June 25, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Verma:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments regarding the proposed rule, *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims,* published by the Centers for Medicare & Medicaid Services (CMS) on May 7, 2018 in the *Federal Register*.

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With more than 2,600 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate the effective use of information management to improve the health and healthcare in the communities they serve.

CHIME appreciates the opportunity to lend our perspective; our comments will be limited to the Promoting Interoperability program, the Request for Information (RFI), and quality reporting. **CHIME is particularly grateful CMS has chosen to exercise some of the flexibility Congress**

afforded the agency under the 2018 Bipartisan Budget Act. A provision in the act permits CMS to remove the "pass/fail" policy that has made the Meaningful Use program, now renamed Promoting Interoperability, a zero-sum game for hospitals. Below, we have outlined our key points and recommendations and provided more detailed feedback in the body of our letter.

1. Finalize the new measures proposed by CMS under the Promoting Interoperability program but keep measures 2 and 3 under the e-prescribing objective voluntary.
2. Allow current policies designed to speed interoperability (i.e., TEFCA and use of 2015 CEHRT) the chance to take root and for patients and providers to benefit from them before considering other policy levers.
3. Address the multiple barriers outlined in our letter which, if left unaddressed, will continue to impede widespread interoperability.

I. Medicare & Medicaid Promoting Interoperability Programs

A. Name Change

We support CMS' proposal to rename the Medicare & Medicaid EHR Incentive Based Program to be the Medicare and Medicaid Promoting Interoperability Programs (hereinafter referred to as the PI Program). We agree that the name change better reflects the desired outcome to pursue interoperability, and since the incentives for Medicare ended in 2015, it is logical to reorient the name away from this moniker.

B. Scoring

As reflected above, CHIME thanks CMS for proposing changes to what was previously referred to as Stage 3 Meaningful Use requirements. Several of the policy changes proposed by CMS address concerns raised by CHIME. As we have commented in the past, the "pass/fail" policy unnecessarily jeopardizes the hard work and investments that providers have made in a good faith effort to be successful in the PI Program, and CMS should streamline reporting redundancies and limit measures to focus on those that will help advance patient care. These goals are consistent with the CMS Meaningful Measures Initiative, which calls for using "a parsimonious set of the most meaningful measures for patients, clinicians, and providers in our quality programs," and which we believe should apply to the PI Program as well as other Medicare quality reporting and pay-for-performance programs.

We believe that the proposed new scoring system and the revised and streamlined set of measures and objectives represent a marked improvement in assessing whether a hospital is a meaningful user of certified electronic health record technology (CEHRT), and that the revised requirements will provide greater flexibility in support of continued progress toward achieving better access to data for both providers and patients. Furthermore, it better aligns the Merit-based Incentive (MIPS) program.

C. 2015 CEHRT

We appreciate that CMS has given providers more time in 2018 to install and begin using their 2015 CEHRT. Given the development time needed for the vendors and thus the extra time needed by providers for installation and workflow redesign, this has been very helpful. Many of our members are still in the midst of receiving and installing the new software and some are backed up with orders to install it. It is also worth noting that some CMS programs still require the use of 2015 CEHRT for an entire year (as opposed to 90 days) beginning in 2019. Unless CMS aligns the reporting periods and changes them all to be 90 days, some providers will need to be ready to have their new software installed and use by January 1, which erodes some of the flexibility CMS has offered. **We recommend CMS make the reporting period for all programs that require the use of 2015 CEHRT be 90 days in 2019.**

D. Objectives & Measures

e-Prescribing Objective

Measure 1: e-Prescribing

We appreciate that CMS will continue to allow hospitals the flexibility to include or exclude prescriptions for controlled substances in calculating performance rates on the e-prescribing measure in 2019. CHIME supports requiring the use of e-prescribing of controlled substances and supports legislation being consider by both the House and Senate to require e-prescribing of controlled. State laws regarding electronic prescribing for controlled substances (EPCS) vary, and this flexibility will allow hospitals to be assessed fairly on this measure in the absence of a federal mandate.

Recommendation: Support.

Measure 2: Query of Prescription Drug Monitoring Program (PDMP)

Our members are committed to helping address the opioid epidemic and taking measurable steps to bend the addiction curve. CHIME's Opioid Task Force is working collaboratively with our members, the private sector including private companies affiliated with our Foundation, and other stakeholders to use technology and data-driven solutions to address this national public health crisis. For many of our members and Foundation firms, this issue is not only a priority, it is personal.

CHIME thus understands the urgency of addressing the nation's opioid epidemic, and we appreciate CMS' desire to contribute solutions that will help stem the tide of opioid addiction. However, we have concerns about making the two proposed new opioid-related e-prescribing measures mandatory beginning in 2020.

We support the use of state PDMPs, but making this mandatory starting in 2020 would be premature. Our concern is that access to this data is not consistent and our members are wrestling with an environment that involves varying state laws and non-homogenous access. For instance, some states preclude providers from ingesting the data from the PDMP into the EHR and thus clinicians must wrestle with two different systems and workflows. Further, many state laws already require providers to query PDMPs when prescribing controlled substances. However, CMS itself acknowledges in the preamble that the integration of PDMPs into a health information exchange or providers' EHR is still developing, and the manual data entry into the CEHRT and manual calculation of the proposed measure would be burdensome for many hospitals.

Our members also report that states vary widely in how they structure and finance their PDMPs. It is not always possible to access the PDMP electronically, and hospitals will face the cost of asking vendors to build these additional features into their CEHRT to comply with this measure. Additionally, in some cases states charge providers PDMP fees, and a mandatory PDMP query measure could add considerably to these costs.

Recommendations:

1. CMS should work with the Office of the National Coordinator (ONC) to adopt standards and certification criteria to support the query of a PDMP as soon as practical.
2. Until such standards are in place and integration of these systems is achievable, this measure should remain voluntary at least for 2019 and 2020.
3. Collaborate with Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to educate providers on opioid grants.
4. Providers are accustomed to looking to CMS for education and outreach and its ability to reach a wide swatch of providers is great. Collaborating with these sister agencies will increase awareness.

Measure 3: Verify Opioid Treatment Agreement

The second new measure proposed by CMS, which would assess how often hospitals verify the existence of an opioid treatment agreement, has merit as a concept because patients benefit when their treating physician has readily available relevant information on their health status and needs. In this case, however, the measure specifications need to be developed further before it can properly be considered as a mandatory PI Program measure. For example, it is not clear how the patient population (those receiving an opioid prescription of at least 30 cumulative days) would be identified, what means hospitals would be expected to use in seeking to identify the existence of a treatment agreement during the previous six months, and what constitutes a treatment agreement. In addition, CMS acknowledges that there are pilots in development focused on improving data exchange among healthcare providers to better integrate behavioral health information, and further, that there is no consensus on the clinical value of opioid treatment agreements. We believe that these pilot tests would be the better place to work on specifications and assessment of the value of this information before adding the measure to the PI Program. At a minimum, the measure should remain voluntary until the specifications are clear.

Recommendation: Keep measure voluntary beyond 2019 because the measure specifications need to be developed further.

Health Information Exchange Objective

Measure 1: Support Electronic Referral Loops by Sending Health Information

CMS renamed the pre-existing measure, "Send Summary of Care" and replaced it with "Support Electronic Referral Loops by Sending Health Information." We appreciate that CMS has removed the thresholds from the previously finalized Stage 3 program for this measure, and has now called for hospitals to create only a summary of care using CEHRT and electronically exchange the summary of care for at least one transition of care or referral.

Should this measure increase over time, we believe there should be a way for patients to opt out of having their information sent electronically should they choose. We are aware of situations where information has been sent, but ended up being sent to a provider who also happened to be the patient's employer, which was not the patient's preference. The rare cases in which patients opt-out of having information sent should not be counted in the measure denominator.

Recommendation: Support.

Measure 2: Support Electronic Referral Loops by Receiving and Incorporating Health Information

CMS has called for combining two pre-existing measures, the "Request/Accept Summary of Care" measure and the "Clinical Information Reconciliation" measure, into a single new measure, "Support Electronic Referral Loops by Receiving and Incorporating Health Information." We agree with CMS' synopsis that the "Request/Accept Summary of Care" measure creates workflow burdens on providers involved with gauging whether an electronic record was indeed requested.

Under the new measure, CMS calls for at least one electronic summary of care record received for patient encounters when a hospital was the receiving party of a transition of care or referral; or for patient encounters when the hospital has never seen the patient before, the hospital must reconcile information pertaining to medication, medication allergy and current problem list. The combination of the two pre-existing measures, said CMS, is intended to focus on the "exchange of information" and reducing administrative burdens. CMS has also said that if this new measure is adopted, then an exclusion would be available for hospitals that are unable to support the receiving and incorporating function in 2019, something CHIME supports.

Our members appreciate that CMS is focused on ways to streamline the workflow for providers, and given the measure is limited to one patient action, we believe this is a substantial improvement over the previously adopted thresholds. We are concerned, however, that if the measure threshold grows over

time, accepting and incorporating information received from external parties into providers' EHR will impose a liability on them. Most of our members are accustomed to sending information to other providers, however, receiving information introduces new challenges that have not previously been addressed. As an example, if ED clinicians query an HIE or other providers, they could get 10 possible "hits" on their patient for possible matching records. If they queried for medications, allergies, labs and problem lists they could get 10 different records back. Some HIEs will combine all the records into a single CCDA but this does not always happen. If it is not presented as a single document, the clinician is facing reconciliation of 10 different sets of records for each of these discrete queries and must manually review them and either "accept" or "reject" the results. Some EHRs allow a clinician to accept or reject the pieces of the CCDA they want, whereas others do not and the entire CCDA must be accepted.

Recommendations:

1. Support new measure and threshold for 2019.
2. If measure threshold increases over time:
    a. Given the outstanding workflows and concerns outlined above, we seek clarification from CMS on how it is defining "incorporate" and whether the intent is that data must simply be received by the accepting provider or whether it must be ingested into the EHR? If it is required to be ingested into the medical record, medical liability concerns must be addressed; and
    b. Providers should be able to continue to pick and choose which information is relevant and useful to patient care and incorporate those data into the electronic record.

Provider Patient Exchange Objective

Measure: Provide Patients Electronic Access to Their Health Information measure and use of application programming interfaces (APIs)

Under CMS' proposal, they call for renaming the "Patient Electronic Access to Health Information" objective to "Provider to Patient Exchange," removing the "Patient Specific Education" measure and renaming the "Provide Patient Access" measure to "Provide Patients Electronic Access to Their Health Information." Under the proposed change, CMS has called for a threshold change such that hospitals would only have to provide timely access to view, download and transmit information for one unique patient and that they are given access to their health information using an application of their choice facilitated by an application programming interface (API).

Our members fully recognize the utility of APIs and expect as their use matures and access to them becomes more widespread, that this will offer a facile way for patients and providers to access medical data. However, as we have communicated numerous times previously, we have a number of concerns that CMS has yet to address, which we have outlined below:

- **Security:** First, the security of APIs is of paramount concern. Our members believe the data they are entrusted with indeed belongs to the patient; however, they have multiple concerns about securing the data with which they have been entrusted. Given the potential wide range of APIs with which hospitals would be required to interface, the potential vector for cyberattacks on the hospital medical record system is increased. To quote one of our larger and well-resourced members who deploys cutting-edge technology within their system: "My worst fear – if we have an open API and patients want to download medical records and they open up their records for a well-intended other institution like [X Provider] and they want to take records and ingest them…they are no longer the gatekeeps so any third-party info can access them."
- **Authentication and validation:** Another concern – which is linked to security – centers around authenticating who is receiving the information and whether the person has a right to see it under federal and state laws regarding the privacy and security of personal health information. Providers don't feel they have any way to validate the third parties (i.e., app developers) seeking access to this data in their EHRs. As another member couched it, this is a "monstrous concern."

- **Inexperience using APIs widely in healthcare:** Use of APIs in healthcare is still in its infancy and few in healthcare have seen this operationalized; therefore, much remains unknown. While providers are excited about this technology, many are also approaching this cautiously.
- **Immature standards:** Finally, no standards have been adopted yet for APIs in healthcare and while we expect ONC to eventually name Fast Healthcare Interoperability Resources (FHIR) as that standard, this is still a draft. Use of APIs has not been widely tested in healthcare – this has just begun. The FHIR standard was not adopted as the standard in 2015 CEHRT because it was deemed immature. The standard, while being adopted by many vendors with the expectation that it will bring greater interoperability, is still a draft standard. Our industry has a lot of experience adopting immature standards and many lessons learned from this experience.
- **Patient education:** Our members are very worried about the level of understanding patients may have about how APIs work and how their information, once its leaves a provider, will be safeguarded.
- **Data blocking:** Providers continue to worry that CMS will deem them to be data blockers if they refuse to connect to an API they consider unsecure. The cybersecurity issues are proliferating daily and risks to patient safety and privacy – as we detail later in our letter – pose a significant threat to our industry.

CMS has also called for removing the "Coordination of Care through Patient Engagement" objective and all associated measures which include secure messaging, use of patient generated data, and view, download or transmit measure. CHIME supports removing this objective and the associated measures.

CHIME fully supports patient access to their health information, which is already required under the Health Insurance Portability and Accountability Act (HIPAA), as well as Clinical Laboratory Improvement Amendments (CLIA) Program for lab results. Moreover, our members are committed to ensuring patients have easy and quick access electronically to the information they need to help manage their care.

Our members also have several questions regarding the objective, "Provide Patients Electronic Access to Their Health Information" measure. This measure is vague and our members are seeking clarification on CMS' intent. The measure calls for "timely" patient access. Our members believe it would be in the best interest of both patients and providers if "timely" was defined. This would remove ambiguity and create consistency. "Timely" has previously been defined as 36 hours; however, we continue to believe this timeframe is too short and that 72 hours is a more reasonable and would give a patient's care team sufficient time to review the record and contact patients with sensitive information.

Recommendations:

1. Support the new measure and threshold for 2019, but do not require widespread use of APIs for at least three years.
2. Address the myriad concerns that have been raised by healthcare providers before widespread use of APIs is mandatory:
    a. CMS should study the ROI associated with the use of APIs.
    b. CMS should limit the providers required use of APIs to ones that are deemed by the provider to be secure;
    c. Allow providers to refuse to connect to an app if the provider deems it unsecure without invoking data blocking rules;
    d. Address security concerns so as not to increase the threat vector for providers which ultimately could result in patient privacy and safety issues; and
    e. Work with federal partners like the Federal Trade Commission (FTC) who has jurisdiction over regulating use of mobile apps that are not governed by HIPAA, to educate patients on the risks of sharing information on APIs.
3. Define "timely" to mean 72 hours.

4. APIs are not in widespread use in healthcare. We urge CMS, ONC and the Office for Civil Rights (OCR) to continue to work with hospitals and other stakeholders to name standards and address security concerns.

Public Health and Clinical Data Exchange Objective

For this objective, CHIME recommends that hospitals select to report two out of the six measures, which include the Syndromic Surveillance, Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry, Clinical Data Registry Reporting, and Electronic Reportable Laboratory Result Reporting. Under the previously adopted requirements, hospitals were required to meet three of the six measures, but under the new proposal CMS has called for hospitals to meet the Syndromic Surveillance and one additional measure of the hospital's choice. Further, hospitals would not be graded on a threshold, rather, they would be required to report "yes"/"no" responses. And, reporting more measures under this proposal would not earn a hospital extra points. Finally, CMS plans to phase this objective and measures out by CY 2022.

Recommendations:

1. Support reducing measure reporting from three to two.
2. However, syndromic reporting is not possible in all states (i.e. California). Therefore, we recommend allowing hospitals to select the two measures of their choosing and not mandate the Syndromic Surveillance measure.

Medicaid Promoting Interoperability Program

We appreciate that CMS is working to align the Medicare Promoting Interoperability program more closely with MIPS, however more alignment is needed with Medicaid. We recognize that CMS is sensitive to the burdens that states could experience if changes are made to the requirements under the Medicaid Promoting Interoperability program. Nonetheless, we believe that unless the Medicare and Medicaid programs are aligned, that this will continue to exact a high administrative burden on providers and vendors and could needlessly drive up the costs of software if vendors must offer potentially different software and providers must maintain different dashboards. Further, clinicians who serve both populations would have to meet two separate sets of requirements.

Recommendation: Align the Medicaid Promoting Interoperability program with the Medicare Promoting Interoperability program.

II. Request for Information on Promoting Interoperability Through CMS Patient Health and Safety Requirements for Hospitals and Other Providers

CHIME appreciates that the Administration has made accessing medical records data electronically for both patients and providers a top priority. Our members are leading initiatives at hospitals, health systems, rural providers and others across the country devoted to helping make this a reality, though their efforts are dampened by ongoing barriers and challenges. They fully appreciate and are committed to using technology and data to care for patients. Below we address CMS' questions outlined in the RFI contained in the rule.

A. Conditions of Participation (CoP)

CMS is querying stakeholders on whether using Medicare CoP will promote interoperability. In short, CHIME does not believe this is the right approach. Simply imposing regulatory requirements that make electronic data exchange a condition for providers to receive Medicare payment does not address the root issues at play. Addressing ongoing barriers is needed to speed greater progress around interoperability.

Importantly too, a distinction must be drawn between speeding and increasing data exchange among providers and achieving a true state of interoperability. The two should not be conflated. Both have been

improving over the past several years. We recommend that CMS speak with KLAS, which has been studying interoperability and examining what information clinicians find most useful.

Achieving a heightened state of interoperability where workflow burdens are minimized for clinicians and patients are presented with data in a more facile manner will require the removal of the barriers we outline in greater detail below. If the desired goal is to truly achieve a more interoperable health system, we fail to see how using the Medicare CoP could achieve this in the absence of addressing these barriers.

We worry that executing a CoP policy intended to drive interoperability will have the unintended effect of marginalizing patient access to care by putting providers who may already be struggling out of business. We are aware of some hospitals that have not been able to achieve Stage 2. A large amount of data rests with physician practices, however, many still cannot accept data; changing the CoP rules will not fix this. Physicians' demand for data is growing. As one member from rural Michigan shared with us, her clinicians are beginning to request the CCDAs. That said, there are many physicians who still regard the CCDA data and the "summaries of care" as bulky and hard to navigate. Addressing the barriers we have identified below will help position better interoperability. Ensuring the data are seamlessly digested and incorporated into the EHR for easy access as part of the clinical workflow is a separate matter, however, and that will take more time to achieve. The industry is working hard at this but there are no quick solutions.

Finally, the policy landscape for EHRs remains unclear to many providers. We are concerned there are several policies aimed at improving the overall state of interoperability as well as increasing data exchange that have yet to be fully implemented. For instance, the 21st Century Cures Act calls for the TEFCA yet this has not been finalized. And, as CMS reorients the Meaningful Use program to the Promoting Interoperability program and ensuing policy changes, we believe these changes must first be implemented and allowed to take root before more policy levers are pulled. Additionally, our members are just now beginning to operationalize the 2015 CEHRT, which CMS and ONC have touted as a key component of interoperability. Information blocking rules are not yet final, and we also expect additional changes to CEHRT from the ONC this year. Allowing interoperability to flourish requires some level of policy certainty for both providers and vendors. We believe the providers must be given time to adapt to these new changes and their impact should be evaluated before considering a CoP mandate.

B. Barriers to Interoperability

There is a myriad of barriers holding back what is possible and if addressed will undoubtedly improve the state of interoperability. These are indeed well-known but remain insufficiently addressed. Section 4004 of the 21st Century Cures Act defines interoperability as technology that, ''(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C) does not constitute information blocking as defined in section 3022(a).'' Based upon our reading of the statute, meeting the spirit of the law will require addressing the barriers we describe below.

- **Defining & Measuring Success:** We recognize CMS' desire to get data into the hands of patients and providers, however, it is unclear how success will be measured. We strongly support the goal of ensuring patients have electronic access to their records but it is also unclear to us how CMS is defining the medical record.
  Recommendations:
  1. CMS should clarify how they are defining interoperability, what constitutes success, and working with stakeholders to identify reasonable benchmarks against which industry will be gauged. If it is increasing the number of CCDAs shared among different providers, that should be clarified.

2. CMS should clarify how they are defining the patient's medical record. CMS has said patients should have access to the entire record. Based on our experience, this is not what patients are demanding. The entire medical record is the legal document. Rather, we believe what CMS intends that patients have access to pieces of their medical record that include entries like lab results, medication history, pathology reports, visit/encounter summaries, discharge instructions, allergy history, problem list, etc.

- **Lack of predictability in policy environment:** One of the most common complaints we have heard from members over the last several years is that the frequency of change and level of uncertainty have created turmoil for providers. Having some level of certainty and stability is needed for providers and vendors to adopt policy changes and institute workflow changes. However, we have found that often policies are developed without adequate time for the industry to adapt and this sets in motion cascading events that lead to last minute changes. It can be hard to take full advantage policy changes, even those that are welcomed, if they come too late.

  Recommendation: Ultimately, having a reasonable and predicable pathway for changing health IT policies. When CMS and ONC rules change frequently, even when changes are welcome by the industry, vendors need to invest time and resources in development of system upgrades, and providers must pay those costs and invest time and resources in implementing changes. This slows down progress on interoperability, at least in the short run. Having more stable and predictable standards, objectives and measures will allow providers to continue to move forward to pursue solutions that improve interoperability.

- **Unique identification of patients:** The lack of a consistent patient identity matching strategy is the most significant challenge inhibiting the safe and secure electronic exchange of health information. As our healthcare system begins to realize the innately transformational capabilities of health IT, this essential core functionality – consistency in patient identity matching – must be addressed. Patients and care providers are missing opportunities to improve people's health and welfare when information about care or health status is not easily available. As data exchange increases among providers, patient data matching errors and mismatches will become exponentially more problematic and dangerous.

  Recommendations:
  - A congressional appropriations prohibition in place since 1999 prohibits the U.S. Department of Health and Human Services (HHS) from promulgating or adopting any final standard for the assignment of a unique health identifier for an individual. This is such a pivotal issue that we believe widespread interoperability efforts will be stymied without this being addressed. Technology has moved well beyond use of a simple alpha-numeric identifier. The new Medicare Beneficiary Identifier, from our perspective, does not address the overarching issue. CMS should acknowledge this barrier and in the absence of the removal of this ban, should support private sector-led efforts to locate a solution to patient identification and provide technical support.
  - CMS should fund pilot projects similar to what ONC did with Beacon grants, to help test private sector-led solutions to drive better patient identification and measure patient outcomes.

- **Consistent set of data exchange standards:** A clear set of uniform standards used by all parties in the healthcare system is needed. This, along with accurately connecting patients to their records, is pivotal to achieving an ecosystem that is more interoperable; unless these two issues can be addressed we believe interoperability will continue to be thwarted. Things as seemingly simple as date of birth and lab values are still reported in disparate ways, making it hard for systems to move beyond swapping data to actually ingesting it and presenting it in a seamless manner to the clinician.

  Recommendations:
  1. The U.S. Core Data for Interoperability (USCDI) is intended to help foster a better state of interoperability, though it has not yet been finalized and will be voluntary. CHIME continues to

believe that a single set of standards named by the federal government is needed to ensure all parties across the healthcare system are exchanging data in a uniform manner.

2. CMS should convene stakeholders across the care continuum (hospitals, physicians, post-acute care and long-term care providers, patients, etc.) to discuss and identify what data elements are of most value to both providers and patients and prioritize work around a discrete set. For instance, it's not clear that the data needed by the long-term post-acute care (LTPAC) sector is in fact well understood by some hospitals.
3. The three levels of interoperability, as identified by the National Committee on Vital and Health Statistics (NCVHS)[1] must be recognized:
    a. Foundational: Allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data.
    b. Structural: An intermediate level that defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered.
    c. Provides interoperability at the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged.[2]

- **Challenges accessing and using Direct Addresses:** According to DirectTrust, the Direct standards are available in 350 EHRs at over 70,000 providers nationwide with approximately 750,000 addresses in existence. Yet, not all providers have a Direct Address, and for some providers it can be difficult to obtain addresses of other providers to transmit information. Furthermore, there is no single directory of Direct addresses. The 21st Century Cures Act calls for HHS, "to establish a provider digital contact information index to provide digital contact information for health professionals and health facilities."

  Recommendation: We recommend HHS engage stakeholders to discuss ways to increase awareness of Direct Addresses.

- **Varying patient consent policies**: The issues surrounding sensitive information transfer are myriad and complex and must be resolved. Providers must navigate patient consent issues under the Health Insurance Portability and Accountability Act (HIPAA) that vary from consent policies involving substance abuse and mental health. The latter are more stringent and governed by policies contained in 42 CFR Part 2. Additionally, state laws regarding privacy of health information are often more stringent than HIPAA. Most of the consent policies that are in place today were designed when medical records were on paper, and few changes in these policies have been made to allow for the electronic exchange of this information. Taken together, this creates a very complex landscape for providers to navigate and impedes the flow of information needed to care for patients.

  Recommendations: CHIME strongly supports the alignment of the Part 2 with HIPAA policies for treatment, payment and healthcare operations. We recognize that this will require congressional action, however, it does represent a significant barrier for providers. A bill aligning Part 2 with HIPAA recently passed the House and we are pleased to see legislation that would indeed align these policies.

- **Costs:** Setting up interfaces and connecting with multiple health information exchanges (HIEs) is costly and stretches provider budgets. Post-acute care providers, behavioral health providers and others who were not eligible to participate in the Medicare and Medicaid PI Programs when financial

[1] National Committee on Vital and Health Statistics (NCVHS) Report on Uniform Data Standards for Patient Medical Record Information, July 6, 2000, pp. 21-22.
[2] Institute of Electrical and Electronics Engineers, IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries, New York, NY: 1990.

incentives were available are at a greater disadvantage. Additionally, providers are on different versions of software with varying levels of data exchange.

Recommendations:

1. Providers must be given adequate time to develop electronic data exchange that is meaningful to patient care in care settings that go beyond hospitals and physician offices to the rest of the care continuum; and
2. CMS should consider the costs of interfaces with other providers and multiple HIEs. It may be cost prohibitive for a provider to connect with all trading partners all at once. Consideration should be given to those providers with whom they share the most patients.
3. Recognition must also be given to the fact that while providers are constantly upgrading their software, there are financial limitations and they are all on different versions of software. What may be affordable for one provider may not be feasible for another.

- **Cybersecurity:** Providers continue to have to balance the act of sharing an increasing amount of information electronically with growing cybersecurity threats that are becoming more aggressive and sophisticated each day. The current regulatory framework overseen by the OCR governing breaches presumes a breach has occurred unless a provider can demonstrate otherwise. This framework is problematic because it lacks clear and practical guidelines for providers, and in practice results in substantial overreporting due to providers' confusion and their fear of repercussions. The extent of reporting has become so voluminous under the current framework that the regulation arguably renders the notification and reporting meaningless for patients, providers, government and other stakeholders. Patients are likely unable to discern when instances of breaches of information could result in personal harm.

  Further, the information reported is so voluminous as to render it meaningless for patients and others interested in addressing real problems to protecting the privacy of patient records. The current HHS policy imposes a stigma on entities reporting a breach in perpetuity. The proposed changes seek a fair mechanism to relieve an entity of being listed as a "violator" once the entity takes action to correct its vulnerabilities.

  Recommendation: A better balance between the protection of protected health information (PHI), continuous and rapid evolution in technology including health technologies, and the practical realities of implementing privacy protections and practices is warranted.

C. CMS Questions

1. ***New Standard: If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?***

   No, we do not believe this is necessary. There are already several requirements tied to Medicare/Medicaid reimbursement. There is no definition of "medically necessary information" and it varies depending upon which party you are in the care continuum. The definition of information blocking that is part of the 21st Century Cures Act also has several terms that still need to be defined by the Administration (i.e., "materially discourage") and without this policy guidance it is also hard to comment meaningfully on this.

   Recommendation: Allow for the policies that are already in the pipeline (i.e. data blocking, use of 2015 CEHRT, TEFCA, etc.) to take root and give the industry time to adapt to these new policies before considering new CoP standards.

2. ***Patient Access: Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health***

information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

Every provider who has qualified for the Promoting Interoperability program has a patient portal, which provides the level of access required by the certification criteria. We do not believe there is a full understanding of what CMS envisions as the data needed by the patient. As described earlier we do not see this as being the entire legal medical record. Rather, we envision this being things like lab results and the information from the patient's last encounter/admission. Based on the use case that CMS continues to promote around patient access to their data, we are unaware of any EHR that can provide a functionality that enables access to the compete record. To make this a requirement of participation would require the industry to shoulder significant new costs associated with added vendor development and implementation expenses.

Recommendation: If it is CMS' intent to add a requirement that providers offer complete access to the medical record, we believe a better place to address this is through the certification process.

3. ***Exchange Requirements:*** ***Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?***

   There is already a significant increase in data exchange as discussed previously and this rate has been increasing over time. As discussed above, there are still several barriers to information exchange without special effort, many which the healthcare industry has no control over; positive patient matching/identification, disharmony between state and federal privacy laws, disharmony between state and federal consent requirements, gaps in existing standards, competing standards, etc.

4. ***Timeframes:*** ***What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?***

   If the decision is to move down this path, then ample time should be allowed for the development of appropriate and compatible certification criteria, software development and implementation, internal process/procedure changes and public education.

5. ***Routine Transfer of Information****: Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?*

   The healthcare industry is just now getting to a place where enough information is in electronic form. The industry is creating new workflows to take advantage of this new level of electronic data and impact their daily processes/routines. These include the regular exchange/transfer of information to remove some of the friction from the healthcare process. The industry needs time to establish best practices, while not having to meet the requirements of new proscriptive standards.

6. ***Non-electronic data sharing:*** ***Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident***

or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

Yes, as this is related to the ability for smaller organizations/practices to bear the burden of the expense of moving to more sophisticated systems and approaches. Many of the clinics that provide much-needed care to the most vulnerable populations operate on a shoestring budget and do not have the funding for this level of automation. Further, even CMS has acknowledged under their discussion of patient portals that some patients like to receive their information in non-electronic forms.

7. ***Legal and other barriers:*** ***Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?***

   As described elsewhere in this letter, there are significant legal barriers that are standing in the way of achieving widespread interoperability like positive patient matching, differences between state/federal privacy and consent laws. Adding more requirements to the healthcare industry without removing these barriers will not move the needle forward; it will only create more confusion in how the new requirements are met.

   There are also significant barriers around the way HHS constitutes breaches. We believe the definition of a breach should be amended in the CFR to remove the language around “acquisition, access, or disclosure“ of PHI, as well as the language that calls for demonstrating a low probability that PHI was compromised (Title 45, Section 164.02). These changes would remove the “presumption of guilt” and provide more clarity for entities to assess risk. We also believe business associates should bear more responsibility for protecting patient information and carrying out notifications of breaches, and that breaches should be listed on OCR’s website for a maximum of three years.

   Additionally, we believe changes to the HITECH statute are needed in some cases to facilitate the aforementioned changes, and that the law should be changed to incent the use of voluntary cybersecurity best practices and afford the Secretary the latitude to exempt providers from certain enforcement actions if these best practices are met.

8. ***Exceptions:*** ***What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?***

   We believe there will always be reasons for exceptions. These need to be considered if the decision is to move down this path.

III. Inpatient Quality Reporting Program and Promoting Interoperability Program – eCQMs

CHIME appreciates the continued alignment of requirements for reporting electronic clinical quality measures (eCQMs) under the Inpatient Quality Reporting (IQR) Program and the Medicare PI Program. We support the proposed removal of seven eCQMs from the IQR Program measure set and eight eCQMs from the PI measure set, which would result in a requirement that hospitals select and report four out of a set of eight eCQMs beginning with the 2020 reporting year (FY 2022 payment determination). Focusing on a more streamlined set of measures would allow vendors to target resources to other system improvements and changes in other PI Program requirements proposed in this rule.

We agree that continuation of the current requirement that hospitals report the four selected eCQMs for one self-selected quarter for the IQR Program (90 days for the PI Program) is appropriate. We note, however, that CMS only discusses the 2019 reporting year (FY 2021 payment determination) with respect to the IQR Program but proposes continuation of the 90-day reporting period for the PI Program for both 2019 and 2020. To be consistent and maintain alignment with the PI Program, the final rule should commit to also requiring eCQM reporting for the IQR Program for only one self-selected quarter in 2020 as well.

Looking ahead, CHIME urges that the current one-quarter/90-day reporting periods for these programs be maintained indefinitely. System upgrades made necessary by changes to measures and PI Program requirements can take months. As future program requirements and systems stabilize, CMS could then propose a longer reporting period through notice and comment rulemaking.

CMS should also consider alignment of the 2019 reporting period for other programs that require use of the 2015 Edition, notably MIPS for physicians and other clinicians paid under the physician fee schedule and the Medicare Shared Savings Program. Several demonstration and pilot programs also require use of the 2015 Edition, such as the Next Generation Accountable Care Organizations, Comprehensive Primary Care Plus, Oncology Care Model, Chronic Care Management, Comprehensive Joint Replacement, Bundled Payment for Care Improvement Advanced Comprehensive End-Stage Renal Disease, and the Certified Community Behavioral Health Centers Pilot Program. Having different reporting periods among all the programs adds to the complexity of managing health information technology.

Recommendations:

1. We support the proposed removal of seven eCQMs from the IQR Program measure set and eight eCQMs from the PI measure set, which would result in a requirement that hospitals select and report four out of a set of eight eCQMs beginning with the 2020 reporting year (FY 2022 payment year).
2. The current one-quarter/90-day reporting periods for these programs be maintained indefinitely.
3. To be consistent and maintain alignment with the PI Program, the final rule should commit to also requiring eCQM reporting for the IQR Program for only one self-selected quarter in 2020 as well.
4. CMS should also consider alignment of the 2019 reporting period for other programs that require use of the 2015 Edition.

IV. Conclusion

CHIME appreciates the opportunity to comment and we welcome the chance to continue to help shape important policies that impact patients, providers and others in the healthcare system. We welcome the chance to help further the state of interoperability in our nation and speed access to medical records and data for patients and providers alike. Should you have any questions about our letter, please contact Mari Savickis, vice president, federal affairs, at mari.savickis@chimecentral.org.

Sincerely,

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