potentially catastrophic consequences.

Charging the In-Network Rate

ACEP also has concerns with a potential requirement to have all health care providers in an in-network facility (i.e., a hospital) charge the in-network rate. The majority of emergency physicians would prefer to practice in-network and ensure that patients are not subject to gaps in their insurance coverage that could lead to unexpected bills and high out-of-network rates. However, the current environment leaves both emergency physicians and their patients subject to the practices of insurance companies, which we believe in some instances, have been inappropriate and interfered with patient access to care. A 2016 survey of physicians in Texas by the Texas Medical Association found among physicians who approached a plan in an attempt to join its network, 35 percent received no response from the plan—this was an increase of 6 percentage points from a survey in 2014, and a 13-point increase from 2012.[8] Furthermore, insurance companies have incredible market power, and therefore, leverage over provider negotiations. In fact, according to the Kaiser Family Foundation, the top three insurers in the large group market had a market share of at least 80 percent in 43 states in 2017.[9]

Beyond the sheer market power of insurers, due to EMTALA, these companies recognize that their policyholders can access emergency care regardless of insurance status or ability to pay, and therefore have no real incentive to enter into fair contracts with emergency physicians beyond what poorly defined or enforced state network adequacy requirements might exist. These companies must be held accountable to negotiate and establish reasonable in-network agreements with hospitals and hospital-based providers.

Requiring all health care providers in an in-network hospital to charge the in-network rate would also distort the contracting dynamic between emergency physician groups and insurers. It would completely remove the physician group's ability to negotiate a contract, as the insurer would know the hospital is requiring then contract and would, therefore, offer only the most unfavorable terms. Please consider the following example:

An emergency physician group practice for which 30 percent of their patients have private insurance, is negotiating with a health plan that accounts for 10 percent of their commercial volume and is in-network with their hospital(s). Upon the next renewal of their network agreement, if the practice doesn't accept the plan's rate offer, they would be forced to leave the hospital(s) and lose 100 percent of their volume due to a rate dispute affecting just 3 percent of their patients (30 percent commercial mix multiplied by 10 percent plan share). Thus, in this scenario, one commercial contract negotiation has a substantial asymmetric downside for the practice.

In addition, this potential requirement would be difficult to operationalize, especially from a timing perspective. Hospital contracts with insurers can be multi-year, so there would too often be scenarios where the hospital

[8] Texas Medical Association, "Survey of Texas Physician 2016: Research Findings," available at: https://www.texmed.org/uploadedFiles/Current/2016_Advocacy/2016_Physician_Survey_Findings.pdf
[9] Kaiser Family Foundation, "Market Share and Enrollment of Largest Three Insurers- Large Group Market," available at: https://www.kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-large-group-market.

has dropped or changed a contract with a particular insurer, yet the physician group contract with that same insurer would not yet have expired, or vice-versa. As well, with consolidation in the health care sector continuing to grow, contracts on either end of the hospital or physician side could be additionally disrupted and go further out of sync.

Registries Request for Information

ONC seeks comment on how the proposals throughout the rule can aid the exchange of EHI between EHRs and clinical data registries for a wide range of public health, quality reporting, and clinical quality improvement initiatives. ACEP appreciates ONC's attention to exploring multiple approaches to advancing the ability of EHRs to exchange data with registries. Access to patient information from EHRs is crucial for registries to achieve their mission of improving quality of care through the collection, analysis, and benchmarking of data on health care diagnoses, treatments, and outcomes. The free flow of data between registries and EHR vendors is also critical to reducing the administrative burden for clinicians and to ensuring the success of payment for performance under MIPS.

We believe that more needs to be done to further the exchange of EHI to improve interoperability, usability, and reduce burden. We need a set of minimum standards for certification and uniform API conventions for accessing standard information. Further, as emergency physicians working in hospitals, we should have access to all the patient's data from the hospital's EHR. However, in many cases, this does not occur. For example, a large number of emergency physicians and groups that use ACEP's clinical data registry, the Clinical Emergency Data Registry (CEDR), to report quality measures are unable to receive any data from their hospitals. Data from hospitals could include critical information such as medications, labs, and other test results for patients. Without these data elements, the measures cannot be fully calculated and scored. Hospitals claim that they cannot share the data for privacy and security purposes, but CMS has indicated that there are no regulations that impede hospitals from doing so. Since this is a serious issue for hospital-based clinicians, we encourage both ONC and CMS to come up with potential solutions to help improve the flow of information between hospital EHRs and registries.

Policies to Improve Patient Matching

Both CMS and ONC are seeking comment on how to improve patient identification to help enhance patient safety efforts, coordinate care, and advance interoperability. As emergency physicians, we recognize the critical importance of being able to quickly identify our patients and track them across different health care settings. When it comes to treating patients with acute medical needs, minutes and even seconds matter, therefore, the inability to know who our patients are, and what other services they may have previously received, really impacts our ability to provide the best possible care. To underscore the problem, in 2016, Harris Health System in Houston reported it had 2,488 records with the name "Maria Garcia;" of those, 231 shared the same birthdate, suggesting some of them refer to the same individual.[10] Notably, if all health care organizations collected certain pieces of demographic data uniformly, patient-match rates would increase significantly.

Therefore, in general ACEP supports efforts to create a patient identifier or tracking system. We are cognizant however about privacy and security concerns around creating a patient identifier. An identifier could become

[10] Giuseppe Lippi et al., "Patient and Sample Identification: Out of the Maze?" Journal of Medical Biochemistry 36 (2017): 1-6, http://dx.doi. org/10.1515/jomb-2017-0003; Harris Health System, "Harris County Hospital District Puts Patient Safety in the Palm of Your Hand" (April 5, 2011), https://www.harrishealth.org/en/news/pages/patient-safety-biometric-palm-scanner.aspx.

as sensitive as a person's social security number, so creating safeguards to protect it is essential. Further, if the patient identifier is based on a patient's date of birth, former address, or any other background piece of information about the patient, even that has its potential issues. Some patients, especially those who have suffered a trauma, may not know or be able to easily recall this information, which could lead to confusion and potential medical errors.

In addition, we ask ONC to consider the concept of an "error reporting registry" to track patient mismatches and common mistakes that may or may not be HIPAA violations. This registry could help inform further process improvements and necessary updates to both the API and provider processes pertaining to patient record matching. A simple, straightforward way for providers and patients to report instances of information blocking under any variety of circumstances, including faxing, would be of great benefit, particularly to smaller providers.

Beyond patient identification, the number of administrative roadblocks that currently exist to get information about our patients is equally as concerning. We often see patients who have received care from another ED, hospital, or provider, sometimes the same day. When a patient comes to the ED, emergency physicians can rarely see any of the information from the previous healthcare encounter. When we reach out to the other ED, hospital, or provider to ask what happened to avoid duplication of workup and make sure nothing is being missed, we are referred to a medical records office instead of the treating provider and are told that we need to have the patient sign a consent form for release of information and that they cannot be given information over the phone. When health care providers have the opportunity to talk directly to each other, they almost always share all the relevant information that is necessary to treat individual patients. Breaking down the barriers that inhibit or delay these types of conversations from taking place could improve clinical workflow and our ability to provide effective patient care, while still preserving patient privacy and data security.

Incongruent Implementation Timelines

Due to the complexity of the ONC and CMS proposed rules, there are a number of overlapping timelines that are not fully aligned and do not seem entirely feasible. For example, the CMS proposed rule has more aggressive timelines for API deployment than the ONC proposed rule (proposals to require some plans to support the functionality by January 2020 – other plans by July 2020). These compressed timeframes could result in problems in software being deployed that is not up to the right standards – and could have implications on patient care. Additionally, the information blocking provisions within both proposed rules will go into effect before the technology upgrades to facilitate information exchange are required and safely implemented. **In all, ACEP recommends that ONC and CMS align the timelines in the final rules while giving all stakeholders sufficient time for implementation. As stated earlier in our letter, we also urge ONC and CMS to publish interim final rules rather than final rules to allow additional opportunity for stakeholder comment.**

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

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