Federation of American Hospitals®

Charles N. Kahn III
President and CEO

June 3, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, DC 20201

Re: 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 Federally-facilitated Exchanges and Health Care Providers [CMS-9115-P]

Dear Administrator Verma:

The FAH appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services's (CMS) *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 Federally-facilitated Exchanges and Health Care Providers* published on March 4, 2019. The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. As we have noted in previous comment letters, the *Health Information Technology for Economic and Clinical Health (HITECH) Act* catalyzed broad adoption of electronic health records (EHRs), but the use of such technology has not yet achieved the quality and efficiency goals desired by stakeholders across the health care sector. The inability of EHRs to both exchange and use

information is a significant barrier to achieving these goals. Congress recognized this barrier in enacting numerous policies in the *21st Century Cures Act*. The FAH appreciates CMS's commitment to advancing interoperability and offers the below comments and recommendations to guide these efforts. Given the significant interaction between the CMS Proposed Rule and the Proposed Rule from the Office of the National Coordinator for Health Information Technology (ONC), the FAH comments on the ONC Proposed Rule are provided herein as Attachment A.

General Comments

Implementation Timeframes

The FAH appreciates the Agency's commitment to improving interoperability and patient access to information and believes many of the policies contained in the Proposed Rule will advance those goals. To be most effective, however, the FAH believes stakeholders must have adequate time to implement the proposed requirements and changes contained in the Proposed Rule. It often takes health IT vendors 18-24 months to build / update their products and then health care providers need additional time to implement the new products. While health care providers are often only given six months to comply with CMS regulations, it can take up to 12 months for a provider organization to review, configure, test, train, and deploy numerous vendor technologies, as well as ensure they did not disrupt hundreds of custom interfaces within their systems.

Alignment with the Promoting Interoperability Programs (PIPs)

The FAH appreciates the recent, significant collaboration between CMS and ONC to move toward a shared vision of interoperable health IT in support of federal health care programs and the patients they serve. The PIP components of several CMS payment systems require hospitals and health care professionals to utilize 2015 Edition CEHRT, and multiple CMS performance measures link to 2015 Edition certification criteria.

In addition to ensuring adequate time for implementation, the **FAH also encourages CMS to ensure that the PIPs for eligible hospitals, eligible critical access hospitals, and eligible clinicians are aligned with the new and updated requirements in the CMS and ONC Proposed Rules.** Particular attention should be given to eliminating all the PIP uses of certification criteria removed by ONC and ensuring that the retained criteria are sufficient for robust support of the PIPs. **The FAH also urges CMS to maintain the reporting period for PIPs at 90 days at least until the transition to FHIR Release 4 has ended.**

III.C. Open API Proposal For MA, Medicaid, CHIP, and QHP Issuers in FFEs

Data Required to be Available Through Open API; Timeframes for Data Availability

The Proposed Rule would require certain health care insurers to implement, test, and monitor the proposed open API accessible to third-party applications and developers. (proposed 42 CFR 422.110, etc.). The Proposed Rule also specifies the type of information that must be available via the API, as well as by when the information must be available. The FAH

encourages CMS to ensure the timing requirements for providing adjudicated claims data via the API are reasonable for the payers that receive the claims to ensure health care providers have adequate time to submit the claims.

Request for Information: Information Sharing Between Payers & Providers through APIs

CMS requests comment on possible future rulemaking to enable a health care provider to request shared patient population information from payers. The FAH believes this information could be of great use to health care providers, particularly those participating in value-based payment models. Some payers are already providing some of this data to providers with whom they have value-based arrangements, but the practice is not widespread.

CMS also requests comment regarding patient notice and consent requirements related to sharing such information. The FAH believes such information sharing is permissible under the HIPAA Privacy Rule for individuals with whom the covered entities have or have had a relationship. With regard to information subject to more stringent protections under 42 CFR Part 2, the FAH believes it would be incumbent on the sharing entity to determine which information cannot be shared.

Issues Related to Denial or Discontinuation of Access to the API

CMS proposes to require all plans impacted by the rule to implement, test, and monitor an openly published API accessible to third-party applications and developers. As part of this proposal, CMS seeks feedback on whether current privacy and security standards, including those under HIPAA, are sufficient to ensure the protection and security of a patient's health information.

Related to the CMS proposals are policies in the ONC Proposed Rule to govern requests from API Users (*e.g.*, third-party applications) to access certified API technology. Currently, many API Data Providers (organizations, such as health care providers, that deploy, or contract with the API Technology Supplier to deploy, the API technology) rely on their API Technology Suppliers (health IT developers that create certified API technology) to perform a review of such requests. The Conditions and Maintenance of Certification proposals in the Proposed Rule, however, would limit the ability of API Technology Suppliers and API Data Providers to keep malicious applications from connecting to the API. For example, the API Technology Supplier can, but is not required to, verify the API User's request to access the API, but this authentication is only at the API User entity level, not for each application the entity seeks to connect. Additionally, as drafted, it appears the ONC Proposed Rule absolves API Technology Suppliers that do not have an authentication process from responsibility for connecting to poorly designed or malicious applications. If finalized, these proposals will cause API Technology Suppliers to scale back their current review processes (*e.g.*, entity-level only as compared to application level) and may cause smaller API Technology Suppliers to abandon their review processes entirely due to the expected volume of API User requests and the limited time in which to perform the verification. This limited verification process is particularly troubling to API Data Providers because, as currently drafted, the ONC Proposed Rule provides them a limited role in this process. While the FAH supports ONC's proposal to give API Data Providers sole authority over

who accesses their APIs, such authority has little meaning when the Proposed Rule would not permit them – and most do not have the resources – to verify the security of API Users' applications.

The lack of a robust vetting process for third-party applications in the CMS and ONC Proposed Rules is troubling. The FAH has long supported patients' rights to access their health care information under HIPAA. Health care providers are familiar with the HIPAA Rules and believe they provide important protections for both patients and providers regarding the exchange of protected health information (PHI). Most third-party applications, however, are not governed by the HIPAA security and privacy requirements. FAH members are very concerned that these applications could expose their EHRs to malware, hacking, and data mining. **Hospitals must be empowered to protect their systems from unproven and potentially harmful applications and, as such, should not be considered "information blocking" for forgoing relationships with questionable applications.**

In addition to security concerns, the FAH cautions CMS and ONC against allowing these unvetted, non-HIPAA-covered, third-party applications fairly open access to patient digital health data without patients fully understanding how those applications might use that data and the implications of that usage. The FAH agrees that it is an individual's prerogative to specify where and to whom to send their designated record set. The FAH does not agree, however, that individuals understand how the information they are sharing will be used and monetized. Most people routinely do not read the entire "terms of use" agreement on every application or website and often mistakenly believe their data is more private or secure than it really is. Recent consumer data privacy events highlight the gap between how companies are using data versus how their customers believe their data is being used. For example, millions of individuals were surprised and angry to learn how Facebook was using and selling their data, while other consumers were not even aware that all their financial information is funneled through three to four credit bureaus, two of which experienced major breaches in the last few years.

Digital data is the currency of the modern technology ecosystem and marketplace, and there are fortunes to be made in mining and monetizing personal digital health data. As such, the rules and processes that govern and protect digital health data must be sensitive to the reality that not all covered entities, business associates, and third parties are created equal. Particularly regarding entities that fall outside of the HIPAA requirements, it is imperative that patients, their families, providers, and consumers can trust that these applications – and the data both sent to and received from them – are secure, private, and clinically sound.

The FAH believes it is possible to support innovation in the marketplace while ensuring the security, privacy, and clinical efficacy of third-party applications through both education and an industry-backed vetting process. In response to the FY19 IPPS Proposed Rule, the FAH urged CMS, ONC, the Office for Civil Rights (OCR), and the Federal Trade Commission (FTC) to undertake a joint campaign to educate patients about the differences between HIPAA and non-HIPAA-covered entities, and how those differences may affect the ways in which their data is used, stored, and shared with others.

Education alone, however, is not enough. Nor is an attestation-only requirement for applications. An industry-backed process to independently vet third-party applications is needed to ensure they are: a) meeting all relevant security standards; b) using data appropriately and in line with consumer expectations; and c) clinically sound (for those applications that offer medical advice**). The vetting process should be at the application level, not just at the entity level; the results of such vetting process should be made public in the form of an application "safe list"; and health care providers and API vendors should be able to refuse to connect to non-vetted applications.**

Security
In order to "pass" the vetting process, an application must meet the most current security standards.

Privacy/Data Usage
The vetting should also examine applications' data usage as compared to the more stringent HIPAA requirements and then publicly report those findings for consumers in an easy-to-understand format, such as a simple comparison chart. The FAH also recommends the assignment of an easy-to-understand letter grade (*e.g.,* A, B, C, etc.) to each application based on its data usage, with an "A" grade signaling HIPAA-level protections. The chart and the letter grade would appear to consumers prior to downloading the application or authorizing it to access their health information. The FAH believes this process would enhance consumers' control over their designated record set by enabling them to make fully informed decisions about where to send that data.

Clinical Soundness
Applications that contain a clinical component would undergo additional vetting to ensure they are clinically sound. The vision for the future includes health care providers pulling information from third-party applications used by their patients and then using that information to make treatment decisions. That vision is only possible if health care providers – and their patients – can trust the integrity of that information.

Publicly Reported "Safe List"
The vetting organization should publicly report the third-party applications that "pass" vetting for security (and clinical soundness, if relevant) as "safe" for vendors and health care providers to connect to their APIs.

Information Blocking Exception
The FAH strongly believes that all applications seeking to connect to a health care providers' APIs must undergo this vetting process and that providers and API vendors that refuse to connect to non-vetted applications should not be considered "information blocking."

The vetting and public reporting process detailed above will go a long way towards ensuring trust while removing the burden of vetting from consumers, health care providers (API Data Providers), and API Technology Suppliers. The FAH also believes the process has parallels to the "best in class" discussions in the CMS and ONC Patient Matching RFIs. Those RFIs

recognize the significant patient safety and patient and provider trust concerns with the current patient matching tools and seek feedback on whether identifying and requiring the use of "best in class" tools would improve accuracy and, by extension, trust. A similar "best in class" thought process can be applied to the vetting of third-party applications, with the "safe list" representing the "best in class" applications.

V. Health Information Exchange and Care Coordination Across Payers: Establishing a Coordination of Care Transaction to Communication Between Plans

CMS proposes that, at the request of a plan's enrollees, payers subject to the requirements in the Proposed Rule must be able to receive and incorporate data from the enrollee's previous health plan(s) within the preceding five-year period. Similarly, payers must also be able to send a previous enrollee's data to the enrollee's current plan for up to five years after the enrollee's disenrollment. CMS believes that such plan to plan exchange of information will improve care coordination and ease enrollees and health care provider burden associated with prior authorization, duplicative step therapy requirements, and duplicative utilization reviews.

The FAH appreciates the Agency's desire to reduce patient and health care provider burden associated with ensuring health plan enrollees receive medically necessary services and treatment. FAH's members have experience with a variety of payers across the country and find that they often differ significantly in the implementation of their utilization management tools, including the types of medical necessity information they require from health care providers. Thus, the envisioned burden reduction and associated efficiencies will only be realized if the payers receiving and incorporating the data actually review and use the information to prevent such duplication.

VIII. Information Blocking Public Reporting

The *Medicare Access and CHIP Reauthorization Act* (MACRA) requires eligible hospitals, critical access hospitals (CAHs), and professionals to demonstrate that they have not knowingly or willfully acted to engage in information blocking, which CMS operationalized through a three-part attestation. In the Proposed Rule, CMS proposes to publicly identify clinicians and hospitals that submit a "no" response – or do not submit a response – to any of the three information blocking attestation statements required under the Medicare PIP or the Quality Payment Program (QPP).

The FAH supports the proposal to identify these clinicians and hospitals. The FAH also supports the proposed 30-day period for eligible hospitals and CAHs to review and submit corrections to the information before it is made public.

IX. Provider Digital Contact Information

Section 4003(c) of the *21st Century Cures Act* directs the Secretary of HHS to create a provider digital contact information index that includes all individual health care providers and facilities to facilitate the exchange of electronic health information. CMS plans to capture this digital contact information through the National Plan and Provider Enumeration System

(NPPES) and, beginning in the second half of 2020, plans to report publicly the names and National Provider Identifiers (NPIs) of providers who do not have their information stored in the NPPES. CMS seeks comment on how to operationalize this public reporting as well as possible enforcement mechanisms to ensure providers make digital contact information publicly available through the NPPES (*e.g.*, MIPS, Medicare enrollment/revalidation process, program integrity, and prior authorization).

The FAH supports CMS's proposal to publicly report the names and NPIs of providers who do not have their digital contact information in the NPPES. Currently, providers seeking to electronically share information with other providers struggle to obtain the direct address information necessary to facilitate that sharing. A national database would ease this burden and facilitate information sharing to the benefit of patients.

While the FAH supports the proposal, we also raise several key operational concerns for CMS's consideration. The FAH urges CMS to ensure that the NPPES can store all the information necessary to correctly identify the provider and their location. For example, for clinicians who practice at multiple locations, the NPPES must be able to differentiate between those locations to ensure that the information being shared reaches the correct clinician at the correct location in a timely manner. It is critical that providers have confidence that the NPPES can identify the correct provider and the provider's location to ensure provider trust in the system and avoid the risk of any potential HIPAA violation. Further, providers want to avoid the risk of any potential HIPAA violation if, for example, a provider were to send a patient's PHI to the correct provider, but unintentionally send it to an incorrect location because the receiving provider no longer practices at the location or practices in multiple locations. Providers also need assurance that such a circumstance – sending information to the wrong location because the NPPES system cannot differentiate locations – would not constitute information blocking.

To build an effective database, ample time is needed to ensure that the NPPES has the capacity to store and timely update the required provider information, as well as effectively identify providers and their practice locations. Providers also need time to submit information to the NPPES and then operationalize use of the database as part of their workflow. **The FAH recommends that CMS evaluate the capacity and effectiveness of the NPPES prior to undertaking enforcement efforts and moderate those efforts accordingly.**

X. Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals

CMS is proposing new Conditions of Participation (CoPs) that would require hospitals (including acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals (IRFs), psychiatric hospitals) and critical access hospitals (CAHs)) to send electronic patient event notifications of a patient's admission, discharge, and transfer (ADT) to other facilities, providers, or community providers with an "established care relationship with the patient" who the hospital has reasonable certainty will receive the notifications. The notification would include basic demographic information on the patient, the name of the sending institution, and diagnosis, unless prohibited by another applicable law. CMS encourages hospitals to offer more robust patient information and clinical data upon request in accordance with applicable laws and is seeking feedback on how to operationalize the proposal.

The FAH supports the direction of this proposal, as we have long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of meaningful, actionable information that supports and enhances patient care within and across settings. The FAH is particularly supportive of efforts to improve patient transfers, including the efficient and effective exchange of information between providers. For example, the timely transfer of information from an acute care hospital to a post-acute care provider (e.g., LTCH or IRF) is important to ensure the post-acute care provider has the complete picture of the patient's needs and the patient receives appropriate, timely services. Conversely, it is important that an acute care hospital receive the information necessary to have a complete picture of the patient's health when a patient is transferred from a post-acute care provider to the hospital. The FAH believes the acute, post-acute, and behavioral health communities can work cooperatively with CMS and other agencies (e.g., OCR) to improve the quality and efficiency of patient care through the timely exchange of actionable information during care transitions. **However, the FAH does not support the proposed CoPs for electronic patient event notifications, as tying ADT notification to CoPs would impede rather than advance innovations that are key to achieving interoperability. Overall, the proposal is premature and punitive. It raises a multitude of questions and significant operational issues and lacks technological functionality, as discussed further below.**

The Proposed CoPs Raise a Multitude of Questions

In order to comply with CoPs, hospitals must clearly understand what it is they must achieve and how they will be surveyed and measured to determine compliance. The proposal lacks both elements and instead raises a multitude of unanswered questions. For example, to whom would the hospital need to send the ADT notification? Would the notification need to be sent to all providers that have an established care relationship with the patient, which could be numerous providers? Or those who have an established care relationship regarding the condition(s) for which the patient was seeking treatment from the hospital? The term "established care relationship with the patient" could be interpreted differently by each provider, let alone each surveying entity. And how would the hospital determine those providers – by searching the patient's medical record (a potential HIPAA or 42 CFR Part 2 violation), or by asking the patient for the names and contact information of each provider to whom he wants the notifications sent? If the former, this places a significant regulatory risk on hospitals, as well as requiring substantial hospital resources. If the latter, this would be dependent on the participation of the patient and the accuracy of the information the patient supplies. Would patient consent be required to send the ADT notification? How would the hospital determine whether the other provider could accept the notification? Would hospitals need to ensure other providers ultimately received it? And if a hospital receives a notification, would it need to incorporate it into an actionable format in the EHR?

These are a sampling of the multitude of questions that would arise in determining compliance and highlight hospitals' significant concerns about their ability to prove their compliance with the CoPs during a survey process. Even if the questions asked above were able to be answered, the thought process that goes into each one would be difficult, if not impossible, for hospitals to document and would be subject to wide-ranging interpretations from surveyors. In addition, the questions reveal that determinations of compliance could hinge not on the

individual provider's action, but on the actions of health IT vendors and other providers over whom the hospital has virtually no control. For example, a hospital may be able to send the notification electronically, but the receiving hospital or post-acute care provider is unable to accept it. Or, a provider may be unable to incorporate the information it receives into its EHR in a format acceptable to the surveyors due to the limitations of the EHR itself, for example, misaligned standards, semantics, and specifications that currently hinder data flow and useable data across vendor platforms.

Significant Operational Issues and Technological Functionality Concerns

As discussed above, the current ecosystem simply is not technologically mature enough to facilitate the movement of this information, as evidenced by the obstacles that currently prevent seamless information exchange. These limitations would make it exceedingly difficult for hospitals to comply with the ADT requirement. For example, EHR capabilities are not standard across all providers, with some particularly having trouble incorporating the information in a way that is actionable for the receiving provider. While CMS states that the requirement would not apply to hospitals that use EHRs that cannot generate these notifications, the proposed rule incorrectly suggests that ADT capability is ubiquitous and that almost all hospital EHRs should have this capability. The proposed rule also incorrectly suggests that sending these notifications is simple and seamless, as evidenced by the estimate in the regulatory impact analysis that the proposal would impose a minimal burden on hospitals. In reality, manual processes can be required to send and receive these notifications, and not all EHRs can accept and/or process inbound ADTs. Some EHRs create a temporary account for the incoming information that then must be handled through human, manual processes to finalize the registration process. In addition, ADT notifications can only provide the reason for admission or patient complaint; the diagnosis is not available until post-discharge.

ADT functionality is not currently required of vendors under the ONC certification rules. It would be inherently inequitable to require hospitals to perform a function that vendors are not required to develop and offer. CMS should require vendor functionality, including better workflow for outbound and inbound ADTs. The responsibility for interoperability, including ADT notifications, must be a multi-stakeholder effort across the entire health care matrix – vendors, business associates, health plans, and other organizations – and should not fall solely on hospitals and other health care providers.

Further, exchanging these notifications is currently only possible in one of two ways: 1) through a health information exchange (HIE); or 2) through direct connecting between the hospital and the receiving provider. If a provider is not connected to a HIE or similar network, of which the most advanced ones are quite costly, it would be an enormous undertaking – both administratively and financially – to connect directly to these other providers and facilities on an individual basis.[1]

These obstacles are amplified with regard to post-acute providers and behavioral health providers because they were ineligible for the EHR Incentive Programs under the *Health*

[1] The FAH also notes that these exchanges are hindered by the lack of a unique patient identifier (UPI), as discussed in more detail in Section XIII of this letter.

Information Technology for Economic and Clinical Health (HITECH) Act, which have been instrumental in enabling acute care hospitals to achieve so much of the potential that health IT offers. As such, post-acute providers and behavioral health providers have not been able to adopt health IT to the extent of other hospitals and CAHs. Thus, if CMS is to move forward with the proposed CoPs, their effectiveness would be minimized due to the lack of providers available to send and receive the information electronically.

CMS attempts to recognize these concerns for post-acute hospitals and behavioral health hospitals by limiting the CoP proposal to hospitals that currently possess EHR systems with the capacity to generate patient event notification. As discussed above, while the FAH appreciates this limitation, it is unclear how this might affect the survey process for hospitals in terms of meeting the CoPs. Also, significant time is needed for post-acute hospitals and behavioral health hospitals to develop the capacity to send and receive these notifications. For example, hospitals with behavioral health units would encounter obstacles unique to this service line. For these units, PHI is not disclosed through the primary inpatient system data feed, as this information is subject to regulations requiring written consent for PHI related to substance use disorder services.

The technological and operational obstacles are significant and developing an ecosystem that can effectively and efficiently send and receive ADT notifications requires time, flexibility, and cooperation across health care stakeholders. The proposed CoPs, however, would impose stringent and static requirements that would undermine this flexibility and the innovation needed to develop broad capacity for these notifications over time.

Alternative Approaches to Advance ADT Notifications

Failure to comply with CoPs carries serious penalties for hospitals and other health care providers, including the potential inability to treat Medicare and Medicaid beneficiaries. Such penalties also have profound consequences for patients as well, as they may lose the ability to receive treatment in their communities. **Imposing these penalties on hospitals and patients in the face of an immature health information ecosystem – and the significant implementation issues raised above – would only restrict rather than facilitate patients' access to care and information exchange. It also would expose hospitals participating in the PIP to significant CoP penalties on top of the penalties providers would already incur under that program.**

Rather than implementing the proposed CoPs, the FAH urges the Administration to work together with the provider community to improve the exchange of such information using incentives and regulatory relief rather than harsh penalties. For example, CMS could pilot this type of ADT notification system through the Center for Medicare and Medicaid Innovation (CMMI) and/or utilize other incentives, such as bonus points for PIP participating hospitals and regulatory relief for post-acute care and behavioral health providers that voluntarily send timely ADT notifications.

In addition, the FAH supports CMS's work to improve the medications list as part of the data element library (DEL) and urges the Agency to continue these efforts and work with OCR to incorporate parts of the DEL into the U.S. Core Data for Interoperability (USCDI) standards.

Patients who frequently transition between acute care, PAC, and community care providers often have large frequently changing medication lists that lead to patient and provider confusion. Additionally, while some PAC and community providers have invested in EHRs, many of these providers do not have systems capable of exchanging this data electronically, resulting in medication lists containing outdated dosages and discontinued medications. Inclusion of the medications list in the DEL (and, ultimately, the USDCI) is aligned with medication reconciliation best practices and existing transition of care requirements. Additional work on standards is needed to normalize the data (*e.g.*, dosage) exchanged between EHRs and would aid in provider collection and reconciliation of medication lists across provider types. As discussed in the FAH's letter in response to the ONC Proposed Rule (see Appendix A), any future updates to the USCDI should be done via the open, annual-cycle process proposed in that Rule to ensure future data classes are fully evaluated and implemented under an appropriate timeline.[2]

CMS could also work with OCR to ensure that there is no HIPAA barrier to post-acute care providers receiving the information necessary to determine whether to accept the patient even if the post-acute care provider does not yet have a direct relationship with the patient. In addition, CMS should focus its efforts on current activities that could advance these notifications, such as through the Trusted Exchange Framework and Common Agreement (TEFCA) and by ensuring that vendors are accountable for the products they develop, particularly the efficient sending of ADT notifications and the receipt and incorporation of those notifications into actionable information.

XI. Request for Information: Advancing Interoperability Across the Care Continuum

CMS seeks comment on ways to advance interoperability amongst providers not included in the EHR incentive programs, such as post-acute care, behavioral health, and community-based providers. CMS also seeks comment on whether hospitals and clinicians should be able to collect and exchange some of the post-acute care standardized patient assessment data elements in their EHRs.

The FAH appreciates CMS's recognition that vital health care providers did not receive funding under the EHR incentive programs and that it is unrealistic to expect these providers to be at the same level of information exchange as the hospitals, CAHs, and physicians that were eligible for such funding. **The FAH also appreciates CMS's interest in improving interoperability across the health care continuum to improve the quality and efficiency of patient care and believes the best way to achieve that goal is through the use of "incentives" – such as financial support and/or regulatory relief – rather than "sticks" – such as CoPs or complex regulatory requirements.** First, the FAH urges CMS to work toward measuring the exchange, incorporation, and use of information across care settings rather than on the use of the EHRs themselves. Such efforts will be instructive not just for the eligible hospitals, CAHs, and physicians participating in the PIP, but also for post-acute care and behavioral health providers who are not part of those programs. This baseline measurement would enable CMS to consider

[2] Also, while the medication list, DEL, and USCDI is designed to be exchanged among health care providers, the FAH recognizes that this information could be provided in response to a patient access request and that it would be essentially unintelligible for most patients. For medications lists in particular, it might be prudent to also design a non-clinical version for patients.

the differences in the adoption and use of EHRs among the different types of post-acute care providers, for example, before taking any administrative action.

Should CMS move forward with financial support for post-acute care and behavioral health providers to encourage the adoption and use of EHRs, such support could be achieved through CMMI and could include: exempting those providers from annual productivity adjustments; providing the fees for those providers to join HIEs, health information networks (HINs), or prescription drug information exchange; and/or increasing reimbursements for those providers that engage in information exchange. Regulatory incentives for post-acute care and behavioral health providers to encourage the adoption and use of EHRs could include exemptions from prior authorization or pre-claim review demonstrations or regulatory waivers for providers that participate in alternative payment models, such as a per-diem for IRFs with shorter than average stays and flexibility regarding the length of stay requirements for LTCHs. In addition, any action by CMS should recognize the significant costs and administrative burden associated with EHRs adoption, as well as the significant time required to develop, test, and implement such technology. As discussed elsewhere in this letter and in response to the ONC Proposed Rule, the current implementation timelines in the rules are far too short to safely and efficiently achieve the desired results.

The FAH also appreciates CMS's attention to the need to collect and exchange post-acute care standardized patient assessment data elements (e.g., functional status). In order for acute care providers and physicians to collect and exchange some post-acute care data elements, those elements would need to be incorporated into the USCDI to ensure consistency across providers. **As discussed above, the FAH supports incorporating parts of the DEL into the USCDI to foster better interoperability between acute care and post-acute care providers as part of the open, annual-cycle USCDI update process proposed in the ONC Proposed Rule. The FAH does not support, however, requiring acute care providers and physicians to collect the post-acute care assessment items contemplated in the *Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT Act)** as these items were designed, tested, and validated for use only in the post-acute settings, and expanding their use outside such settings would be overly burdensome on acute care and other types of providers who are significantly less familiar with these items and their accompanying guidance, causing confusion and leading to unnecessary duplication of efforts.

XII. Advancing Interoperability in Innovative Models

The FAH appreciates CMS's desire to CMMI models to engage with health care providers and pilot actions to advance interoperability and patient access to their data.

In the FY19 IPPS/LTCH Proposed Rule, CMS requested feedback on future directions for the PIP to reduce burden, support alignment with other CMS programs, advance interoperability, and promote innovative uses of health IT. The FAH responded to that request for feedback and believes that several recommendations applicable to future directions for the PIP are also applicable to CMMI models. For example, the FAH supports the idea of developing and/or designating some "priority health IT activities" as alternatives to the current measures-based Program. While an initial list of such activities should be applicable to the PIP as well as

CMMI model participants, the CMMI models provide an opportunity to pilot additional activities that then could be incorporated into the PIP.

Such a process could also be applied to participation in a trusted exchange framework such as that envisioned by the Draft Trusted Exchange Framework and Common Agreement (TEFCA) ONC released last year. While FAH members currently participate in regional and state health information exchanges, the Draft TEFCA offers potential for enhanced interoperability through voluntary engagement with Qualified HINs that could be tested in CMMI models. For example, CMMI model hospitals could pilot participation in the TEFCA while non-CMMI model hospitals participating in the TEFCA could receive bonus points under the PIP or be deemed meet the Health Information Exchange objective. This would allow for a purely voluntary participation in the TEFCA as it becomes operational and appropriately reward those hospitals and health systems who are early testers of the framework. Ideally, participation in the TEFCA would be deemed participation in the PIP.

A third opportunity for CMMI to advance interoperability would be to pilot the sending and receiving of electronic notifications, such as upon an inpatient's ADT. As discussed above, CMS's proposal to amend the CoPs to require hospitals, CAHs, and psychiatric hospitals to send electronic ADT notifications leaves numerous unanswered questions and operational considerations and is simply not appropriate to require of hospitals at this time. Instead, the FAH suggests pilot testing the sending and receiving of electronic ADT notifications as part of a CMMI model. This pilot would allow participating providers and the Agency to work through the numerous hurdles involved in setting up the technological infrastructure and accompanying processes required to send these notifications.

The FAH agrees with CMS that CMMI models could be a good environment in which to test the adoption of leading health IT standards and pilot emerging standards. The success of such testing, however, depends on the full cooperation and engagement of health IT developers and vendors, as health care providers are usually purchasing, not building, this technology. The FAH does not believe it would be appropriate for a health care provider to be ineligible to participate in a CMMI model due to lack of engagement by a health IT developer. The FAH also cautions CMS to be cognizant of the significant resources involved in adopting and piloting non-mature standards lest the health IT-related efforts and corresponding difficulties overwhelm the primary purpose of the model. For example, if ONC finalizes FHIR v2.0 in the Final Rule, and CMS decides to pilot test FHIR v4.0 in a CMMI model, an organization using v4.0 would be unable to communicate with an organization using v2.0 without building a "bridge" or utilizing some sort of intermediary. If the purpose of the CMMI model is to improve care coordination and efficiency, such a communication difficulty would hinder rather than help these efforts.

XIII. Request for Information: Policies to Improve Patient Matching

The FAH appreciates CMS's and ONC's commitment to improving patient matching and agrees with other stakeholders that the lack of a unique patient identifier (UPI) has significantly hindered efforts in this area. The FAH supports the use of a UPI but recognizes that Congressional action is needed to permit the use of federal funding to adopt and implement a UPI. In the absence of such Congressional action, the 2017 ONC Patient Matching Algorithm

Challenge[3] was a good first step in identifying the current techniques employed for patient matching operations. More must be done, however, to catalyze the advancement and wide-spread deployment of top-tier tools.

To address patient matching concerns, the FAH encourages CMS and ONC to convene stakeholders from across the industry to develop a private sector-led strategy with government support. As recommended in an industry-stakeholder paper in 2018, this strategy would involve a "neutral coordinating organization" to determine the "standards-based infrastructure to improve patient matching."[4] The Agencies could then support the widespread adoption of the standards-based infrastructure through their regulatory authority. The FAH believes such an approach would reduce the current variability in patient matching capabilities within each local system and exchange.

In addition to the AHIMA paper discussed above, the FAH encourages CMS and ONC to carefully consider recommendations from other organizations that have studied the current deficiencies in patient matching. An October 2018 report from The PEW Charitable Trusts provides several recommendations for near- and long-term actions to improve patient matching. For example, the report discusses opportunities to improve patient demographic data by capturing patients cell phone numbers and email addresses, as well as opportunities to reduce the variation in recording demographic data by adopting the U.S. Postal Service standard for addresses.[5]

****

The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership with CMS and ONC as we strive to advance the use of health IT to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

[3] HHS Press Release, *HHS Names Patient Matching Algorithm Challenge Winners* (Nov. 21. 2017), available at: https://www.hhs.gov/about/news/2017/11/08/hhs-names-patient-matching-algorithm-challenge-winners.html.
[4] Journal of AHIMA, *Advancing a Nationwide Patient Matching Strategy* (July-August 2018), available at: http://bok.ahima.org/doc?oid=302539#.XLdByjBKiUk.
[5] The PEW Charitable Trusts, *Enhanced Patient Matching is Critical to Achieving Full Promise of Digital Health Records* (Oct. 2018), available at: https://www.pewtrusts.org/-/media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf.