



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

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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 400 member hospitals and health systems, the California Hospital Association (CHA) 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 CHA has prepared comments for the consideration by both agencies.

CHA 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 moving forward the interoperable exchange of health information across the entire health care system. In California, 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. CHA welcomes the support of the federal government in establishing policies that increase the seamless flow of health information and reduce burden on patients and providers.

The proposed rules represent a sea change in the framework under which health care providers, health insurance plans, and health information technology (HIT) developers and vendors capture and exchange highly sensitive health information. 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. Further, an overly complex regulatory framework, if not carefully constructed, may stifle innovation and further complicate the current public-private initiatives taking root and accelerating change, absent a need for additional regulation.

CHA urges the agencies to consider more detailed comments provided by our national colleagues, including the American Hospital Association and the Federation of American Hospitals. In this letter, CHA provides comments on provisions that are of critical importance to California hospitals. In general,

CHA supports CMS' 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 agencies' consideration, to ensure that implementation of proposed policies does not create additional regulatory burden in the health care system, contrary to the administration's goals to reduce regulatory burden on hospitals.

In summary:

- CHA urges CMS and ONC to reconsider its proposed implementation timelines, allowing appropriate time to advance the exchange of health information without creating unintended consequences of additional burden.
- CHA opposes CMS' proposed revision to the Medicare and Medicaid hospital Conditions of Participation (CoPs) to require electronic patient event notifications, and instead urges the agency to consider alternative mechanisms for promoting admission, discharge and transfer (ADT) notifications, such as modifying the measures under the HIE objective of the Hospital and Critical Access Hospital Promoting Interoperability programs.
- CHA supports CMS' proposal to require that public health plans make patient health information available electronically through a standardized, open application programming interface (API) and urges CMS to develop policies for health plans to share information on shared patient populations with providers via API in the near future.
- CHA is concerned that ONC has proposed a definition of electronic health information (EHI) far beyond what Congress intended under the 21st Century Cures Act, and urges the agency to limit the information in the definition of EHI to the data classes and elements required for certification under the US Core Data for Interoperability (USCDI).
- CHA opposes the inclusion of payment and price information within the definition of EHI and believes overregulation in this area could impede emerging private sector efforts to promote price transparency.
- CHA urges ONC to implement information-blocking provisions via an interim final rule with a comment period that is effective no earlier than 18 months following publication of the interim final rule, and include a significant period of education and non-enforcement for all regulated actors.

CHA 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 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 currently possess EHR systems with the capacity to generate electronic patient event notifications to do so at the time of an inpatient's admission, discharge or transfer to another facility or community provider.

CHA believes ADT notifications would advance clinically appropriate exchange of information. However, we believe that ADT notifications as a CoP requirement — with the possible noncompliance penalty of decertification — are unworkable and inappropriate due to a number of important factors described in detail below. We agree that ADT notifications promote appropriate care transitions and exchange of information across settings. Many California hospitals currently use ADT notifications and find them particularly useful when sent to a targeted group of community providers who assume financial risk for shared patient populations. For this reason, the use of such notifications may evolve naturally as health information exchange technology evolves. Alternatively, as discussed below, 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.

Conditions of Participation Should not be Revised in Piecemeal

CHA appreciates the work undertaken by CMS in recent years to promote a less burdensome regulatory framework for the Medicare CoPs, which supports our collective goals of high-quality, patient-centered care in a rapidly changing health care delivery system. The agency has made some significant improvements in both the CoP and subsequent interpretive guidance. However, we believe the current piecemeal approach to CoP revisions does not adequately keep pace with or address the breadth of ongoing transformation in the health care system. Recent changes in law have demanded more fully integrated health care services, putting patients' health, safety, well-being and preferences at the forefront — and the hospital CoPs and related guidance need continued updating to reflect these changes. **CHA believes revisions to the CoPs must be viewed in their totality, through a shared lens of overarching and agreed-upon principles and a vision for the future.**

Operational Challenges of ADT Notifications

The proposed CoP is not an appropriate mechanism for promoting ADT notification for several additional operational reasons. First, by limiting the proposed standard to hospitals that currently have EHR systems with the capacity to generate patient event notifications, CMS recognizes that not all hospitals have been eligible for programs promoting adoption of EHR systems. CMS further acknowledges that there is no specific ONC certification standard for sending and receiving electronic patient event notifications. **CHA appreciates that CMS has proposed an exception for hospitals without the capacity to send notifications. However, we believe the necessity of the exception demonstrates the inappropriateness of the proposal as a revision of the CoPs.** The CoPs are important requirements that all hospitals must meet to protect patient health and safety and to ensure that high-quality care is provided to **all** patients. CHA anticipates that many post-acute and behavioral health providers, as well as small and rural critical access hospitals, would meet the exception. These are some of the settings where care transitions and care coordination are most significant, and it would be counterproductive for only some hospitals to adhere to the CoPs. Further, care coordination goals cannot be met when only some providers participate in the transmission of patient event notifications.

Second, 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. The proposed CoP would require the hospital to send ADT notifications "to licensed and qualified practitioners, other patient care team members, and PAC services 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.” 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. But unlike some states that have one statewide HIE for all providers, California’s diverse population and geography are served by more than 15 HIEs in 39 of California’s 58 counties. In many counties, 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.**

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. CHA expects that these burdens will be eased in the future as the TEFCA is advanced to facilitate greater exchange of information through HIEs, as patient matching improves, and as provider electronic addresses are more readily available. **At this time, however, the burden of the proposed CoP would be substantial, and the goals of improved care coordination are not met when a hospital sends an ADT notification to other members of a patient’s care team that are unable to receive the message.**

As noted, part of this burden relates to the long-standing challenges in patient matching. CHA is concerned that, due to lack of a standardized patient identifier, hospitals experience major challenges in transferring health information in addition to common patient identification and matching issues. California’s hospitals provide care to the nation’s largest homeless population. Patient matching issues are acutely felt for medically indigent and homeless patients, who often do not have a primary care provider and may not have a permanent address. Until we have addressed the issues of patient matching 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. That penalty, in California, comes with a significant fine — up to \$250,000 per event. In addition, because of California’s especially strict privacy laws for mental health patients, California psychiatric hospitals would be particularly challenged to determine which health care providers, if any, would be appropriate under state law to receive ADT notifications for patients receiving mental health services. This would have to be determined on a patient-by-patient basis — not automatically.

Finally, CMS’ proposal allows for some flexibility in the technical standards for implementing ADT notifications. This proposal will allow hospitals to develop individualized processes and procedures for implementing the transmission of these notifications. However, California hospitals are concerned that those flexibilities will lead to significant variation in surveyor determinations if included as a CoP. In California, the state survey agency — the California Department of Public Health — employs more than 800 surveyors in 16 district offices around the state. Historically, there has been tremendous variability in the interpretation of state and federal requirements, even those that are clearly defined and have been in effect for decades. California experiences this variation within our state, and we are

acutely aware of the varying surveyor interpretations between states and across regional offices. CMS surveyors, who are typically clinicians, have no training in health information exchange or health information privacy laws, making these vague standards even more difficult to consistently identify and survey across hospitals. The cost to the state agencies to appropriately educate all state surveyors on these complex issues is insurmountable. **CHA urges CMS to not finalize the proposed CoP.**

CHA Supports Alternative Mechanisms to Promote ADT Notifications

As an alternative to creating a CoP, CMS should work with stakeholders to consider modifying the measures under the Health Information Exchange objective of the Hospital and Critical Access Hospital Promoting Interoperability Programs to promote ADT notifications. Given the proposed application of the CoP to hospitals with the capacity for generating ADT notifications, the CoP would essentially only apply to hospitals currently participating in the PIP. Using this program would allow hospitals some flexibility in learning how best to integrate ADT notifications into their workflow and EHR systems, without the significant consequence of Medicare decertification for noncompliance. Two current health information exchange measures involve sending and receiving a summary of care for transitions of care and referrals. Hospitals' experience with these measures should be reviewed in considering a new ADT notification measure. If such a measure was developed and aligned with the promoting interoperability performance category under the Quality Payment Program for eligible clinicians, it would also support improved care coordination throughout the health care system, unlike the proposed CoP for hospitals.

As is the case with all new PIP measures, if CMS makes proposed changes to the PIP measure sets to promote the transmission of ADT notifications, we urge the agency to allow appropriate time for vendors to update and test EHR systems — at least 18 to 24 months — with an additional year for hospitals to train staff and update workflows before the measure would be required for reporting. In addition, ONC should include a national ADT notification infrastructure as a core function under the final version of the TECCA to promote transmission of patient event notifications.

INFORMATION BLOCKING — PUBLIC REPORTING

CMS proposes to publicly report on Hospital Compare and Physician Compare, respectively, the names of hospitals and clinicians who submit a “no” response to any of the three attestation statements, as an appropriate disincentive under the information-blocking statute. **While CHA believes that hospitals and clinicians are already financially disincentivized from engaging in information blocking under the PIP, we do not object to public reporting on the attestation statement responses.** However, hospitals and clinicians have reported that, under CMS' reporting program systems, any actor that attempts to respond “no” to any attestation statements cannot move forward in reporting additional measures. This may lead to clinicians and hospitals responding “yes” simply to move forward in the reporting system. **CMS must address this technical limitation to ensure the data reported are accurate and valid prior to initiating public reporting of the attestation statements.**

API REQUIREMENTS FOR HEALTH PLANS

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 Children's Health Insurance Program (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. **CHA 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. CHA urges CMS to allow appropriate time so that the release of this information by API is done correctly rather than done quickly.**

Most importantly, CHA 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 likely no longer will 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, or used for marketing or other purposes.

CHA urges CMS to work with stakeholders to establish an industry-backed, third-party vetting process for applications that will give patients the confidence that their health information is secure, while being clear that HIPAA protections no longer apply. In addition, we believe there is much to be done in the area of health care consumer and privacy literacy. CHA stands ready to work with the agencies in helping consumers understand the opportunities and challenges of such policies.

Request for Information on Sharing Information Between Payers and Providers Through APIs

In the proposed rule, CMS notes that payers and providers may seek to coordinate care and share information on an overlapping patient population in a single transaction. CMS seeks comment for future possible rulemaking on allowing a provider to access or download information from a payer on a shared patient population through an open API. CHA supports the development of a future proposal that would allow providers to access more information from payers on shared patient populations. Our member hospital and health system experience is that when information is shared under risk and value-based arrangements, there are improvements in care coordination and management of the total cost of care. We look forward to working with the agency on specifics of these proposals in the near future.

PROVIDER DIGITAL CONTACT INFORMATION

The 21st Century Cures Act requires the Secretary to create a provider digital contact information index. CHA supports this provision in the law, as hospitals also often lack the appropriate contact information when transferring health information to community providers. To meet this requirement, CMS states that it has updated the National Plan and Provider Enumeration System (NPPES) to capture digital contact information for individuals and facilities. The NPPES supplies National Provider Identifier (NPI) numbers to providers, maintains the NPI record, and makes the information available online. As of June 2018, the NPPES can capture one or more pieces of digital contact information, such as a Direct Address,

endpoints for secure information exchange such as a FHIR server URL, or query endpoint associated with a health information exchange. NPPES has also added a public API, which can be used to obtain contact information stored in the database.

CMS notes that many providers have not yet submitted digital contact information, and what is listed is frequently out of date. To increase participation, CMS proposes to publicly report the names and NPIs of providers that do not have digital contact information stored in the NPPES beginning in the second half of 2020. CHA is concerned that CMS is placing much of the burden for collecting this information on providers, rather than the agency, as Congress intended. We urge the agency to better educate providers on the availability of the new digital contact fields on the NPPES. Further, CMS must give providers adequate time to familiarize themselves with the availability of these fields. CMS must also take steps to ensure the contact information is accurate and up to date. **We do not oppose public reporting of providers that have not updated the NPPES with their digital contact information, but appropriate notification to the provider in advance of public reporting, with appropriate time to make corrections and updates, would be a valuable tool for ensuring the most complete information. Additional reminders for updates and other agency efforts to ensure the database contains reliable and valid information is imperative — otherwise, the data collection effort is moot.**

PROVIDER NETWORK DIRECTORY VIA API

Under current law, payers that would be regulated under the proposed rule are required to make available their provider network directory on a website — or, in the case of QHPs in FFEs, publicly accessible in a machine-readable format. In California, Senate Bill 137 (Chapter 649, Statutes of 2015) provides a comprehensive framework for regulating provider directories. For QHPs, the law requires the use of Symphony, a specific provider directory. California's law requires that plans update their provider directories weekly, provider directories must be publicly accessible online without any restrictions or limitations, and plans must conduct biannual or annual provider verification through outreach and notification to ensure provider directory accuracy. While not perfect, the QHP process in California seems to be working.

CMS proposes to go further than current state law and require payers — except for QHPs in FFEs — to make standardized information about their provider networks available through API technology, so that third-party software can access and publish the information. CHA supports the proposal and believes the availability of provider network directory information via API has potential to make this information more accessible and convenient for patients and providers.

REQUEST FOR INFORMATION ON ADVANCING INTEROPERABILITY ACROSS CARE CONTINUUM

To inform future rulemaking, CMS seeks comment on potential strategies for advancing interoperability across care settings, including the inpatient psychiatric facility and post-acute care settings. More specifically, CMS seeks comment in three different areas outlined below. Generally, CHA agrees with the goals of interoperability across the continuum, but offers the following for consideration in future rulemaking.

Policy Strategies for Financial Support for Technology and Adoption

CMS acknowledges that Congress limited HITECH funds to hospitals and clinicians, and the current PIP programs were designed for the inpatient and ambulatory settings. CMS invites comments on specific policy strategies HHS could adopt to financially support technology adoption across the care continuum.

CHA represents hospital and health system-affiliated providers across the care continuum, including 82 inpatient psychiatric facilities, 71 inpatient rehabilitation hospitals, 67 hospital-based skilled-nursing facilities, 60 home health agencies, and 16 long-term acute care hospitals. For many years, these providers have been challenged in adoption of health information technology for a number of reasons. The major challenge has been financial resources. However, even with resources, vendors have not been readily available to take on these projects due to a largely singular focus in the hospital and ambulatory space where financial resources and aggressive timelines for implementation to meet PIP metrics have outpaced vendors' ability to keep up.

While CHA supports financial resources to facilitate the adoption of health information technology for all providers, we do not believe the current HITECH framework and PIP approach are appropriate. We have learned a great deal from the program's implementation, and any new funding source should be informed by our past experience. In addition, in the absence of funding, many post-acute care (PAC) providers have moved forward in adopting technology, particularly those that are part of larger health systems. CHA PAC members note that, while they have adopted the platform of their health system, the modules used for the PAC settings have been largely "home grown" due to the existing gag clauses and other barriers to sharing best practices, as well as work flows among other PAC providers using the same EHR systems.

While expanding the current program to an additional set of providers may seem like an easy approach, we are concerned that, at this point in implementation, many of the current PIP program requirements would be overly burdensome for many PAC providers to incorporate into existing platforms. **Therefore, CHA urges the agency to consider an assessment of PAC providers to determine their level of HIT adoption, scope of technology being utilized, and degree of interoperability before considering financial support that would likely be tied to specific metrics and quality measures. With limited financial resources available, such an assessment and further development of meaningful measures of interoperability for the PAC continuum would inform targeted and well-planned strategies, which would accelerate the change underway without creating unnecessary regulatory complexity that could slow progress. (See comments below)**

Lastly, in the short term, we urge HHS to also consider removing regulatory barriers that prevent the sharing of EHR technology with PAC providers. More specifically, current federal law creates serious barriers to achieving these goals. As Congress has recently recognized, the Stark Law — which was originally enacted to ban physicians from referring patients to facilities where the physician has a financial interest (self-referral) — has developed and expanded over the years so that it now bans or impedes arrangements that encourage hospitals and doctors to work together in a clinically integrated model designed to improve patient care at reduced cost. By requiring that compensation be fixed in advance and based only on hours worked, the Stark Law effectively prevents — or, at best, creates substantial barriers to — payments tied to achievements in quality and efficiency. In addition, the anti-kickback statute and civil monetary penalties create further barriers and complications. Many care coordination activities — such as assisting physician practices by making phone calls to patients to schedule well visits, routine diagnostic tests, and follow-up visits; providing patients transportation to physicians' offices for care; providing electronic health record (EHR) technology or support; and providing other data analytic tools to assist physicians in making treatment decisions for patients — are currently prohibited, limited, or complicated by the Stark Law. While there is a Stark Law exception addressing EHR technology and support, the current rules do not allow hospitals to bear the full financial

cost of the EHR and instead require physicians to bear a portion of the financial costs. This same challenge remains for sharing EHR technology with our PAC providers.

Measure Concepts That Address PAC Interoperability

As previously stated, CHA urges the agency to consider an assessment of PAC providers to determine level of HIT adoption, scope of technology being utilized, and degree of interoperability before considering financial support that would likely be tied to specific metrics and quality measures. With limited financial resources available, such an assessment would inform targeted and thoughtful strategies that would accelerate the change currently underway without creating unnecessary regulatory complexity that could slow progress. CHA urges CMS to work through the Measures Application Partnership Post Acute Care Workgroup to further articulate and prioritize measurement gaps across the continuum. Such measures may include but not be limited to interoperability. CMS has recently begun collecting information to help further assess care coordination. Experience in collecting and reporting this information will provide valuable insights for future committee discussion.

Collection of SPADE in Certified EHRs

CMS is seeking comment on whether hospitals and physicians (who have been generally eligible for the PIP and have adopted CEHRT) should adopt the capability to collect and electronically exchange a subset of the same PAC standardized patient assessment data elements (SPADE) (for example, functional status, pressure ulcers/injuries) in their EHRs through the expansion of the USCDI process.

CHA agrees that, in the long term, certified EHRs should have the capability to exchange SPADE items, regardless of setting. In addition, any process by which future SPADE items are specified for EHRs should align with the same process for other providers. We also agree that, in the future, it would be a logical step to consider for the USCDI process all reliable and valid SPADE items. With that said, that time has not yet come, and we caution the agency in moving forward without additional stakeholder consultation.

As CMS has noted, the exclusion of PAC providers from the Medicare and Medicaid PIP has resulted in these providers lagging in adoption of health information technology. Despite this, some California hospitals found it valuable to modify their health information technology to incorporate some of the SPADE items to efficiently maintain and exchange a more complete set of health information for the patients they treat. However, the agency has continued to refine these elements over time, causing significant and costly reprogramming of EHRs and other technology used in the PAC setting.

Because consensus on the SPADEs across PAC settings is still evolving, CMS should be cautious in considering for the USCDI only data elements that are meaningful, reliable, valid, and that can differentiate patient characteristics or quality of care. Further, that process should not begin until after we have seen these data elements implemented on a national basis and providers are confident in the data being reported.

As the IMPACT Act implementation has taken place, PAC providers have been overburdened by the collection of SPADEs that have shown little to no difference between patients and fail to have the desired clinical impact on quality of care improvement. In some cases, data elements have been implemented and then removed, even in cases where providers felt that the elements appropriately captured their patients' clinical characteristics. This fluctuation in the standardized data elements has

been challenging and burdensome for many providers. CMS has yet to release its final report on the national beta test. Until CMS releases that report, as well as a corresponding data file for analysis by stakeholders, we do not believe this process should begin. Notably, while CHA supports inclusion of the SPADEs in the USCDI process, that should not be considered support for adoption into certification criteria for hospitals. Additionally, we do not believe it would be appropriate to consider any form of data collection by hospitals of the SPADEs at this time.

If CMS proceeds in using the **USCDI process to meet the goals of interoperability of these data elements as set forth in the IMPACT Act, we encourage the agency to ensure appropriate consensus in identifying a subset of SPADEs that will be most meaningful in successful care coordination. Slower adoption of data elements is preferable to a process that would require future expensive upgrades to EHR systems to address problematic data elements.**

CHA 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 California hospitals are committed to sharing health information that leads to more informed patients and higher-value, efficient, coordinated care, **we are concerned that — as proposed — the information-blocking provisions will add significant regulatory burden. This is contrary to the administration’s goals to reduce burden on health care providers. In more detail below, CHA offers specific comments related to the proposed definition of electronic health information, the proposed definitions of regulated actors under the information-blocking statute, and proposed information-blocking exceptions. In addition, we urge the agency to consider a significant period of non-enforcement as entities across the health care system are educated about and develop compliance procedures and policies on the new requirements.**

Definition of Electronic Health Information

Definition of EHI Is Overly Broad and Goes Beyond Congressional Intent

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. **CHA is concerned that this expansive definition of EHI goes beyond Congress’ intent of the scope of information required to be shared, and conflicts with the permissive use provisions of HIPAA. Additionally, an expansive definition of EHI will unnecessarily complicate implementation of the congressional policies to improve communications among providers in caring for their patients, especially across the care continuum, and especially in light of the very expansive definition of health care provider that ONC proposes.**

Section 3022 of the Public Health Service Act applies a set of congressional policies to a number of different actors, each with their own duties with respect to health care. Developing a uniform set of

policies for four different actors is problematic, especially given the different roles each of these actors plays in the delivery of health care. 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. **CHA opposes the inclusion of payment information within the definition of EHI. More specifically, we respond to ONC's request for comments on the inclusion of price information within this definition later in this letter.**

It is also important that providers are not faced with reviewing a significant quantity of information about a patient's past 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.

Data Under the USCDI Should Define EHI

As part of its updates to certification requirements, ONC proposes to replace the Common Clinical Data Set (CCDS) and replace it with the USCDI standard to increase the minimum baseline of data classes commonly available for interoperable exchange. In addition, ONC proposes to establish a predictable, transparent, and collaborative process to expand the USCDI going forward, including providing stakeholders with the opportunity to comment on the USCDI's expansion. **CHA urges ONC to limit the definition of EHI to the proposed data classes and elements required for certification under the USCDI, which can be updated or expanded upon over time. This definition would provide regulated actors with certainty on which information is required to be shared, and ensures actors are sharing information on an even playing field where all CEHRT captures the required information, reducing regulatory burden for all. If ONC wishes to expand the definition of EHI in the future, it could do so through its proposed process to expand the USCDI with opportunity for a notice and public comment period.**

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 — which might, for example, include emails or text messages among staff. In effect the proposed rule would require all of this 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.

Proposed Definition of EHI Conflicts with HIPAA and Creates Unnecessary Regulatory Complexity

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 health 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.

A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: (1) to the individual (unless required for access or accounting of disclosures); (2) treatment, payment, and health care operations; (3) opportunity to agree or object; (4) incident to an otherwise permitted use and disclosure; (5) public interest and benefit activities; and (6) limited data set for the purposes of research, public health or health care operations. The HIPAA regulations allow covered entities to rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make. The HIPAA regulations also emphasize providing the minimum information necessary for the intended purpose of the communication. **These are important safeguards in protecting patient privacy, which would be effectively eliminated by the proposed rule.**

Conversely, the 21st Century Cures Act prohibits health care providers, and 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." **CHA is concerned that any time a hospital declines to provide access to a patient's information — in the exercise of professional judgment under HIPAA — it will be accused of information blocking. This proposed rule also places hospitals in an untenable position where state and federal health information privacy laws, or the relevant facts, are unclear: the hospital would have to choose between disclosing the information (and risking a breach) or not disclosing the information (and risking an allegation of information blocking).** The proposed exceptions do not provide adequate reassurance that hospitals would be protected from information-blocking claims by the OIG for declining to make available certain EHI in a manner that is currently protected under HIPAA. CHA 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. Further, any future changes to the HIPAA disclosure requirements that conflict with more restrictive state laws — such as those in California — would be unduly burdensome.

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. ONC specifically seeks comment on the technical, operational, legal, cultural, environmental, and other challenges to creating price transparency within health care. **As previously stated, CHA opposes the inclusion of payment information within the definition of EHI and offers the following additional comments for consideration.**

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. In other words, Congress would have been required to include in the text of its legislation a specific directive to the Secretary to also include price information as part of EHI. 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 standard charges for services. No such directive appears in the language of Section 3022. **The Secretary may not intuit such an authority absent a clear and direct mandate or grant of discretion to do so pursuant to statute.**

Health care providers, in collaboration with other private partners, have already undertaken several 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 laws in states, like California, that lead the country in cost and quality information transparency.

First, in reading the request for comments, we were struck by the language used and reminded of the complexities of this issue. As stakeholders that come from various perspectives, we do not have a common set of definitions for the terms "price," "cost," and "charge." Going forward, we urge the agency to adopt the [HFMA price transparency task force report](#) definitions of several key terms that we believe will promote shared understanding and allow for meaningful dialogue between the agency and stakeholders.

As a first step, it is important to first disentangle "cost" from "price." When searching for an airline ticket, the price we see is the cost to the purchaser, not the cost to the airline and service partners that need to deliver the product. Similarly, when we talk about "price" and price "transparency" in health care, generally we are describing the price of the service to the purchaser; not the cost it takes to deliver that product to the recipient of the service. While other consumer industries perform a single function — such as airlines flying passengers from point A to point B — hospitals do far more than provide a unit of service, such as a knee replacement.

Hospitals provide emergency services to those who cannot pay, conduct groundbreaking research, and train the physicians and health care professionals of tomorrow. These services have great societal benefits, but they also incur costs that consumers may not realize when making purchasing decisions.

Hospital "prices" are also affected by the uniqueness of the communities they serve. Micro-economies, geographical differences, demographics of all the patients served, the level of discount and charity care provided to the uninsured and underinsured, their share of patients covered by public programs like Medicaid — all factor into the unit "price" of a knee replacement that a hospital can offer. Because many of those costs are not paid for in full by anyone, hospitals must make up the difference by "cost-shifting," which increases the unit cost of a knee replacement relative to other hospitals.

A singular focus on price is a significant and complicated issue. A concerted effort to address price must coincide with a concerted effort from our health and policy leaders to recognize the *costs* of the entire system to make that price more meaningful. This is particularly important for those who are uninsured.

More importantly, however, is the role of the payer. More than 90 percent of individuals in the U.S. have health coverage, and their payer — whether Medicare, Medicaid or a private insurance plan — establishes their cost-sharing obligation. That obligation takes into account whether the plan covers the service, whether the provider is in the plan's network, the plan's cost-sharing requirements, and, if applicable, the individual's deductible. Hospitals contract with more than 1,300 payers nationally, and the vast majority offer multiple (sometimes dozens or more) health plans with different benefit structures. Payers are the best source of information on what a covered individual's out-of-pocket costs may be for a given service.

We agree that hospitals also have a role to play in making meaningful information available to consumers and in making health care more affordable. Patients often request their out-of-pocket cost estimates, and hospitals and health systems will continue to provide them. California has some of the most consumer-friendly state laws in the country related to transparency and financial assistance policy. **In addition, under state law, hospitals must provide patients with a good faith estimate of the expected out-of-pocket costs to the patient for their health care services. Few states have such requirements. In doing so, we use technology that has evolved to meet our needs. ONC should not proceed in making complex regulatory requirements that will slow the adoption of innovative new technology that is working. California hospitals and health systems have made significant progress in providing meaningful price information that patients can understand and use to make health care decisions in advance of treatment.**

The efforts underway in California and across the country are mindful of proprietary information to the extent that is an issue, as well as ensuring compliance with state law requirements that have impact on making such information available. **ONC should not substitute an unworkable mandate on health care providers and other actors that contravene the efforts already underway; any effort to do so will slow ongoing work in this area and will add significant burden on providers. CHA has been very supportive of efforts of the Secretary to reduce or eliminate administrative burdens, especially duplicative ones, on health care providers, and we encourage the Secretary to avoid diverting providers' attention from furnishing the best clinical patient care to addressing price information matters under a federal mandate.**

It is also 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 also serve as a price comparison tool.

EHI as the vehicle to make this information available to patients is inefficient; it would require a vast amount of resources on the part of every health care provider to accommodate this type of mandate. Furthermore, it is duplicative of existing tools that are emerging at a far lower costs than an add-on to an existing electronic health record platform.

Apart from the issue of a patient electronic health record not being a suitable vehicle to gather price information, CHA does not believe that the current state of health IT can support the scope of the type of price information that ONC believes should be included as EHI. We believe that HIPAA transaction standards under title XI of the Social Security Act would require updating to accommodate the vast amount of disparate information ONC seeks to include as price information.

Definitions of Actors Regulated Under the Information Blocking Statute

The 21st Century Cures Act prohibits information blocking by health care providers, health IT developers, networks, and exchanges. Health IT developers, networks, and exchanges are subject to different penalties than providers, which are required to be subject to “appropriate disincentives,” which CMS proposes as public reporting of information-blocking attestation statements. In the proposed rule, ONC defines these actors broadly. Specifically, ONC proposes to use the very broad definition of health care provider established under the HITECH ACT.

Significantly, the agency also notes that a health care provider could also be operating as a different type of actor — such as a health information network — under certain circumstances. This is because the definition of a health information network under the proposed rule relates to individuals or entities that facilitate exchange of EHI between one or more unaffiliated individuals or entities, which many hospitals and health systems do routinely as part of care coordination efforts. Similarly, ONC provides a definition for health IT developers that acknowledges the role of providers as self-developers of CEHRT. ONC proposes that a self-developer of CEHRT would be treated as a health care provider for the purposes of information blocking. **CHA supports the proposal related to self-developers as it reduces confusion about the information-blocking penalties to which an individual or entity is subject. CHA urges the agency to reverse its position and clarify that if an individual or entity’s primary role is as a provider, they cannot also be considered a different type of actor for the purposes of information blocking.** This revision would be consistent with the statute’s requirement that penalties imposed by reason of the information blocking rules are not duplicative; this nonduplication requirement was intended to apply both to penalties imposed under other provisions of law as well as penalties that may be imposed by the OIG under section 3022 of the Public Health Service Act.

Information Blocking Exceptions

The 21st Century Cures Act directs the Secretary to identify reasonable and necessary activities and practices that do not constitute information blocking. In the proposed rule, ONC identifies seven exceptions that would not implicate information blocking. Each exception is subject to strict conditions that give the actor the burden of proof in demonstrating compliance with each exception. CHA appreciates ONC’s efforts to identify a thorough list of activities that may interfere with the access, exchange, or use of EHI, but are reasonable and necessary under certain circumstances. However, CHA is concerned with the significant burden placed on hospitals in demonstrating compliance with exception conditions. Each time a requester makes a request that a hospital deems infeasible, the hospital would be required to timely respond and provide a detailed written explanation of its reasons for denial. Hospitals frequently receive infeasible requests, including from patients and their family members, payers, researchers, and others. For example, data requests made of hospitals by researchers are more appropriately handled by entities that are charged and qualified to release specific information. Many of these requests do not merit a detailed written explanation of the reason for denial. It is also inappropriate to place the burden to prove a request is infeasible on the provider.

In addition, CHA urges ONC to expand the conditions for the “Preventing Harm” exception, which allows for reasonable and necessary practices to prevent harm to a patient or another person. Specifically, ONC defines the types of risk of patient harm to include an exception for disclosures where a licensed health care professional determines disclosure is likely to endanger the life or physical safety of the patient or another person. **CHA urges ONC to clarify that instances of emotional harm could be included in the definition. For example, clinicians may wish to avoid a situation where a patient learns of a significant diagnosis that would adversely affect their mental state through an electronic transmission of information, prior to a face-to-face encounter where the clinicians can provide important context and information about the care plan that could otherwise put the patient at ease.**

The OIG should consider providing subregulatory guidance that describes additional specific examples of the types of actions that would fall into exceptions categories most likely to be used by providers, such as preventing patient harm, promoting the privacy or security of EHI, and responding to infeasible requests.

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 protection of patient health information, as well as substantial staff education and training, and patient education. CHA urges ONC to issue an interim final rule with comment period, and clarify that information-blocking provisions will be 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, CHA 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.

CHA urges ONC to approach its disincentive policy in phases. It should begin with a long period of non-enforcement, during which the agencies conduct expanded education and training efforts. ONC and the OIG should also emphasize corrective action over financial penalties, with the latter being reserved only for actors displaying a pattern of noncompliance or disregard of the information-blocking rule that results in patient harm. The disincentive for actors with a pattern of violations should be tailored to the severity of the violations.

UPDATING THE 2015 EDITION CERTIFICATION CRITERIA

ONC proposes a number of updates to the 2015 Edition Certification Criteria, including adoption of a standardized approach to open APIs by requiring the use of the FHIR standard. ONC also proposes to expand the set of data classes and constituent data elements to be shared by naming the USCDI Version

1 as a standard. CHA generally supports these proposals and believes they will result in a more streamlined transfer of health information. CHA urges ONC to consider comments from stakeholders, in particular from health IT developers, on the appropriate timeline to implement these changes — generally 18 to 24 months following publication of a final rule. Providers must be given at least one additional year to upgrade their CEHRT.

EHI Data Export

ONC proposes a new certification criterion that would require certified health IT developers to be able to export all data from all patient records that the developer produces or maintains. The new criterion is intended to support two specific use cases: system transition and patient access. The system transition use case would allow exporting of the entire health IT database for a patient group upon request by a provider. Such an export would be required to be accompanied by a data map. CHA strongly supports this proposal, which will allow hospitals and health systems to avoid “vendor lock-in,” a common issue for hospitals that report health IT developers often purposefully make it difficult for their customers to get their data out of the system to ensure they will not switch to a competitor’s product.

CHA also supports the proposed patient access use case, which would allow for a user of the EHR system to export a single patient’s entire EHR upon request by the patient. We believe this is an important update that will increase patient access to their health information. However, we understand that ONC may be considering broadening the criteria to enable a third-party health IT developer or application to request such data on behalf of the patient, potentially via an API. As ONC considers expanding API access to EHI exports, it must consider bandwidth issues that could occur if third-party applications begin a practice of daily data exports for a large patient population. Such a scenario could lead to system crashes, creating a significant patient safety risk for hospitals. While patient access to data is vitally important, it must not put at risk patients who are actively being cared for in a hospital or health system.

Privacy-Related Criteria Changes

ONC proposes to update the Data Segmentation for Privacy (DS4P) 2015 Edition certification criteria. Currently, certified health IT models must support privacy tagging of EHI at the document level only. The new criteria, though still based on the C-CDA and the HL7 DS4P standard, must enable tagging at the document, section, and element levels. ONC proposes another new certification criterion, “consent management for APIs,” to facilitate data segmentation involving APIs. Modules would be required to align with the open source Consent2Share API Implementation Guide, designed to work with FHIR standards for APIs. The new DS4P and consent management criteria would become effective with the subsequent ONC final rule.

CHA members are concerned about the privacy-related criteria requirements and their implementation timeline. ONC notes that uptake of the current, simpler, DS4P standards has been minimal so far. More granular privacy tagging and consent management APIs potentially could improve exchange of EHI subject to special handling (e.g., related to behavioral health or child abuse). However, modules drilling down to the element level will be more complex and costly to develop than the current criteria, with costs being pushed downstream to users. Further, the putative benefits of granular tagging (e.g., eliminating workarounds to satisfy specific state regulations) may not be fully realizable without increased conformity among federal and state privacy provisions. Finally, we note that ONC identifies some ambiguity as to which FHIR release versions are, in fact, supported by the Consent2Share

Implementation Guide. **CHA encourages ONC to consider deferring adoption of the DS4P and consent management criteria at least until an API FHIR standard version is finalized and the Consent2Share guide is revised to conform to that version.** The additional time could be used for testing strategies to mitigate our members' concerns about unintended privacy consequences that might arise when patients unknowingly allow redirection of their EHI to others through third-party APIs that may not be HIPAA-compliant.

CONDITIONS OF CERTIFICATION AND MAINTENANCE OF CERTIFICATION

Developer Gag Clause Removal

ONC proposes a new "Communications" Condition of Certification that would not allow health IT developers to restrict or prohibit ("gag") communication among users of their modules about a module's real-world function and the developer's support of the module. Developers would be required to notify all customers within six months of the effective date of ONC's subsequent final rule, that any existing "gag clause" contract provision will not be enforced by the health IT developer. Only a few exceptions to the gag clause prohibition would be permitted. **CHA supports the proposed Communications Condition and customer notification deadline.** Our member hospitals often informally share important information with each other to advance patient care (e.g., emerging antibiotic resistance patterns, care coordination strategies). However, our members have been precluded from similar sharing about their health IT module experiences by their contracts with health IT developers. Gag clauses can delay the identification of module features through unintended consequences, such as interfering with clinical workflow, impeding care coordination, and presenting potential patient safety threats.

CHA appreciates the opportunity to provide comments on the proposed rules. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688 or Megan Howard, senior policy analyst, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/

Alyssa Keefe
Vice President, Federal Regulatory Affairs