College of Healthcare Information Management Executives

June 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. 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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals,* published by the Centers for Medicare & Medicaid Services (CMS) on May 3, 2019 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 2,900 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 and quality reporting. **CHIME applauds CMS' ongoing work to bring greater stability to inpatient hospital care, reduce reporting burden for providers, advancing use of the 2015 Edition CEHRT, and offering new opportunities to advance patient matching strategies as well as other clarifications intended to advance interoperability. Below, we have outlined our key points and recommendations and provided more detailed feedback in the body of our letter.**

1. **Opioid measures:** Allow current opioid-related quality measures to mature and get refined and assessed before adopting new measures.
2. **Quality measures:** Ensure that for new proposed quality measures, the intent is clearly defined and they are likely to drive a change in behavior that is outweighed by the administrative burden added.

3. **Privacy:** Strengthen collaboration with ONC, OCR, and FTC to ensure that appropriate safeguards and adequate oversight of third-party apps occur, especially relative to the new requirements for providers to facilitate access to patient data via APIs.
4. **Patient matching:** Develop patient matching best practice guidelines and continue to explore the Medicare Beneficiary Identifier as well as other options to improve patient matching.
5. **Patient-generated health data (PGHD):** Collaborate with stakeholders to improve the quality of PGHD as we determine appropriate use cases for this data PGHD integration within the regulatory frameworks, without requiring its use.
6. **Care continuum:** Speed adoption of fully interoperable systems along the care continuum as a means to mitigate the risk of errors.

I. Medicare and Medicaid Promoting Interoperability Programs

CMS proposes several changes to the Medicare Promoting Interoperability Program which are intended to increase the level of stability, reduce the burden on hospitals, and clarify certain existing policies.

A. EHR Reporting Periods

We appreciate that CMS is providing additional flexibility for the EHR reporting period in CY 2019. Specifically, our members support CMS eliminating the October 1, 2019 reporting period deadline for an hospital that has not successfully demonstrated it is a meaningful electronic health record (EHR) user in a prior year. We further support CMS' proposal to provide these hospitals all of CY 2019 to complete their respective 90-day EHR reporting period for FY 2020 payment adjustment year as this will provide a reasonable opportunity for them to report through the end of 2019. We furthermore continue to support a 90-day reporting policy for the 2020 which CMS finalized last year and a 90-day reporting period for 2021 which CMS has proposed in this rule.

With respect to the 2020 reporting period for Medicare hospitals, CMS is proposing to narrow the available window from which providers can select their data for reporting. Under CMS' proposal, providers would be limited to selecting data from the continuous 90-day EHR reporting period they select, as opposed to the entire year. CHIME urges CMS not to finalize this change because it would require a significant investment to redesign systems the costs of which outweigh any perceived benefit to the Promoting Interoperability program and it could reduce how successful a hospital could be in meeting measures. Instead, we strongly urge CMS to retain the current policy which allows providers to draw data from throughout the calendar year to calculate their reported measure.

Recommendations:

1. Allow a full calendar year to complete reporting.
2. Do not finalize the proposed change to the data collection window from a full year to the selected 90-day reporting period.

B. Proposed Changes to Measures Under the Electronic Prescribing Objective

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

Our members have a sustained commitment 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.

We appreciate CMS' ongoing work to advance policies designed to help stem the tide of opioid addiction. We also appreciate the agency's responsiveness to our comments on this topic as proposed in the FY 2019 proposed rule and the need to pursue these changes thoughtfully in conjunction with the provisions enacted in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) signed into law last year.

In 2019 CMS introduced two new opioid measures, one of them being querying a PDMP. We support CMS's proposal to continue the Query of PDMP measure as an optional measure in 2020 affording a full 5 bonus points, and if finalized as optional to remove the exclusions. Our members believe PDMP systems are still maturing in their development and use and appreciate CMS recognizing some of the interoperability barriers providers face with integrating PDMP data into their EHRs. We agree with CMS' assessment that the SUPPORT Act's new requirements pertaining to PDMPs in combination with other factors are likely to significantly affect the maturation, requirements, and use of PDMPs and state networks upon which the Query of PDMP measure is dependent. We believe CMS' proposed changes which will provide a more reasonable path to implementation and use of this measure.

Additionally, we support CMS' proposal for 2019 to replace the current numerator and denominator with a "yes/no" response during attestation for the Query of PDMP measure. This change offers our members greater flexibility and reduced burden in an environment where PDMPs are still evolving and while CMS works toward restructuring the measure.

Recommendation:

1. Maintain the Query of PMDP measure as optional.

Measure: e-Prescribing

CMS states that if the agency finalizes the proposed changes to the Query of PDMPs, the agency plans to make the e-Prescribing measure worth up to 10 points in 2020 and subsequent years, instead of 5. CMS also seeks comments on future timing for requiring a measure that includes EHR-PDMP integration and on the value of the measure for advancing the effective prevention and treatment of opioid use disorder, especially in relation to the requirements of the SUPPORT Act described above.

If CMS finalizes the Query of PDMP measure, CHIME supports a corresponding change in the bonus points for the e-Prescribing measure. However, we believe there are challenges for a measure focused on EHR-PDMP integration.

As previously noted, we support the use of state PDMPs, but 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. In addition, our members are concerned by the lack information regarding how the vendor community will respond to such a requirement.

Access to the PDMP data is not consistent and our members continue to wrestle 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 this in the preamble.

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 certified EHRs (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. As further information, our members use a single EHR vendor, but the EHR does not issue the query to the PDMP entity storing the data. Our members contract with third-party vendors to conduct the PDMP query and process the transaction to load the information into the EHR. Our members report these query vendors use different pricing models, for example a per query transaction fee or a set fee for a specific time period. Without first understanding the cost implications for providers and the value proposition for the healthcare system, we are concerned that CMS could hamper EHR-PDMP integration efforts presently underway.

Finally, our members strongly support the use of a single set of standards for data flowing from PDMPs. We were pleased to see the SUPPORT Act provision on standards. Section 3990 of the SUPPORT Act says the Secretary of the U.S. Department of Health & Human Services (HHS), "may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information
Technology."

Recommendations:

1. CMS should not set a mandatory implementation timeframe for the EHR-PDMP requirement;
2. CMS should continue to collaborate with the vendors and providers to evaluate the value of the EHR-PDMP integration requirement; and
3. CMS should allow the operationalization of the PMDP provisions contained in the SUPPORT Act to foster better interoperability and PDMP / EHR integration.

Measure: Verify Opioid Treatment Agreement

The second opioid measure CMS introduced in 2019 was verifying an opioid treatment agreement for at least one patient prescribed a Schedule II opioid. CMS in their proposed rule has called for removing this measure for 2020. CHIME strongly supports the intent of this measure, however in our comments in response to last year's proposed rule, we recommended that CMS make this

measure voluntary because the measure specifications still needed significant development work. Among the steps that many states are taking to address the opioid crisis is to support opioid treatment agreements as a best practice or to require their use in certain programs. These practices allow for and encourage innovation in the care provided to the affected population. However, there is not yet agreement around what constitutes a treatment plan. We therefore appreciate CMS' recognizing the challenges with reporting on this measure.

Recommendation:

If CMS decides to retain this measure, we urge that it remain an optional measure eligible for bonus points.

C. Health Information Exchange Objective

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

CMS proposes to revise the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to more clearly capture the previously established policy regarding CEHRT use. The agency states its intent to incorporate several of these proposals into its regulations.

Recommendation:

We recommend finalizing this clarification.

II. 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 Hospital Inpatient Quality Reporting (IQR) Program and the Medicare Promoting Interoperability 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 (2022 payment). Focusing on a more streamlined set of measures would allow vendors and providers to target resources to other system improvements and changes in other Promoting Interoperability program requirements proposed in this rule.

A. Proposed Adoption of Two Opioid-Related eCQMs

CMS also proposes to adopt two new opioid-related clinical quality measures: 1) the safe use of opioids-concurrent prescribing CQM, and 2) hospital harm-opioid-related adverse events eCQM. We applaud CMS for its renewed focus on adopting quality measures that have a clear intent and value proposition.

However, with respect to the Safe Use of Opioids- Concurrent Prescribing CQM measure, our members do not believe that the intent has been clearly identified. Our members also report that they already maintain policies and practices which are designed to identify potential adverse events related to the administration of opioids in the hospital setting. As a result, they believe that the "Hospital Harm- Opioid-Related Adverse Events eCQM" will add to the reporting burden. As

currently described, our members report that they do not expect either of these measures to drive the types of changes in behavior that will impact the opioid crisis.

Recommendations:

1. Do not adopt the "Safe Use of Opioids-Concurrent Prescribing CQM;"
2. Do not adopt the "Hospital Harm-Opioid-Related Adverse Events eCQM;" and
3. Focus attention on adoption of the PDMP Query measure, as well as, enabling clinicians to begin adoption of the e-prescribing of controlled substances which will be required starting January 1, 2021, pursuant to Section 2003 of the SUPPORT Act.

III. Future Direction of the Promoting Interoperability Program

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

CMS also sought feedback on a potential metric to evaluate healthcare provider efficiency using EHRs and posed several questions to help inform its thinking in this area. The purpose of CMS' proposal appears to be to support provider adoption of particular technologies as a measure of their efficiency. We believe CMS is well-intentioned in trying to adopt new policies to support, measure, and improve provider efficiency given the burdens clinicians report in using certified EHRs.

However, our members are concerned that efficiency metrics would have unintended consequences that could detract from CMS' ultimate goals to reduce provider burden, advance interoperability, and facilitate high-value care for patients. We believe a movement to implement CMS-driven operational efficiency plans would dramatically shift the focus of our collective work away from providing high quality, high value services tailored to patient needs. In other words, we believe efficiency metrics would lead technology vendors to focus on the metric itself and distract from the need to derive value from the technology we are using. Further, given the significant changes currently underway to advance interoperability, we believe providers are best positioned to determine the technology that is most effective for their system or practice. Additionally, we are concerned that measurements that drive toward a specific technology could significantly undermine the motivation for ongoing efficiency innovations. Providers have the most direct insights and opportunities to identify and effectuate efficiencies within their own systems and practices.

Recommendation:

While our members do not believe that measurement of the use of specific technology interfaces is appropriate, we do encourage CMS to continue its focus on streamlining regulations and reducing provider burden. We believe doing so offers significantly more opportunity for efficiency within the healthcare system.

RFI on Including Medicare Promoting Interoperability Program Data on the Hospital Compare Website

CMS sought comment on its plan to post Medicare Promoting Interoperability Program measure(s) on the Hospital Compare website. CHIME appreciates the opportunity to provide our perspectives on this approach. CMS says they, "believe an eligible hospital or CAH's performance rate on one or more of the Medicare Promoting Interoperability Program measures would constitute other

relevant data because it would help consumers make informed decisions regarding their health care team, such as knowing whether and to what extent their health care provider is involved in health information exchange or providing patients with electronic access to their health information." We support patients having access to information that can help them make informed healthcare decisions, we do not believe that sharing information on a hospital's performance on Promoting Interoperability will achieve the intended purpose. For instance, being able to send CCDs could constitute success

Recommendation:

We recommend that CMS work closely with ONC to focus their attention on the concerns we raised in our recent letter around the ability to consumer healthcare data; too much attention is being placed on exporting data.

RFI on the Provider to Patient Exchange Objective

As part of the MyHealthEData initiative, CMS is taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their computable health information and can be assured that their health information will follow them as they move throughout the healthcare system from provider to provider, payer to payer. Last year, CMS asked stakeholders for input on a measure under the Promoting Interoperability program that would give providers credit for maintaining an "open API," or standards-based API, which allows patients to access their health information through a preferred third-party application. At the time, CHIME was among the commenters with significant concerns about the threats this approach poses to security and privacy.

We appreciate that CMS has sought to clarify and update its proposals. CMS writes, "We wish to note, however, that the term 'open API' does not imply that any and all applications or application developers would have unfettered access to individuals' personal or sensitive information nor would it allow for any reduction in the required protections for privacy and security of patient health information." CMS also says that patients would have to authenticate themselves to the provider and access would be limited to that particular patient. ONC has proposed to make the standards-based API criterion part of the 2015 Edition base EHR definition, which would ensure that this functionality is ultimately included in the CEHRT definition required for participation in the Promoting Interoperability Program. If finalized, ONC has proposed that health IT developers would have 24 months from the publication of the final rule to implement these changes to certified health IT products.

Our members strongly support patient access to their medical data. However, we continue to have significant privacy and security concerns associated with the transfer of this data to third parties. We outlined our concerns in detail in our recent interoperability comment letter (page 39) to CMS and ONC. For example, we continue to have concerns that must be adequately resolved:

- It is still unclear how providers are expected to know what types of risks they are undertaking in connecting to third party apps.
- The 21st Century Cures Act requires ONC to consult with the Office for Civil Rights (OCR) on security barriers related to electronic health information (EHI) exchange and that guidance has not yet been published as far as we know.
- Mitigating challenges associated with providers validating the scope of access to patient data via a third-party app.

- Clarification from ONC is needed around what processes vendors are expected relative to security processes in granting apps access to the EHRs.
- There is no certification process apps must undergo and no requirement that app management companies must sign business associate agreements.

Our members take seriously their responsibility to safeguard and keep private patient information as required by HIPAA. Once a patient's medical record is downloaded via an open API to an app at the patient's request, that information is no longer protected by HIPAA unless the app is sponsored by a HIPAA covered entity. Worrisome is that patients may not understand: 1) that Health Insurance Portability and Accountability Act (HIPAA) no longer applies; and 2) how the app intends to use their data. The terms and conditions may be lengthy, and patients may skip over them in favor of convenience. The terms and conditions also may or may not specify that the app developer could re-use or sell their data – including sensitive data – to others like third-party data brokers.

Our members are concerned that one bad actor could destroy consumer and patient trust in healthcare apps, dismantling efforts to further interoperability and improve patient access to their information. Our members believe more education is needed so that patients are fully aware of the benefits and risks associated with their data being reused without their knowledge. We are very worried that patients are unaware of how their data is being used once it is released and, in some cases, may be under the false impression that it is still safeguarded under HIPAA. We outlined these concerns in detail our recent letter to the Federal Trade Commission. We continue to believe it is imperative that patients are fully informed about how their medical data will be used once they release it to third parties. We believe more coordination among the various federal regulatory agencies on this issue including CMS, ONC, OCR, and the FTC is needed.

Before CMS and ONC further facilitate patient access to their data via APIs, we believe that appropriate oversight must be in place to govern how patient data is not just accessed by third parties, but also how it is being used. In short, patients must be able to trust the apps they are sending their data to and have full awareness of how their data will be used. We must stress the dire lack of consumer and patient trust in apps which could be created if their data is misused. Further, once data is released, while data sharing can be revoked, there is no way to walk back what has already been shared. And, the ability to monetize data is only growing. Adding more healthcare data to the existing data streams available for purchase without adequate safeguards will erase consumer trust and create more privacy challenges.

And, as we discuss in our recent letter to CMS and ONC, the ONC proposed interoperability rule does not appear to include those technology companies that manage apps, nor does it cover the third-party apps themselves under proposed data blocking policies as among the actors who must comply with these policies. Therefore, unless these policies are changed, a big chunk of the healthcare sector like providers and EHR vendors will have to abide by one set of rules governing promoting the sharing of patient information, and third-party apps and those managing the app ecosystem will not. This will create an unlevel playing field and further perpetuate the notion that healthcare apps are the Wild West. OCR has also made it clear that "The HIPAA Rules do not impose any restrictions on how an individual or the individual's designee, such as an app, may use the health information that has been disclosed pursuant to the individual's right of access."

As smart phones, social media and other apps become integral parts of everyday life, the definition of "healthcare data" is changing. Companies tracking location, payments, or both can easily discern if a patient is sick, how sick the patient is, or what type of illness the patient has. For example, a cancer patient drives to her specialist and has an hour-long appointment. She brings

her phone, and in the waiting room, she may open her Facebook, Instagram and web search apps. All three apps collect location data, and all three apps can collectively know she is seeing a cancer specialist. That data is then aggregated and sold to third-party data brokers, making her extremely sensitive illness known to faceless companies and people. A recent story in the *New York Times* outlined just how much data apps are collecting – some of it health – and demonstrated how easy it was to ascertain the whereabouts of citizens using location tracking data, including visits to a family planning clinic and a dermatologist's office.[1] The article also noted just how lucrative the location data is – estimated to be $21 billion in 2018.

Considering the concerns outlined above, we believe a prudent approach would require an "informed consent" by apps seeking access to healthcare data at a patient's request that clearly and unambiguously informs patients how their data will be used. The app developer should also address questions with the purpose of further educating patients on whether they truly want to trust this third party or not. For instance:

- Do you sell identifiable information?
- If yes, is it used only for research?
- Do you use the data for marketing?

Recommendation:

CMS should work closely with ONC, OCR, and the FTC to ensure that appropriate safeguards and adequate oversight of third-party apps occur, especially relative to the new requirements for providers to facilitate access to patient data via APIs.

Patient Matching RFI

We are encouraged by CMS' continued acknowledgement that patient matching is critically important to interoperability and the nation's health IT infrastructure as healthcare providers must be able to share patient health information and accurately match a patient to his or her data from a different health care provider in order for many anticipated interoperability benefits to be realized. We appreciate CMS' commitment to support ONC's work promoting the development of patient matching initiatives, including with the issuance of this RFI which seeks information on how it can promote interoperability without requiring a unique patient identifier (UPI).

As our healthcare system moves toward nationwide health information exchange, this essential core functionality – consistency in patient identification – remains conspicuously absent. For this reason, CHIME is also extremely encouraged by the historical action recently taken by the House of Representatives to advance a consistent patient identification strategy. On June 12, the House of Representatives took the historic step when it passed an amendment that would remove a prohibition on funding for a national patient identification strategy. And, on June 19 the House voted to pass the Labor-H appropriations bill and the UPI ban was not included for the first time since 1999.

Our members have seen that 20-year prohibition as a barrier to interoperability and a risk to patient safety. While there are still several steps that are needed to overturn the ban, we believe this is a significant step forward in dismantling the policy barriers that have handcuffed our industry for 20 years.

[1] Your Apps Know Where You Were Last Night, and They're Not Keeping It Secret, New York Times, December 10, 2018.

As we have discussed in previous comment letters to CMS, we believe there is value in examining the feasibility of expanding the Medicare Beneficiary Identifier (MBI). The Medicare Beneficiary Identifier (MBI) replaced the use of the Social Security Number beginning in 2018 (now referred to as the Medicare ID card). CMS has conveyed in other rulemaking that it is exploring an expansion of the Medicare ID card by requiring a CMS-wide identifier which is used for all beneficiaries and enrollees in healthcare programs under CMS administration and authority. CHIME believes the idea to expand use of the Medicare ID card holds merit and we encourage CMS to continue exploring this approach. Our members have deduced that it would not be hard for them to have to track this ID since they already track numerous patient IDs issued by multiple payers for patients. According to a RAND study on the patient identity issue, the savings from implementing a unique ID amounts to $77 billion a year.[2] Therefore, the savings from implementing such a policy would be significant.

As CMS explores patient matching, we encourage the agency to also consider biometrics as a possible option. We are aware that the National Institute for Standards in Technology (NIST) recently released a standard for the use of biometrics.[3] If a biometric is ultimately adopted it must work in a variety of healthcare settings. For instance, one member noted that they use retina scans for patients who cannot get their date of birth correct. That said, while we believe biometrics have an important place and hold much promise, there are nonetheless limitations, including:

- **Variability among vendors**: While hard to replicate a biometric image, there can be variability between vendors. Most readers don't store the actual image, just specific points of the image. Biometrics are reading an image and taking and converting points into a hash. For instance, in the case of a fingerprint, different readers will come up with different readings and there is no way to reengineer the hash back to the fingerprint so this becomes another number in essence. However, if you had the hash and the actual patient ID (i.e., SSN), the combination of the two is virtually impossible to replicate and is virtually unique.

- **Costs**: Implementing biometrics is costly, especially for providers regardless of their size.

- **Its use may not work well in all settings of care**: There are situations when you need to identify a patient in certain settings of care prior to their arrival, such as in the post-acute space, therefore, without the patient actually being present, use of a biometric may be impractical.

- **There are potential risks with EHRs and these apps.** The list could include entering information into the wrong patient record (having multiple patient records open, side by side, or overlaying patient records); untangling (i.e., separating) co-mingled patient information; mistakenly creating duplicate charts; and assigning a test to the wrong patient.

- **Pediatrics**: In January 2019, the Joint Commission added a new required reporting element of performance[4] to align with NPSGF 01.01.01[5], aimed at patient identification, and recommends using distinct methods for identifying newborns in hospitals, such as mother's first and last name plus gender. CMS also requested input on whether they should require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in the Federally Facilitated Exchange (FFE) to use either a patient

[2] https://www.rand.org/pubs/monographs/MG753.html
[3] https://www.nist.gov/programs-projects/biometrics
[4] https://www.jointcommission.org/assets/1/18/R3_17_Newborn_identification_6_22_18_FINAL.pdf
[5] https://jntcm.ae-admin.com/assets/1/6/NPSG_2019_Presentation_-_FINAL.pdf

matching algorithm with a proven success rate of a certain percentage. Other requirements included were that the algorithm and real-world processes associated with the algorithm used are validated by HHS or a third party, or a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a third party. We believe these ideas have merit, especially if expanding the Medicare ID is not feasible and considering our below comments concerning certification. As we describe in the Maintenance of Certification section of our letter, we believe vendors should be required to share their patient matching rate with providers in order to meet the MOC.

Additionally, we wish to reiterate our feedback that the agency should support connecting EHRs to other complementary verifying data sources for identify proofing purposes. Our members believe providers should have access to CMS claims data to improve patient matching. We also note that NIST recommends standardizing the display of patient identifiers across various systems, from the registration system through to the EHR. Human factors engineers recommend that information be presented consistently and predictably. CMS can support this in recognizing the key risk areas of EHR design and advancing these standards by requiring:

1. Information critical to patient identification is consistently displayed in a reserved area to avoid wrong patient errors;
2. Cues/alerts are provided to reduce the risk of entering information and writing orders in the wrong patient's chart; and
3. Supporting efficient and easy identification of inaccurate, outdated, or inappropriate items in lists of grouped information by having information presented clearly and in a well-organized manner. Information required to accurately identify the patient is clearly displayed on the electronic display of system screens.

Recommendations:

1. Best practice guidelines should include the use of a standardized process for patient identification and capturing patient information no matter where registration occurs;
2. We encourage CMS to continue exploring the possibility of expanding the use of the Medicare ID;
3. CMS should work with ONC to ensure that vendors as part of their Maintenance of Certification are required to share their patient matching rates and other related information (as discussed in greater detail in that section of our letter);
4. If a biometric is ultimately adopted, it must work in a variety of healthcare settings; and
5. CMS should make claims data readily available in a timely manner to providers through a FHIR-based API; doing so will help providers better match patients.

RFI on Integration of Patient-Generated Health Data into EHRs Using CEHRT

CMS included an additional RFI on the use of patient-generated health data (PGHD), which could be a key tool in reducing provider burden and empowering patients to make decisions about their own healthcare. PGHD presents healthcare providers an opportunity to monitor and track a patient's health-related data from information that is provided by the patient and not the provider. As CMS notes in this RFI, increasingly affordable wearable devices, sensors, and other technologies capture PGHD, providing new ways to monitor and track a patient's healthcare experience. Capturing important health information through devices and other tools between medical visits could help improve care management and patient outcomes, potentially resulting in increased cost savings.

CHIME agrees with CMS' statement that although many types of PGHD are being used in clinical settings today, the continuous collection and integration of patients' health-data into EHRs to inform clinical care has not been widely achieved across the healthcare system. Our members are beginning to collect and use PGHD and we support CMS' and ONC's vision around PGHD integration. However, this is a truly nascent frontier for our healthcare system. Our members' early experiences have helped to identify several frontend issues to address and milestones to reach before PGHD adds value for the provider, the patient, and the healthcare system overall. These include:

- **Improving the quality of PGHD.** Many of our members report that they are starting to actively bring in PGHD data and they can take in this information from other sites. However, they also find the data itself is not accurate and as a result it is not usable. For example, the data often contains outdated treatment information and medication lists with prescriptions that are no longer active. A foundational – and absolutely essential – step for advancing CMS' goals around PGHD integration is to improve the ability of EHRs to consume this data and combine it with native data in a form that is usable to providers to meaningfully impact the care they deliver.

- **Crosswalking TEFCA and CMS frameworks and requirements.** CHIME believes there is significant overlap between the provisions of CMS' proposed regulation and ONC's Trusted Exchange Framework and Common Agreement (TEFCA). While we appreciate that CMS and ONC have sought to work together on their respective rulemakings, these regulations also present operational challenges for our members as they attempt to plan and develop internal project workplans as well as shape their priorities with their vendors. We encourage the agencies to consider that TEFCA deals with discreet data and connections between organizations, but it does not address how organizations are going to consume and use the voluminous healthcare data that is already available. We believe that additional coordination between ONC and CMS would help to reconcile and align the interdependent, but still misaligned frameworks and provide stakeholders a more stepwise approach toward interoperability generally, and PGHD integration more specifically.

- **Use a bonus structure to facilitate PGHD integration.** Because of the variation in the type of data and the usability of the data currently available, we encourage an early focus on adoption of PGHD and refinement of the data and workflows for its use. Our members believe that this can best be accomplished using bonus structures in the Medicare program.

  A bonus structure also provides appropriate flexibility for providers and patients to determine if PGHD is applicable and beneficial for their situation. As part of this emerging opportunity, our members are assessing whether PGHD may be best suited for population health approaches. They are also examining whether PGHD offers the broad and positive impacts for patients and specialists who are managing an acute situation or procedure. Our members are particularly cautious about requirements for PGHD integration, again because the benefits of the data are not yet clear and may not be equitable across all patients. Additionally, clinicians continue to express significant concerns around liability.

- **Collaboration around expectations for PGHD use is needed**. With PGHD collection and use still in its infancy, the norms for its review and use by providers are still evolving. Our members urge CMS to prioritize work on ensuring the data is actionable and that it can be

incorporated into provider workflows before the agency proceeds with setting a timeline for PGHD-related requirements.

- **Set and manage patient expectations**. It is critical that patients also have reasonable expectations for how and how frequently their data will be reviewed and used by providers. One aspect of this issue involves provider liability and specifically the limitations around liability that may be needed. Therefore, we encourage CMS to continue to collaborate with providers and other key stakeholders on this issue.

Recommendations:

1. CMS and ONC should collaborate to harmonize and synchronize their multiple rules and regulatory frameworks to better support PGHD.
2. Continued collaboration with stakeholders to improve the quality of PGHD is needed.
3. CMS should utilize a bonus structure if PGHD integration is pursued; we do not support mandates.
4. CMS should work with ONC, vendors, and providers to develop timelines for technology maturation and adoption.

RFI on Engaging in Activities that Promote the Safety of the EHRs

CMS is appropriately focused on addressing patient safety issues that may emerge because of implementation of EHRs. Certainly, the introduction of new workflows, technologies, and data presents new challenges, and with it the risk of certain errors, resulting in harm to patients. We appreciate that CMS is proactively considering how it can employ the Promoting Interoperability program with hospitals to further mitigate the specific safety risks that may arise from technology implementation. One of the potential options CMS states it is exploring is how it can encourage use of ONC's SAFER Guides.

In addition, CHIME encourages CMS to consider alternative options that will improve communication between providers along the care continuum. Our members report confidence in communications between hospitals due to the advances in interoperable systems. However, they believe additional attention and incentive structures are needed to support fully interoperable systems among independent provider practices. The communication between providers in the community and hospitals is vital to ensuring safe transitions of care for patients. The lack of fully interoperable systems along the care continuum threatens to undermine other steps that our members are taking to protect the safety of their patients.

Recommendations:

1. Develop incentives and supports to ensure the data being sent and received along the care continuum is accurate and usable.
2. Develop best practices or use cases in support of interoperable communications between providers.

IV. Conclusion

We appreciate the opportunity to comment and welcome the chance to continue to help shape important policies that impact patients, providers, and others in the healthcare system. We are committed to furthering interoperability in our nation and accelerating 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 of Federal Affairs, at msavickis@chimecentral.org.

Sincerely,

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