September 27, 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: 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; and other provisions* published on August 9, 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. **We have been a strong supporter of CMS' ongoing work to achieve greater alignment and efficiency across Medicare and Medicaid's various reporting requirement programs. We have been very supportive of CMS' efforts to reduce burdens overall for clinicians and providers, including removing measures and simplifying the Promoting Interoperability programs and aligning the Promoting Interoperability requirements between the hospitals and clinicians. While we believe the MIPS Value Pathways (MVPs) holds promise, we have concerns about how this could interplay with the alignment that CMS has achieved to date between the hospital and clinician programs.**

A more detailed discussion of these and other topics is provided below.

I. Key Recommendations

1. **MVP:**
    a. **CMS should clarify how the changes proposed under the new MVP, which ultimately will include changes to the Promoting Interoperability Performance**

Category of MIPS, will interplay with the hospital Promoting Interoperability Program and the efforts to date to better align these programs;

   b. **We urge CMS to make the MVP Program voluntary during the first years of its implementation; and**
   c. **We request that CMS take into consideration the impact of changes to the Promoting Interoperability measures, given the other significant policy mandate providers will be absorbing under 21st Century Cures rules pertaining to interoperability.**

2. **Improvement Activities (IA): CMS should incrementally increase the threshold of one clinician in a group being required to submit an IA as 50 percent is too steep of an increase and will jeopardize some clinicians' abilities (including in rural areas) to meet this.**
3. **Future of Promoting Interoperability:**
   a. **CHIME strongly supports anything that can be done to maximize data already collected and available in an EHR.**
   b. **Do not implement a measure on the efficient use of EHRs; instead, continue to focus on streamlining regulations and reducing provider burden.**
   c. **CMS should work closely with the Office of the National Coordinator (ONC), Office for Civil Rights (OCR), and the Federal Trade Commission (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.**
   d. **CHIME supports a bonus payment for early adoption of a FHIR-certified API.**
   e. **Patient access to data:**
      i. **Align timeframes for both clinicians and providers to make patient information available through an API and portals within 36 hours**
      ii. **Do not move forward with an alternate measure under the Provider to Patient Exchange objective that would require clinicians to use technology certified to the Electronic Health Information (EHI) criterion to provide the patient(s) their complete electronic health data contained within an EHR until there is a clear understanding of what constitutes EHI; and**
      iii. **CHIME supports a voluntary activity that encourages bi-directional exchange of health information across the care continuum.**
   f. **Patient matching:**
      i. **Best practice guidelines should include the use of a standardized process for patient identification and capturing patient information no matter where registration occurs;**
      ii. **We encourage CMS to continue exploring the possibility of expanding the use of the Medicare ID;**
      iii. **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); and**
      iv. **If a biometric is ultimately adopted, it must work in a variety of healthcare settings;**
   g. **Patient-generated health data (PGHD):**
      i. **CMS and ONC should collaborate to harmonize and synchronize their multiple rules and regulatory frameworks to better support PGHD;**
      ii. **Continued collaboration with stakeholders to improve the quality of PGHD is needed;**

   iii. **CMS should utilize a bonus structure if PGHD integration is pursued; we do not support mandates;**
   iv. **CMS should work with ONC, vendors and providers to develop timelines for technology maturation and adoption; and**
   v. **We recommend against adding any mandatory measures around use of patient portals or API use.**

h. **Safety of EHRs:**
   i. **Incentives and support are needed to ensure the data being sent and received along the care continuum is accurate and usable; and**
   ii. **Best practices or use cases in support of interoperable communications between providers are also needed.**

1. **MVP Framework (0732)**

   a. ***Guiding Principles***

CMS has proposed a new, conceptual participation framework for clinicians that would go into effect in 2021. CMS has established a goal of moving away from siloed activities and measures toward a more aligned set of measure options which are more relevant to a clinician's scope of practice that is meaningful to patient care. The MVP framework also aims to align and connect measures and activities across the four MIPS performance areas (quality, cost, Promoting Interoperability and IAs) for different specialties or conditions. Clinicians would be in one MVP associated with their specialty or with a condition, reporting on the same measures and activities as other clinicians and groups in that MVP. Additionally, CMS plans to use the MVP framework to provide enhanced data and feedback to clinicians.

CMS has laid out four guiding principles for the MVP:

1. Fewer measures to reduce burden, simplify scoring, and lead to sufficient comparative data.
2. Include measures and activities that would result in comparative performance data for clinicians and patients.
3. Measures that encourage performance improvements in high priority areas.
4. Reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

Recommendation: CHIME supports CMS' MVP proposal, which will establish a glidepath to participation in APMs. However, as with any new program, there are likely to be implementation challenges and uncertainty around how this will impact alignment efforts with the hospital Promoting Interoperability program. Therefore, we recommend it remain voluntary for a transitional period of time.

   b. ***MVP and Promoting Interoperability***

CMS says that the MVP framework would incorporate Promoting Interoperability (PI) measures and that the agency plans to continue to align hospital and clinician PI programs. CMS further notes they plan for the clinician PI program to be an integral part of the MVP. The agency explains that initially there would be a single set of PI measures, but in future iterations of MVP CMS says they may customize PI measures in each MVP. It's unclear to us, however, how the hospital PI

program will remain aligned with the clinician PI program as the Agency executives its plan over the long term.

CMS does make clear that there are no changes planned for the clinician Promoting Interoperability performance category in 2020 as the agency begins to implement the MVP. CHIME is unclear, however, how the agency plans to keep clinician and hospital Promoting Interoperability measures aligned, something CHIME has strongly supported, and which has reduced administrative burdens on providers.

Recommendations:

1. **CHIME appreciates that CMS is not making changes in the clinician Promoting Interoperability performance category in 2020, however, we request CMS elaborate on its plans to keep the clinician and hospital PI measures aligned after 2020 under the new MVP paradigm; and**
2. **We request that CMS take into consideration the impact of changes related to the MVP and to the Promoting Interoperability measures, given the other significant policy mandate providers will be absorbing under 21st Century Cures rules pertaining to interoperability. We have outlined a myriad of deadlines providers and clinicians must meet in our recent letter to ONC on the Trusted Exchange Framework and Common Agreement (TEFCA) (page 4).**

c. MVP and Reduction of Measures

CMS said their MVP proposal would reduce reporting burdens on clinicians by limiting the number of required specialty or condition specific measures so all clinicians or groups reporting on a clinical area would be reporting the same measure set(s). Additionally, CMS is calling for measuring clinicians on a unified set of measures and activities based on condition/specialty which would then lay on top of a base set of population health measures that would apply to nearly all MVPs. Further, CMS says the most significant change with MVPs is that eventually all MIPS eligible clinicians would no longer be able to select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be connected around a clinician specialty or condition.

Our members hear from different specialties within their facilities and systems that they want measures that make the most sense for them and we believe CMS' proposal will help allay some of these concerns.

Recommendation: CHIME supports the reduction of measures and the move to more specialty-specific ones.

1. MIPS Performance Category Measures and Activities (40745)

i. Improvement Activities Performance Category (40762)

a. Improvement Activities Data Submission: Group Reporting (40763)

Under current CMS policy, if one clinician within a group is reporting an activity for 90 days during the reporting period, the group can also report on that activity and the group gets the same score on the activity.

CMS has proposed increasing the group reporting threshold from at least one clinician to at least 50 percent of the group beginning with the 2020 performance year. Additionally, at least 50

percent of a group's National Provider Identifiers (NPIs) must perform the same activity for the same continuous 90 days in the performance period beginning with the 2020 performance year.

We are concerned about the significant jump that CMS has proposed to increase the group reporting threshold from one clinician to 50 percent of the entire group. Some members – including those in rural areas – report that their clinicians are only able to locate a few IAs. They are very concerned that they will be unable to locate IAs for which half their clinicians can participate in. We therefore disagree with CMS that, "increasing the minimum threshold for a group to receive credit for the IAs performance category will not present additional complexity and burden for a group."

Recommendation: CMS should incrementally increase the threshold of one clinician in a group being required to submit an IA as 50 percent is too steep of an increase and will jeopardize some clinicians' abilities (including in rural areas) to meet this.

ii. Promoting Interoperability (40766)

CMS has proposed a series of policies pertaining to the Promoting Interoperability performance category in Calendar Year (CY) 2021 (2023 payment year) including:

- **90-Days:** CMS calls for establishing a minimum performance period of a continuous 90-day period in CY 2021, up to and including the full calendar year.
- **Prescription Drug Monitoring Programs (PDMPs):** CMS calls for making the Query of PDMP measure optional in CY 2020.
- **Opioids**:
    - CMS has proposed removing the numerator and denominator for the Query of PDMP measure and instead requiring a ''yes/no'' response beginning in CY 2019.
    - CMS also calls for removing the Verify Opioid Treatment Agreement measure beginning in CY 2020.

Recommendations: We support all of these proposals as they align with the hospital measures.

iii. Future Direction of Promoting Interoperability Performance Category (page 40777)

CMS has requested feedback on a series of requests for information. CHIME is pleased to offer our perspective.

1. Request for Information (RFI) on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category (page 40777)

Among the topics CMS seeks comment on concerns potentially adding opioid measures for future inclusion that might be relevant to specific clinical priorities or goals related to addressing opioid use disorder (OUD) prevention and treatment. CMS requested feedback on leveraging the capabilities of Certified Electronic Health Records Technology (CEHRT) where possible, including: near automatic calculation and reporting of numerator, denominator, exclusions and exceptions to

minimize manual documentation required of the provider; and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible.

Recommendation: CHIME strongly supports anything that can be done to maximize the OUD prevention and treatment data already collected and available in an EHR.

2. Request for Information (RFI) on a Metric To Improve Efficiency of Providers Within EHRs (40799)

CMS also seeks 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.

3. Request for Information (RFI) on the Provider to Patient Exchange Objective (40780)

As part of the MyHealthEData initiative, CMS says they are 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 health care system from provider to provider, payer to payer.

Open APIs (Page 40782)

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 clarified that an ''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." Additionally, with respect to patient access, a patient will need to authenticate him/herself to a health care organization that is the steward of their data (for example, username and password) and the access provided to an app will be for that one patient. CMS also says that, "The overall HIPAA Security Rule, HIPAA Privacy Rule, and other cybersecurity obligations that apply to HIPAA covered entities remain the same and would need to be applied to an API in the same way they are currently applied to any and all other interfaces a health care organization deploys in production."

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 before we can move to a safe environment for sharing patient data:

- 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 had not yet been given as of the time we submitted this comment letter.
- 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 the Health Insurance Portability and Accountability Act (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 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 reuse or sell their data – including sensitive data – to others like third-party data brokers. A recent op-ed by the CIO of New York Presbyterian outlines these concerns nicely.

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 in our recent letter to the Federal Trade Commission, as well as in two letters to congressional committees (Senate HELP & House Energy & Commerce) of jurisdiction. 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 an appropriate oversight framework 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 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. 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." Therefore, unless these policies are changed, a large segment of the healthcare sector – namely providers and EHR vendors -- will have to abide by one set of rules governing the sharing of patient information while 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."

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.

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

Immediate Access

CMS recounts how the existing Provide Patients Electronic Access to Their Health Information measure specifies that the MIPS eligible clinicians provide the patient timely access to view online, download and transmit his or her health information, and further specifies that patient health information must be made available to the patient within four business days of its availability to the MIPS eligible clinicians.

In the recent CMS interoperability and patient access rule, CMS proposed that certain health plans and payers be required to make patient health information available through an open, standards-based API no later than one business day after it is received by the health plan or payer.

CMS is seeking comment on whether MIPS eligible clinicians should make patient health information available immediately through an open, standards-based API, no later than one business day after it is available to the MIPS eligible clinicians in their CEHRT.

Recommendations: Adopt a threshold of 36 hours for making patient information available via an API, as well as through a patient portal as this would align with the hospital threshold for making patient information available.

Persistent Access and Standards-Based APIs

CMS says the existing Provide Patients Electronic Access to Their Health Information measure does not specify the overall operational expectations associated with enabling patients' access to their health information. For instance, the measure only specifies that access must be ''timely.'' CMS asked whether, if ONC's proposed FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability performance category for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs.

Recommendation: CHIME supports a bonus payment for early adoption of a FHIR-certified API.

Available Data

CMS notes how ONC has proposed to adopt a new 2015 Edition certification criterion for the EHI export, the purpose of which is to provide patients and providers with the ability to securely export the entire EHR for a single patient (or multiple patients) in an electronic format. Building on this, CMS asks whether an alternative measure under the Provider to Patient Exchange objective that would require clinicians to use technology certified to the EHI criterion to provide the patient(s) their complete electronic health data contained within an EHR.

CHIME has repeatedly expressed our strong concerns with the definition of EHI and has gone so far as to request ONC engage in a supplemental notice of proposed rulemaking (SNPRM). We outlined these concerns in detail in our joint letter to CMS and ONC here. We believe until this occurs and more clarity is obtained around the parameters of EHI, it would be premature to move forward with incorporating an alternative measure that would require clinicians to use technology

certified to the EHI criterion to provide the patient(s) their complete electronic health data contained within an EHR.

CMS furthermore seeks input on whether the agency should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bi-directional exchange of health information with community partners, such as post-acute care, long-term care, behavioral health, and home and community-based services to promote better care coordination for patients with chronic conditions and complex care needs. CHIME refers CMS to our previously submitted comment letter which addresses how to improve information sharing across the care continuum (page 25). 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. **Do not move forward with an alternate measure under the Provider to Patient Exchange objective that would require clinicians to use technology certified to the EHI criterion to provide the patient(s) their complete electronic health data contained within an EHR until there is a clear understanding of what constitutes EHI; and**
2. **CHIME supports a voluntary activity that encourages bi-directional exchange of health information across the care continuum.**

Patient Matching

CMS seeks comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. CMS also wants input on how they can leverage their authority to provide support to those working to improve patient matching.

CHIME applauds CMS' and ONC's efforts to improve patient matching. For purposes of this solicitation, we refer CMS to our recent combined interoperability letter to CMS and ONC (page 15). Given CHIME's long-standing support of the need for a patient identification strategy and the importance from both a patient safety and interoperability standpoint of being able to connect the right patient with their records, we strongly support both agencies recognizing the importance of matching patients correctly with their medical records. We reiterate the recommendations we made earlier.

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); and**
4. **If a biometric is ultimately adopted, it must work in a variety of healthcare settings.**

4. Request for Information (RFI) on Integration of Patient-Generated Health Data Into EHRs Using CEHRT (40783)

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 front-end 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 discrete 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. 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.
- **Portal use remains low:** Given the low use of portals to date, which has been documented as being low and a recent article in the Journal of the American Medical Association (JAMA) found low API use among patients, we feel it is premature to add a measure.

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; and**
5. **We recommend against adding any mandatory measures around use of patient portals or API use.**

5. Request for Information (RFI) on Engaging in Activities That Promote the Safety of the EHR

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. 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; and**
2. **Develop best practices or use cases in support of interoperable communications between providers.**

I. 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 helping 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 of Federal Affairs, at msavickis@chimecentral.org.

Sincerely,

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President and CEO
CHIME

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