June 3, 2019

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Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Don Rucker, MD
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Department of Health and Human Services
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***Subject: CMS–9115–P; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers; Proposed Rule; and RIN 0955–AA01; 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; Proposed Rule; Federal Register (Vol. 84, No. 42), March 4, 2019***

Dear Ms. Verma and Dr. Rucker:

On behalf of our more than 200 member hospitals and health systems, the Florida Hospital Association (FHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) proposed rules to advance interoperability of health information. While the proposed rules were issued separately, the policies in each are very much intertwined, and FHA has prepared comments for the consideration of both agencies.

FHA shares the ONC and CMS goals of improved interoperability and patient access to health information. We believe the proposed rules represent an important step in achieving the interoperable exchange of health information across the entire health care system. In Florida, hospitals and health systems, clinicians, health plans, and health information exchange (HIE) networks are working together to support the exchange of health information across the state. In order to further strengthen CMS's and ONC's proposals and to better support the interoperability intent of these rules, there is a vital need to thoughtfully sequence the various components and proposals so that vendors and providers have adequate time for development, greater upfront emphasis is placed on building provider capacity to utilize the data received, and to ensure adequate outreach and education initiatives are provided to both providers and patients. It is imperative that policymakers and stakeholders exercise caution to avoid unintended consequences that could arise if implementation of such policies is not thoughtful and appropriately timed.

In general, FHA supports CMS's and ONC's efforts to make changes that support the standardization and transmission of health information. However, we raise a number of concerns for the consideration of the agencies to ensure that implementation of proposed policies do not create additional regulatory burden in the health care system, contrary to the administration's goals to reduce regulatory burden on hospitals. Our comments will focus on the following areas:

- Implementation timeframes and the need to allow the necessary time to advance the exchange of health information and the development of application programming interfaces (APIs) without creating unintended consequences or added burden;
- CMS's proposed revision to the Medicare and Medicaid hospital Conditions of Participation (CoP) to require electronic patient event notifications related to admission, discharge and transfer (ADT);
- ONC's proposed definition of electronic health information (EHI); and
- The inclusion of payment and price information within the definition of EHI.

***FHA Comments on CMS–9115–P; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers; Proposed Rule***

**MEDICARE AND MEDICAID HOSPITAL CONDITIONS OF PARTICIPATION**

CMS proposes to revise the Medicare and Medicaid Conditions of Participation (CoPs) to include a provision that would require hospitals – including short-term acute, long-term care, rehabilitation, psychiatric, children's, cancer, and critical access hospitals – that possess electronic health record (EHR) systems with the capacity to generate electronic patient event notifications to do so at the time of an inpatient's admission, discharge and transfer (ADT) to another facility or community provider. Hospitals would have to convey, at a minimum, the patient's basic personal or demographic information, as well as the name of the sending institution, treating practitioner's name, and, if not prohibited by other applicable law, the diagnosis. The proposed CoP would require the hospital to send ADT notifications "to licensed and qualified practitioners, other patient care team members, and PAC service providers and suppliers who: (1) receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital has a reasonable certainty of receipt of notifications."

While the FHA understands the intent of the proposal related to patient event notification, we have significant concerns regarding providers' ability to meet these requirements. If finalized, standard electronic patient event notification would require providers to have EHR systems with the ability to connect. If all providers were to utilize a standard EHR, this proposal would be possible. However, for providers that utilize different EHRs, the seamless exchange of information suggested by CMS would be technically and administratively burdensome.

While we agree that much of what CMS aims to accomplish can happen, we must underscore the significance of making this a CoP as a provider's entire Medicare reimbursement would be at

risk. In addition to a lack of a certification standard to support event notification, providers should not be faced with such risk until the following implementation challenges and questions are addressed through future rule making:

- *Admission*: CMS calls for providers, upon admission, to send alerts to other clinicians/providers with whom the patient has an established relationship. Many of our members' patients, however, do not have a primary care provider, and the proposed rule does not adequately address this situation.

- *Patient matching and safety issues*: Our members are concerned about CMS's request that providers only send a few pieces of data, which we feel is insufficient to match patients. Within each data segment, there are hundreds of pieces of data that can be sent. With CMS requesting only a few data points, we have serious concerns about the ability to match patients on the receiving end. For example, if the only data points are the patient's name, diagnosis, name of treating provider and sending institution. there will be challenges matching patients correctly.

  In the absence of access to an HIE that facilitates exchange with the range of providers with whom a patient might have an established care relationship, hospitals would be required to dedicate significant resources outside their EHI technology to identify and match a patient with appropriate providers in the patient's care team, as well as determine how and where to send the information and whether the provider "has a reasonable certainty" of receiving the notification.

  Part of this burden relates to the long-standing challenges in patient matching. Due to the lack of a standardized patient identifier, hospitals could experience major challenges in transferring health information in addition to common patient identification and matching issues. Patient matching issues most acutely impact medically indigent and homeless patients, who often do not have a primary care provider and may not have a permanent address. Until we have resolved the patient matching issue from a policy perspective, hospitals must choose between complying with federal requirements and exposing themselves to risk of penalty under state and federal law for a privacy breach if protected health information is inadvertently sent to the wrong place or provider.

- *Compliance burdens*: CMS believes this proposal would impose minimal additional costs on hospitals and the cost would largely be limited to the one-time cost for initial implementation of the notification system, to revision of policies and procedures as they relate to discharge planning, and for communicating these changes to affected staff. We believe CMS has significantly underestimated the complexity of meeting this mandate, and we do not agree with the agency's estimation that this should require little effort and be a one-time cost.

- *Identifying receiving providers/clinicians*: CMS says a hospital would only need to send notifications to those practitioners for whom the hospital has reasonable certainty of receipt of notifications. Again, while we appreciate the intention behind this, it would

seem nearly impossible for providers to identify which providers need to receive alerts without some sort of system or registry in place that correctly identifies the patient's primary care provider.

The proposal's broad scope of recipients would place a significant burden on hospitals to determine the appropriate recipients for each individual patient, particularly hospitals unable to participate by using HIE ADT notifications. CMS states that it believes this proposal will allow hospitals to use a diverse set of strategies when implementing patient event notifications and proposes to require that the notifications be sent directly by the hospital or through an intermediary that facilitates HIE. When ADT notifications are sent through an HIE, care coordination and management can be improved by easily automating messages to recipients that are identified on the HIE. In many counties across the country, particularly those that are very rural, there is no HIE to which a hospital can connect. For these hospitals, the proposal to directly send ADT notifications is particularly problematic and could put these uniquely challenged providers disproportionately at risk for decertification, a far greater penalty than the penalties under current programs that facilitate HIE.

- *Diagnosis*: CMS requires that diagnosis be included in the information shared. However, often this information is not available upon admission. For most of our members the final diagnosis is not present until after discharge. Receiving providers must understand hospitals are sending a presenting symptom, however it is not considered a true diagnosis. In any subsequent rules, clarity is needed on the requirement to provide a diagnosis at the time of admission.

Finally, the use of such notifications may evolve naturally as health information exchange technology evolves. Alternatively, CMS might consider using the Promoting Interoperability Program (PIP) and the Trusted Exchange Framework and Common Agreement (TEFCA) to advance this type of EHI exchange in lieu of using a CoP to require ADT notifications.

For these reasons, the FHA does not support the proposal to make ADT notification a CoP. While we consider this an inappropriate policy level, we do support ADT as a meaningful use measure and a key step in moving forward with promoting interoperability.

**API REQUIREMENTS FOR HEALTH PLANS AND PAYERS**

The 21s Century Cures Act requires that patients be able to access their information via APIs "without special effort." CMS proposes to require that public health plans make patient health information available electronically through a standardized, open API, which will allow third-party applications to electronically access the information. Specifically, the requirement would apply to Medicare Advantage (MA) organizations, Medicaid state agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers in federally facilitated exchanges (FFEs). The information made available through an API would have to include patient claims and encounter data, provider directory data, clinical data (including lab data) held by the organization, as well as drug benefit data, including pharmacy directory and formulary data. CMS proposes to make these requirements effective in 2020 – January 1, 2020, for MA and QHP plans, and July 1, 2020, for Medicaid and CHIP plans. FHA

supports this proposal and believes it will empower patients with more information about their care. However, we urge CMS to reconsider its timelines for implementation. Plans and developers alike have suggested implementation by 2020 would not just be difficult, but impossible, due to operational and technical challenges in standardizing API technology.

Most importantly, FHA urges CMS to consider taking steps to address privacy concerns prior to requiring the release of protected health information to third-party applications. Since the passage of HIPAA in 1996, patients have understood that their health information will be kept confidential. However, commercial application companies generally are not HIPAA-covered entities. Therefore, when information flows from a hospital's or health plan's information system to a third-party application, it would likely no longer be protected by HIPAA. Most individuals will not be aware of this change and may be surprised when commercial application companies share health information obtained from a hospital or health plan, such as diagnoses, medications, or test results, in ways that are not allowed by HIPAA. Furthermore, individuals may consider the hospital or health plan to be responsible if their data are sold to a third party and used for marketing or other purposes.

Due to the concerns outlined, CMS should delay its proposal for several years to work with affected stakeholders and ensure accurate API feeds between health plans and the public. In addition, we believe that CMS needs to develop a program through which all APIs would be certified. This would reduce providers' burden and liability when contracting with such an application. CMS may also consider developing an additional safe harbor for providers in relation to sharing patient data with an API. Apps that clear this certification process would be deemed eligible to connect with providers via an API. If an app didn't pass or seek certification, then a provider would not be required to connect. This would provide more assurance to providers and patients that the app was operating in good faith and adhering to a standard set of principles and would also limit the potential accusation that providers are information blocking.

***FHA Comments on RIN 0955–AA01; 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; Proposed Rule***

**INFORMATION BLOCKING**

The 21st Century Cures Act represented a major shift in the health information sharing framework. While Florida hospitals are committed to sharing health information that leads to more informed patients and higher-value, efficient, coordinated care, we are concerned that the proposed information blocking provisions will add significant regulatory burden. This is contrary to the administration's goals to reduce burden on health care providers. We urge the agency to consider a significant period of non-enforcement as health care entities are educated about and develop compliance procedures and policies on the new requirements. Our comments are as follows:

*Definition of Electronic Health Information*

ONC proposes to define EHI to mean electronic protected health information (ePHI) within the meaning of HIPAA. ONC would further expand the EHI definition to include any other information that is transmitted by or maintained in electronic media, identifies an individual (or with respect to which there is a reasonable basis to believe the information can be used to

identify the individual), and relates to (i) the past, present or future health condition of an individual; (ii) the provision of health care to an individual; or (iii) *the past, present or future payment* for the provision of health care to an individual. FHA is concerned that this expansive definition of EHI goes beyond Congress' intended scope of information required to be shared and conflicts with the permissive use provisions of HIPAA.

Providers should not be faced with reviewing a significant quantity of information about a patient's history that is not relevant to the treatment of the patient's present condition. With respect to health care providers furnishing clinical care to patients, often on an urgent or emergency basis, the intent of Section 3022 is to make available the pertinent information expeditiously. Thus, the definition of EHI is intended to focus on a narrow set of data that will help providers provide the best clinical care to patients.

Health care providers focus on the clinical care of their patients and getting access to the relevant patient health information to make the best treatment decisions for each patient is paramount. Health care providers are also constantly seeking to improve how they deliver care to improve patient outcomes and increase efficiency. The 21st Century Cures Act provides a host of policies intended to achieve that result. Matters related to past, present or future payment information, as proposed to be included in the definition of EHI, are not relevant to any of those goals.

The definition of EHI should not be so expansive as to include "any other information that is transmitted by or maintained in electronic media." We do not believe that it is technically possible – without substantial regulatory and resource burdens – to provide all information maintained in electronic media. Because hospitals and health systems often have multiple electronic systems for billing and clinical information among different departments, it is unclear whether their systems could even handle an export of all information transmitted or maintained in electronic media. In effect the proposed rule would require all disparate information to be compiled in a single electronic record, which could jeopardize the health IT infrastructure of a hospital, health system, or other health care provider.

The 21st Century Cures Act represented a major shift in the health information sharing framework. The basic principle of HIPAA was in defining and limiting the circumstances in which an individual's protected heath information may be used or disclosed by covered entities. Under HIPAA, the only required disclosures of information are granted to individuals (or their personal representatives) specifically when they request access to, or an accounting of disclosures of, their protected health information, and to HHS when it is undertaking a compliance investigation or review or enforcement action.

Conversely, the 21st Century Cures Act prohibits health care providers, health IT developers, networks and exchanges from engaging in information blocking, defined by the statute as "a practice by a health care provider, health IT developer, health information exchange, or health information network, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent or materially discourage access, exchange, or use of electronic health information." FHA is concerned that any time a hospital declines to provide access to a patient's information – in the exercise of professional judgment standard established under HIPAA – it will be accused of information blocking. FHA urges the agency to

align its proposals for the disclosure of EHI with the policies currently established under the HIPAA regulation for mandatory and permissive disclosures by health care providers.

*Request for Comments on Price Information*
ONC states that its expansive definition of EHI could include information on an individual's health insurance eligibility and benefits, billing for health care services, and payment information for services to be provided or already provided, which may include price information. ONC does not define the term price information in the proposed rule but notes that it has a "unique role" in possibly establishing a framework to prevent the blocking of price information.

Despite the agency's views to the contrary, nothing in the language of Section 3022 of the Public Health Service Act or the legislative history of the 21st Century Cures Act gives rise to any implication that Congress intended EHI to include price information. The goals of the Act's health IT provisions were focused on improving the efficacy of health IT to assist in patient clinical care. Had Congress intended to establish a policy that ONC should also include price information as part of the information blocking provisions of Section 3022, it would have had to do so directly. When Congress seeks to establish a lawful requirement to provide certain information, it must do so unambiguously. An example of such an unambiguous requirement for price information from health care providers is section 2718(e) of the Public Health Service Act, as added by section 1001 of the Affordable Care Act; under that law, hospitals are required to provide a list of their standards charges for services. No such directive appears in the language of Section 3022.

It is unclear why an electronic health record would be the best vehicle for price information related to a patient's past, present, or future health care needs, especially in the context of the proposed information blocking rule. The electronic health record to which a provider refers in making treatment plans or decisions is not the type of record that should include information on bills the patient has paid or might pay in the future. The EHI the provider needs is the record of clinical care; this record should not serve as a price comparison tool.

Health care providers, in collaboration with other private partners, have already undertaken significant efforts to improve price transparency for their patients and patient caregivers. Including "price" information in EHI will only complicate and slow the progress that has been made through private and public partnerships, and through state laws.

In addition, disclosing negotiated prices will not provide patients with the information they want and need about what is covered under their policies and what the out-of-pocket costs will be for their care. What is even worse, however, is that disclosing this information would likely facilitate price fixing in an already concentrated commercial health insurance industry and other types of collusion that could lead to higher prices for consumers. FHA opposes the inclusion of payment information within the definition of EHI.

*Time Period of Education and Non-Enforcement*
As previously mentioned, the 21st Century Cures Act information blocking provisions represent a significant change in the health information sharing framework for the entire health care system. As proposed, the information blocking provisions would be effective the day of a final

rule's publication. However, providers, vendors, health plans, health information networks, and exchanges need time to understand the new regulations and develop plans for organizational and individual compliance. Such planning requires development of, or modifications to, policies regarding patient health information protection, as well as substantial staff education and training and patient education. FHA urges ONC to issue an interim final rule with comment period and clarify that information blocking provisions are effective no earlier than 18 months following publication of the interim final rule.

We also ask that ONC and the OIG conduct more substantial and in-depth outreach and education efforts for the policies that are finalized. Given the vast array of actors (the definition of health care provider alone is very expansive) and differing needs for understanding expectations as they exchange EHI among themselves, patients and other parties in compliance with the information blocking rule, FHA believes that a significant period of non-enforcement is required to ensure adequate time for all regulated actors to adapt to and understand what is required for compliance with this new framework; this is especially important given the wide variety of requests a health care provider receives.

FHA appreciates the opportunity to provide comments on the proposed rules. If you have any questions, please do not hesitate to contact me kathyr@fha.org.

Sincerely,

Kathy Reep

Kathy Reep
Vice President/Financial Services