September 10, 2018

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

Dear Administrator Verma:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services' (CMS) proposed rule, "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program," published on July 27th.

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 2,700 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 technology to improve the health and healthcare in the communities they serve.

We are particularly supportive of the agency's proposals to revamp the Merit-based Incentive Program's (MIPS) Promoting Interoperability performance category to be less complicated, facilitating eligible clinician participation; increasingly align the Promoting Interoperability requirements between the hospitals (contained in the Inpatient Prospective Payment System (IPPS) rule) and clinicians (contained in the Quality Payment Program (QPP) rule); and to foster the use of technology to support patient access and satisfaction through new communication technology-based services such as the virtual check-in and the remote

evaluation of pre-recorded information. A more detailed discussion of these and other topics is provided below.

I. Key Recommendations

1. **MIPS eligible clinicians pool:** Halt policies which continue to reduce the number of clinicians eligible for MIPS until the MIPS program matures and the final four performance category weights making up the total MIPS composite score are reached.
2. **Quality performance category:** Establish a minimum of any 90-day reporting period for the quality performance category which would align with hospital requirements.
3. **Opioid measures:** Keep both measures (Query of Prescription Drug Monitoring and Verify Opioid Treatment Agreement) voluntary for the foreseeable future recognizing the challenges we have outlined in our letter which must be addressed.
4. **Provide Patients Electronic Access to Their Health Information measure:** Support new measure, but recommend CMS not require widespread use of application programming interfaces (APIs) for at least three years after the final standard has been published.
5. **HIE measures for future consideration:** Rather than creating new measures interoperability can better be achieved through appropriate stakeholder collaboration.
6. **Medicaid clinicians:** A 90-day reporting period should be allowed and ideally, alignment with requirements for Medicare providers should be adopted as providers are still wrestling with three sets of requirements.
7. **Cybersecurity:** A holistic approach should be taken by the agency to addressing these ever-growing threats and every possible avenue to help providers fight these threats which pose risks to patient safety should be explored.
8. **Telehealth / "Communication Technology-based Services":** We strongly endorse CMS' proposal to create this new category of services.
9. **Interoperability**: Addressing root cause issues which stymie interoperability like a uniform set of standards and a way to uniquely identify patients will be more effective than requiring mandates through Conditions of Participation (CoP) or health information exchange measures (HIE) to the program.

II. Quality Payment Program (QPP)

Merit-Based Incentive Program

A. General policies

Low-volume threshold and expanding eligibility

Currently, a MIPS-eligible clinician can become MIPS exempt by virtue of being a new Medicare provider, by reaching Alternative Payment Model (APM) Qualifying Participant (QP) or Partial Qualifying Participant status, or through meeting a low-volume threshold criterion. There are two existing low-volume threshold criteria: 1) a clinician meets the threshold if furnishing services totaling $90,000 or less in allowed charges for covered professional services; or 2) furnishing Medicare Physician Fee schedule (PFS) services to 200 or fewer Part B-enrolled individuals. CMS proposes to add a third criterion, exempting from MIPS those clinicians with 200 or fewer covered professional services. CMS projects the added number of clinician newly exempt from MIPS based upon the proposed criterion to be very small because of substantial overlap with those already meeting an existing low-volume criterion.

CHIME notes, however, that more clinicians already are exempt from MIPS than actually participate in the program. As a result, the group of clinicians whose performance is actually being scored is constrained and is skewed towards positive performance because of the still relatively low composite score threshold (30 points for 2019 to avoid a downward adjustment). Because MIPS adjustments must be budget-neutral (i.e. penalties must fund any rewards)), a constrained, skewed participant pool has the

effect of a few “losers” and many “winners” but each of the winners receives a very small or even no reward. Such a structure is demoralizing for clinicians who try to achieve continuous improvement. Further constraints on the MIPS participation pool seem ill-advised.

We also note that the proposed ability for exempt clinicians to “opt-in” combined with proposed broadening of MIPS-participant clinician types (see below) will – by CMS’ projections -- add at most 50,000 to the participant pool. Since the “opt-in” group is likely to include only positive performers, the skew of the pool towards good performance will not be lessened and the rewards may fall even further. Any further limitation of the MIPS participant pool, such as the new exemption criterion, therefore, seems to be of questionable value operationally, even though required by statute.

Recommendation: Halt policies which continue to reduce the number of clinicians eligible for MIPS until the MIPS program matures and the final four performance category weights making up the total MIPS composite score are reached.

Definition of MIPS-Eligible Clinician

Starting 2019 - in addition to physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists – physical therapists, occupational therapists, clinical social workers, and clinical psychologists would be included under the definition of a MIPS eligible clinicians, according to the agency’s proposal. Further, CMS is also considering adding qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals as MIPS eligible clinicians. Our members appreciate that there are some clinicians presently excluded from MIPS who may want to participate in the program. We are worried, however, that many of these clinicians do not have or are not adept at using certified electronic health records (EHRs), so that they may find the Promoting Operability performance category particularly challenging. Further, the measures and category score weights are still evolving; this already presents challenges for “experienced” MIPS participants and will be doubly so for novices.

Recommendation: Delay the inclusion of these additional clinicians into to the MIPS eligible definition for another year (2020).

Performance Category Weights

CHIME appreciates the flexibilities given by Congress under the Balanced Budget Act passed in February 2018 which allows, among other things, for the cost category to be reduced from the initial required weight of 30% starting in 2019 to a weight ranging from more than 10% but less than 30% for years 2-5 (2018-2022) We support the agency’s proposal to reduce the cost category to 15% for 2019. Some members also feel this will be helpful especially since last year’s cost data were not readily accessible to most MIPS clinicians.

While we support reducing the weight of the cost category, we are concerned about correspondingly reducing the weight of the quality category to offset the increasing weight assigned to the cost category It would be our preference that increases to the cost category weight come from reallocation of weight currently assigned to the Improvement Activity category; however, we understand CMS is bound by a weighting formula dictated by statute, without provision for discretion to change the Improvement Activity category weight. Nevertheless, we want to emphasize that our desire to transfer weight from the Improvement Activity category as needed to preserve the weight of the quality category is driven first and foremost by our members’ substantial concerns with the Improvement Activity category itself. Our members report that their EHR vendors continue to struggle to create and implement EHR software that allows providers to appropriately document their Improvement Activity activities, and our members also firmly believe that provider entities that are succeeding in raising quality while lowering costs are already implementing many of the activities described on the Improvement Activity measurement list. Finally, our members have found that numerous Improvement Activity measures are poorly defined and therefore lack methodological validity and rigor appropriate for use in the MIPS program.

Recommendations:

1. **Support reducing the cost category to 15% from 30%; and**
2. **CMS should convene a stakeholder group or a technical advisory panel to examine the IA category and make recommendations to the Secretary about possible revisions.**

Reporting Periods

CMS has said they will maintain a one-year reporting period for the quality performance category in 2019. We continue to believe clinicians should have the option to report for a minimum of 90 days for the quality category, aligning with hospital inpatient quality reporting (IQR) reporting periods. Such alignment would foster the volume-to-value transition.

Recommendation: Allow for a minimum of any 90-day reporting period for 2019.

Performance Threshold, Exceptional Performance & Bonus Points

We support CMS' proposal to increase the performance threshold from 15 points to 30 and from 70 points to 80 for exceptional performance. We also appreciate that CMS is attempting to reduce some of the complexity of the program by limiting the use of bonus points, as these have created confusion for our members.

Recommendation: Support.

Facility-based Scoring

We continue to support CMS' policy of allowing facility-based scoring; this allows clinicians whose performances are tightly linked to those of their facilities to be scored on measures meaningful to them and in which they can more readily participate. Further, facility-based clinician scoring tightens the alignment across Medicare programs, which CHIME regards as highly desirable.

Recommendation: Support.

Cybersecurity

Our members continuously cite cybersecurity and the many threats thereto as among their top priorities and concerns. We understand, based upon conversations with CMS staff, that the agency will not pursue creating an activity for clinician credit within the Improvement Activities performance category that would give clinicians credit for engaging in activities which advance their cyber posture. We are disappointed about this decision as there are limited meaningful ways to offer incentives to clinicians to undertake the necessary efforts that otherwise might seem onerous. However, we hope the agency will consider Stark exceptions around cyber donations as they consider modernizing the existing exceptions. We are furthermore pleased to see the Office of the Inspector General's recent request for information (RFI) around antikickback safe harbors mulling cyber donations and subsidies.

Additionally, we want to draw CMS' attention to recent articles which indeed move the needle past theoretical to reality in so far as cyber threats have now been shown to actually have caused patient harm:

- A recent study by University of California Cyber Team concluded that patients indeed are being harmed by compromised medical devices.
- Recent research coming out of Vanderbilt that relied on data from the U.S. Department of Health & Human Services (HHS) found that data breaches are tied to patient deaths.

Recommendation: We strongly urge CMS to take a holistic approach to the threats posed by cybersecurity attacks and look for every possible avenue to help providers fight these threats which pose risks to patient safety.

B. Performance Categories

1. Promoting Interoperability

New Scoring

CHIME is thankful CMS listened to our feedback, and we are pleased to support the new scoring methodology proposed by CMS which would remove the base vs performance methodology and create a single set of measures and objectives which are aligned with hospital requirements. Our members have found the MIPS scoring system confusing and moving to a single set of measures streamlines the requirements.

Recommendation:

1. **We support CMS' proposal, though we recommend that given the more limited number of bonus points available, we urge CMS to monitor scoring patterns under the new approach to ensure that providers are fully recognized for their achievements (e.g., compare prior and new approach category scores for previously high-scoring providers to determine the magnitude of any score drops induced by the category requirement restructuring).**
2. **Many of our members feel strongly that the clinicians who have worked hard to become high performers must continue to be rewarded as such and that ensuring they continue to get credit for meeting higher thresholds will help ensure the program accounts for this.**

ePrescribing Objective / Measures

Measure 1: ePrescribing

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

Recommendation: Support:

CMS has proposed adding two new measures under the ePrescribing objective, similar again to what was finalized for hospitals: 1) Query of prescription drug monitoring program (PDMP); and 2) Verify Opioid Treatment Agreement. As we explained in our response to CMS' proposed inpatient prospective payment system (IPPS) rule, we have some concerns with these measures. While we support retaining these new measures, we believe they will only be impactful if everyone is playing by the same rules, EHRs can access and store the data (for research, follow up, and malpractice reasons), and everyone has access to nationally shared data (i.e. data sharing across state borders must be addressed).

Measure 2: Query of Prescription Drug Monitoring

Query of Prescription Drug Monitoring is a new measure. It would be optional for 2019 and mandatory after that. If reported in 2019 would get 5 bonus points. CMS proposes that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.

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. Since we have concerns about making this mandatory after 2019, we appreciate that CMS is calling for an exclusion in 2020 for any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. However, we worry this exeption is too narrowly tailored.

Our concerns around making this requirement mandatory in 2020 is that access to these data is not consistent and our members are wrestling with an environment that involves varying state laws and non-homogenous access. These challengs include:

- 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.
- Some states preclude providers from ingesting the data from the PDMP into the EHR and thus clinicians are forced to interact with two different systems, leading to degradation of clinical workflow efficienty. Thus the automated ability for clincians to query PDMPs directly from their EHR varies across clincians and vendors and some of these issues are rooted in state laws as far as what is permitted. For example, our members in Texas report their PDMP has said they are prohibited from integreating with the EHR due to state law. Members in Indiana also report a similar situation and these are just two examples. According to Pew Chartible Trusts 24 states have no access to an integration solution. A more recent study by the Electronic Health Records Association (EHRA) asserts there are 28 states without integration.
- The state requirements that prohibit a full integreation result in a manual data entry into the CEHRT and manual calculation of the proposed measure would be burdensome for many clincians. What the new opioid measures will amount to for clinicians in states that do not permit full integration will be a query of the PDMP database, creating a screen shot or print of the PDMP record, scanning the copy and inserting it into the EHR, a process that will be cumbersome and time consuming.
- The issues highlighted above have been acknowledged by Congress and CHIME has supported efforts to address these issues by recommending a series of steps which can be taken which we describe in our comments to the Senate Committee on Health, Education, Labor & Pensions.
- Clinicians 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. **If the measure is finalized as mandatory after 2019, we recommend the exclusion be extended beyond state law prohibitions to other issues like technical ones and costs.**

Measure 3: Verify Opioid Treatment Agreement

The second new opioid measure proposed by CMS would be optional for 2019 and mandatory after that. If reported in 2019 a clinician would get 5 bonus points. CMS has proposed that for at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician

seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT.

Our members believe the measure has conceptual merit because patients benefit when their treating physician has all the readily available and relevant information on their health status and needs. However, there are several challenges clinicians will face in meeting this measure which include:

- 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.
- Data exchange of behavioral health remains remains extremely challenging. These issues are rooted in different state privacy laws, the way federal laws treat patient consent to share behavioral health / substance abuse information vs. how other less sensitive information can be shared under the Health Insurance Portability and Accountability Act (HIPAA), a challenge acknowleded by Congress and many healthcare stakeholders. In addition, CMS acknowledges that there are pilots in development focused on improving data exchange among healthcare providers to better integrate behavioral health information, yet the barriers to exchanging information experienced by pilot participants remain largely unaddressed.
- There is still no consensus on the clinical value of opioid treatment agreements. At a minimum, the measure should remain voluntary until the specifications are clear.
- Our vendor partners report that coding for this measure is next to imossible and these issues must be ironed out before clinicians are required to meet this. The Electronic Health Record Association (EHRA) has declared the opioid measures "impossible."

Also, CMS says they plan on requiring providers to use the NCDCP SCRIPT v10.6 medication history request and response transactions for the 6 month look-back period. We have heard concerns from some of our members concerning the hard cutover to the NCDPD SCRIPT v. 2017071 standard. Because CMS Medicare Advantage (MA) / Part D rules for prescribers require them to use the new version of the SCRIPT standard, prescribers will have to use the new version of the SCRIPT standard starting January 1, 2020. In the past CMS has allowed for a transition to a new standard but this policy will not afford one. So, even though 2020 will be a 90-day reporting period for MIPS, clinicians really have to move to the new version of the SCRIPT standard on January 1, 2020 because if they prescribe for Part D beneficiaries they have to upgrade by this date and providers aren't going to use two versions of the SCRIPT standard at the same time. Finally, we have already been alerted by some members that they are being asked by their EHR vendor to invest millions of additional dollars to obtain a package of upgrades that includes the new version of the SCRIPT standard (v. 2017071).

Recommendation:

1. **Keep Measure #3 voluntary beyond 2019 because the measure specifications need to be developed further. At the very least we request CMS align the requirements with what was finalized for hospitals such that the measure is voluntary through 2020.**
2. **CMS should collaborate on pilot tests to exchange behavorial health / substance abuse information electronically to further the work on specifications needed to faciliate information exchange and assessment of the value of this information before adding the measure to the PI Program.**
3. **Concerning moving to the NCPDP 2017071 standard we recommend CMS:**
   a. **Conduct provider outreach to ensure those who must comply with the Promoting Interoperability programs are aware of this change.**
   b. **Reach out to providers to ascertain the costs associated with this change.**

c. **Allow for enforcement discretion following the January 1, 2020 deadline to accommodate those who may be unable to meet the deadline for using the new standard.**

Health Information Exchange Objective / Measures

Measure 1: Support Electronic Referral Loops by Sending Health Information

We appreciate that CMS is making interoperability a high priority. In that spirit CMS has called for renaming the existing Summary of Care measure the Support Electronic Referral Loops by Sending Health Information.

Recommendation: Support.

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

CMS has called for a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, which combines the preexisting measures, Request/Accept Summary of Care and Clinical Information Reconciliation measures, which we discuss more below.

Under the new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, CMS is only calling for clinicians to meet this for at least one electronic summary of care record received for patient encounters during the performance period for which a clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the clinician has never before encountered the patient, the clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list. While the minimum threshold to meet this measure is one summary of care, to maximize the 20 points allowable under this measure, a clinician would need to perform this for as many patients possible.

In reviewing this measure, we have identified the following ongoing challenges clinicians will face:

- Varying availability and capability of HIEs:
    - The ability of HIEs to handle data exchange still varies. Data received through some regional HIEs cannot be parsed out and is "clogging" provider systems. For instance, some providers trying to exchange information with another in a different state will receive their very own data back from the other provider. Smaller clinician practices will be unable to handle the volume of data that this measure is ultimately intended to handle.
    - Not all clinicians have access to an HIE and thus rely on Direct messaging.
- Readiness of other providers:
    - Measure still relies on actions of others. For the very same reasons we have articulated in the past, we worry about holding clinicians accountable for the ability of others in the healthcare ecosystems to send them data.
- Reconciliation
    - Our members report that reconciling data remains very hard. And, this is complicated when a receiving provider ends up getting the very same records (their own) that they shared through an HIE.
- CCDAs: Today the CCDAs are still very hard to consume. We appreciate that CMS will allow a provider to use an CCD template and we expect this could be helpful, however, challenges associated with how data is mapped could remain. If there is no standard for the way one organization exchanges data with another then the struggles we see today will persist.

Finally, CMS states that if they adopt their proposal to reorient the Promoting Interoperability program as laid out in the rule that that, "an exclusion would be available for MIPS eligible, something we believe would be very helpful."

Recommendations:

1. **Given the challenges identified above, we support the strongly support CMS proposal to allow clinicians to claim an exemption for this measure.**
2. **As CMS considers future MIPS Promoting Interoperability requirements and providers begin to grapple with forthcoming rules around data blocking, the agency should consider the capabilities of all providers in exchanging data which may not be related to an unwillingness to share data electronically so much as it may be rooted in other issues (i.e. technical, cost of interfaces, lack of HIE).**

Provider to Patient Exchange Objective and Measures

Under this objective, the Provider to Patient Exchange – previously referred to as the Patient Electronic Access objective - CMS has proposed a single measure, Provide Patients Electronic Access to Their Health Information. We appreciate CMS' intention behind this measure which they explain, "builds upon the goal of improved access and exchange of patient data, patient centered communication and coordination of care using CEHRT." We continue to have concerns, however, with the requirements clinicians would have to meet around use of APIs. Under this measure, clinicians would have to make available patient information using an app of the patient's choice.

Our members fully recognize the utility of APIs and expect as their use matures and as access to them becomes more widespread, that this will offer a more facile way for patients and providers to access medical data. However, as we have communicated numerous times previously, we have several 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." We believe this issue has not been adequately addressed.
- **Cost:** Increasingly we are hearing from members about exorbitant fees associated with establishing interfaces and we seek clarification around how CMS will treat providers from an information blocking standpoint who are unable to afford all of the costs. We do not believe a provider should be deemed to be blocking information if the reason is rooted in the cost of establishing an interface.
- **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:** In addition to concerns with costs, 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 pose a significant threat to our industry.
- **Patient needs:** As noted earlier, we support the use of APIs, however, our members still hear from patients who are not interested in these tools.

Recommendations:

1. **Support the new measure and threshold for 2019, but recommend CMS not require widespread use of APIs for at least three years after the final standard has been published.**
2. **Address the myriad concerns that have been raised by healthcare providers before widespread use of APIs is mandatory:**
   a. **CMS should limit the providers required use of APIs to ones that are deemed by the provider to be secure;**
   b. **Allow providers to refuse to connect to an app if the provider deems it unsecure without invoking data blocking rules;**
   c. **Address security concerns so as not to increase the threat vector for providers which ultimately could result in patient privacy and safety issues; and**
   d. **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. **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.**
4. **Convene some patient user groups to best understand the data they are seeking and their level of electronic health literacy, akin to the beneficiary user groups convened to review the CMS public reporting websites (e.g., Physician Compare) to better ferret out what data patients really want and in what manner.**

Public Health and Clinical Data Exchange Objective and Measures

Under the Public Health and Clinical Data Exchange objective (renamed from Public Health and Clinical Data Registry Reporting objective) clinicians would be required to report on two measures of their choice from the following list of measures (exclusions available): Immunization Registry Reporting; Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting. If finalized, this would align with what was finalized for the hospitals which we support.

Recommendation: Support.

Measures Proposed for Removal

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. We agree with CMS that removing these measures will reduce program complexity and burdens.

Recommendation: Support.

Future Measures Under Consideration and Spurring Interoperability (RFI)

CMS has said they are considering two new measures for possible future inclusion in the Promoting Interoperability program aimed at better supporting interoperability. CMS has said they are considering adding these new measures in the future to better support long-term, post-acute care and behavioral health providers.

- **Support Electronic Referral Loops by Sending Health Information Across the Care Continuum:** If such a measure were adopted, CMS has said it would, for at least one transition of care or referral to a provider of care other than a MIPS eligible clinician that the MIPS eligible clinician create a summary of care record using CEHRT; and electronically exchanges the summary of care record.
- **Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum:** For at least one electronic summary of care record received by a MIPS eligible clinician from a transition of care or referral from a provider of care other than a MIPS eligible clinician, that the MIPS eligible clinician conduct clinical information reconciliation for medications, mediation allergies, and problem list.

We appreciate that CMS is looking for ways to better support the care continuum, however, we believe the pathway to achieving this is one that should be rooted in collaboration Further, we worry that creating these new measures tries to address the non-acute care setting yet there is no additional funding to help accomplish this. In considering new measures the five issues described below must be addressed, issues we write about in greater detail in our comments on the Home Health proposed rule:

1. **Standardized data:** How to standardize the bi-directional data to and from acute care/post-acute providers remains an outstanding concern.
2. **Different provider / patient needs:** Depending on the clinical condition, and even the setting a patient is being transitioned to, long-term and post-acute care providers may need different types of information. We encourage CMS continue to work on identifying and further outlining these needs.
3. **Timely access to data:** Receiving CCDs in a timely manner from acute care providers continues to present challenges regardless of whether the post-acute provider uses an HIE or whether they are receiving Direct Messages.
4. **Workflow /non-technology issues:** Many of the issues that delay the information transfer are related to workflow / communication issues and have nothing to do with technology that is used to exchange information. However, some issues are related to the ongoing challenge with bi-directional data flow.
5. **Costs:** High interface exchange fees coupled with per transaction fees often make data exchange cost prohibitive.
6. **Fairness:** The responsibility for a two-way information transfer rests with both parties, and it is unfair to penalize only one party for incomplete or failed transfers.

Finally, in the Request for Information (RFI) included in the rule, CMS seeks ideas from the public on how best to accomplish the goal of fully interoperable health IT and EHR systems for providers and suppliers and how to advance the MyHealthEData initiative for patients. In addition to the ones we already highlighted in our IPPS comment letter in response to the RFI, are a better solution we believe than approaching this through mandates involving Conditions of Participate (CoP). Building on our previous comments we have also heard from members that an API between CMS to vendors, similar to what the Veteran's Administration (VA) is doing would be very helpful. As noted in a recent VA blog they state, "We will provide API access to developers for Veteran-designated mobile and web-based apps, clinician-designated applications for those who serve them, and choice care act partners responsible for coordinating their care via "bulk" access."

Recommendations:

1. **CMS should convene long-term providers, post-acute providers and EHR vendors to discuss how medication reconciliations can better be supported and how this can be achieved working together collaboratively; and**
2. **CMS should recognize that whatever measures are developed that the responsibility for a two-way information transfer rests with both parties and it's unfair to penalize only one entity especially since the ability meet it could rest outside their control; and**
3. **Do not adopt mandates to attempt to tackle interoperability through CoP, rather, root cause issues like a uniform set of standards and a way to uniquely identify patients must be addressed; and**
4. **Provide an API for vendors and developers to access patient data held by CMS.**

Medicaid

We appreciate that CMS has attempted to better align the electronic clinical quality measurement requirements which will consist of the same list of quality measures available for MIPS in 2019.

While we strongly support CMS' efforts to align the Promoting Interoperability policies between hospitals and Medicare clinicians, we continue to have concerns about how Medicaid clinicians will be treated. The Medicaid programs need to align with the others. Basically, many facilities are still dealing with three different set of rules, although the IPPS and Physician rules are increasingly aligned.

We appreciate that CMS finalized in the 2019 hospital IPPS rule that states are permitted to adopt the new scoring system, however ideally, they would be required to do so to bring greater alignment with other provider requirements. CMS has also said the reporting period for Medicaid clinicians under the Medicaid Promoting Interoperability program would be a full year; our members continue to believe this should be 90 days.

CMS has made some changes to the current measures. In the event a state does not adopt the new scoring system outlined in the final IPPS rule for Medicare hospitals, then they must meet Stage 3 requirements. However, CMS has called for changing several measures for 2019: the VDT measure would drop from 10% to 5%; Secure Electronic Messaging would drop from 25% to 5%; and for the Syndromic Surveillance Reporting Measure for EPs CMS plans to amend the language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting.

Recommendations:

1. **Set a 90-day reporting period for Medicaid Promoting Interoperability;**
2. **Support the changes to the Stage 3 measures described above; and**
3. **Ideally require Medicaid to have the same set of Promoting Interoperability requirements as Medicare.**

III. <u>Physician Fee Schedule Proposed Rule</u>

Telemedicine

Over the past several years CMS' policies to reimburse for telehealth and connected care in general have been gradual but we have been encouraged by more recent policies recognizing the potential for these services. Our members are particularly pleased to see the direction CMS is taking to enlarge its view to include more connected care policies. Such policies would allow CMS to more nimbly respond to the rapid pace of interactive technology changes. Just as we strongly supported CMS' decision in 2017 to begin reimbursing clinicians for remote patient monitoring at the start of 2018, we now enthusiastically support CMS' proposal this year to create a new suite of services, "communication technology-based services."

CMS has called for reimbursing clinicians when: 1) "Remote Evaluation of Pre-Recorded Patient Information," such as when a patient sends an image or video to a clinician (often referred to as "store

and forward"); and 2) "Brief Communication Technology-based Service," when a clinician checks in with a patient (aka virtual check-in), a service that has typically been bundled with other services and would now be separately billable. While Section 1834(m) includes store and forward as part of the definition of telehealth, CMS has determined that because the services they say will be performed under the "Remote Evaluation of Pre-Recorded Patient Information" are not intended to replace separately payable in-person visits, Medicare is able to reimburse for situations when the a clinician is reviewing an image or video shared by a patient so long as it is not related to an evaluation and management (E/M) service occurring within the past seven days or a procedure within the next 24 hours. We appreciate that CMS has found a mechanism for reimbursing these services without running afoul of Section 1834(m). CMS has said concerning the Brief Communication Technology-based Service that clinicians would be able to bill for it if the service did not occur within the previous seven days or within 24 hours of a procedure, and that the provider-patient conversation lasts between 5-10 minutes. While our members are very enthusiastic about CMS' proposal, we do believe some of the restrictions for billing this service may be too stringent and we offer our recommendations for expanding them below.

Recommendations: We strongly support CMS' proposal to create a category of services called "communication technology-based services."

Appropriate Use

CMS continues its progress through the various phases of Appropriate Use Criteria (AUC) implementation as specified in the Protecting Access to Medicare Act (PAMA), although on a schedule substantially delayed from that outlined in PAMA. Statute requires that there be significant hardship exceptions to the AUC consultation and reporting requirements. The proposed criteria for an AUC consultation significant hardship exception include: insufficient internet access – specific to the location where an advanced diagnostic imaging service is ordered by the ordering professional; EHR or clinical decision support mechanisms (CDSM) vendor issues – including situations where ordering professionals experience temporary technical problems, installations or upgrades that temporarily impede access to the CDSM, vendors cease operations, or CMS de-qualifies a CDSM; or extreme and uncontrollable circumstances – including disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems.

Recommendation: CHIME supports the creation of appropriate hardship exceptions to compliance with AUC regulations as proposed. We are particularly supportive of the exceptions for EHR or CDSM issues, as practitioners and facilities are regularly subject to disruptions inherent in IT-dependent processes such as AUC usage. CHIME also agrees with CMS' proposal for self-attestation of an EHR / CDSM hardship by ordering professionals as an approach that minimizes regulatory burden.

IV. Conclusion

CHIME appreciates the opportunity to comment and welcomes the changes to discuss our comments with then agency in greater depth. Should you have questions about our letter please contact Mari Savickis, vice president of federal affairs at mari.savickis@chimecentral.org.

Sincerely,

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