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June 3, 2019

Seema Vema
Admistrator
Center for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, MD

Re: ***RIN 0938-AT79, 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 (Vol. 84, No. 42), March 4, 2019.***

Dear Ms. Verma:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 hospital, health system, PACE and post-acute members, thank you for the opportunity to opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) multi-faceted proposed rule to promote electronic health information.

NJHA fully supports CMS's intent to expand the ability of hospitals and health systems, health plans and others to share information that is useful in ensuring patients get the care they need and that it is safe and efficient care. However, we believe the desire for greater interoperability of information exceeds the infrastructure currently in place. Further, the conditions of participation (CoP) for hospitals and psychiatric hospitals are not the right vehicle to use in prompting hospitals to be interoperable. Additionally, the infrastructure to do what CMS proposes for post-acute care settings, Medicare Advantage (MA) plans, Medicaid, Children's Health Insurance Program (CHIP) and Qualified Health Plans (QHP) also is not in place yet. **We urge CMS not to finalize the provision in this proposed rule that would make the electronic exchange of admission, discharge and transfer (ADT) information a CoP and to delay the provisions for the sharing of information by various kinds of health plans until feasible.**

We believe it is important to share patients' ADT information with those involved in the care of each patient, as well as with the patient. To do so through interoperable exchange of data is easier than through other means currently at our disposal, but requires the existence of an infrastructure that only is partially constructed at this time. Currently, many of our members are able to share electronic health record (EHR) information, including ADT data, with others in their geographic area through their regional health information exchanges or through other services.

CMS's proposed rule would impose additional requirements on hospitals as part of the CoPs and on QHPs, MA organizations, state Medicaid agencies, CHIP agencies and others to achieve greater interoperability. This rule is must be assessed in relation to the Office of the National Coordinator for Health Information Technology's (ONC) proposed rule on information blocking; the Promoting Interoperability Program and its rules; the CoPs and anticipated amendments to those COPs that will come from the burden reduction rule proposed last fall; and the discharge planning rule that CMS proposed more than three years ago, but has not yet finalized.

NJHA fully understands that allowing hospitals and other providers to share important information with each other in a timely and efficient manner is critical and that doing so through an interoperable health information system would be easier than the current hodgepodge of communication strategies. It also is useful for patients to have access to their information. When it works, it is easier, more efficient and timelier than other ways in which patient information is shared.

However, CMS's proposal to make the transfer of ADT information a CoP is inconsistent with congressional intent for how the Department of Health and Human Services (HHS) would use the CoPs and how CMS would regulate the meaningful use of health information technology. Further, it assumes the existence of an infrastructure to make the exchange of such information routinely possible when that infrastructure is still being built. It also creates a situation in which hospitals trying to achieve compliance with this rule and the information blocking rule will find themselves trying to navigate through many redundant, conflicting and confusing requirements – all while risking their ability to participate in Medicare and Medicaid and incurring substantial fines. **We urge CMS to take a step back and consider how public policies can facilitate the development of the needed infrastructure rather than trying to force hospitals to create it under the threat of extraordinary penalties if they do not.**

Congress in the Health Information Technology for Economic and Clinical Health (HITECH) Act gave the agency the responsibility for overseeing the use of EHRs. From that authority, CMS created the set of regulations now known as the Promoting Interoperability Program (nee: Meaningful Use Program). This is the vehicle Congress intended for the agency to use in regulating the exchange of information between hospitals, patients, other caregivers and others who may have a legitimate reason to view information about the treatment of patients, not the CoPs.

Further, CMS's proposal to create this CoP comes on top of existing programs and requirements to advance the interoperability CMS has established in the Promoting Interoperability Program. It is unclear why CMS has chosen to use a different mechanism entirely – the CoPs – to advance information exchange.

CMS should use one program to impose requirements related to the use of information technology rather than including some in the CoPs, some in the Promoting Interoperability Program and

potentially some in other programs. When requirements for a set of activities are spread through different regulatory programs, it becomes confusing and difficult to navigate through the distinct and often competing requirements. **NJHA urges CMS not to create separate streams of regulatory requirements for interoperability. Continuing to align requirements for the use of electronic health information through the Promoting Interoperability Program exclusively will reduce confusion and eliminate unnecessary burden**.

While we recognize that the exchange of ADT information likely has benefits for the patient and the entire care team, it is just one of many actions hospitals are taking to ensure the safe, high quality treatment of patients. Arguably, many of those other actions are far more important to patient outcomes than the exchange of ADT information. Yet, when one looks at the conflation of the multiple rules that apply to the use of electronic patient data, it is easy to see that hospitals would be at risk for extraordinary penalties for failure to exchange ADT information electronically – penalties that could far exceed the appropriate penalties already established for failure to adhere to other critically important requirements.

. In the event that the hospital made a mistake and failed to send the ADT via electronic transmission as described in this proposed rule, it would violate this CoP. If the hospital did not have a reason for its failure that fell into one of the exceptions in the information blocking rule, the hospital also would be at risk of being considered an information blocker. For the hospital, the ONC proposed rule dictates that the penalty for being an information blocker is to fail the Promoting Interoperability Program. The penalty for failing the Promoting Interoperability Program is three-quarters of the hospital's market-basket update. **Based on the proposed inpatient payment rule for fiscal year 2020, that penalty would be 2.4 percent of its Medicare payments. Thus, hospitals are at risk of losing millions in Medicare payment for failing to exchange ADT information as part of the Promoting Interoperability Program**. Further, because the hospital would have certified that it was not an information blocker as a requirement of the Promoting Interoperability Program, it could potentially be liable under the False Claims Act, which carries a penalty of up to three times the amount of the claim and up to $11,000 per claim.

These are extraordinary penalties, especially in a field where 30 percent of hospitals have negative operating margins. By proposing additional penalties – to make the exchange of ADT information required as a CoP – CMS also would put a hospital's ability to participate in Medicare and Medicaid at risk. This could cause hospital closures and create access problems for patients. Moreover, the financial penalty is far stronger than other program penalties that are likely of greater importance to patients. Specifically, CMS's proposed policies put hospitals at far greater risk for failure to share ADT information than for failure to protect a patient's information, failure to publicly report on the quality it provides and excessive mortality rates.

With substantial penalties in existence as part of the Promoting Interoperability Program, it is unclear why CMS believes that it is necessary to add this CoP. Further, the potential penalties for

non-compliance are so out of proportion to those for other actions that are critically important to patients, it makes one question why CMS has put such an emphasis on the transmission of ADT information. **NJHA urges CMS to rethink the signal it is sending to the field about where hospitals priorities should be focused, and whether ADT transmission is, in fact, as important as the severe penalty provisions suggest.**

We also recognize that a hospital's compliance with the CoP is judged by a survey team. That survey team needs expertise, training and clarity regarding what they are looking for as evidence of compliance.

To judge compliance with the rule, surveyors would have to be able to see that hospitals sent ADT notices and review decisions where the hospital did not send the information. The rule potentially allows hospitals not to send the information if they do not have patient consent to do so. It clearly allows hospitals not to send if they do not have a "reasonable certainty" it would be received. Nothing in this rule makes clear what the expectations are for recording why the hospital did not forward the ADT information. EHRs do not have a field in which to capture the reason why the hospital staff believed that the potential recipient does not have the capacity to receive the ADT information or that patient consent was not obtained.

NJHA believes it is a mistake for CMS to make any part of interoperability, including the sharing of ADT data, a CoP for Medicare and Medicaid and urge the agency to withdraw this proposed rule and continue to articulate requirements for interoperability and use of EHRs in the Promoting Interoperability Program.

In the proposed rule, CMS requests information for future rulemaking on strategies for advancing interoperability across care settings, particularly noting the importance for outcomes when patients move from an acute care hospital to a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF) or long-term care hospital (LTCH) or if the patient receives home health agency services. CMS expresses concern that poor patient outcomes may result from poor communication among these providers.

NJHA supports CMS's goal of advancing interoperability in post-acute care settings. **However, CMS first needs to ensure that the technological and organizational infrastructure exist to facilitate meaningful interoperability between post-acute care providers and general acute-care hospitals** – critical building blocks that do not widely exist today.

Both our hospital and post-acute care members are making substantial investments to improve transitions of care across settings. However, the transitioning from the ownership of EHRs to actual information exchange to and from post-acute care providers remains limited. The biggest impediment to this exchange continues to be incompatible health information technology systems. To work around the limitations of the current system, some members report using "data extraction" software to access selected fields of desirable data from the medical record of the referring hospital.

As CMS considers moving forward, it must bear in mind that post-acute care providers' sizes and resources are highly variable, ranging from national chains that have invested many millions in building their own post-acute care health information technology systems to one or two site organizations with limited funds available for health information technology investment. The American Hospital Association's (AHA) 2017 Annual Survey of the hospital field found that almost 90 percent of IRF respondents use a certified EHR system, while only 57 percent of LTCH respondents have one. A November 2018 ONC Data Brief reported that 66 percent of SNFs and 78 percent of home health agencies used an EHR in 2017.

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 mandated more consistent patient assessments across post-acute care settings to improve transitions of care and coordination over an episode of care. This process still is in the early stages with only one item implemented for two out of the five patient assessment domains.

We do not support expanding hospital and physician interoperability requirements to include post-acute care patient assessment items, as post-acute care patient assessment items generally do not align with the clinical focus and protocols of general acute-care hospitals and physicians. In general, doing so would impose substantial burden on referring general acute-care hospitals, with no material improvement in the sharing of useful information.

One exception may be the patient assessment item "discharge assessment of functional status," which might be appropriate for consideration as an *optional* item for general acute-care hospitals because of the growing interest in making hospital discharges to post-acute care more evidence-based and consistent to improve transitions of care. Further, such data could be relevant under a possible new payment approach for post-acute care, such as a unified post-acute care prospective payment system, a payment model that is being developed per an IMPACT Act mandate.

We are opposed to creating additional Medicare CoPs or conditions for coverage (CoCs) for post-acute care providers to promote interoperability of health information. This mechanism raises multiple concerns including the absence of a technical and organizational infrastructure to enable electronic health information exchange, an impediment that is particularly acute for post-acute care providers.

The agency proposes to apply the same application programming interface (API) standards proposed by ONC to Medicare MA organizations, Medicaid and CHIP fee-for-service programs, Medicaid managed care plans, CHIP managed care entities and QHP issuers in states utilizing a federally-facilitated exchange (FFEs). We support the agency's aim to ensure alignment across insurers and providers. While clinical information originates with one, or many, providers, much of the administrative data, such as a patient's coverage details, originates with the patient's health plan. This can cause friction as patients try to piece together disparate pieces of information to get the full picture of their care and their related financial obligations. Alignment in standards will

help remove some of the friction in order to ensure patients have simple and easy access to their health information.

However, we are concerned that the ONC rule only proposes standards for sharing clinical data, whereas CMS is proposing that health plans would be required to make both clinical *and administrative* data available through the open API. While we do believe these data could be useful for patients for the reasons detailed above, we urge the agency to not require sharing of administrative data via an open API until CMS specifies a standard. Without standards and specifications, it is difficult for various parties to exchange this information in an efficient way. We are aware that CMS has utilized the Blue Button 2.0 API specification to make its own administrative data available, but it is unclear from CMS's proposal if it would require health plans to do the same. Consequently, in order to promote adequate pathways for sharing administrative data, CMS should prioritize adding administrative data elements – such as claims and encounter data, provider remittances and coverage details – to the U.S. Core Data for Interoperability (USCDI), which would lead to the development of FHIR financial resources and inclusion of such data in a single API specification.

In addition, CMS proposes to include provider directory data in the open API requirements. While we are supportive of improving access to and the accuracy of provider directory data, we note that the current provider directory standards were written for FHIR version 3 and that the standard has not been adopted by the field. The health care field has indicated that they will not be adopting FHIR version 3 since it is not backwards compatible. Currently, vendors are either using FHIR version 2 or version 4, and ONC has proposed to use version 2. We believe that before CMS requires plans to make provider directory available via an open API more work would be needed to build the provider directory specification in FHIR version 4. Without a consistent standard across plans, app developers would have to rebuild their tools multiple times to work with the various proprietary APIs. This would ultimately prevent the type of innovation for consumer facing apps that CMS hopes to encourage.

Finally, we remain concerned about the privacy and security of a patient's health information when entered into a third-party application. While patients should have access to their health information, including the right to use the information as they see fit, it is unclear whether patients understand the ramifications of their actions when sharing their data with third-party vendors. Once shared, their data can be shared with other actors or used to generate advertisements. It also may be at risk for being further exposed as third-party vendors are not required to encrypt patient's data, leaving the data vulnerable to hacking. **We continue to encourage the agency to promote the safety and security of these data at every measure.**

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NJHA sincerely appreciates your consideration of these issues. Additionally, please do not hesitate to contact me at (609) 275-4000 should you or a member of your team have any questions.

Sincerely,

Jonathan Chebra
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